State Medical Board of Ohio

30 E. Broad St., 3rd Floor
Columbus, Ohio 43215
(614) 466-3934
www.med.ohio.gov

Legislative Bill Report
03-08-2019

HB63 PHARMACY BENEFIT MANAGERS

Regarding pharmacy benefit managers, pharmacists, and the disclosure to patients of drug price information.

BILL SUMMARY

• Prohibits health plan issuers and third-party administrators from requiring or directing pharmacies to collect cost-sharing beyond a certain amount from individuals purchasing prescription drugs.

• Prohibits issuers and administrators from retroactively adjusting pharmacy claims other than because of a technical billing error or a pharmacy audit.

•Prohibits issuers and administrators from charging claim-related fees unless those fees can be determined at the time of claim adjudication.

• Requires pharmacists, pharmacy interns, and terminal distributors of dangerous drugs to inform patients if the cost-sharing required by the patient's plan exceeds the amount that may otherwise be charged and prohibits those persons from charging patients the higher amount.

• Provides for license or certificate of authority suspension or revocation and monetary penalties for failure to comply with the bill.

• Requires the Department of Insurance to create a web form for consumers to submit complaints relating to violations of the bill.

HB68 HEARTBEAT BILL

To generally prohibit an abortion of an unborn human individual with a detectable heartbeat and to create the Joint Legislative Committee on Adoption Promotion and Support.

BILL SUMMARY

• Generally prohibits a person from knowingly and purposefully performing or inducing an abortion with the specific intent of causing or abetting the termination of the life of an unborn human individual whose fetal heartbeat has been detected.

• Provides that a person who violates the above prohibition is guilty of performing or inducing an abortion after the detection of a fetal heartbeat, a felony of the fifth degree.

•Provides that a physician is not in violation of the above prohibition if that physician performs a medical procedure designed to or intended to prevent the death of a pregnant woman or prevent a serious risk of substantial and irreversible impairment of a major bodily function of the pregnant woman.

• Provides that a person is not in violation of the prohibition if that person has performed an examination for the presence of a fetal heartbeat and the method used does not reveal a fetal heartbeat.

• Provides that the prohibition does not repeal or limit any other provision of law that restricts or regulates the performance or inducement of an abortion by a particular method or during a particular stage of pregnancy.

SB7 TEMPORARY STATE OCCUPATIONAL LICENSES-MILITARY

Regarding temporary state occupational licenses for members of the military and their spouses.

BILL SUMMARY

• Requires state occupational licensing agencies, under certain circumstances, to issue temporary licenses or certificates to members of the military and spouses who are licensed in another jurisdiction and have moved or will move to Ohio for duty.

• Specifies that temporary licenses or certificates under the bill are to be issued to an individual for a duration of not more than three years.

•Requires a state licensing agency to deny or revoke a temporary license or certificate issued under the bill under certain circumstances.

• Requires the Director of Administrative Services to prepare a report for each fiscal year on the number and type of temporary licenses or certificates issued during the fiscal year under the bill.

Legislative Report

March 8, 2019
Prepared by: Jonithon LaCross

MY TRACKED BILLS

Bill Information

HB29 DEXTROMETHORPHAN SALES *(KOEHLER K)*

To prohibit sales of dextromethorphan without a prescription to persons under age 18.

CURRENT STATUS

2/19/2019 - House Health, (First Hearing)

HB46 STATE GOVT EXPENDITURE DATABASE *(GREENSPAN D)*

To require the Treasurer of State to establish the Ohio State Government Expenditure Database.

CURRENT STATUS

2/27/2019 - House State and Local Government, (First Hearing)

HB50 CHARTER COUNTY HOSPITAL PATENTS *(GREENSPAN D)*

To require that all rights to and interests in charter county hospital employee discoveries, inventions, or patents are the property of the charter county hospital.

CURRENT STATUS

2/26/2019 - House Civil Justice, (Second Hearing)

HB61 HEALTH PROVIDER RESIDENTIAL INFO *(LANESE L, LISTON B)*

To include forensic mental health providers, mental health evaluation providers, and regional psychiatric hospital employees as individuals whose residential and familial information is exempt from disclosure under the Public Records Law.

CURRENT STATUS

2/19/2019 - House Civil Justice, (First Hearing)

HB63 PHARMACY BENEFIT MANAGERS *(LIPPS S, WEST T)*

Regarding pharmacy benefit managers, pharmacists, and the disclosure to patients of drug price information.

CURRENT STATUS

3/12/2019 - House Health, (First Hearing)

HB68 HEARTBEAT BILL *(HOOD R, KELLER C)*

To generally prohibit an abortion of an unborn human individual with a detectable heartbeat and to create the Joint Legislative Committee on Adoption Promotion and Support.

CURRENT STATUS

2/26/2019 - House Health, (First Hearing)

SB1 REDUCE REGULATORY RESTRICTIONS *(MCCOLLEY R, ROEGNER K)*

To require certain agencies to reduce the number of regulatory restrictions and to continue the provision of this act on and after August 18, 2019.

CURRENT STATUS

3/5/2019 - Senate Government Oversight and Reform, (Third Hearing)

SB7 TEMP STATE OCCUPATIONAL LICENSES-MILITARY *(LEHNER P, HACKETT R)*

Regarding temporary state occupational licenses for members of the military and their spouses.

CURRENT STATUS

2/27/2019 - Senate Transportation, Commerce and Workforce, (Second Hearing)

SB9 HEALTH PLAN CLAIM INFORMATION *(HUFFMAN M)*

To require health plan issuers to release certain claim information to group plan policyholders.

CURRENT STATUS

3/13/2019 - Senate Insurance and Financial Institutions, (Second Hearing)

SB14 DRUG PRICE INFORMATION DISCLOSURE *(MAHARATH T)*

Regarding pharmacy benefit managers, pharmacists, and the disclosure to patients of drug price information.

CURRENT STATUS

2/12/2019 - Introduced

SB20 CONTROLLED SUBSTANCES DISPOSAL *(MAHARATH T)*

Regarding the disposal of controlled substances.

CURRENT STATUS

2/13/2019 - Referred to Committee Senate Health, Human Services and Medicaid

SB25 MEDICAID WORK, EDUCATION REQUIREMENTS *(HUFFMAN M)*

Regarding work and education requirements for the Medicaid program.

CURRENT STATUS

2/26/2019 - Senate Health, Human Services and Medicaid, (First Hearing)

SB27 FETAL REMAINS-SURGICAL ABORTIONS *(UECKER J)*

To impose requirements on the final disposition of fetal remains from surgical abortions.

CURRENT STATUS

2/26/2019 - Senate Health, Human Services and Medicaid, (First Hearing)

SB29 MEDICAID COPAYMENTS *(DOLAN M)*

Regarding Medicaid copayment requirements.

CURRENT STATUS

2/19/2019 - Senate Health, Human Services and Medicaid, (Second Hearing)

SB51 NON-OPIOID DIRECTIVES AND THERAPIES *(MAHARATH T)*

Regarding non-opioid directives and non-opioid therapies.

CURRENT STATUS

2/13/2019 - Referred to Committee Senate Health, Human Services and Medicaid

SB61 NURSE ANESTHETISTS *(BURKE D)*

Regarding the authority of certified registered nurse anesthetists to select, order, and administer certain drugs.

CURRENT STATUS

2/26/2019 - Introduced

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MEMORANDUM

TO: Amol Soin, M.D., Chair, Policy Committee
Members, Policy Committee

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Rule Review Progress

DATE: March 8, 2019

Attached please find the Rule Review Spreadsheet and status of the rules under review.

Action Requested: No Action Requested

Rule	Rule Description	Date to Committee	Comm approval	Board approval	Sent for Comment	Board Approval	CSI filing	Board Approval	JCARR filing	Rules Hearing	Board Review	Board Adoption	New Effective Date	Current Review Date
4730-1-01	Regulation of Physician Assistants - Definitions	12/9/15 11/8/15	03/09/16	03/09/16	03/11/16	05/11/16	08/02/17		06/20/18	07/24/18		09/12/18	09/30/18	09/30/23
4730-1-02	*Physician Assistant Practice*	*04/12/16*		*04/13/16*	*04/15/16*	*06/08/16*	*08/02/17*		*06/20/18*	*07/24/18*			*09/30/18*	*rescinded*
4730-1-03	*Duties of a Supervising Physician*	*04/12/16*		*04/13/16*	*04/15/16*	*06/08/16*	*08/02/17*		*06/20/18*	*07/24/18*			*09/30/18*	*rescinded*
4730-1-04	*Supervision*	*04/12/16*		*04/13/16*	*04/15/16*	*06/08/16*	*08/02/17*		*06/20/18*	*07/24/18*			*09/30/18*	*rescinded*
4730-1-05	Quality Assurance System	12/09/15	03/09/16	03/09/16	12/22/17 3/11/2016	03/14/18	04/02/18		06/20/18	07/24/18				08/07/23
4730-1-06	Licensure as a physician assistant	12/9/15 11/4/2015		04/13/16	6/20/17 4/15/2016	7/12/17 6/8/2016	8/2/2017		07/02/18 6/20/2018	07/24/18		09/12/18	09/30/18	09/30/23
4730-1-06.1	Military provisions related to certificate to practice as a physician assistant								06/20/18	07/24/18				09/30/20
4730-1-07	Miscellaneous Provisions	12/09/15		04/13/16	04/15/16	06/08/16	08/02/17		06/20/18	07/24/18		09/12/18	09/30/18	09/30/23
4730-1-08	Physician assistant delegation of medical tasks and administration of drugs	11/04/15		11/04/15	11/06/15		02/01/16	04/13/16	05/05/16	06/13/16			07/31/16	07/31/21
4730-2-01	Physician Delegated Prescriptive Authority - Definitions	05/10/16			05/13/16	08/10/16	08/02/17		06/20/18	07/24/18		09/12/18	Amended 9/30/18	03/19/19
4730-2-02	*Educational Requirements for Prescriptive Authority*	*12/09/15*	*03/09/16*	*03/09/16*	*03/11/16*	*05/11/16*	*08/02/17*		*06/20/18*	*07/24/18*			*09/30/18*	*rescinded*
4730-2-03	*Application for a Provisional Certificate to Prescribe*	*04/12/16*	*04/13/16*		*04/15/16*	*06/08/16*	*08/02/17*		*06/20/18*	*07/24/18*			*09/30/18*	*rescinded*
4730-2-04	Period of on-site supervision of physician-delegated prescriptive authority	05/10/16			12/22/17	03/14/18	04/02/18		08/20/18	09/26/18		11/14/18	11/30/18	11/15/23
4730-2-05	Addition of valid prescriber number after initial licensure	05/10/16			12/22/17	03/14/18	04/02/18		08/20/18	09/26/18		11/14/18	11/30/18	11/15/23
4730-2-06	Physician Assistant Formulary	05/10/16			05/13/16									06/30/19
4730-2-07	Standards for Prescribing	05/10/16			05/13/16	08/10/16	08/02/17		06/20/18	07/24/18			Amended 9/30/18	06/30/19
4730-2-08	*Standards for Personally Furnishing Drugs and Therapeutic Devices*	*05/10/16*			*05/13/16*	*08/10/16*	*08/02/17*		*06/20/18*	*07/24/18*			*09/30/18*	*rescinded*
4730-2-09	*Standards for Personally Furnishing Samples of Drugs and Therapeutic Devices*	*05/10/16*			*05/13/16*	*08/10/16*	*08/02/17*		*06/20/18*	*07/24/18*			*09/30/18*	*rescinded*
4730-2-10	Standards and Procedures for use of OARRS		03/09/16	03/09/16	03/11/16	05/11/16	08/02/17		06/20/18	07/24/18		09/12/18	09/30/18	09/30/23
4730-3-01	Criminal Records Checks - (For Physician Assistants) - Definitions	04/12/16		04/13/16	04/15/16	06/08/16	08/02/17		06/20/18	07/24/18			Amended 9/30/18	06/30/19
4730-3-02	Criminal Records Checks	04/12/16		04/13/16	04/15/16	06/08/16	08/02/17		06/20/18	07/24/18			Amended 9/30/18	06/30/19
4730-4-01	Definitions				02/21/18	07/11/18	08/03/18		refiled 2/15/19 10/24/2018	11/28/18				

Rule	Rule Description	Date to Committee	Comm approval	Board approval	Sent for Comment	Board Approval	CSI filing	Board Approval	JCARR filing	Rules Hearing	Board Review	Board Adoption	New Effective Date	Current Review Date
4730-4-03	Office Based Treatment for Opioid addiction				02/21/18	07/11/18	08/03/18		refiled 2/15/19 10/24/2018	11/28/18				
4730-4-04	Medication assisted treatment using naltrexone				02/21/18	07/11/18	08/03/18		refiled 2/15/19 10/24/2018	11/28/18				
4731-1-01	Limited Practitioners - Definition of Terms	07/13/16			5/15/17 7/13/2016	7/12/17 9/14/2016	08/07/17						01/24/12	01/24/17
4731-1-02	Application of Rules Governing Limited Branches of Medicine or Surgery			12/10/14 05/13/15	05/14/18	09/14/16	09/24/18		07/01/15			09/09/15	09/30/15	09/30/20
4731-1-03	General Prohibitions	07/13/16			07/13/16	09/14/16	09/26/17		08/31/18			no change		08/31/23
4731-1-04	Scope of Practice: Mechanotherapy	04/13/16		04/13/16	04/15/16	09/14/16	09/26/17		12/12/18 9/24/2018	10/25/18		12/12/18	12/31/18	12/31/23
4731-1-05	Scope of Practice: Massage Therapy	07/13/16			6/20/18 7/13/2016	09/14/16	9/24/18 9/26/2017		09/24/18	10/25/18		12/12/18	12/31/18	12/31/23
4731-1-06	Scope of Practice: Naprapathy	04/13/16		04/13/16	04/15/16	09/14/16	09/26/17		08/31/18			no change		08/31/23
4731-1-07	Eligibility of Electrologists Licensed by the Ohio State Board of Cosmetology to Obtain Licensure as Cosmetic Therapists Pursuant to Chapter 4731 ORC and Subsequent Limitations	07/13/16				09/14/16	09/26/17		09/24/18	10/25/18		12/12/18	12/31/18	12/31/23
4731-1-08	Continuing Cosmetic Therapy Education Requirements for Registration or Reinstatement of a License to Practice Cosmetic Therapy	10/10/18			07/18/18	09/14/16	10/31/18 2/20/2018							12/31/17
4731-1-09	Cosmetic Therapy Curriculum Requirements	07/13/16			07/13/16	09/14/16	09/26/17		08/31/18			no change		08/31/23
4731-1-10	Distance Education	07/13/16			07/13/16	09/14/16	09/26/17		09/24/18	10/25/18	01/09/19	01/09/19	01/31/19	01/31/24
4731-1-11	Application and Certification	07/13/16			5/15/17 7/13/2016	07/12/17 9/14/2016	08/07/17							01/24/17
4731-1-12	Examination	2/10/16 12/9/2015	12/09/15	12/09/15	12/11/15	02/10/16	03/07/16	*05/11/16*	08/16/16	09/19/16	10/19/16	11/09/16	11/30/16	11/30/21
4731-1-13	Examination Failure; Additional Training	07/13/16			5/15/17 7/13/2016	7/12/17 9/14/2016	08/07/17							01/24/17
4731-1-14	*Preliminary Education Certificate*					*09/14/16*								*rescinded*
4731-1-15	Determination of Standing of School, College or Institution	07/13/16			07/13/16	09/14/16	09/26/17		09/24/18	10/25/18		12/12/18	12/31/18	12/31/23
4731-1-16	Massage Therapy curriculum rule (Five year review)	2/10/16 12/9/2015	12/09/15	12/09/15	6/20/18 12/11/2015	02/10/16	8/24/18 3/7/2016	*05/11/16*	10/24/18 8/16/2016	11/28/18 9/19/2016	01/09/19 10/19/16	1/9/19 11/9/2016	01/31/19	11/30/21
4731-1-17	Instructional Staff	07/13/16			07/13/16	09/14/16	09/26/17		09/24/18	10/25/18				01/24/17

Rule	Rule Description	Date to Committee	Comm approval	Board approval	Sent for Comment	Board Approval	CSI filing	Board Approval	JCARR filing	Rules Hearing	Board Review	Board Adoption	New Effective Date	Current Review Date
4731-1-18	Grounds for Suspension, Revocation or Denial of Certificate of Good Standing, Hearing Rights	07/13/16			5/15/17 7/13/2016	7/12/17 9/14/2016	08/07/17							01/24/17
4731-1- 19	Probationary Status	07/13/16			5/15/17 7/13/2016	7/12/17 9/14/2016	08/07/17							01/24/17
4731-1-23	*Home Study Schools*													*rescinded*
4731-1-24	Massage Therapy Continuing Education		03/09/16	2nd - 3/29/17 3/9/2016	03/09/16		10/26/16							
4731-1-25	Determination of Equiv. Military Educ. For CT/MT		04/08/15	05/13/15	07/23/15		07/23/15		7/1/2015 9/24/15	11/02/15	12/09/15	12/09/15	12/31/15	12/31/20
4731-2-01	Public Notice of Rules Procedure	10/14/15	10/14/15	10/14/15	04/15/16	06/08/16		11/08/17 7/12/2017	09/19/17	10/25/17			12/07/17	12/07/22
4731-4-01	Criminal Records Checks - Definitions				02/20/19									06/29/19
4731-4-02	Criminal Records Checks				02/20/19									06/29/19
4731-5-01	Admission to Examinations	05/11/16			2/8/17 5/13/2016	07/13/16			06/09/17	no change				06/09/22
4731-5-02	Examination Failure; Inspection and Regrading	05/11/16			2/8/17 5/13/2016	07/13/16			06/09/17	no change				06/09/22
4731-5-03	Conduct During Examinations	05/11/16			2/8/17 5/13/2016	07/13/16			06/09/17	no change				06/09/22
4731-5-04	Termination of Examinations	05/11/16			2/8/17 5/13/2016	07/13/16			06/09/17	no change				06/09/22
4731-6-01	Medical or Osteopathic Licensure: Definitions	1/10/18 5/11/2016			2/26/18 2/8/17 5/13/2016	07/13/16	09/25/18		05/23/17	06/23/17		08/09/17	08/31/17	08/31/22
4731-6-02	Preliminary Education for Medical and Osteopathic Licensure	1/10/18 5/11/2016			2/26/18 2/8/17 5/13/2016	07/13/16	09/25/18		06/09/17	no change				06/09/22
4731-6-03	Eligibility for the Medical and Osteopathic Examination	05/11/16			2/26/18 2/8/17 5/13/2016	07/13/16	09/25/18		06/09/17	no change				06/09/22
4731-6-04	Demonstration of proficiency in spoken English	05/11/16			2/26/18 2/8/17 5/13/2016	07/13/16	09/25/18		06/09/17	no change				06/09/22
4731-6-05	Format of Medical and Osteopathic Examination	1/10/18 5/11/2016			2/26/18 2/8/17 5/13/2016	07/13/16	09/25/18		05/23/17	06/23/17		06/09/17	08/31/17	08/31/22
4731-6-07	Passing Average on Examination	05/11/16			2/26/18 2/8/17 5/13/2016	07/13/16	09/25/18		06/09/17	no change				06/09/22
4731-6-10	Clinical Competency Examination	05/11/16			2/26/18 2/8/17 5/13/2016	07/13/16	09/25/18		05/23/17	06/23/17		06/09/17	08/31/17	06/09/22
4731-6-14	Examination for physician licensure	1/10/18 5/11/2016			2/26/18 2/8/2017	07/13/16	09/25/18		06/09/17	no change				04/29/19
4731-6-15	Eligibility for Licensure of National Board Diplomats and Medical Council of Canada Licentiates	1/10/18 5/11/2016			2/26/18 2/8/17 5/13/2016	07/13/16	09/25/18		06/09/17	no change				06/09/22

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4731-6-16	Eligibility for Medical or Osteopathic Licensure by Endorsement of Licenses Granted by Other States	1/10/18 5/11/2016			2/26/18 2/8/2017	07/13/16	09/25/18		06/09/17	no change				04/29/19
4731-6-20	*Requests for medical or osteopathic licensure application*													*rescinded*
4731-6-21	Application Procedures for Certificate Issuance; Investigation; Notice of Hearing Rights	1/10/18 5/11/2016			2/26/18 2/8/17 5/13/2016	07/13/16	09/25/18		05/23/17	06/23/17		08/09/17	08/31/17	08/31/22
4731-6-22	Abandonment and Withdrawal of Medical and Osteopathic Licensure Applications	1/10/18 5/11/2016			2/26/18 2/8/17 5/13/2016	07/13/16	09/25/18		05/23/17	06/23/17		08/09/17	08/31/17	08/31/22
4731-6-30	Training Certificates	1/10/18 5/11/2016			2/26/18 2/8/17 5/13/2016	07/13/16	09/25/18		05/23/17	06/23/17		08/09/17	08/31/17	08/31/22
4731-6-31	Limited Preexamination Registration and Limited Certification	1/10/18 5/11/2016			2/26/18 2/8/17 5/13/2016	07/13/16	09/25/18		06/09/17	no change				06/09/22
4731-6-32	Visiting Faculty Certificates	1/10/18 5/11/2016			2/26/18 2/8/17 5/13/2016	07/13/16	09/25/18		05/23/17	06/23/17		08/09/17	08/31/17	08/31/22
4731-6-33	Special Activity Certificates	1/10/18 5/11/2016			2/26/18 2/8/17 5/13/2016	07/13/16	09/25/18		05/23/17	06/23/17		08/09/17	08/31/17	08/31/22
4731-6-34	Volunteer's Certificates	1/10/18 5/11/2016			2/26/18 2/8/17 5/13/2016	07/13/16	09/25/18		05/23/17	06/23/17		08/09/17	08/31/17	08/31/22
4731-6-35	Processing applications from service members, veterans, or spouses of service members or veterans.	01/10/18		05/13/15	2/26/18 2/8/2017		9/25/18 1/8/2015		06/09/17	no change		09/09/15	09/30/15	09/30/20
4731-7-01	Method of Notice of Meetings												12/31/15	12/31/20
4731-8-01	Personal Information Systems				02/20/19								no change	04/21/21
4731-8-02	Definitions												no change	04/21/21
4731-8-03	Procedures for accessing confidential personal information												no change	04/21/21
4731-8-04	Valid reasons for accessing confidential personal information												no change	04/21/21
4731-8-05	Confidentiality Statutes	3/9/16 1/13/2016			01/15/16			04/13/16	05/05/16	06/13/16			07/31/16	07/31/21
4731-8-06	Restricting & Logging access to confidential personal information	3/9/16 1/13/2016			01/15/16			04/13/16	04/21/16					04/21/21

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4731-9-01	Record of Board Meetings; Recording, Filming, and Photographing of Meetings		08/13/14	8/13/14 5/13/15	02/20/19		01/08/15		07/01/15			09/09/15	09/30/15	09/30/20
4731-10-01	Definitions	06/08/16	06/08/16	06/08/16	06/09/16	08/10/16	07/31/17		02/02/18					02/02/23
4731-10-02	Requisite Hours of Continuing Medical Education for License Renewal or Reinstatement	06/08/16	06/08/16	06/08/16	6/20/17 6/9/2016	08/10/16	09/26/17					05/09/18	05/31/18	05/31/23
4731-10-03	CME Waiver	06/08/16	06/08/16	06/08/16	06/09/16	08/10/16	07/31/17		02/02/18			05/09/18	05/31/18	05/31/23
4731-10-04	Continuing Medical Education Requirements for Restoration of a License	06/08/16	06/08/16	06/08/16	06/09/16	08/10/16	07/31/17					05/09/18	05/31/18	05/31/23
4731-10-05	Out-of-State Licensees	06/08/16	06/08/16	06/08/16	06/09/16	08/10/16	07/31/17		02/02/18			05/09/18	05/31/18	05/31/23
4731-10-06	Licensure After Cutoff for Preparation of Registration Notices	06/08/16	06/08/16	06/08/16	06/09/16	08/10/16	07/31/17		02/02/18			05/09/18	05/31/18	05/31/23
4371-10-07	Internships, Residencies and Fellowships	06/08/16	06/08/16	06/08/16	06/09/16	08/10/16	07/31/17		02/02/18			05/09/18	05/31/18	05/31/23
4371-10-08	Evidence of Continuing Medical Education	06/08/16	06/08/16	06/08/16	6/20/17 6/9/2016	08/10/16	09/26/17					05/09/18	05/31/18	05/31/23
4731-10-09	Continuing Medical Education Requirement for Mid-term Licensees	06/08/16	06/08/16	06/08/16	6/20/17 6/9/2016	08/10/16	09/26/17					05/09/18	05/31/18	05/31/23
4731-10-10	Continuing Medical Education Requirements Following License Restoration	06/08/16	06/08/16	06/08/16	6/20/17 6/9/2016	08/10/16	09/26/17					05/09/18	05/31/18	05/31/23
4731-10-11	Telemedicine Certificates	06/08/16	06/08/16	06/08/16	06/09/16	08/10/16	07/31/17		02/02/18			05/09/18	05/31/18	05/31/23
4731-11-01	Controlled substances; General Provisions Definitions		revision 3/11/15	8/13/2014 4/13/16	5/11/18 Revision 4/13/17 revision 9/19/16 1/22/15 4/15/16	6/13/18 6/8/2016	6/14/18 05/11/17 7/5/2016	11/08/17	Refiles 10/16/18 refiled 8/20/18 refiled 9/19/17 refiled 6-16- 17 refiled 2/8/17 refiled 1/13/17 11/3/2016	9/26/18 10/25/17 07/26/17 12/8/2016		12/12/18	12/23/18	12/07/22
4731-11-02	Controlled Substances - General Provisions			10/8/14 05/13/15	5/11/18 Revision 4/13/17	06/13/18	6/14/18 05/11/17 1/8/2015		Refiled 10/16/18 8/20/18 6/16/17 8/24/15 7/1/2015	9/26/18 07/26/17 11/2/2015	10/14/15	12/12/18	12/23/18	12/31/20
4731-11-03	Schedule II Controlled Substance Stimulants			10/8/14 5/13/15			01/08/15		8/24/15 7/1/2015	11/02/15	10/14/15	10/14/2015	12/31/15	12/31/20
4731-11-04	Controlled Substances: Utilization for Weight Reduction			11/12/14 05/13/15			01/08/15		1/5/16 8/24/15 7/1/2015	11/02/15	10/14/15		02/29/16	02/28/21

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4731-11-04.1	Controlled substances: Utilization for chronic weight management			9/10/14 05/13/15			01/08/15		8/24/15 7/1/2015	11/02/15	10/14/15	10/14/15	12/31/15	12/31/20
4731-11-05	Use of Drugs to Enhance Athletic Ability			10/8/14 05/13/15			01/08/15		8/24/15 7/1/2015	11/02/15	12/09/15	12/09/15	12/31/15	12/31/20
4731-11-06	*Waivers for new uses*													*rescinded*
4731-11-07	Research Utilizing Controlled Substances			9/10/14 05/13/15			01/08/15		07/01/15			09/09/15	09/30/15	09/30/20
4731-11-08	Utilizing Controlled Substances for Self and Family Members	2/10/16 12/9/2015	12/09/15	12/09/15	12/11/15	02/10/16	03/07/16	05/11/16	08/17/16					08/17/21
4731-11-09	Prescribing to persons the physician has never personally examined.	03/09/16	revision 3/26/15 3/11/15 10/8/14	revision 9/19/16 1/14/15 05/13/15 10/8/14 4/13/16	1/22/2015 4/15/16	06/08/16	07/05/16		refiled 2/8/17 refiled (res &new) 1/13/17 11/3/2016	12/08/16			03/23/17	03/23/22
4731-11-11	Standards and procedures for review of "Ohio Automated Rx Reporting System" (OARRS).		revision 3/25/15 3/11/15	revision 1/14/15 05/13/15 10/8/14	7/23/15 1/22/2015		07/23/15		09/24/15	11/02/15	12/09/15	12/09/15	12/31/15	12/31/20
4731-11-12	*Office-Based Opioid Treatment*			*08/31/14*			*rescind filing 8/3/18 3/28/2014*		*10/24/18 10/20/14*	*11/28/18 11/24/14*		*01/14/15*	*01/31/15*	*01/31/20*
4731-11-13	Prescribing of Opioid Analgesics for Acute Pain				04/13/17		05/11/17			07/26/17		filed 8/21/17	08/31/17	08/31/22
4731-11-14	Prescribing for subacute and chronic pain				05/11/18	06/13/18	06/14/18		Refiled 10/16/18 8/20/2018	09/26/18		12/12/18	12/23/18	12/23/23
4731-12-01	Preliminary Education for Licensure in Podiatric Medicine and Surgery	02/10/16	02/10/16	02/10/16	7/13/16 2/12/2016	04/13/16	07/11/16	09/14/16	03/28/17	05/03/17		06/14/17	06/30/17	06/30/22
4731-12-02	Standing of Colleges of Podiatric Surgery and Medicine	02/10/16	02/10/16	02/10/16	7/13/16 2/12/2016	04/13/16	07/11/16	09/14/16	03/28/17	05/03/17		06/14/17	06/30/17	06/30/22
4731-12-03	Eligibility for the Examination in Podiatric Surgery and Medicine (see note below)	02/10/16	02/10/16	02/10/16	7/13/16 2/12/2016	04/13/16	07/11/16	09/14/16	04/19/17	NA				04/19/22
4731-12-04	Eligibility of Licensure in Podiatric Medicine and Surgery by Endorsement from Another State	02/10/16	02/10/16	02/10/16	7/13/16 2/12/2016	04/13/16	07/11/16	09/14/16	03/28/17	05/03/17		06/14/17	06/30/17	06/30/22
4731-12-05	Application Procedures for Licensure in Podiatric Medicine and Surgery, Investigation, Notice of Hearing Rights.	02/10/16	02/10/16	02/10/16	7/13/16 2/12/2016	04/13/16	07/11/16	09/14/16	03/28/17	05/03/17		06/14/17	06/30/17	06/30/22
4731-12-06	Visiting Podiatric Faculty Certificates	02/10/16	02/10/16	02/10/16	7/13/16 2/12/2016	04/13/16	07/11/16	09/14/16	03/28/17	05/03/17		06/14/17	06/30/17	06/30/22

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4731-12-07	Podiatric Training Certificates	02/10/16	02/10/16	02/10/16	7/13/16 2/12/2016	04/13/16	07/11/16		03/28/17	05/03/17		06/14/17	06/30/17	06/30/22
4731-13-01	Conduct of Hearings - Representative; Appearances	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	04/13/16	05/05/16	06/13/16			07/31/16	07/31/21
4731-13-02	Filing Request for Hearing	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	04/13/16	05/05/16	06/13/16			07/31/16	07/31/21
4731-13-03	Authority and Duties of Hearing Examiners	11/04/15	11/04/15	11/04/15	12/12/16 11/6/2015		7/31/17 2/1/2016	6/13/18 4/13/2016	6/20/18 5/5/2016	7/24/18 6/13/2016		09/12/18	09/30/18	07/31/21
4731-13-04	Consolidation	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	04/13/16	04/21/16	- -				04/21/21
4731-13-05	Intervention	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	04/13/16	04/21/16	- -				04/21/21
4731-13-06	Continuance of Hearing	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	04/13/16	8/4/16 5/5/2016	06/13/16		09/14/16	09/30/16	09/30/21
4731-13-07	Motions	11/04/15	11/04/15	11/04/15	12/12/16 11/6/2015		7/31/17 2/1/2016	6/13/18 4/13/2016	6/20/18 5/5/2016	07/24/18		09/12/18	09/30/18	04/21/21
4731-13-07.1	Form and page limitations for briefs and memoranda				12/12/16		07/31/17	06/13/18	06/20/18	07/24/18	09/12/18	09/12/18	09/30/18	09/30/23
4731-13-08	Filing	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	04/13/16	05/05/16	06/13/16			07/31/16	07/31/21
4731-13-09	Service	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	04/13/16	05/05/16	06/13/16			07/31/16	07/31/21
4731-13-10	Computation and Extension of Time	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	04/13/16	05/05/16	06/13/16			07/31/16	07/31/21
4731-13-11	Notice of Hearings	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	04/13/16	05/05/16	06/13/16			07/31/16	07/31/21
4731-13-12	Transcripts	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	04/13/16	05/05/16	06/13/16			07/31/16	07/31/21
4731-13-13	Subpoenas for Purposes of Hearing	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	04/13/16	05/05/16	06/13/16			07/31/16	07/31/21
4731-13-14	Mileage Reimbursement and Witness Fees	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	04/13/16	04/21/16	- -				04/21/21
4731-13-15	Reports and Recommendations	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	04/13/16	05/05/16	06/13/16			07/31/16	07/31/21
4731-13-16	Reinstatement or Restoration of Certificate	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	04/13/16	05/05/16	06/13/16			07/31/16	07/31/21
4731-13-17	Settlements, Dismissals, and Voluntary Surrenders	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	04/13/16	04/21/16	- -				04/21/21
4731-13-18	Exchange of Documents and Witness Lists	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	04/13/16	05/05/16	06/13/16			07/31/16	07/31/21
4731-16-19	*Prehearing conference*													*rescinded*
4731-13-20	Depositions in Lieu of Live Testimony and Transcripts in place of Prior Testimony	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	04/13/16	05/05/16	06/13/16			07/31/16	07/31/21
4731-13-20.1	Electronic Testimony								05/05/16	06/13/16			07/31/16	07/31/21
4731-13-21	Prior Action by the State Medical Board	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	04/13/16	04/21/16	- -				04/21/21
4731-13-22	Stipulation of Facts	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	04/13/16	04/21/16	- -				04/21/21
4731-13-23	Witnesses	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	04/13/16	8/4/16 5/5/2016	06/13/16			09/14/16	09/30/21
4731-13-24	Conviction of a Crime	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	04/13/16	04/21/16	- -				04/21/21
4731-13-25	Evidence	11/04/15	11/04/15				02/01/16	04/13/16	05/05/16	06/13/16			07/31/16	07/31/21
4731-13-26	Broadcasting and Photographing Administrative Hearings	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	04/13/16	04/21/16	- -				04/21/21
4731-13-27	Sexual Misconduct Evidence	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	04/13/16	04/21/16	- -				04/21/21

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4731-13-28	Supervision of Hearing Examiners	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	04/13/16	04/21/16	- -				04/21/21
4731-13-29	*Requirements for pre-hearing exchange of information*													*rescinded*
4731-13-30	Prehearing Conference	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	04/13/16	04/21/16	- -				04/21/21
4731-13-31	Transcripts of Prior Testimony	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	04/13/16	04/21/16	- -				04/21/21
4731-13-32	Prior Statements of the Respondent	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	04/13/16	04/21/16	- -				04/21/21
4731-13-33	Physician's Desk Physician	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	04/13/16	04/21/16	- -				04/21/21
4731-13-34	Ex Parte Communication	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	04/13/16	05/05/16	06/13/16			07/31/16	07/31/21
4731-13-35	Severability	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	04/13/16	04/21/16	- -				04/21/21
4731-13-36	Disciplinary Actions	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	04/13/16	05/05/16	06/13/16			07/31/16	07/31/21
4731-14-01	Pronouncement of Death	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	03/09/16	03/15/16	04/20/16			06/30/16	06/30/21
4731-15-01	Licensee Reporting Requirement; Exceptions	06/08/16	06/08/16	06/08/16	06/09/16	08/10/16	07/31/17		11/17/17					11/17/22
4731-15-02	Healthcare Facility Reporting Requirement	06/08/16	06/08/16	06/08/16	06/09/16	08/10/16	07/31/17		11/17/17					11/17/22
4731-15-03	Malpractice Reporting Requirement	06/08/16	06/08/16	06/08/16	06/09/16	08/10/16	07/31/17		11/17/17					11/17/22
4731-15-04	Professional Society Reporting	06/08/16	06/08/16	06/08/16	06/09/16	08/10/16	07/31/17		11/17/17					11/17/22
4731-15-05	Liability; Reporting Forms; Confidentially and Disclosure	06/08/16	06/08/16	06/08/16	06/09/16	08/10/16	07/31/17		11/17/17					11/17/22
4731-16-01	Rules governing impaired physicians and approval of treatments programs - Definitions	06/08/16	06/08/16	06/08/16	06/09/16	08/10/16	08/29/17		11/17/17					11/17/22
4731-16-02	General Procedures in Impairment Cases	06/08/16	06/08/16	06/08/16	06/09/16	08/10/16	08/29/17		11/17/17					11/17/22
4731-16-03	*Mental or physical impairment*													*rescinded*
4731-16-04	Other Violations	06/08/16	06/08/16	06/08/16	06/09/16	08/10/16	08/29/17		11/17/17					11/17/22
4731-16-05	Examinations	06/08/16	06/08/16	06/08/16	06/09/16	08/10/16	08/29/17		11/17/17					11/17/22
4731-16-06	Consent Agreements and Orders for Reinstatement of Impaired Practitioners	06/08/16	06/08/16	06/08/16	06/09/16	08/10/16	08/29/17		11/17/17					11/17/22
4731-16-07	Treatment Provider Program Obligations	06/08/16	06/08/16	06/08/16	06/09/16	08/10/16	08/29/17		11/17/17					11/17/22
4731-16-08	Criteria for Approval	06/08/16	06/08/16	06/08/16	06/09/16	08/10/16	08/29/17		11/17/17					11/17/22
4731-16-09	Procedures for Approval	06/08/16	06/08/16	06/08/16	06/09/16	08/10/16	08/29/17		11/17/17					11/17/22
4731-16-10	Aftercare Contracts	06/08/16	06/08/16	06/08/16	06/09/16	08/10/16	08/29/17		11/17/17					11/17/22
4731-16-11	Revocation, Suspension, or Denial of Certificate of Good Standing	06/08/16	06/08/16	06/08/16	06/09/16	08/10/16	08/29/17		11/17/17					11/17/22
4731-16-12	Out-of-State Impairment Cases	06/08/16	06/08/16	06/08/16	06/09/16	08/10/16	08/29/17		11/17/17					11/17/22
4731-16-13	Patient Consent; Revocation of Consent	06/08/16	06/08/16	06/08/16	06/09/16	08/10/16	08/29/17		11/17/17					11/17/22
4731-16-14	Caffeine, Nicotine, and Over-The Counter Drugs	06/08/16	06/08/16	06/08/16	06/09/16	08/10/16	08/29/17		11/17/17					11/17/22

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4731-16-15	Patient Rights	06/08/16	06/08/16	06/08/16	06/09/16	08/10/16	08/29/17		11/17/17					11/17/22
4731-16-16	*Practice Prohibition*	*06/08/16*	*06/08/16*	*06/08/16*	*12/17/18 6/9/2016*	*08/10/16*	*1/11/19 8/29/2017*		*11/17/17*					*11/17/22*
4731-16-17	Requirements for the one-bite program	03/14/18			03/21/18		05/30/18		10/24/18	11/28/18		01/09/19	01/31/19	01/31/24
4731-16-18	Eligibility for the one-bite program	03/14/18			03/21/18		05/30/18		10/24/18	11/28/18		01/09/19	01/31/19	01/31/24
4731-16-19	Monitoring organization for one-bite program	03/14/18			03/21/18		05/30/18		10/24/18	11/28/18		01/09/19	01/31/19	01/31/24
4731-16-20	Treatment providers in the one-bite program	03/14/18			03/21/18		05/30/18		10/24/18	11/28/18		01/09/19	01/31/19	01/31/24
4731-16-21	Continuing care for the one-bite program	03/14/18			03/21/18		05/30/18		10/24/18	11/28/18		01/09/19	01/31/19	01/31/24
4731-17-01	Exposure-Prone Invasive Procedure Precautions - Definitions	2/10/16 12/9/2015	12/09/15	12/09/15	12/11/15	02/10/16	03/07/16	05/11/16	10/20/16 8/16/2016	09/19/16	10/19/16	12/14/16	12/31/16	12/31/21
4731-17-02	Universal Precautions	2/10/16 12/9/2015	12/09/15	12/09/15	12/11/15	02/10/16	03/07/16	05/11/16	08/16/16	09/19/16	10/19/16	11/09/16	11/30/16	11/30/21
4731-17-03	Hand Washing	2/10/16 12/9/2015	12/09/15	12/09/15	12/11/15	02/10/16	03/07/16	05/11/16	08/17/16					08/17/21
4731-17-04	Disinfection and Sterilization	2/10/16 12/9/2015	12/09/15	12/09/15	12/11/15	02/10/16	03/07/16	05/11/16	10/20/16 8/16/2016	09/19/16	10/19/16	12/14/16	12/31/16	12/31/21
4731-17-05	Handling and Disposal of Sharps and Wastes	2/10/16 12/9/2015	12/09/15	12/09/15	12/11/15	02/10/16	03/07/16	05/11/16	08/17/16					08/17/21
4731-17-06	Barrier Techniques	2/10/16 12/9/2015	12/09/15	12/09/15	12/11/15	02/10/16	03/07/16	05/11/16	08/17/16					08/17/21
4731-17-07	Violations	2/10/16 12/9/2015	12/09/15	12/09/15	12/11/15	02/10/16	03/07/16	05/11/16	08/16/16	09/19/16	10/19/16	10/19/16	11/09/16	11/30/21
4731-18-01	Standards for Surgery	01/13/16			1/17/18 1/15/2016	03/14/18	06/27/18							05/04/00
4731-18-02	Use of Light Based Medical Devices	01/13/16			1/17/18 1/15/2016	03/14/18								06/30/05
4731-18-03	Delegation of the Use of Light Based Medical Devices	01/13/16			1/17/18 1/15/2016	03/14/18								06/30/05
4731-18-04	Delegation of the Use of Light Based Medical Devices; Exceptions	01/13/16			1/17/18 1/15/2016	03/14/18								05/31/07
4731-19-01	*Duty of License to Report HIV or HBV Infection; Confidentiality*	*2/10/16 12/9/2015*	*12/09/15*	*12/09/15*	*12/11/15*	*02/10/16*	*03/07/16*	*05/11/16*	*08/16/16*	*09/19/16*	*10/19/16*	*Rescinded11/ 9/2016*	*11/30/16*	*Rescinded11/ 9/2016*
4731-19-02	*Licensee's Duty to Report Infection with HIV or HBV*	*2/10/16 12/9/2015*	*12/09/15*	*12/09/15*	*12/11/15*	*02/10/16*	*03/07/16*	*05/11/16*	*08/16/16*	*09/19/16*	*10/19/16*	*Rescinded 11/9/2016*	*11/30/16*	*Rescinded 11/9/2016*
4731-19-03	*Confidentiality; Reporting by Board*	*2/10/16 12/9/2015*	*12/09/15*	*12/09/15*	*12/11/15*	*02/10/16*	*03/07/16*	*05/11/16*	*08/16/16*	*09/19/16*	*10/19/16*	*Rescinded11/ 9/2016*	*11/30/16*	*Rescinded11/ 9/2016*
4731-19-04	*Voluntary Compliance*	*2/10/16 12/9/2015*	*12/09/15*	*12/09/15*	*12/11/15*	*02/10/16*	*03/07/16*	*05/11/16*	*08/16/16*	*09/19/16*	*10/19/16*	*Rescinded 11/9/2016*	*11/30/16*	*Rescinded 11/9/2016*
4731-19-05	*Duty to Refrain from Certain Procedures*	*2/10/16 12/9/2015*	*12/09/15*	*12/09/15*	*12/11/15*	*02/10/16*	*03/07/16*	*05/11/16*	*08/16/16*	*09/19/16*	*10/19/16*	*Rescinded11/ 9/2016*	*11/30/16*	*Rescinded11/ 9/2016*
4731-19-06	*Board Procedures*	*2/10/16 12/9/2015*	*12/09/15*	*12/09/15*	*12/11/15*	*02/10/16*	*03/07/16*	*05/11/16*	*08/16/16*	*09/19/16*	*10/19/16*	*Rescinded 11/9/2016*	*11/30/16*	*Rescinded 11/9/2016*
4731-19-07	*Confidential Monitoring Program*	*2/10/16 12/9/2015*	*12/09/15*	*12/09/15*	*12/11/15*	*02/10/16*	*03/07/16*	*05/11/16*	*08/16/16*	*09/19/16*	*10/19/16*	*Rescinded11/ 9/2016*	*11/30/16*	*Rescinded11/ 9/2016*

Rule	Rule Description	Date to Committee	Comm approval	Board approval	Sent for Comment	Board Approval	CSI filing	Board Approval	JCARR filing	Rules Hearing	Board Review	Board Adoption	New Effective Date	Current Review Date
4731-20-01	Surgery Privileges of Podiatrist - Definition of Foot	03/09/16	03/09/16	03/09/16	03/11/16	05/11/16	07/31/17	02/14/18				05/09/18	05/31/18	05/31/23
4731-20-02	Surgery: Ankle Joint	03/09/16	03/09/16	03/09/16	03/11/16		07/31/17	02/14/18				05/09/18	05/31/18	05/31/23
4731-21-01	*Drug Treatment of Intractable Pain - Definitions*	*2/10/2016 3/8/16 4/12/16*	*02/10/16*	*03/09/16*	*7/13/16 3/11/2016*	*06/13/18*	*6/14/18 7/11/2016*	*10/19/16*	*Refiled 10/16/18 rescind filed 8/20/18 5/23/2017*	*06/23/17*		*08/09/17*	*08/31/17*	*rescinded 12/23/18*
4731-21-02	*Utilizing Prescription Drugs for the Treatment of Intractable Pain*	*2/10/2016 3/8/16 4/12/16*	*02/10/16*	*03/09/16*	*7/13/16 3/11/2016*	*06/13/18*	*6/14/18 7/11/2016*	*10/19/16*	*Refiled 10/16/18 rescind filed 8/20/18 5/23/2017*	*06/23/17*		*08/09/17*	*08/31/17*	*rescinded 12/23/18*
4731-21-03	*Continuing Medical Education*	*2/10/2016 3/8/16 4/12/16*	*02/10/16*	*03/09/16*	*7/13/16 3/11/2016*	*06/13/18*	*6/14/18 7/11/2016*	*10/19/16*	*Refiled 10/16/18 rescind filed 8/20/18 5/23/2017*	*06/23/17*		*08/09/17*	*08/31/17*	*rescinded 12/23/18*
4731-21-04	*Tolerance, Physical Dependence and Addiction*	*2/10/2016 3/8/16 4/12/16*	*02/10/16*	*03/09/16*	*7/13/16 3/11/2016*	*06/13/18*	*6/14/18 7/11/2016*	*10/19/16*	*Refiled 10/16/18 rescind filed 8/20/18 5/23/2017*	*06/23/17*		*08/09/17*	*08/31/17*	*rescinded 12/23/18*
4731-21-05	*Violations*	*2/10/2016 3/8/16 4/12/16*	*02/10/16*	*03/09/16*	*7/13/16 3/11/2016*	*06/13/18*	*6/14/18 7/11/2016*	*10/19/16*	*Refiled 10/16/18 rescind filed 8/20/18 5/23/2017*	*no change*				*rescinded 12/23/18*
4731-21-06	*Exceptions*	*2/10/2016 3/8/16 4/12/16*	*02/10/16*	*03/09/16*	*7/13/16 3/11/2016*	*06/13/18*	*6/14/18 7/11/2016*	*10/19/16*	*Refiled 10/16/18 rescind filed 8/20/18 5/23/2017*	*06/23/17*		*08/09/17*	*08/31/17*	*rescinded 12/23/18*
4731-22-01	Emeritus Registration - Definitions	2/10/2016 4/12/16	02/10/16	03/09/16	7/13/16 3/11/2016		07/11/16	09/14/16	(Revised 6-5-17 for XML version) 5/23/2017	06/23/17		08/09/17	08/31/17	08/31/22
4731-22-02	Application	2/10/2016 4/12/16	02/10/16	03/09/16	7/13/16 3/11/2016		07/11/16	09/14/16	05/23/17	06/23/17		08/09/17	08/31/17	08/31/22
4731-22-03	Status of Registrant	2/10/2016 4/12/16	02/10/16	03/09/16	7/13/16 3/11/2016		07/11/16	09/14/16	05/12/17					05/12/22
4731-22-04	Continuing Education Requirements	2/10/2016 4/12/16	02/10/16	03/09/16	7/13/16 3/11/2016		07/11/16	09/14/16	05/12/17					05/12/22
4731-22-05	*Documentation of Status*													*rescinded*
4731-22-06	Renewal of Cycle of Fees	2/10/2016 4/12/16	02/10/16	03/09/16	7/13/16 3/11/2016		07/11/16	09/14/16	05/12/17					05/12/22
4731-22-07	Change to Active Status	2/10/2016 4/12/16	02/10/16	03/09/16	7/13/16 3/11/2016		07/11/16	09/14/16	05/23/17	06/23/17		08/09/17	08/31/17	08/31/22
4731-22-08	Cancellation of or Refusal to Issue an Emeritus Registration	2/10/2016 4/12/16	02/10/16	03/09/16	7/13/16 3/11/2016		07/11/16	09/14/16	05/12/17					05/12/22

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4731-23-01	Delegation of Medical Tasks - Definitions	3/9/16 1/13/2016			01/15/16		04/04/16	05/11/16	08/16/16	09/19/16	10/19/16	11/09/16	11/30/16	11/30/21
4731-23-02	Delegation of Medical Tasks	3/9/16 1/13/2016			01/15/16		04/04/16	05/11/16	08/16/16	09/19/16	10/19/16	11/09/16	11/30/16	11/30/21
4731-23-03	Delegation of Medical Tasks: Prohibitions	3/9/16 1/13/2016			01/15/16		04/04/16	05/11/16	08/17/16					08/17/21
4731-23-04	Violations	3/9/16 1/13/2016			01/15/16		04/04/16	05/11/16	08/17/16					08/17/21
4731-24-01	Anesthesiologist Assistants - Definitions	10/10/18			10/30/18		1/11/19 11/7/2013		02/19/14					03/19/19
4731-24-02	Anesthesiologist Assistants; Supervision	10/10/18			10/30/18		1/11/19 11/7/2013		02/19/14					03/19/19
4731-24-03	Anesthesiologist Assistants; Enhanced Supervision	10/10/18			10/30/18		1/11/19 11/7/2013		02/19/14					03/19/19
4731-24-04	*Anesthesiologist Assistants; Prohibitions*						*11/07/13*		*06/17/14*	*04/23/14*		*06/11/14*	*06/17/14*	*rescinded*
4731-24-05	Military Provisions Related to Certificate to Practice as an Anesthesiologist Assistant	10/30/18 10/10/2018		7/19/14 5/13/15			1/11/19 11/14/2014		1/8/2015 7/1/15			09/09/15	09/30/15	09/30/20
4731-25-01	Office-Based Surgery - Definition of Terms	3/9/16 1/13/2016		10/19/16 05/11/16	01/15/16		07/31/17	02/14/18						03/01/23
4731-25-02	General Provisions	3/9/16 1/13/2016			01/15/16	05/11/16	07/31/17	02/14/18				05/09/18	05/31/18	05/31/23
4731-25-03	Standards for Surgery Using Moderate Sedation/Analgesia	3/9/16 1/13/2016			01/15/16	05/11/16	07/31/17	02/14/18				05/09/18	05/31/18	08/31/23
4731-25-04	Standards for Surgery Using Anesthesia Services	3/9/16 1/13/2016			01/15/16	05/11/16	07/31/17	02/14/18				05/09/18	05/31/18	05/31/23
4731-25-05	Liposuction in the Office Setting	3/9/16 1/13/2016			01/15/16	05/11/16	07/31/17	02/14/18						03/01/23
4731-25-07	Accreditation of Office Settings	3/9/16 1/13/2016			01/15/16	05/11/16	07/31/17	02/14/18				05/09/18	05/31/18	05/31/23
4731-25-08	Standards for Surgery				01/17/18		06/27/18							
4731-26-01	Sexual Misconduct - Definitions	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	03/09/16	03/15/16	04/20/16			06/30/16	06/30/21
4731-26-02	Prohibitions	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	03/09/16	03/15/16	04/20/16				06/14/21
4731-26-03	Violations; Miscellaneous	11/04/15	11/04/15	11/04/15	11/06/15		02/01/16	03/09/16	03/15/16	04/20/16			06/30/16	06/30/21
4731-27-01	Definitions				05/11/18		08/03/18		02/03/19					02/02/24
4731-27-02	Dismissing a patient from the medical practice				05/11/18		08/03/18		02/06/19	03/12/19				06/29/19
4731-27-03	Notice of termination of physician employment or physician leaving a practice, selling a practice, or retiring from the practice of medicine				05/11/18		08/03/18		02/06/19	03/12/19				06/29/19
4731-28-01	Mental or Physical Impairment	2/10/16 12/9/2015	12/09/15	12/09/15	12/11/15	02/10/16	03/07/16		05/23/17	06/23/17		08/09/17	08/31/17	08/31/22
4731-28-02	Eligibility for confidential monitoring program				04/10/17		02/06/18		05/30/18	07/09/18		08/08/18	08/31/18	08/31/23

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4731-28-03	Participation in the confidential monitoring program				04/10/17		02/06/18		05/30/18	07/09/18		08/08/18	08/31/18	08/31/23
4731-28-04	Disqualification from continued participation in the confidential monitoring program				04/10/17		02/06/18		05/30/18	07/09/18		08/08/18	08/31/18	08/31/23
4731-28-05	Termination of the participation agreement for the confidential monitoring program				04/10/17		02/06/18		05/30/18	07/09/18		08/08/18	08/31/18	08/31/23
4731-29-01	Standards and procedures for operation of a pain management clinic.	02/10/16			07/13/16		07/11/16	12/14/16	03/28/17	05/03/17		06/14/17	06/30/17	06/30/22
4731-30-01	Internal Management Definitions	09/12/18										09/12/18	09/23/18	
4731-30-02	Internal Management Board Metrics	09/12/18										09/12/18	09/23/18	
4731-31-01	Requirements for assessing and granting clearance for return to practice or competition. (concussion rule)	02/14/18		05/13/15	02/26/18		5/16/18 6/2/2015		09/08/15			09/09/15	09/18/15	09/18/20
4731-32-01	Definition of Terms						03/23/17		06/09/17	07/10/17		08/09/17	09/08/17	09/08/22
4731-32-02	Certificate to Recommend Medical Marijuana						03/23/17		06/09/17	07/10/17		08/09/17	09/08/17	09/08/22
4731-32-03	Standard of Care						03/23/17		06/09/17	07/10/17		08/09/17	09/08/17	09/08/22
4731-32-04	Suspension and Revocation of Certificate to Recommend						03/23/17		06/09/17	07/10/17		08/09/17	09/08/17	09/08/22
4731-32-05	Petition to Request Additional Qualifying Condtion or Disease						03/23/17		06/09/17	07/10/17		08/09/17	09/08/17	09/08/22
4731-33-01	Definitions	02/14/18	02/14/18	02/14/18	02/21/18		08/03/18		refiled 2/15/19 10/24/2018	11/28/18				
4731-33-03	Office-Based Treatment for Opoid Addiction	02/14/18	02/14/18	02/14/18	02/21/18		08/03/18		refiled 2/15/19 10/24/2018	11/28/18				
4731-33-04	Medication Assisted Treatment Using Naltrexone						08/03/18		refiled 2/15/19 10/24/2018	11/28/18				
4731-34-01	Standards and Procedures to be followed by physicians when prescribing a dangerous drug that may be administered by a pharmacist by injection.			04/11/18	04/19/18		06/27/18							
4731-35-01	Consult Agreements				01/18/19									
4731-35-02	Standards for managing drug therapy				01/18/19									
4759-1-01	*Public notice of rule adoption*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*

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4759-1-02	*Notice of board meeting*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-1-03	*Personal information systems*			04/11/18	04/19/18	07/11/18	09/25/18							*To Be rescinded*
4759-2-01	Definitions			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-3-01	*Duties of Board members*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-3-02	*Executive secretary/executive director*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-3-03	*Minutes of board meetings*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-3-04	*Cooperation and communication with professional organizations*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-3-05	*Advisory committees*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-3-06	*Parliamentary procedures*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-3-07	*Adjudication hearings*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-4-01	Applications			04/11/18	04/19/18	07/11/18	09/25/18							
4759-4-02	Preprofessional experience			04/11/18	04/19/18	07/11/18	09/25/18							
4759-4-03	Examination			04/11/18	04/19/18	07/11/18	09/25/18							
4759-4-05	*Licensure by reciprocity*													*To be rescinded*
4759-4-06	*Status categories*													*To be rescinded*
4759-4-07	*Failure to maintain licensure*													*To be rescinded*
4759-4-08	Limited permit			04/11/18	04/19/18	07/11/18	09/25/18							
4759-4-09	License certificates and permits			04/11/18	04/19/18	07/11/18	09/25/18							
4759-4-10	*Prorated initial license fee*													*To be rescinded*
4759-4-11	*Criminal records check*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-4-12	Consideration of military experience, education, training and term of service			04/11/18	04/19/18	07/11/18	09/25/18							
4759-4-13	Temporary license for military spouse			04/11/18	04/19/18	07/11/18	09/25/18							
4759-5-01	Supervision of persons claiming exemption			04/11/18	04/19/18	07/11/18	09/25/18							
4759-5-02	Student practice exemption			04/11/18	04/19/18	07/11/18	09/25/18							
4759-5-03	Plan of treatment exemption			04/11/18	04/19/18	07/11/18	09/25/18							
4759-5-04	Additional nutritional activities exemption			04/11/18	04/19/18	07/11/18	09/25/18							
4759-5-05	Distribution of literature exemption			04/11/18	04/19/18	07/11/18	09/25/18							
4759-5-06	Weight control program exemption			04/11/18	04/19/18	07/11/18	09/25/18							
4759-6-01	Standards of practice innutrition care			04/11/18	04/19/18	07/11/18	09/25/18							
4759-6-02	Standards of professional performance			04/11/18	04/19/18	07/11/18	09/25/18							

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4759-6-03	Interpretation of standards			04/11/18	04/19/18	07/11/18	09/25/18							
4759-7-01	*Filing of complaints*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-8-01	*Representatives; appearances communications; applicability*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-8-02	*Filing Request for Hearing*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-8-03	*Notice of hearings*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-8-04	*Authority and duties of attorney hearing examiners*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-8-05	*Consolidation*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-8-06	*Intervention*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-8-07	*Continuance of Hearing*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-8-08	*Motions*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-8-09	*Filing*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-8-10	*Service on parties*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-8-11	*Computation and Extension of Time*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-8-12	*Transcripts*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-8-13	*Subpoenas for Purposes of Hearing*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-8-14	*Mileage Reimbursement and Witness Fees*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-8-15	*Reports and Recommendations*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-8-16	*Exchange of Documents and Witness Lists*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-8-17	*Pre-hearing conference*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-8-18	*Requirements for pre-hearing exchange of information*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-8-19	*Status conference*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-8-20	*Depositions and transcripts of prior testimony*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-8-21	*Prior action by the board*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-8-22	*Stipulation of Facts*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-8-23	*Witnesses*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-8-24	*Conviction of a Crime*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-8-25	*Rules of evidence*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*

Rule	Rule Description	Date to Committee	Comm approval	Board approval	Sent for Comment	Board Approval	CSI filing	Board Approval	JCARR filing	Rules Hearing	Board Review	Board Adoption	New Effective Date	Current Review Date
4759-8-26	*Broadcasting and Photographing Administrative Hearings*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-8-27	*Sexual misconduct evidence*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-8-28	*Reinstatement of license*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-8-29	*Settlements, Dismissals, and Voluntary Surrenders*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-9-01	Severability			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-10-01	*Definitions*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-10-02	*Procedures for accessing confidential personal information*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-10-03	*Valid reasons for accessing confidential personal information*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-10-04	*Confidentiality Statutes*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-10-05	*Restricting & Logging access to confidential personal information in computerized personal information systems*			04/11/18	04/19/18	07/11/18	09/25/18							*To be rescinded*
4759-11-01	Miscellaneous Provisions			04/11/18	04/19/18	07/11/18	09/25/18							
4761-1-01	*Public hearings on adoption, amendment, or rescission of rules: methods of public notice*												*02/28/19*	*Rescinded*
4761-1-02	*Notice of board meetings*												*02/28/19*	*Rescinded*
4761-2-01	*Board Organization*								*01/19/19*				*02/28/19*	*Rescinded*
4761-2-02	*Personnel*								*01/19/19*				*02/28/19*	*Rescinded*
4761-2-03	Board Records			04/11/18	04/19/18	07/11/18	09/25/18		11/15/18	12/17/18			02/28/19	02/28/24
4761-2-05	*Personal information systems*												*02/28/19*	*Rescinded*
4761-3-01	Definition of terms			04/11/18	04/19/18	07/11/18	09/25/18		11/15/18	12/17/18			02/28/19	02/28/24
4761-4-01	Approval of educational programs			04/11/18	04/19/18	07/11/18	09/25/18		11/15/18	12/17/18			02/28/19	02/28/24
4761-4-02	Monitoring of Ohio respiratory care educational programs								11/15/18	12/17/18			02/28/19	02/28/24
4761-4-03	Recognition of military educational programs for active duty military members and/or military veterans								11/15/18	no change				11/15/23
4761-5-01	Waiver of licensing requirements pursuant to division (B) of section 4761.04 or the Revised Code													04/24/18

Rule	Rule Description	Date to Committee	Comm approval	Board approval	Sent for Comment	Board Approval	CSI filing	Board Approval	JCARR filing	Rules Hearing	Board Review	Board Adoption	New Effective Date	Current Review Date
4761-5-02	Admission to the Ohio credentialing examination													05/06/15
4761-5-04	License application procedure													
4761-5-05	*Non-resident practice of respiratory care*								*01/19/19*				*02/28/19*	*Rescinded*
4761-5-06	Respiratory care practice by polysomnographic technologists													12/31/17
4761-5-07	*Criminal records check*												*02/28/19*	*Rescinded*
4761-6-01	Limited permit application procedure			04/11/18	04/19/18	07/11/18	09/25/18		11/15/18	12/17/18			02/28/19	02/28/24
4761-7-01	Original license or permit, identification card or electronic license verification			04/11/18	04/19/18	07/11/18	09/25/18		11/15/18	12/17/18			02/28/19	02/28/24
4761-7-03	Scope of respiratory care defined								11/15/18	no change				11/15/23
4761-7-04	Supervision								11/15/18	no change				11/15/23
4761-7-05	Administration of medicines								11/15/18	no change				11/15/23
4761-8-01	Renewal of license or permits													08/15/18
4761-8-02	*Licenses not in active practice*								*01/19/19*				*02/28/19*	*Rescinded*
4761-9-01	Defnition of respiratory care continuing education			04/11/18	04/19/18	07/11/18	09/25/18		11/15/18	12/17/18			02/28/19	02/28/24
4761-9-02	Gemera; RCCE requirements and reporting mechanism													
4761-9-03	Activities which do not meet the Ohio RCCE requirements			04/11/18	04/19/18	07/11/18	09/25/18		11/15/18	12/17/18			02/28/19	02/28/24
4761-9-04	Ohio respiratory care law and professional ethics course criteria			04/11/18	04/19/18	07/11/18	09/25/18		11/15/18	12/17/18			02/28/19	02/28/24
4761-9-05	Approved sources of RCCE			04/11/18	04/19/18	07/11/18	09/25/18		11/15/18	12/17/18			02/28/19	02/28/24
4761-9-07	Auditing for compliance with RCCE requirements													
4761-10-01	Ethical and professional conduct			04/11/18	04/19/18	07/11/18	09/25/18		11/15/18	12/17/18			02/28/19	02/28/24
4761-10-02	Proper use of credentials								11/15/18	no change				11/15/23
4761-10-03	Providing information to the Board													
4761-11-01	*Filing of complaints*								*01/19/19*				*02/28/19*	*Rescinded*
4761-11-02	*Administrative procedure for refusal to issue or renew a license or permit, deny, suspend, or revoke a certificate or license*								*01/19/19*				*02/28/19*	*Rescinded*
4761-11-03	*Board imposition of penalties*								*02/06/19*	*03/12/19*				*To be rescinded*
4761-11-04	*Representation; appearance; communication applicability*												*02/28/19*	*Rescinded*
4761-11-05	*Authority and duties of the board or hearing examiner*												*02/28/19*	*Rescinded*

Rule	Rule Description	Date to Committee	Comm approval	Board approval	Sent for Comment	Board Approval	CSI filing	Board Approval	JCARR filing	Rules Hearing	Board Review	Board Adoption	New Effective Date	Current Review Date
4761-11-06	Continuance of Hearing												02/28/19	Rescinded
4761-11-07	Filing								01/19/19				02/28/19	Rescinded
4761-11-08	Service												02/28/19	Rescinded
4761-11-09	Computation and Extension of Time												02/28/19	Rescinded
4761-11-10	Motions												02/28/19	Rescinded
4761-11-11	Transcripts								01/19/19				02/28/19	Rescinded
4761-11-12	Subpoenas for Purposes of Hearing												02/28/19	Rescinded
4761-11-13	Mileage Reimbursement and Witness Fees								01/19/19				02/28/19	Rescinded
4761-11-14	Reports and Recommendations								01/19/19				02/28/19	Rescinded
4761-11-15	Exchange of Documents and Witness Lists												02/28/19	Rescinded
4761-11-16	Depositions and transcripts of prior testimony								01/19/19				02/28/19	Rescinded
4761-11-17	Witnesses												02/28/19	Rescinded
4761-11-18	Expert testimony								01/19/19				02/28/19	Rescinded
4761-11-19	Exhibits												02/28/19	Rescinded
4761-12-01	Initial application fee													
4761-12-02	Renewal fees								01/19/19				02/28/19	Rescinded
4761-12-03	Replacement of license or certificate												02/28/19	Rescinded
4761-13-01	Definitions for accessing confidential personal information								01/19/19				02/28/19	Rescinded
4761-13-02	Procedures for accessing confidential personal information								01/19/19				02/28/19	Rescinded
4761-13-03	Valid reasons for accessing confidential personal information								01/19/19				02/28/19	Rescinded
4761-13-04	Confidentiality Statutes								01/19/19				02/28/19	Rescinded
4761-13-05	Restricting & Logging access to confidential personal information in computerized personal information systems								01/19/19				02/28/19	Rescinded
4761-14-01	Accepting and storing hyperbaric technologist certifications												02/28/19	Rescinded

Rule	Rule Description	Date to Committee	Comm approval	Board approval	Sent for Comment	Board Approval	CSI filing	Board Approval	JCARR filing	Rules Hearing	Board Review	Board Adoption	New Effective Date	Current Review Date
4761-15-01	Miscellaneous Provisions			04/11/18	04/19/18	07/11/18	09/25/18		11/15/18	12/17/18			02/28/19	02/28/24
4762-1-01	Military Provisions Related to Certificate to Practice Acupuncture or Oriental Medicine		08/06/14	8/6/14 05/13/15			1/8/2015 7/1/15		09/24/15	11/02/15	12/09/15	12/09/15	12/31/15	12/31/20
4774-1-01	Definitions	3/9/16 1/13/2016			01/15/16		04/04/16		10/20/16 8/16/2016	09/19/16		12/14/16	12/31/16	12/31/21
4774-1-02	Application for Certificate to Practice	3/9/16 1/13/2016			01/15/16		04/04/16		08/16/16	09/19/16	10/19/16	11/09/16	11/30/16	11/31/2021
4774-1-02.1	Military Provisions related to Certificate to Practice as a Radiologist Assistant		07/09/14	8/6/14 05/13/15			1/8/2015 7/1/15					09/09/15	09/30/15	09/30/20
4774-1-03	Renewal of Certificate to Practice	3/9/16 1/13/2016			01/15/16		04/04/16		08/16/16	09/19/16	10/19/16	11/09/16	11/30/16	11/30/21
4774-1-04	Miscellaneous Provisions	3/9/16 1/13/2016			01/15/16		04/04/16		08/17/16					08/17/21
4774-2-01	Definitions	3/9/16 1/13/2016			01/15/16		04/04/16		08/17/16					08/17/21
4774-2-02	Criminal Records Checks	3/9/16 1/13/2016			01/15/16		04/04/16		08/16/16	09/19/16	10/19/16	11/09/16	11/30/16	11/30/21
4778-1-01	Definition				04/19/18		08/24/18		01/24/19					01/29/19
4778-1-02	Application				04/19/18		08/24/18		01/24/19					01/29/19
4778-1-02.1	Military Provisions related to Certificate to Practice as a Genetic Counselor		08/06/14	4/11/18 8/6/14 05/13/15	04/19/18		8/24/18 1/8/2015 7/1/15		01/24/19			09/09/15	09/30/15	09/30/20
4778-1-03	Special Activity License				04/19/18		08/24/18		01/24/19					01/29/19
4778-1-05	Collaboration Agreement			04/11/18	04/19/18		08/24/18		01/24/19					01/29/19
4778-1-06	Miscellaneous Provisions			04/11/18	04/19/18		08/24/18		01/24/19					01/29/19
4778-2-01	Definitions			04/11/18	04/19/18		08/24/18		01/24/19					01/29/19
4778-2-02	Criminal Records Check				04/19/18		08/24/18		01/24/19					01/29/19
DRAFT	Misbranded Drugs													
NOTE RE: 4731-12-03 for next review	what had been known as NBPME Parts I, II, and III will now be designated as the American Podiatric Medical Licensing Examination (APMLE) Parts I, II, and III													

Legal Dept. Rules Schedule

As of 2/26/19

To March Board for Approval to Refile
4731-1-17

To March Policy Committee
Military Rules for all License Types

Sent for Initial Comment – deadline 3/6/19
4731-4-01 4731-4-02
4731-7-01 4731-9-01

Sent for Initial Comment – deadline 2/8/19
4731-35-01 4731-35-02

Rules at CSI
4731-18 Chapter (anti-trust review)

Comment deadline 11/22/18
4731-1-08

Comment deadline (resubmitted)
4731-1-24

Comment deadline 8/24/17
4731-1-01 4731-1-13
4731-1-11 4731-1-18
4731-1-19

Comment Deadline 5/31/18
4731-31-01

Comment Deadline 7/13/18
4731-18-01 4731-25-08
4731-34-01

Comment Deadline 10/12/18
4731-1-02 4731-1-05
4731-6 Chapter 4759 Chapter

Comment Deadline 1/29/19
4731-16-16 4731-24-03
4731-24-01 4731-24-04
4731-24-02

At JCARR- Hearing 2/27/19
4778-1-02 4778-2-01
4778-1-02.1 4778-2-02
4778-1-05 4778-1-06

At JCAAR – no change – jurisdiction ends 5/5/19
4731-27-01

At JCAAR – no change – jurisdiction ends 4/24/19
4778-1-01 4778-1-03

At JCAAR – Hearing 3/12/19
4761-11-03 4731-27-03
4731-27-02

Refiled with JCARR – on 3/4/19 JCARR Agenda
4730-4-01 4731-33-01
4730-4-03 4731-33-03
4730-4-04 4731-33-04
4731-11-12

Anticipated Schedule for 2019 Policy Committee

January:	*Consult Agreements – sent for initial comment–deadline 2/8/19*
February:	*4731-7-01 (Method of Notice of Meetings) ;4731-9-01 (Record of Board Meetings) ;4731-4-01;4731-4-02 (Criminal Records Checks) – to February Policy Committee*
March:	*Military Rules for all License Types*
April:	Dietetics Rules
May:	MAT Detox Rule
June:	Respiratory Care Rules – 4761 – 2nd group
July:	4731-11-03; 4731-11-04; 4731-11-041;4731-11-05; 4731-11-11 (Controlled Substance Rules)

State Medical Board of Ohio

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MEMORANDUM

TO: Amol Soin, M.D., Chair, Policy Committee
Members, Policy Committee

FROM: Nathan T. Smith, Senior Legal and Policy Counsel

DATE: March 8, 2019

RE: Proposed Ohio Administrative Code rules related to licensure, renewal and continuing education for military service members

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The attached proposed Ohio Administrative Code ("OAC") rules update and consolidate the Medical Board's current military rules which carry out the requirements of Ohio Revised Code sections 5903.03, 5903.04, 5903.10, 5903.12, and 5903.121 for occupational licensure, renewal of licensure, expedited processing of license applications, and continuing education.

Provisions from fourteen (14) different rules in seven (7) OAC chapters are proposed to be consolidated into three (3) rules in one OAC chapter. The following proposed rules consistently apply the above referenced laws to all Medical Board license types:

4731-36-01 Military Provisions Related to Education and Experience Requirements for Licensure
4731-36-02 Military Provisions Related to Renewal of License and Continuing Education
4731-36-03 Processing applications from service members, veterans, or spouses of service members or veterans.

Also, the following rules are proposed to be rescinded so that the above listed proposed Chapter 4731-36 rules will constitute the Board's military rules for all licenses:

4730-1-06.1 Military provisions related to certificate to practice as a physician assistant
4731-1-25 Determination of equivalent military education for cosmetic therapy or massage therapy.
4731-6-35 Processing applications from service members, veterans, or spouses of service members or veterans.
4731-24-05 Military provisions related to certificate to practice as an anesthesiologist assistant.
4759-4-12 Consideration of military experience, education, training and term of service.
4759-4-13 Temporary license for military spouse
4761-4-03 Recognition of military educational programs for active duty military members and/or military veterans
4761-12-01 Initial application fee
4762-1-01 Military provisions related to certificate to practice acupuncture or oriental medicine.
4774-1-02.1 Military provisions related to certificate to practice as a radiologist assistant.
4778-1-02.1 Military provisions related to certificate to practice as a genetic counselor.

Lastly, the following rules are proposed to be amended to remove existing military provisions. Among these amended rules, rules 4761-8-01 and 4761-9-02 have additional respiratory care licensure and continuing education changes requested by the Board's Licensure department for consistency with Medical Board processes and statutory changes in these areas:

4730-1-06 Licensure as a physician assistant
4761-8-01 Renewal of license or permits
4761-9-02 General RCCE requirements and reporting mechanism

REQUESTED ACTION:

Approve that the proposed rules be sent to interested parties for comment in initial circulation and be referred to the Respiratory Care and Dietetics advisory councils as well as the PAPC for review.

4731-36-01 Military Provisions Related to Education and Experience Requirements for Licensure

(A) Definitions

For purposes of this chapter:

(1) "Armed forces" means any of the following:

(a) The armed forces of the United States, including the army, navy, air force, marine corps, and coast guard;

(b) A reserve component of the armed forces listed in paragraph (A)(1)(a) of this rule;

(c) The national guard, including the Ohio national guard or the national guard of any other state;

(d) The commissioned corps of the United States public health service;

(e) The merchant marine service during wartime;

(f) Such other service as may be designated by Congress; or

(g) The Ohio organized militia when engaged in full-time national guard duty for a period of more than thirty days.

(2) "Board" means the state medical board of Ohio.

(B) Education and service for eligibility for licensure.

(1) In accordance with section 5903.03 of the Revised Code, the following military programs of training, military primary specialties, and lengths of service are substantially equivalent to or exceed the educational and experience requirements for licensure as a physician assistant and for a prescriber number:

(a) An individual serving in a military primary specialty listed in paragraph (B)(1)(b) of this rule must be a graduate of a physician assistant education program approved by the accreditation review commission on education for the physician assistant.

(b) Service in one of the following military primary specialties for at least two consecutive years while on active duty, with evidence of service under honorable conditions, including any experience attained while practicing as a physician assistant at a health care facility or clinic operated by the United States department of veterans affairs, may be substituted for a master's degree for eligibility for a license to practice as a physician assistant pursuant to section 4730.11 of the Revised Code and for a prescriber number pursuant to section 4730.15 of the Revised Code ;

(i) Army: MOS 65D;

(ii) Navy: NOBC 0113;

(iii) Air force: AFSC 42G;

(iv) The national guard of Ohio or any state;

(v) Marine: Physician assistant services are provided by Navy personnel;

(vi) Coast guard;

(vii) Public health service.

(2) For purposes of section 5903.03 of the Revised Code, the board has determined that there are no military programs of training, military primary specialties, or lengths of service that are substantially equivalent to or that exceed the educational and experience requirements for licensure as a cosmetic therapist or massage therapist.

(3) For purposes of section 5903.03 of the Revised Code, the board has determined that there are no military programs of training, military primary specialties, or lengths of service that are substantially equivalent to or that exceed the educational and experience requirements for licensure to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery.

(4) For purposes of section 5903.03 of the Revised Code, the board has determined that there are no military programs of training, military primary specialties, or lengths of service that are substantially equivalent to or that exceed the educational and experience requirements for licensure as a dietitian.

(5) For purposes of section 5903.03 of the Revised Code, the board recognizes respiratory care educational programs offered by branches of the United States military that have been issued provisional accreditation, initial accreditation, continuing accreditation or other accreditation status conferred by the commission on accreditation for respiratory care (CoARC) or their successor organization that permits respiratory care programs offered by the United States military to continue to enroll and/or graduate students.

(6) For purposes of section 5903.03 of the Revised Code, the board has determined that there are no military programs of training, military primary specialties, and lengths of service that are substantially equivalent to or exceed the educational and experience requirements for licensure as an acupuncturist or oriental medicine practitioner.

(7) For the purposes of section 5903.03 of the Revised Code, the board has determined that there are no military programs of training, military primary specialties, or lengths of service that are substantially equivalent to or exceed the educational and experience requirements for licensure as a radiologist assistant.

(8) For the purposes of section 5903.03 of the Revised Code, the board has determined that there are no military programs of training, military primary specialties, or lengths of service that are substantially equivalent to or exceed the educational and experience requirements for licensure as a genetic counselor.

4731-36-02 Military Provisions Related to Renewal of License and Continuing Education

(A) Renewal of an expired license or certificate to practice without a late free or re-examination.

(1) An expired license or certificate to practice pursuant to Chapter 4730., 4731., 4759., 4761., 4762., 4774., or 4778. of the Revised Code shall be renewed upon payment of the renewal fee provided for in Chapter 4730., 4731., 4759., 4761., 4762., 4774., or 4778. of the Revised Code and without a late fee or re-examination if the holder meets all of the following requirements:

(a) The licensee is not otherwise disqualified from renewal because of mental or physical disability;

(b) The licensee meets the requirements for renewal for the particular license or certificate to practice pursuant to Chapter 4730., 4731., 4759., 4761., 4762., 4774., or 4778. of the Revised Code ;

(c) Either of the following situations applies:

(i) The license was not renewed because of the licensee's service in the armed forces, or

(ii) The license was not renewed because the licensee's spouse served in the armed forces, and the service resulted in the licensee's absence from this state.

(d) The licensee or the licensee's spouse, whichever is applicable, has presented satisfactory evidence of the service member's discharge under honorable conditions or release under honorable conditions from active duty or national guard duty within six months after the discharge or release.

(B) Continuing education.

(1) Extension of the continuing education period for the license or certificate to practice pursuant to Chapter 4730., 4731., 4759., 4761., 4762., or 4778. of the Revised Code:

(a) The holder of a license or certificate to practice may apply for an extension of the current continuing education reporting period in the manner provided in section 5903.12 of the Revised Code by submitting both of the following:

(i) A statement that the licensee has served on active duty, whether inside or outside of the United States, for a specified period of time during the current continuing education reporting period.

(ii) Proper documentation certifying the active duty service and the length of that active duty service.

(b) Upon receiving the application and proper documentation, the board shall extend the current continuing education reporting period by an amount of time equal to the total number of months that the licensee spent on active duty during the current continuing education reporting period. Any portion of a month served shall be considered one full month.

(2) The board shall consider relevant education, training, or service completed by a licensee as a member of the armed forces in determining whether a licensee has met the continuing education requirements needed to renew the license.

(3) For purposes of sections 5903.12 and 5903.121 of the Revised Code, anesthesiologist assistants in Chapter 4731. of the Revised Code, acupuncturists in Chapter 4762. of the Revised Code, and radiologist assistants in Chapter 4774. of the Revised Code are not required to report continuing education coursework to the board.

4731-36-03 Processing applications from service members, veterans, or spouses of service members or veterans

(A) The board shall include questions on all applications for licensure, renewal, reinstatement or restoration of licensure for all applicants for licensure or certificate to practice pursuant to Chapters 4730., 4731., 4759., 4761., 4762., 4774., and 4778. that inquire as to whether the applicant is:

(1) A service member;

(2) A veteran; or

(3) The spouse or surviving spouse of a service member or veteran.

(B) If the applicant for licensure, biennial renewal, reinstatement, or restoration of licensure responds affirmatively to any of the questions discussed in paragraph (A) of this rule, the board shall process the application in the following manner:

(1) Route the application to a board staff member who is responsible for monitoring the application and communicating with the applicant regarding the status of the application, including informing the applicant of any documentation needed for the board to process the application;

(2) Expedite the processing of the application, even if the application was received later in time than other applications that are pending processing;

(3) Provide information regarding available continuing education waivers to applicants if the applicant or the applicant's spouse will be imminently deployed; and

(4) Track, on an annual basis, the total number of applications submitted by service members, veterans, spouses or surviving spouses of service members or veterans, and the average number of business days expended by the board to process those applications.

4730-1-06 Licensure as a physician assistant.

(A) All applicants for a physician assistant license shall file a written application under oath in the manner provided by section 4730.10 of the Revised Code.

(B) No application shall be considered filed, and shall not be reviewed, until the fee required by section 4730.10 of the Revised Code has been received by the board.

(C) An application shall be considered complete when all of the following requirements are met:

(1) The fee required pursuant to section 4730.10 of the Revised Code has been received by the board;

(2) Verification of the applicant's current certification has been received by the board directly from the "National Commission on Certification of Physician Assistants";

(3) All information required by section 4730.10 of the Revised Code, including such other facts and materials as the board requires, has been received by the board; and

(4) The applicant has complied with the requirements of paragraph (A) of rule 4730-3-02 of the Administrative Code and the board has received the results of the criminal records checks and any other forms required to be submitted pursuant to paragraph (A) of rule 4730-3-02 of the Administrative Code.

(5) The board is not conducting an investigation, pursuant to section 4730.26 of the Revised Code, of evidence appearing to show that the applicant has violated section 4730.25 of the Revised Code or applicable rules adopted by the board.

(D) All application materials submitted to the board will be thoroughly investigated. The board will contact individuals, agencies, or organizations for information about applicants as the board deems necessary. As part of the application process, an applicant may be requested to appear before the board or a representative thereof to answer questions or provide additional information.

(E) Applications received from service members, veterans, or spouses of service members or veterans shall be identified and processed in accordance with rule 4731-6-35 of the Administrative Code.

(F) The following processes apply when an application is not complete within six months of the date the application is filed with the board:

(1) If the application is not complete because required information, facts, or other materials have not been received by the board, the board may notify the applicant in writing that it intends to consider the application abandoned if the application is not completed.

(a) The written notice shall:

(i) Specifically identify the information, facts, or other materials required to complete the application; and

(ii) Inform the applicant that the information, facts, or other materials must be received by the deadline date specified; that if the application remains incomplete at the close of business on the deadline date

the application may be deemed to be abandoned and no further review of the application will occur; and that if the application is abandoned the submitted fees shall neither be refundable nor transferable to a subsequent application.

(b) If all of the information, facts, or other materials are received by the board by the deadline date and the application is determined to be complete, the board shall process the application and may require updated information as it deems necessary.

(2) If the application is not complete because the board is investigating, pursuant to section 4730.26 of the Revised Code, evidence appearing to show that the applicant has violated Chapter 4730. of the Revised Code or applicable rules adopted by the board, the board shall do both of the following:

(a) Notify the applicant that although otherwise complete, the application will not be processed pending completion of the investigation; and

(b) Upon completion of the investigation and the determination that the applicant is not in violation of statute or rule, process the application, including requiring updated information as it deems necessary.

(G) The holder of a physician assistant license issued under section 4730.11 of the Revised Code who did not have a qualifying master's degree or higher at the time of licensure and did not receive a valid prescriber number with the license may obtain a valid prescriber number by meeting the requirements of division (E)(3) of section 4730.11 of the Revised Code.

(H) A physician assistant license must be renewed in the manner and according to the requirements of section 4730.14 of the Revised Code.

(I) To qualify for renewal of a physician assistant license, the holder shall comply with the following:

(1) Each applicant for renewal shall certify that the applicant has completed the requisite hours of CME since the start of the licensure registration period.

(2) Except as provided in paragraph (I)(4) of this rule, a physician assistant shall have completed one hundred hours of CME during the licensure registration period.

(3) Pursuant to the provisions of section 4745.04 of the Revised Code, the board shall permit a physician assistant to earn one hour of CME for each sixty minutes spent providing health care services in Ohio, as a volunteer, to indigent and ~~unisured~~ uninsured persons, up to a maximum of thirty-three hours per CME period. Physician assistants seeking to receive credit toward CME requirements shall maintain a log of their qualifying activities. The log shall indicate the dates the health care services were provided, the number of hours spent providing health care services on those dates, the location where the health care services were provided, and the signature of the medical director or the medical director's designee.

(4) Proration of hours required:

(a) If the physician assistant license is initially issued prior to the first day of the second year of a licensure period, the licensee shall be required to earn fifty total hours; if the license is issued on or after the first day of the second year of the licensure period and prior to the first day of the eighteenth month of that

licensure period, the licensee shall be required to earn twenty-five total hours; if the license is issued on or after the first day of the eighteenth month of a licensure period, the licensee shall not be required to earn any hours of CME for that licensure period.

(b) Pursuant to the provisions of section 4745.04 of the Revised Code, the board shall permit a physician assistant to earn one hour of CME for each sixty minutes spent providing health care services in Ohio, as a volunteer, to indigent and uninsured persons, when it is documented as required by paragraph (I)(3) of this rule, up to the following maximums:

(i) For a physician assistant required to earn fifty total hours, a maximum of sixteen hours for that CME period.

(ii) For a physician assistant required to earn twenty-five total hours, a maximum of eight hours for that CME period.

(5) Only those hours earned from the date of licensure to the end of the licensure period shall be used towards the total hour requirement as contained in this rule.

(6) Completion of the CME requirement may be satisfied by courses acceptable for the individual to maintain NCCPA certification.

(J) To qualify for renewal of a physician assistant license with a valid prescriber number, the physician assistant shall comply with all of the following requirements:

(1) Completion of the requirements in paragraph (I) of the rule;

(2) Except as provided in paragraph (J)(4) of this rule, completion of at least twelve hours of category I continuing education in pharmacology as certified by the "Ohio Association of Physician Assistants," "Ohio State Medical Association," Ohio Osteopathic Association," Ohio Foot and Ankle Medical Association," a continuing medical education provider accredited by the ACCME and approved by the board, "American Academy of Physician Assistants," "American Council on Pharmacy Education," or and advanced instructional program in pharmacology approved by the Ohio board of nursing.

(a) Certification is a process whereby ACCME accredited providers define their respective continuing medical education program requirements for periodic submission to the board for approval.

(b) The board may approve each association's continuing medical education requirements which consist of continuing medical education category I courses and activities that are deemed acceptable for completing the requisite hours of continuing education in pharmacology by each licensee who has a valid prescriber number.

(3) If the physician assistant prescribes opioid analgesics or benzodiazepines, the applicant for renewal shall certify having been granted access to OARRS, unless one of the exemptions in section 4730.49 of the Revised Code is applicable.

(4) If the renewal of the license with a valid prescriber number is the first renewal after the holder has completed the five hundred hours of on site supervision required by section 4730.44 of the Revised Code, the requisite hours of pharmacology continuing education are as follows:

(a) If the five hundred hours were completed prior to the first day of the second year of the licensure period, the licensee shall be required to earn six total hours of pharmacology continuing education;

(b) If the five hundred hours were completed on or after the first day of the second year of the licensure period and prior to the eighteenth month of that licensure period, the licensee shall be required to earn three total hours;

(c) If the five hundred hours were completed on or after the first day of the eighteenth month of a licensure period, the licensee shall not be required to earn any hours of pharmacology continuing education for that licensure period.

~~(K) A physician assistant who served on active duty in any of the armed forces, as that term is defined in rule 4730-1-06.1 of the Administrative Code, during the licensure period may apply for an extension of the continuing education period by meeting the requirements of rule 4730-1-06.1 of the Administrative Code.~~

4761-8-01 Renewal of license or permits.

~~(A) Renewal applications:~~

~~At least one month prior to the license or limited permit expiration date established under paragraphs (D) and (E) of rule 4761-7-01 of the Administrative Code, the board shall send each license and limited permit holder a renewal application by first class mail to the holder's last known address of record.~~

(A ~~B~~) License renewal:

On or before June thirtieth of every even year, persons holding a license to practice respiratory care shall apply for renewal in accordance with section 4761.06 of the Revised Code, complete the prescribed application in the manner determined by the board, ~~electronic or paper renewal form (form rcb-049, revised 12/12/2012),~~ submit the renewal fee ~~established in rule 4761-12-02 of the Administrative Code~~, and complete the required continuing education in accordance with rule 4761-9-02 of the Administrative Code.

~~(1) Any license renewal application that is post-marked after the June thirtieth expiration date shall, in addition to the renewal fee, include a late renewal fee equal to one-half the renewal fee established in rule 4761-12-02 of the Administrative Code.~~

~~(2) Initial license holders that have held a license for less than six months before the June thirtieth biennial expiration date will not be required to file a renewal application or renewal fee for the following biennial term.~~

(B ~~C~~) Limited permit renewal.

On or before the expiration date, ~~June thirtieth of each year,~~ persons holding a limited permit shall apply for renewal in accordance with section 4761.06 of the Revised Code, complete the prescribed application in the manner determined by the board, ~~paper renewal form (form rcb-004, revised 12/2012),~~ and submit the renewal fee. ~~established in rule 4761-12-02 of the Administrative Code, and complete the following, as applicable:~~

~~(1) Any limited permit renewal application that is post-marked after the June thirtieth expiration date shall, in addition to the renewal fee, include a late renewal fee equal to one-half the renewal fee established in rule 4761-12-02 of the Administrative Code.~~

~~(2) Initial limited permit holders that have held a limited permit for less than six months before the annual June thirtieth expiration date will not be required to file a renewal application or renewal fee for the following year.~~

~~(3) Holders of a limited permit issued in accordance with paragraphs (A)(1)(a) and (A)(1)(b) of rule 4761-6-01 of the Administrative Code shall resubmit proof of meeting the requirements of those paragraphs.~~

~~(4) Holders of limited permits issued in accordance with paragraph (A)(1)(c) of rule 4761-6-01 of the Administrative Code shall submit proof of current employment as a provider of respiratory care and proof~~

~~of meeting the continuing education requirements specified in paragraph (C)(2) of rule 4761-9-02of the Administrative Code.~~

~~(D) The board shall provide an electronic license or limited permit verification website to allow the public, a license holder or limited permit holder to search for and verify the current authorization status, initial issue date and expiration date of a license or limited permit. Additionally, the electronic license or limited permit verification website shall inform the public if any administrative action has been taken against the license or limited permit holder.~~

(C~~E~~) A license or permit holder who fails to renew in accordance with the schedule established under this rule shall have the license or limited permit ~~paragraphs (A) and (B) of this rule shall have the license or permit~~ placed ~~on lapsed or~~ in expired status ~~thirty days after the expiration date of the license or limited permit. In such cases, the expiration date recorded by the board will be the actual date of expiration in accordance with paragraphs (D) and (E) of rule 4761-7-01 of the Administrative Code, not the date the action is posted on the board's records~~.

~~(F) A license or limited permit holder who continues to practice respiratory care in Ohio for more than thirty days after the actual date of expiration in accordance with paragraphs (D) and (E) of rule 4761-7-01 of the Administrative Code shall be subject to disciplinary action under section 4761.09 of the Revised Code.~~

(D~~G~~) An expired ~~lapsed~~ license ~~or license placed in an inactive status in accordance with rule 4761-8-02 of the Administrative Code~~ may be reinstated or restored, as applicable, in accordance with division (C) of section 4761.06 of the Revised Code. ~~to active status by completing the following:~~ If an applicant fails to complete the reinstatement or restoration application process within six months of application filing, the board may notify the applicant in writing of its intention to consider the application abandoned. If no response to that notice is received by the board within thirty days, the board shall consider the application as abandoned and no further processing shall be undertaken with respect to that application.

~~(1) A complete license reinstatement application (form rcb-023, revised 4/17/2013)~~

~~available on the board's website www.respiratorycare.ohio.gov.~~

~~(2) If the license is lapsed or inactive less than five years, the applicant must provide a license verification letter from any state in which a license is or was held, if applicable, and notarized proof of respiratory care continuing education (RCCE) in accordance with paragraph (K) of this rule.~~

~~(3) If the license is lapsed or inactive more than five years from the last expiration date on record with the board,, the applicant must provide proof of current licensure in another state whose standards for licensure are at least equal to those in effect in the state of Ohio at the time of renewal application, or the applicant must successfully pass a re-examination equivalent to the examination recognized by the board to originally obtain a license in the state of Ohio pursuant to rule 4761-5-01 of the Administrative Code. This provision does not apply to a military service member or spouse of a military service member that was prevented from renewing a lapsed or inactive license within five years of the license expiration date due to active duty military service. If active duty military service applies, the board will extend the filing deadline for a period of time equal to the number of days in active duty military service beyond the five year date.~~

~~(4) Payment of the appropriate renewal fees and late fees in accordance with rule 4761-12-02 of the Administrative Code. If the applicant is a military service member or spouse of a military service member and was unable to renew the license on or before the license expiration date due to active duty miltary service, the late fee shall be waived.~~

~~(5) Incomplete license reinstatement applications will be held open for ninety days following notification of incomplete requirements by regular mail. After sixty days, a final notice of incomplete application will be mailed by certified mail, return-receipt requested. If the final notice is returned as unclaimed by the United States postal service, the board shall mail the final notice to the last address of record by regular mail. The final notice shall be deemed served on the date of mailing by regular mail. If, by the end of the ninety day period, the application remains incomplete, it will be considered abandoned. After ninety days, if desired, the applicant must submit a new application, including fee.~~

~~(H) A lapsed limited permit may be reinstated by completing the following:~~

~~(1) Contact the board to obtain the prescribed paper renewal application (form rcb-004, revised 12/2012).~~

~~(2) Complete the prescribed paper renewal application.~~

~~(3) If the limited permit was issued based on enrollment or graduate status under division (B)(1)(a) of section 4761.05 of the Revised Code, proof of meeting the requirements of division (A)(1) of section 4761.06 of the Revised Code.~~

~~(4) If the limited permit was issued based on employment in the practice of respiratory care under division (B)(1)(b) of section 4761.05 of the Revised Code, proof of meeting the requirements of division (A)(2) of section 4761.06 of the Revised Code.~~

~~(5) Incomplete limited permit reinstatement applications will be held open for ninety days following notification of incomplete requirements by regular mail. After sixty days, a final notice of incomplete application will be mailed by certified mail, return receipt requested. If the final notice is returned as unclaimed by the United States postal service, the board shall mail the final notice to the last address of record by regular mail. The final notice shall be deemed served on the date of mailing by regular mail. If, by the end of the ninety day period, the application remains incomplete, it will be considered abandoned. After ninety days, if desired, the applicant must submit a new application, including fee.~~

(E~~I~~) A license reinstated or restored in accordance with paragraph (D~~G~~) of this rule will expire on the next biennial expiration date.

~~(J) A limited permit reinstated in accordance with paragraph (H) of this rule will expire on the next annual expiration date.~~

(K) If a licensee has not completed the requisite RCCE contact hours, a license is not eligible for license renewal or reinstatement. The number of RCCE contact hours required for restoration ~~reactivation~~ of an expired ~~lapsed~~ license ~~or limited permit issued in accordance with division (B)(1)(b) of section 4761.05 of the Revised Code~~ shall be equal to the amount required of the applicant had the license ~~or limited permit~~ not ~~lapsed~~ expired and must have been completed within the two years prior to the date of application for restoration. ~~The total number of contact hours required will include the hours due to be reported at~~

~~the time the license or permit lapsed and any due thereafter until the time of application for reinstatement. The continuing education requirements set forth in Chapter 4761-9 of the Administrative Code shall apply equally to an individual seeking reactivation of a lapsed license or limited permit issued in accordance with division (B)(1)(b) of section 4761.05 of the Revised Code. If a lapsed licensee holds an active license in another state, the board may consider the continuing education requirements of that state for the purposes of determining equivalence with Ohio's requirements. The board may require applicants to complete continuing education contact hours needed to equal the biennial requirement in the state of Ohio under rule 4761-9-02 of the Administrative Code. If the lapsed licensee is a military service member or spouse of a military service member, the board may consider any applicable waiver of continuing education under paragraph (G)(2) of rule 4761-9-02 of the Administrative Code for the purposes of determing the number of RCCE contact hours required for the reactivation of a lapsed license or limited permit.~~

4761-9-02 General RCCE requirements and reporting mechanism.

(A) Licensees and limited permit holders shall verify the successful attainment of RCCE from sources approved by the board as set forth in rule 4761-9-05 of the Administrative Code.

(B) RCCE contact hours shall be obtained during the term of collection as set forth in paragraphs (C)(1) and (C)(2) of this rule. RCCE contact hours shall be earned prior to the license or limited permit expiration date for the renewal period. RCCE contact hours earned during the term of collection in excess of required contact hours cannot be applied towards a subsequent renewal period, unless the RCCE contact hours are earned after the filing date of a completed renewal application that is filed prior to the end of the renewal cycle for the specific authorization type held. A renewal application will be deemed complete when the renewal application form is filled out in its entirety, all continuing education required has been reported and is valid and the full renewal fee has been submitted.

(C) Continuing education earned for license or limited permit renewal must minimally include the following content requirements:

(1) An applicant for license renewal shall complete twenty contact hours of relevant RCCE every two years, beginning with the license renewal date and ending on the license expiration date established under paragraph (D) of rule 4761-7-01 of the Administrative Code, unless a waiver is granted under paragraph (G) of this rule. RCCE earned for license renewal must include the following content requirement:

(a) One contact hour of RCCE on Ohio respiratory care law or professional ethics as set forth in rule 4761-9-04 of the Administrative Code; and

(b) At least fifteen of the required contact hours must include content relating to the provision of clinical respiratory care as defined under section4761.01 of the Revised Code; and

(c) The remaining four contact hours may include indirectly related content, including, but not limited to, activities relevant to specialized aspects of respiratory care, such as education, supervision, management, health care cost containment, cost management, health quality standards, disease prevention, health promotion, or abuse reporting.

(2) An applicant for renewal of a limited permit issued under paragraph (A)(1)(c) of rule 4761-6-01 of the Administrative Code, shall complete ten contact hours of relevant RCCE every year, beginning with the limited permit renewal date and ending on the limited permit expiration date established under paragraph (E) of rule 4761-7-01 of the Administrative Code, unless a waiver is granted under paragraph (G)(2) of this rule. RCCE earned for license renewal must include the following content requirement:

(a) One contact hour of RCCE on Ohio respiratory care law or professional ethics as set forth in rule 4761-9-04 of the Administrative Code; and

(b) At least seven of the required contact hours must include content relating to the provision of clinical respiratory care as defined under section 4761.01 of the Revised Code; and

(c) The remaining two contact hours may include indirectly related content, including, but not limited to activities relevant to specialized aspects of respiratory care, such as education, supervision,

management, health care cost containment, cost management, health quality standards, disease prevention, health promotion, or abuse reporting.

(D) In lieu of completing RCCE contact hours required under paragraphs (C)(1)(b), (C)(1)(c), (C)(2)(b) and (C)(2)(c) of this rule, applicants may submit proof of successfully passing any written professional examination administered by the national board for respiratory care, inc. (NBRC), including the written registry examination for advanced respiratory therapists, the recredentialing examination for certified respiratory therapists, the written examination for certified pulmonary function technologists, the written examination for registered pulmonary function technologists, or the written examination for perinatal/pediatric respiratory care. The registered polysomnographic technologist examination administered by the board of registered polysomnographic technologists (BRPT) and the certified asthma educator examination administered by the national asthma certification board (NACB) are also accepted written examinations.

~~(E) If applicable, the application form for license or limited permit renewal shall include a section for recording RCCE compliance. Licensees or limited permit holders shall complete the section to certify the completion of the required contact hours of RCCE for the current renewal period.~~

(F) It shall be the responsibility of the licensee to maintain and keep all records to serve as documentation for any audit which may be conducted in accordance with rule 4761-9-07 of the Administrative Code pertaining to the completion of RCCE requirements; including, but not limited to certificates of completion, transcripts, letters of attendance, or attendance registers. Records shall be maintained for a period of one year after the end of a registration period. ~~four years or two renewal periods for the holders of a license issued under section 4761.04 of the Revised Code and for a period of three years or three renewal periods for the holders of a limited permit issued under division (B)(1)(b) of section 4761.05 of the Revised Code~~. Legible copies shall be sent to the board only in response to an audit.

(G) Waiver of RCCE requirements.

(1) A first time license holder in the state of Ohio who has been licensed for more than six months, but less than one year from the license expiration date must complete at least one half of the RCCE requirements listed in paragraph (C)(1) of this rule, including one contact hour on Ohio respiratory care law or professional ethics. First time license holders who have held a license for less than six months from the biennial license expiration date will not be required to complete the RCCE requirements for the current term of collection, but will have to complete the RCCE requirements for the following biennial renewal period.

~~(2) At the time of filing an application for license or limited permit renewal, a request to waive the RCCE requirements may be filed. The board may grant the following waivers if documentation requested is provided:~~

~~(a) The applicant is an active duty military service member or the spouse of an active duty service member serving outside of Ohio. Applicants for renewal of a license or limited permit presenting a copy of military service orders for self or a spouse may be eligible for the following:~~

~~(i) Waiver of all RCCE required if on active duty military service and active duty service time exceed more than one half of the term of collection for the authorization type held.~~

~~(ii) Extension of due date for completion of required RCCE, if on active duty military service for periods of time less than one half of the term of collection for the authorization type held. In these cases, the board shall extend the RCCE completion due date for a period of time equal the the time spent in active duty military service.~~

~~(b) Waiver of all RCCE required if applicant has been prevented from completing the RCCE requirement due to a documented medical disability for more than one half of the term of collection for the authorization type held.~~

(2) For purposes of obtaining a RCCE waiver, the applicant or licensee shall have the burden of establishing that the illness or absence affected the reasonable opportunity to participate in RCCE activities. No more than 2 hours will be subtracted from the RCCE requirement for each month which is approved for reduction of hours. Application for RCCE waiver shall be completed by the applicant or licensee and submitted to the board at least sixty days prior to the end of the RCCE period. Applicants shall not sign and submit the renewal application prior to receiving approval from the board of the waiver request.

(B) The board shall not waive the total RCCE requirement for any RCCE period.

(C) The board shall not grant a RCCE waiver for consecutive RCCE periods.

(D) Applicants shall be eligible to apply for RCCE waiver only if the applicant's illness or absence from the United States lasted a minimum of six consecutive months and occurred in its entirety within a single RCCE period.

4730-1-06.1 Military provisions related to certificate to practice as a physician assistant. (Propose to rescind)

~~(A) Definitions~~

~~(1) "Armed forces" means any of the following:~~

~~(a) The armed forces of the United States, including the army, navy, air force, marine corps, and coast guard;~~

~~(b) A reserve component of the armed forces listed in paragraph (A)(1)(a) of this rule;~~

~~(c) The national guard, including the Ohio national guard or the national guard of any other state;~~

~~(d) The commissioned corps of the United States public health service;~~

~~(e) The merchant marine service during wartime;~~

~~(f) Such other service as may be designated by Congress; or~~

~~(g) The Ohio organized militia when engaged in full-time national guard duty for a period of more than thirty days.~~

~~(2) "Board" means the state medical board of Ohio.~~

~~(B) Education and service for eligibility for licensure.~~

~~In accordance with section 5903.03 of the Revised Code, the following military programs of training, military primary specialties, and lengths of service are substantially equivalent to or exceed the educational and experience requirements for licensure as a physician assistant and for the certificate to prescribe:~~

~~(1) An individual serving in a military primary specialty listed in paragraph (B)(2) of this rule must be a graduate of a physician assistant education program approved by the accreditation review commission on education for the physician assistant.~~

~~(2) Service in one of the following military primary specialties for at least three consecutive years while on active duty, with evidence of service under honorable conditions, including any experience attained while practicing as a physician assistant at a health care facility or clinic operated by the United States department of veterans affairs, may be substituted for a master's degree for eligibility for a license to practice as a physician assistant and for a certificate to prescribe, pursuant to sections 4730.11 and 4730.44 of the Revised Code:~~

~~(a) Army: MOS 65D;~~

~~(b) Navy: NOBC 0113;~~

~~(c) Air force: AFSC 42G;~~

~~(d) The national guard of Ohio or any state;~~

~~(e) Marine: Physician assistant services are provided by Navy personnel;~~

~~(f) Coast guard;~~

~~(g) Public health service.~~

~~(C) Renewal of an expired license without a late free or re-examination.~~

~~(1) An expired license to practice as a physician assistant shall be renewed upon payment of the biennial renewal fee provided in section 4730.14 of the Revised Code and without a late fee or re-examination if the holder meets all of the following three requirements:~~

~~(a) The licensee is not otherwise disqualified from renewal because of mental or physical disability;~~

~~(b) The licensee meets the requirements for renewal under section 4730.14 of the Revised Code;~~

~~(c) Either of the following situations applies:~~

~~(i) The license was not renewed because of the licensee's service in the armed forces, or~~

~~(ii) The license was not renewed because the licensee's spouse served in the armed forces, and the service resulted in the licensee's absence from this state.~~

~~(d) The licensee or the licensee's spouse, whichever is applicable, has presented satisfactory evidence of the service member's discharge under honorable conditions or release under honorable conditions from active duty or national guard duty within six months after the discharge or release.~~

~~(2) Pursuant to section 4730.48 of the Revised Code, a certificate to prescribe expires on the same date as the physician assistant's license to practice as a physician assistant. There is no late fee or examination requirement for late renewal.~~

~~(D) Continuing education.~~

~~(1) Extension of the continuing education period for the licensure to practice as a physician assistant or for the certificate to prescribe:~~

~~(a) The holder of a physician assistant license or certificate to prescribe may apply for an extension of the current continuing education reporting period in the manner provided in section 5903.12 of the Revised Code by submitting both of the following:~~

~~(i) A statement that the licensee has served on active duty, whether inside or outside of the United States, for a period in excess of thirty-one days during the current continuing education reporting period.~~

~~(ii) Proper documentation certifying the active duty service and the length of that active duty service.~~

~~(b) Upon receiving the application and proper documentation, the board shall extend the current continuing education reporting period by an amount of time equal to the total number of months that the licensee spent on active duty during the current continuing education reporting period. Any portion of a month served shall be considered one full month.~~

~~(2) The board shall consider relevant education, training, or service completed by a licensee as a member of the armed forces in determining whether a licensee has met the continuing education requirements needed to renew the license or the certificate to prescribe.~~

4731-1-25 Determination of equivalent military education for cosmetic therapy or massage therapy. (Propose to rescind)

~~For purposes of section 5903.03 of the Revised Code, the board has determined that there are no military programs of training, military primary specialties, or lengths of service that are substantially equivalent to or that exceed the educational and experience requirements for licensure as a cosmetic therapist or massage therapist.~~

4731-6-35 Processing applications from service members, veterans, or spouses of service members or veterans. (Propose to rescind)

~~(A) The board shall include questions on all applications for licensure, biennial renewal, or restoration of licensure that inquire as to whether the applicant is:~~

~~(1) A service member;~~

~~(2) A veteran; or~~

~~(3) The spouse or surviving spouse of a service member or veteran.~~

~~(B) If the applicant for licensure, biennial renewal submitted by regular mail, or restoration of licensure responds affirmatively to any of the questions discussed in paragraph (A) of this rule, the board shall process the application in the following manner:~~

~~(1) Route the application to a board staff member who is responsible for monitoring the application and communicating with the applicant regarding the status of the application, including informing the applicant of any documentation needed for the board to process the application;~~

~~(2) Expedite the processing of the application, even if the application was received later in time than other applications that are pending processing;~~

~~(3) Provide information regarding available continuing education waivers to applicants if the applicant or their spouse will be imminently deployed;~~

~~(4) Request that the applicant who is seeking licensure as a physician assistant by meeting the requirements of division (C)(3) of section 4730.11 of the Revised Code or a certificate to prescribe by meeting the requirements of division (B)(4) of section 4730.44 of the Revised Code, submit documentation to the board demonstrating that the requirements of that section are met; and~~

~~(5) Track, on an annual basis, the total number of applications submitted by service members, veterans, spouses or surviving spouses of service members or veterans, and the average number of business days expended by the board to process those applications.~~

~~(C) For purposes of paragraph (B)(4) of this rule:~~

~~(1) Acceptable forms of documentation for the application for licensure as a physician assistant includes a document issued by the appropriate office of the armed forces, as that term is defined in section 5903.01 of the Revised Code, showing the applicant is a service member or veteran who has experience practicing as a physician assistant for at least three consecutive years while on active duty, with evidence of service under honorable conditions, in any of the armed forces.~~

~~(2) Acceptable forms of documentation for the applicant for a physician assistant's certificate to prescribe includes an affidavit from an appropriate office of the armed forces, as that term is defined in section 5903.01 of the Revised Code, attesting that the applicant has held valid authority to prescribe therapeutic devices and drugs, including at least some controlled substances during service in the armed forces.~~

4731-24-05 Military provisions related to certificate to practice as an anesthesiologist assistant. (Propose to rescind)

~~(A) Definitions.~~

~~(1) "Armed forces" means any of the following:~~

~~(a) The armed forces of the United States, including the army, navy, air force, marine corps, or coast guard;~~

~~(b) A reserve component of the armed forces listed in paragraph (A)(1)(a) of this rule;~~

~~(c) The national guard, including the Ohio national guard or the national guard of any other state;~~

~~(d) The commissioned corps of the United States public health service;~~

~~(e) The merchant marine service during wartime;~~

~~(f) Such other service as may be designated by Congress; or~~

~~(g) The Ohio organized militia when engaged in full-time natonal guard duty for a period of more than thirty days.~~

~~(2) "Board" means the state medical board of Ohio.~~

~~(B) Eligibility for licensure.~~

~~For the purposes of section 5903.03 of the Revised Code, the board has determined that there are no military programs of training, military primary specialties, or lengths of service that are substantially equivalent to or exceed the educational and experience requirements for licensure as an anesthesiologist assistant.~~

~~(C) Renewal of an expired license.~~

~~An expired license to practice as an anesthesiologist assistant shall be renewed upon payment of the biennial renewal fee provided in section 4760.06 of the Revised Code and without a late fee or re-examination if the holder meets all of the following requirements:~~

~~(1) The licensee is not otherwise disqualified from renewal because of mental or physical disability;~~

~~(2) The licensee meets the requirements for renewal under section 4760.06 of the Revised Code;~~

~~(3) Either of the following situations applies:~~

~~(a) The license was not renewed because of the licensee's service in the armed forces, or~~

~~(b) The license was not renewed because the licensee's spouse served in the armed forces, and the service resulted in the licensee's absence from this state.~~

~~(4) The licensee or the licensee's spouse, whichever is applicable, has presented satisfactory evidence of the service member's discharge under honorable conditions or release under honorable conditions from active duty or national guard duty within six months after the discharge or release.~~

~~(D) For purposes of sections 5903.12 and 5903.121 of the Revised Code, anesthesiologist assistants are not required to report continuing education coursework to the board.~~

4759-4-12 Consideration of military experience, education, training and term of service. (Propose to rescind)

~~(A) Eligibility for licensure.~~

~~In accordance with Chapter 5903. of the Revised Code, the board has determined that there are no military programs of training, military specialties and lengths of service that are substantially equivalent to or which exceed the educational and supervised training requirements for licensure as a dietitian.~~

~~(B) Definitions related to military service and veteran status.~~

~~(1) "Military," in accordance with division (A) of section 5903.03 of the Revised Code, means the armed forces of the United States or a reserve component of the armed forces of the United States, including the Ohio national guard or the national guard of any other state.~~

~~(2) "Member" means any person who is serving in the military,~~

~~(3) "Veteran" means any person who has completed service in the military, and who has been discharged under honorable conditions or who has been transferred to the reserve with evidence of satisfactory service.~~

~~(C) License renewal and continuing education.~~

~~(1) For military members in active duty, the board shall waive the requirements of paragraph (C) of rule 4759-4-04 of the Administrative Code for jurisprudence continuing education.~~

~~(2) In accordance with section 5903.10 of the Revised Code, a licensee whose license expired due to the licensee's service in the armed forces of the United States or a reserve component of the armed forces of the United States, including the Ohio national guard or the national guard of any other state, shall be eligible for renewal of the expired license in accordance with section 4759.06 of the Revised Code, if the following conditions are met:~~

~~The licensee presents the board with satisfactory evidence that, not more than twelve months prior to the date the evidence is submitted to the board, the licensee was honorable discharged or separated under honorable conditions.~~

~~(D) Prorated initial license fee.~~

~~In accordance with paragraph (D) of rule 4759.08 of the Revised Code the board shall waive the prorated initial license fee for military service members.~~

~~(E) Prioritizing veterans and military members licensure applications.~~

~~Applications completed in accordance with section 4759.06 of the Revised Code will be processed within one to two business days.~~

4759-4-13 Temporary license for military spouse. (Propose to rescind)

~~(A) An individual whose spouse is ordered to active military duty in this state is eligible for a temporary military spousal license to practice as a licensed dietitian in accordance with section 4759.06 of the Revised Code.~~

~~(B) An application for a temporary military spousal license shall include the following:~~

~~(1) Proof that the applicant is married to an active duty service member of the armed forces of the United States;~~

~~(2) Proof that the applicant holds a valid, unrestricted license to practice dietetics in another jurisdiction of the United States;~~

~~(3) Proof that the applicant's spouse is assigned to a duty station in Ohio and the applicant is also assigned to a duty station in Ohio pursuant to the spouses's active duty military orders; and~~

~~(4) The initial application fee of one hundred twenty-five dollars.~~

~~(C) A temporary military spouse license shall expire six months after the date of issuance and is not renewable.~~

4761-4-03 Recognition of military educational programs for active duty military members and/or military veterans. (Propose to rescind)

~~The board recognizes respiratory care educational programs offered by branches of the United States military that have been issued provisional accreditation, initial accreditation, continuing accreditation or other accreditation status conferred by the commission on accreditation for respiratory care (CoARC) or their successor organization that permits respiratory care programs offered by the United States military to continue to enroll and/or graduate students.~~

4761-12-01 Initial application fee. (Propose to rescind)

~~(A) The fee for a license shall be seventy-five dollars.~~

~~(B) The fee for a limited permit shall be twenty dollars.~~

~~(C) A fifty per cent discount shall apply for veterans or persons on active duty military service.~~

4762-1-01 Military provisions related to certificate to practice acupuncture or oriental medicine. (Propose to rescind)

~~(A) Definitions.~~

~~(1) "Armed forces" means any of the following:~~

~~(a) The armed forces of the United States, including the army, navy, air force, marine corps, or coast guard;~~

~~(b) A reserve component of the armed forces listed in paragraph (A)(1)(a) of this rule;~~

~~(c) The national guard, including the Ohio national guard or the national guard of any other state.~~

~~(d) The commissioned corps of the United States public health service;~~

~~(e) The merchant marine service during wartime;~~

~~(f) Such other service as may be disignated by congress; or~~

~~(g) The Ohio organized militia when engaged in full-time national guard duty for a period of more than thirty days.~~

~~(2) "Board" means the state medical board of Ohio.~~

~~(B) Eligibility for licensure.~~

~~In accordance with section 5903.03 of the Revised Code, the board has determined that there are no military programs of training, military primary specialties, and lengths of service that are substantially equivalent to or exceed the educational and experience requirements for licensure as an acupuncturist or oriental medicine practitioner.~~

~~(C) Renewal of an expired license.~~

~~An expired license to practice acupuncture or oriental medicine shall be renewed upon payment of the biennial renewal fee provided in section 4762.06of the Revised Code and without a late fee or re-examination if the holder meets all of the following requirements:~~

~~(1) The licensee is not otherwise disqualified from renewal because of mental or physical disability;~~

~~(2) The licensee meets the requirements for renewal of the applicable licensure type under section 4762.06 of the Revised Code;~~

~~(3) Either of the following situations applies:~~

~~(a) The license was not renewed because of the licensee's service in the armed forces, or~~

~~(b) The license was not renewed because the licensee's spouse served in the armed forces, and the service resulted in the licensee's absence from this state.~~

~~(4) The licensee or the licensee's spouse, whichever is applicable, has presented satisfactory evidence of the service member's discharge under honorable conditions or release under honorable conditions from active duty or national guard duty within six months after the discharge or release.~~

~~(D) Extension of the continuing education period.~~

~~(1) An oriental medicine practitioner may apply for an extension of the current continuing education reporting period in the manner provided in section5903.12 of the Revised Code.~~

~~(a) The licensee shall submit both of the following:~~

~~(i) A statement that the licensee has served on active duty, whether inside or outside of the United States, for a period in excess of thirty-one days during the current continuing education reporting period.~~

~~(ii) Proper documentation certifying the active duty service and the length of that active duty service.~~

~~(b) Upon receiving the application and proper documentation, the board shall extend the current continuing education reporting period by an amount of time equal to the total number of months that the licensee spent on active duty during the current continuing education reporting period. Any portion of a month served shall be considered one full month.~~

~~(2) An acupuncturist is not required to report continuing education coursework to the board.~~

4774-1-02.1 Military provisions related to certificate to practice as a radiologist assistant. (Propose to rescind)

~~(A) Definitions~~

~~(1) "Armed forces" means any of the following:~~

~~(a) The armed forces of the United States, including the army, navy, air force, marine corps, and coast guard;~~

~~(b) A reserve component of the armed forces listed in paragraph (A)(1)(a) of this rule;~~

~~(c) The national guard, including the Ohio national guard or the national guard of any other state;~~

~~(d) The commissioned corps of the United States public health service;~~

~~(e) The merchant marine service during wartime;~~

~~(f) Such other service as may be designated by Congress; or~~

~~(g) The Ohio organized militia when engaged in full-time national guard duty for a period of more than thirty days.~~

~~(2) "Board" means the state medical board of Ohio.~~

~~(B) Eligibility for licensure~~

~~For the purposes of section 5903.03 of the Revised Code, the board has determined that there are no military programs of training, military primary specialties, or lengths of service that are substantially equivalent to or exceed the educational and experience requirements for licensure as a radiologist assistant.~~

~~(C) Renewal of an expired license~~

~~An expired license to practice as a radiologist assistant shall be renewed upon payment of the biennial renewal fee provided in section 4774.06 of the Revised Code and without a late fee or re-examination if the holder meets all of the following three requirements~~

~~(1) The licensee is not otherwise disqualified from renewal because of mental or physical disability;~~

~~(2) The licensee meets the requirements for renewal under section 4774.06 of the Revised Code;~~

~~(3) Either of the following situations applies:~~

~~(a) The license was not renewed because of the licensee's servicei n the armed forces, or~~

~~(b) The license was not renewed because the licensee's spouse servedin the armed forces, and the service resulted in the licensee's absence from this state.~~

~~(4) The licensee or the licensee's spouse, whichever is applicable, has presented satisfactory evidence of the service member's discharge under honorable conditions or release under honorable conditions from active duty or national guard duty within six months after the discharge or release.~~

~~(D) For purposes of sections 5903.12 and 5903.121 of the Revised Code, radiologist assistants are not required to report continuing education coursework to the board.~~

4778-1-02.1 Military provisions related to certificate to practice as a genetic counselor. (Propose to rescind)

~~(A) Definitions~~

~~(1) "Armed forces" means any of the following:~~

~~(a) The armed forces of the United States, including the army, navy, air force, marine corps, and coast guard;~~

~~(b) A reserve component of the armed forces listed in paragraph (A)(1)(a) of this rule;~~

~~(c) The national guard, including the Ohio national guard or the national guard of any other state;~~

~~(d) The commissioned corps of the United States public health service;~~

~~(e) The merchant marine service during wartime;~~

~~(f) Such other service as may be designated by Congress; or~~

~~(g) The Ohio organized militia when engaged in full-time national guard duty for a period of more than thirty days.~~

~~(2) "Board" means the state medical board of Ohio.~~

~~(B) Eligibility for licensure.~~

~~For the purposes of section 5903.03 of the Revised Code, the board has determined that there are no military programs of training, military primary specialties, or lengths of service that are substantially equivalent to or exceed the educational and experience requirements for licensure as a genetic counselor:~~

~~(C) Renewal of an expired license.~~

~~An expired license to practice as a genetic counselor shall be renewed upon payment of the biennial renewal fee provided in section 4778.06 of the Revised Code and without a late fee or re-examination if the holder meets all of the following three requirements:~~

~~(1) The licensee is not otherwise disqualified from renewal because of mental or physical disability;~~

~~(2) The licensee meets the requirements for renewal under section 4778.06 of the Revised Code;~~

~~(3) Either of the following situations applies:~~

~~(a) The license was not renewed because of the licensee's service in the armed forces, or~~

~~(b) The license was not renewed because the licensee's spouse served in the armed forces, and the service resulted in the licensee's absence from this state.~~

~~(4) The licensee or the licensee's spouse, whichever is applicable, has presented satisfactory evidence of the service member's discharge under honorable conditions or release under honorable conditions from active duty or national guard duty within six months after the discharge or release.~~

~~(D) Extension of the continuing education period~~

~~(1) The holder of a genetic counselor license may apply for an extension of the current continuing education reporting period in the manner provided in section 5903.12 of the Revised Code by submitting both of the following:~~

~~(a) A statement that the licensee has served on active duty, whether inside or outside of the United States, for a period in excess of thirty-one days during the current continuing education reporting period.~~

~~(b) Proper documentation certifying the active duty service and the length of that active duty service.~~

~~(2) Upon receiving the application and proper documentation, the board shall extend the current continuing education reporting period by an amount of time equal to the total number of months that the licensee spent on active duty during the current continuing education reporting period. Any portion of a month served shall be considered one full month.~~

Ohio State Medical Board of Ohio

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MEMORANDUM

TO: Amol Soin, M.D., Chair, Policy Committee
Members, Policy Committee

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Rules regarding Pharmacy Consult Agreements

DATE: March 8, 2019

On January 18, 2019, the draft consult agreement rules were circulated to interested parties. To date, over 200 comments have been received from physicians, pharmacists and hospital systems around the state. A spreadsheet listing each comment and the comment letters and e-mails have been provided to you.

- Nearly all comments recommended the deletion of the following sections:

  (1) Rule 4731-35-01(A)(1)(i): requirement for physician approval prior to the adjustment to the dose of a controlled substance;
  (2) Rule 4731-35-02(A)(2): requirement for physician to periodically assess the patient at least one time per year.
  (3) Rule 4731-35-02(A)(7): requirement for physician to promptly review records of all services provided to the patient under the consult agreement.
  (4) Rule 4731-35-02(C)(4): requirement for notification and consent of the physician prior to any adjustment in current drug therapy;
  (5) Rule 4731-35-02(D)(1): requirement for regular meetings between the primary physician and managing pharmacist to review a written consult report.

The consensus of the commenters is that these provisions are too restrictive and essentially render the consult agreement useless. **I recommend deleting these sections from the rules**.

- Many of the comments expressed concerns about the wording of the informed consent provisions of the rules and suggested that the rules be modified to reflect the consent provisions in the rules promulgated by the Board of Pharmacy, as follows:

  (1) Rule 4731-35-01(A)(1)(b): Delete the word "informed" and indicate that the patient's consent to drug therapy management is based on Rule 4729:1-6-01 (H) and (I) of the Administrative Code. The Pharmacy Board rule indicates that the patient consent must be obtained prior to the pharmacist managing the care and that the patient must be advised that a pharmacist may be utilized in the management of the patient's care and that the patient or individual authorized to act on behalf of the patient have a right to elect to participate in and withdraw from the consent agreement. The rule also allows the consent to be obtained as part of the patient's initial consent to treatment.
  (2) Rule 4731-35-02(A)(3): Delete language in (a) through (d) regarding the details regarding the consent of the patient and adding language to reflect the requirements from the Board of Pharmacy's rule at 4729:1-6-01(H) and (I) of the Administrative Code.

I recommend making the changes to align the consent language with the Pharmacy Board's language.

- Several commenters expressed concern with the language around the scope of the managing pharmacist in Rule 4731-35-02(B)(1) and (2). It was suggested that this section could be deleted since the language of Rule 4731-35-01(A)(1)(c)-(f) and Rule 4729:1-06-02(b)-(e) already require these items to be outlined in the consult agreement.

I recommend deleting sections (B)(1) and (B)(2) from Rule 4731-35-02.

- Several sections were duplicative or required some clean-up to align with the language from the Board of Pharmacy:

  (1) Rule 4731-35-01(A)(1)(h): language added to match the language in Rule 4729:1-6-02(A)(1)(g) which indicates that the agreement may include a requirement that a managing pharmacist send a consult report to each consulting physician.

  (2) Rule 4731-35-02(A)(2): Modify the references to the sections of the consult agreement dealing with the scope of the agreement for the institutional and ambulatory outpatient facility section.

  (3) Rule 4731-35-02(A)(5): Revise the situations where an amendment to consult agreement is required so it is limited to times when the scope of the permitted procedures expands past what was contemplated.

  (4) Rule 4731-35-01(B): For recordkeeping, add language to indicate that a physician group or institution may also be the entity maintaining the records.

  (5) Rule 4731-35-01(C)(1)(b)(i), (ii): Delete duplicative words at the beginning of each paragraph.

  (6) Rule 4731-35-01(C)(1)(d): Add some language to clarify the meaning of the section.

  (7) Rule 4731-35-02(A)(6): Add some language to indicate that pharmacist's training can be verified through the credentialing process for institutional facilities.

  (8) Rule 4731-35-02(D)(2)(a): Clarify that notification is required if the pharmacist's license is revoked, suspended or denied by the Board of Pharmacy;

  (9) Rule 4731-35-02(D)(2)(b) and (c): Clarify that these sections only apply if the pharmacist is prescribing controlled substances.

I recommend making these changes to clarify and clean up the language in the rules.

Requested Action: Make recommendation to the full Board to file the rules as amended with the Common Sense Initiative

4731-35-01 **Consult Agreements.**

(A) Requirements of a consult agreement.

(1) A consult agreement shall include all of the following:

(a) Identification of the physician(s) and pharmacist(s) authorized to enter into the agreement. They may include:

(i) Individual names of physicians and pharmacists;

(ii) Physician or pharmacist practice groups; or

(iii) Identification based on institutional credentialing or privileging.

(b) A description of the patient's ~~informed~~ consent to drug therapy management pursuant to the consult agreement **as set forth in paragraphs (H) and (I) of Rule 4729:1-06-01 of the Administrative Code**.

(c) The specific diagnoses and diseases being managed under the agreement, including whether each disease is primary or comorbid.

(d) A description of the drugs or drug categories managed as part of the agreement.

(e) A description of the procedures, decision criteria, and plan the managing pharmacist is to follow in acting under a consult agreement. Such a description should provide a reasonable set of parameters of the activities a managing pharmacist is allowed to perform under a consult agreement.

(f) A description of the types of blood, urine or other tests permitted pursuant to section 4729.39 of the Revised Code that may be ordered and evaluated by the managing pharmacist as long as the tests relate directly to the management of drug therapy. This may include specific tests or categories of testing that may be ordered and evaluated.

(g) A description of how the managing pharmacist shall maintain a record of each action taken for each patient whose drug therapy is managed under the agreement. All prescribing, administering, and dispensing of drugs shall be documented using positive identification pursuant to paragraph (N) of rule 4729-5-01 of the Administrative Code.

(h) A description of how communication between a managing pharmacist and physician acting under a consult agreement shall take place at regular intervals specified by the physician who authorized the agreement. **The agreement may include a requirement that the managing pharmacist send a consult report to each consulting physician.**

~~(i) A requirement for physician approval prior to adjustment to the dose of a controlled substance.~~

(j) A provision that allows a physician to override a decision made by the managing pharmacist when appropriate.

(k) An appropriate quality assurance mechanism to ensure that managing pharmacists only act within the scope authorized by the consult agreement.

(l) A description of a continuous quality improvement (CQI) program used to evaluate effectiveness of patient care and ensure positive patient outcomes. The CQI program shall be implemented pursuant to the agreement.

(m) The training and experience criteria for managing pharmacists. The criteria may include privileging or credentialing, board certification, continuing education or any other training requirements. The agreement shall include a process to verify that the managing pharmacists meet the specified criteria.

(n) A statement that the physicians and pharmacists shall meet minimal and prevailing standards of care at all times.

(o) An effective date and expiration date.

(p) Any other requirements contained in rules 4729:1-6-01, 4729:1-6-02 and 4729:1-6-03 of the administrative code.

(2) Institutional or ambulatory outpatient facilities may implement a consult agreement and meet the requirements of paragraphs (A)(1)(**c**~~b~~) to (A)(1)(**f**e) of this rule through institutional credentialing standards or policies. Such standards or policies shall be referenced as part of the consult agreement and available to an agent of the board upon request.

(3) The agreement shall be signed by the primary physician, which may include a medical director or designee if the designee is licensed pursuant to Chapter 4731. of the Revised Code, and one of the following:

(a) The terminal distributor's responsible person, which may include the responsible person's designee if the designee meets the qualifications of the responsible person pursuant to Chapter 4729. of the Revised Code; or

(b) A managing pharmacist licensed pursuant to Chapter 4729. of the Revised Code if that pharmacist is not practicing at a pharmacy or institutional facility licensed as a terminal distributor of dangerous drugs.

(4) All amendments to a consult agreement shall be signed and dated by the

primary physician, which may include a medical director or designee if the designee is licensed pursuant to Chapter 4731. of the Revised Code, and one of the following:

(a) The terminal distributor's responsible person, which may include the responsible person's designee if the designee meets the qualifications of the responsible person pursuant to Chapter 4729. of the Revised Code; or

(b) A managing pharmacist licensed pursuant to Chapter 4729. of the Revised Code if that pharmacist is not practicing at a pharmacy or institutional facility licensed as a terminal distributor of dangerous drugs.

~~(5)~~ Amendments to the consult agreement are required when **t**~~T~~he scope of the managing pharmacist's permitted procedures expands past what was contemplated within the agreement~~; or~~

(a) ~~The subtraction, or addition of an authorized pharmacist; or~~

~~(c) The subtraction or addition of an authorized physician; or~~

~~(d) Other significant changes to the existing agreement~~.

(6) A consult agreement shall be valid for a period not to exceed two years.

(7) Only Ohio licensed physicians practicing in Ohio and Ohio licensed pharmacists may participate in a consult agreement pursuant to section 4729.39 of the Revised Code.

(B) Recordkeeping. The primary physician**, physician group or institution as defined in rule 4729-17-01 of the Administrative Code** shall maintain a copy of the original consult agreement, and all amendments made thereafter, and a record of actions made in consultation with the managing pharmacist regarding each patient's drug therapy. These records shall be maintained in such a manner that they are readily retrievable for at least three years from the date of the last action taken under the agreement. Such consult agreements shall be considered confidential patient records.

(C) Managing Drug Therapy.

(1) For the purpose of implementing the management of a patient's drug therapy by an authorized managing pharmacist acting pursuant to a consult agreement, the primary physician must:

(a) Provide the managing pharmacist with access to the patient's medical record; and

(b) Establish the managing pharmacist's prescriptive authority as one or both

of the following:

(i) ~~A prescriber.~~ A prescriber authorized to issue a drug order in writing, orally, by a manually signed drug order sent via facsimile or by an electronic prescribing system for drugs or combinations or mixtures of drugs to be used by a particular patient as authorized by the consult agreement. For all prescriptions issued by a pharmacist pursuant to this paragraph, the pharmacist shall comply with rules 4729-5-30 and 4729-5-13 of the Administrative Code; and or

(ii) ~~An agent of primary physician.~~ With respect to non-controlled dangerous drugs only, an agent of the consulting physician(s). As an agent of the consulting physician(s), a pharmacist is authorized to issue a drug order, on behalf of the consulting physician(s), in writing, orally, by a manually signed drug order sent via facsimile or by an electronic prescribing system for drugs or combinations or mixtures of drugs to be used by a particular patient as authorized by the consult agreement, and

(c) Specifically authorize the managing pharmacist's ability to:

(i) Change the duration of treatment for the current drug therapy; adjust a drug's strength, dose, dosage form, frequency of administration, route of administration, discontinue a drug, or to prescribe new drugs; and or

(ii) Order blood, urine and other tests related to the drug therapy being managed and to evaluate those results, and

(d) **Identify the e**~~E~~xtent to which, and to whom, the managing pharmacist may delegate drug therapy management to other authorized pharmacists under the agreement.

(D) Review of consult agreements. Upon the request of the state medical board, the primary physician shall immediately provide a copy of the consult agreement, amendments, and any relating policies or documentation pursuant to this rule and section 4729.39 of the revised code. The state medical board may prohibit the execution of a consult agreement, or subsequently void a consult agreement, if the board finds any of the following:

(1) The agreement does not meet the requirements set for in section 4729.39 of the revised code or this division of the administrative code; or

(2) The consult agreement, if executed, would present a danger to patient safety.

4731-35-02 **Standards for managing drug therapy.**

(A) A physician may elect to manage the drug therapy of an established patient by entering into a consult agreement with a pharmacist. The agreement is subject, but not limited to, the following standards:

(1) The primary physician must ensure that the managing pharmacist has access to the patient's medical record, the medical record is accurate, and that while transferring the medical record, the primary physician ensures the confidentiality of the medical record.

(2) The physician must have an ongoing physician-patient relationship with the patient whose drug therapy is being managed, including an initial assessment and diagnosis by the physician prior to the commencement of the consult agreement. ~~The physician shall periodically assess the patient, at least one time per year.~~

(3) **With the exception of inpatient management of patient care at an institutional facility as defined in rule 4729-17-01 of the Administrative Code, t**~~T~~he physician, prior to the effective date of the consult agreement, and prior to a pharmacist managing the patient's drug therapy, shall communicate the content of the proposed consult agreement to each patient whose drug therapy is managed under the agreement, in such a manner that the patient or the patient's representative understands scope and role of the managing pharmacist, which includes the following:

(a) **That a pharmacist may be utilized in the management of the patient's care;**~~That participation in the consult agreement is voluntary and that the patient may choose not to participate;~~

(b) **That the patient or an individual authorized to act on behalf of a patient has the right to elect to participate in and to withdraw from the consult agreement.**~~That the agreement will not be utilized unless the patient or the patient's authorized representative consents to the consult agreement;~~

~~(c) That the consent can be revoked by the patient at any time; and~~

(d) ~~That the consult agreement and the patient's consent will be disclosed to the patient's primary care physician and any other treating physician or healthcare provider.~~

Consent may be obtained as part of the patient's initial consent to treatment.

(4) The diagnosis by the physician must be within the physician's scope of practice.

(5) The physician shall meet the minimal and prevailing standards of care.

(6) The physician must ensure that the pharmacist managing the patient's drug therapy has the requisite training, and experience related to the particular

diagnosis for which the drug therapy is prescribed.**Physicians practicing at institutional or ambulatory outpatient facilities may meet this requirement through institutional credentialing standards or policies.**

(7) The physician shall ~~promptly~~ review the records of all services provided to the patient under the consult agreement.

~~(B) Scope of managing pharmacist.~~

~~(1) Based on the managing pharmacist's training and education, the physician must establish the extent and scope of the managing pharmacist's authority to:~~

~~(a) Change the duration of treatment for the current drug therapy; adjust a drug's strength, dose, dosage form, frequency of administration, route of administration, discontinue a drug, or to prescribe new drugs, including that prior physician approval is required before an adjustment to the dose for controlled substances; and~~

~~(b) Order blood, urine and other tests related to the drug therapy being managed and to evaluate those results.~~

~~(2) The primary physician must also establish:~~

~~(a) Decision criteria the managing pharmacist is to consider when acting pursuant to sections (B)(1)(a), and (B)(1)(b) of this section; and~~

~~(b) A plan the managing pharmacist is to follow prior to conducting an authorized action pursuant to sections (B)(1)(a), and (B)(1)(b) of this section; and~~

~~(c) A plan the managing pharmacist is to follow after having conducted an authorized action pursuant to sections (B)(1)(a), and (B)(1)(b) of this section.~~

(C) Quality assurance mechanisms. The following quality assurance mechanisms shall be implemented to verify information contained within the consult agreement, and ensure the managing pharmacist's actions are authorized and meet the standards listed in sections (A) and (B) of this rule:

(1) Verification of ongoing physician-patient relationship. A physician-patient relationship can be established by detailing criteria set forth in section (A)(2) of this rule, within the consult agreement.

(2) Verification that physician diagnosis is within the physician's scope of practice. Establishing that a diagnosis is within the physician's scope of practice may be established by detailing the criteria set forth in section (A)(4) of this rule, within the consult agreement.

(3) Verification that pharmacist's training and experience is related to the drug therapy. Establishing that a pharmacist's requisite training and experience with a particular drug therapy is related to the diagnosis for which the drug therapy is prescribed, may be established by detailing the criteria set forth in section (A)(6) of this rule, within the consult agreement.

~~(4) When the managing pharmacist changes the duration of treatment for the current drug therapy; adjusts a drug's strength, dose, dosage form, frequency of administration, route of administration, discontinues a drug, prescribes a new drug, or orders urine or blood tests, as authorized under section B)(1)(a), and (B)(1)(b) of this rule, the managing pharmacist must:~~

~~(a) Notify the primary physician prior to any action. The notification shall include a description of:~~

~~(i) The decision criteria considered by the managing pharmacist in deciding to conduct an authorized action; and~~

~~(ii) A description of the proposed authorized action the managing pharmacist intends to conduct.~~

~~(b) Obtain the consent of the primary physician to conduct the proposed authorized action.~~

(D) Continuous quality improvement program. The following should be included in the development of a continuous quality improvement program in order to evaluate the effectiveness of patient care and ensure positive patient outcomes:

~~(1) Regular meetings. The primary physician and managing pharmacist must meet on a regular basis as established in the consult agreement, during which the managing pharmacist is to provide the primary physician with a written consult report, detailing:~~

~~(a) Changes or modifications made to patient's drug therapy and the decision criteria used by the managing pharmacist;~~

~~(b) Urine or blood tests authorized by the managing pharmacist, and the decision criteria used by the managing pharmacist;~~

~~(c) Evaluations made by the managing pharmacist;~~

~~(d) A summary of the managing pharmacist's annual follow-up consultation with patient;~~

~~(e) Other information that may be relevant to evaluating the effectiveness of the drug therapy regime.~~

(2) Notifications to primary physician. The managing pharmacist must notify the primary physician of the following situations regarding any pharmacist authorized to manage drug therapy under the agreement:

(a) A pharmacist has had their ~~substance prescriber registration is~~ **pharmacist license** revoked, suspended, or denied by the state board of pharmacy;

(b) **If prescribing controlled substances, a~~A~~** pharmacist has failed to renew their controlled substance prescriber registration;

(c) **If prescribing controlled substances, a~~A~~** pharmacist fails to obtain or maintain a valid D.E.A. registration;

(E) Overriding decisions of managing pharmacist. Any authorized physician identified under the consult agreement may override any decision, change, modification, evaluation or other action by any pharmacist acting pursuant to consult agreement or under the direction of the managing pharmacist, that was made with respect to the management of the patient's drug therapy under the consult agreement.

Name	Email	Organization	Comments	Attachments
Comments for Chpt 4731-35				pdf or Word document (link)
36 physicians, Dept. of Internal Medicine	Alicia.Powers@osumc.edu	OSU Medical	All same basic letter -- Oppose ©(4) and (D)(1)	
7 physicians, Heart and Vascula Center	Melissa.Snider@osumc.edu	OSU Medical	Same basic letter. Oppose ©(4) and (A)(2).	
Ahmad, Faraz, M.D.	Faraz.Ahmad@osumc.edu		Requiring prior approval it will serve as a barrier to proving quality timely care. Additionally, it would restrict pharmacists from practicing to their full potential	
Albana, Nicholas, Pharm. D.	Nicholas.Albano@utoledo.edu		Restrict a pharmacist's ability to treat patients under a consult agreement; Placing a phone call each time for these routine tasks will cause patient care delays in therapy and possibly safety issues on missed adjustments.	
Aldrich, Sarah, Pharm.D.	Sarah.Aldrich2@UToledo.Edu	Univ of Toledo, Pharm	(C)(4) and (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as part of the collaborative care model currently provided in my clinic	
Alessandrini, Evie, M.D., Chief Medical Officer	candace.sabers@uchealth.com	UC Health	Oppose numerous provisions	
Almadani, Bashar, M.D.	<Bashar.AlmadaniMD@ProMedica.org>	ProMedica Health Systems	Opposes ©(4)	
Arend, Julie, CNP	JArend@pauldingcountyhospital.com		Opposes ©(4); supports Pharmacy Bd rule	
Arendt, Daniel, Pharm.D	Daniel.Arendt2@UHhospitals.org	UH	4731-35-02©(4) requiring physician approval before any change negates purpose of the consult agreement.	
Armstsrong, Delilah, M.D.	Kathryn.Hunter@UHhospitals.org	UH Primary Care	Oppose ©(4) and (D)(1)	
Bahrey, Kathleen, Pharm.D.	k-bahrey@onu.edu		(C)(4) and {D)(l) of 4731-35-02 Standards for managing drug therapy will effectively demolish the physician-pharmacist team and revoke the opportunity for pharmacists to effectively share in chronic disease state management.	
Baldwin, Tonya, M.D.	llmaul66@buckeye-express.com	Mercy Health - St. Charles	Opposes ©(4); supports Pharmacy Bd rule	
Bang, Michael, M.D.	mbang@medonehp.com	Ohio Health	I appreciate the added clarity that the medical board has provided specific to physician participation in a consult agreement. The requirements for notification and consent prior to action by a pharmacist, as well as the requirement for regular meetings to review a written consult report represent my greatest concerns.	
Bartman, Veronique, M.D.	Veronique.Bartman@osumc.edu	OSU Family Medicine	Opposes ©(4) and (D)(1)	
Beatty, Stuart, Pharm.D.	beatty.52@osu.edu		Opposes ©(4) and (D)(1)	
Berg, Rebecca, Pharm D.	rberg@axesspointe.org		Will increase burden on physicians, decrease patient care. Current agreemens have algorithms for provision of care.	
Bernardon, Dean, M.D.	llmaul66@buckeye-express.com	Mercy Health - St. Charles	Same as Dr. Baldwin	
Berning, Sarah, PharmD student	berninsn@mail.uc.edu		Opposes all.	
Bialecki-Haase, Dee, M.D., Chief Medical Officer –	Janet.VanNest@ProMedica.org	Paramount Insurance Company	Opposes ©(4); supports Pharmacy Bd rule	
Bielefeld, Michael, M.D.	bielefeldmd@netscape.net		Opposes ©(4)	
Bishop, Kent, M.D., Chief Medical Officer	MaryBeth.Delaney@ProMedica.org	Promedica Physicians Group	Oppose ©(4)	
Bishop, Megan, Pharm D candidate	m-bishop.2@onu.edu		Concerned about 4731-35-01(A)(1)(i), (A)(1)(k), and (A)(1)(l) and 4731-35-02(C)(4) and (D)(1). Will limit the pharmacist's ability to provide efficient and adequate patient care, but also warrant additional work to physicians	
Bonenfant, Sara, Pharm D candidate	sloftus1@neomed.edu		would erase pharmacist's ability to act under a consult agreement unless the pharmacists gets prior approval for anything they want to do; negatively affect patient care.	
Boulanger, Bernard, M.D., Chief Clinical Officer; Williams, Sherrie, M.D., Med. Dir.; Kuhn, Jay, RPh., Dir. Pharmacy	cwadsworth@metrohealth.org	MetroHealth	Opposes (B)(2), ©(4), and (D)	
Boyd, Ernie	eboyd@ohiopharmacists.org	Ohio Pharmacist Association	Agrees with Colleen Harrell, Pharm.D.	

Bullock, Carolyn, D.O.	Carolyn.Bullock@ohiohealth.com	Ohio Health	I appreciate the added clarity that the medical board has provided specific to physician participation in a consult agreement. The requirements for notification and consent prior to action by a pharmacist, as well as the requirement for regular meetings to review a written consult report represent my greatest concerns.
Cairns, Craig, VP Medical Affairs	jadamson@lmhealth.org	Licking Memorial Hospital	Opposes ©(4)
Cataland, Spiro, M.D.	Aaron.Dush@osumc.edu	OSU Medical	Opposes (A)(2) and ©(4).
Chaffee, Roger, M.D., Medical Director,	chaffeer@summahealth.org	Summa Health Heart & Vascular Institute	Opposes ©(4)
Chambers, Ashley E, M.D.	Ashley.Chambers@ohiohealth.com	Ohio Health	Opposes ©(4) and (D)(1)
Chaudary, Riaz, M.D.	llmaul66@buckeye-express.com	Mercy Health - St. Charles	Same as Dr. Baldwin
Ciaccia, Antonio, Dir. Gov't and Public Affairs	aciaccia@ohiopharmacists.org	OH Pharmacist Association	Opposes numerous provsions
Clark, Aaron, D.O.	Aaron.Clark@osumc.edu	OSU Medical	Opposes ©(4); requests an exception for pharmacists who practice in a team-based environment, within a providers office, such that the provider is available in real-time during all hours for which the pharmacist is managing patients
Clemons, Marilee, Pharm.D.	Marilee.Clemons@UToledo.Edu	Univ Toledo Medical Center	Oppose ©(4). Should mimic Pharm Bd rules.
Columber, Heather, D.O.	Heather.Columber@ohiohealth.com	Ohio Health	Same as Dr. Bullock
Cooke, Glenn, M.D.	Kim.Crabtree@ohiohealth.com	Ohio Health	Opposes ©(4) and (D)(1)
Cooper, Cathy, M.D.	COOPERC@ccf.org		It's unfortunate that we need to cosign for these highly educated folks- whom we use as a resource and guide in managing rx. Please reconsider- this has been seamless and now that changes are coming- it will once again complicate and delay patient care.
Davidorf, Frederick, M.D.	davidorf.1@osu.edu	OSU Medical	Supports the Pharmacy Bd rules
Davis, Melissa, M.D.	Melissa.Davis@osumc.edu	OSU Medical	Requirement to get pre-approval will cause delays for the patients and add to our administrative burden
Dean, Jacob, M.D.	mhartzler@cedarville.edu	Western Med. Family Physicians	Rule should mirror the Pharmacy Board rule
Deering, Scott, M.D.	scottdeering@sbcglobal.net	Bowling Green Orthopedics	Opposes ©(4); supports Pharmacy Bd rule
Deichstetter, Kaley, PharmD student	deichsky@mail.uc.edu		Opposes all.
Din, Shahab Ud, MD		University of Toledo	Opposes ©4); supports Pharmacy Bd Rule
Doughty, Yana, Pharm.D.	Yana.Steklova@UToledo.Edu	University of Toledo Medical	Opposes ©(4)
Dunkin, David, D.O.	Ashleigh.Dible@memorialohio.com	Memorial Family Medicine	Same as Dr. Kapraly
Eggers, Garrett, Pharm.D.	eggersg@ccf.org	OH Society of Health System Pharmacists	Objections to numerous provisions of the rules.
Eitniear, Lindsey Ann, Pharm. D., Ass't Pharmacy Dir.	<Lindsey.Taylor@utoledo.edu>	Univ Toledo Medical Center	Oppose ©(4) and (D)(1)
El Gamal, Hasham, M.D.	Kristen.Monarch@ProMedica.org		Opposes ©(4); supports Pharmacy Bd rule
Ellis, Michael, M.D., Chief Medical Offficer	Danelle.Mooi@utoledo.edu	Univ Toledo Medical Center	Opposes ©(4)(a) and (b)
Engelhart, Taylor, PharmD	tengelhart@axesspointe.org		Will burden the physicians, limit access to care and delay therapy benefits
Esber, Heather, Program Mgr, Comprensive Diabetis Program	Heather.Esber@ohiohealth.com	Ohio Health	Opposes ©(4) and (D)(1)
Everly, Lukas Pharm.D	leverly@neomed.edu	NEOMED	Requiring physician pre-approval of changes cripples ability of pharmacists to use their expertise.
Farwig, Phillip, Pharm.D.	Phillip.Farwig@osumc.edu	OSU Medical	Same basic letter as 36 Physicians in Dept of Internal Medicine
Federman, Douglas, MD		University of Toledo	Opposes ©4); supports Pharmacy Bd Rule
File, Thomas, M.D.	FileT@summahealth.org	Summa Health	Oppose requirement for pharmacist to get pre-approval.
Fish, John, M.D.	Melissa.Flanders@ProMedica.org		Opposes ©(4); supports Pharmacy Bd rule
Foglio, Julie, Pharm.D.	jefoglio@gmail.com		Opposes section C-4(a).

Fox, Alan S.	alan.foxrph@yahoo.com	Ohio - American Society of Consultant Pharmacists	Opposes ©(4) and (D)(1)
Fuerst, Matthew, MD	Matthew.Fuerst@ohiohealth.com	Ohio Health	Same as Dr. Bullock
Gaiser, Darla, RPh, Dir. Center for Coordinated Care	GaiserD@Firelands.com	Firelands Regional Medical Center	request that a second look be taken at the overall tone as well as the specific tenets of these proposed draft rules; has specific suggestions.
Geise, Regann N., Pharm student	Regann.Geise@rockets.utoledo.edu	University of Toledo College of Pharmacy APhA-ASP students	Oppose requirement for pharmacist to get pre-approval.The suggested rule changes restrict the abilities of the pharmacist in these agreements, demonstrated in the proposed requirement for the physician to review the agreement with the patient, and even allowing the patient to opt out of seeing the pharmacist in the agreement.
Gentile, Nicholas, Dir. Advocacy	NGentile@ashp.org	American Society Health-Systems Pharmacists	Objections to numerous provisions
Godios, Rhianna, Pharm.D., Pharmacist Program Coordinator for the Anticoagulation Management Service	godiosr@summahealth.org	Summa Health - Akron	Opposes ©(4)
Gomez, Carlos, M.D.	carlosgmd@gmail.com	Wood County Hospital	Opposes ©4); supports Pharmacy Bd Rule
Goyal, Rashmi, MD		University of Toledo	Opposes ©4); supports Pharmacy Bd Rule
Grimm, Abbey, Pharm D candidate	grimm.232@buckeyemail.osu.edu		will not only increase burden on both pharmacists and physicians, but it will delay care to patients.
Gustafson, Kyle, Pharm.D.	KGustafson@swgeneral.com	Southwest General Hosp	Opposes ©(4) The real value of a consult agreement to the patient, and to the physician, is the ability for medications to be adjusted, changed, and titrated without placing an additional demand on the physician's time.
Haidar, Wael, M.D., Chief Clinical Officer	AMGordon@mercy.com	Bon Secour Mercy Health	Oppose 4731-35-01(A)(1)(i); 4731-35-02 numerous provisions
Haldiman, Matt, RPh	Matt.Haldiman@ohiohealth.com		Oppost (C)(4) and (D)(1). Allowing the pharmacist to function at the top of her/his license utilizing previously approved protocols within a consult agreement will allow us to continue to provide guideline-based, time-sensitive, and patient-centered care through our partnership In consult agreements.
Harrell, Colleen, Pharm. D., Lead Clinical Pharmacist	Colleen.Harrell@ProMedica.org	Promedica Toledo Hosp	Opposes ©(4); supports Pharmacy Bd rule
Hejeebu, Srinivas, DO		University of Toledo	Opposes ©4); supports Pharmacy Bd Rule
Hiler, Rebekah, Pharm.D. candidate	hilerrv@mail.uc.edu		Opposes ©(4)
Hinch, Bryan, MD		University of Toledo	Opposes ©4); supports Pharmacy Bd Rule
Hoersten, Barb, RPh	BHoersten@pauldingcountyhospital.com		Opposes ©(4); supports Pharmacy Bd rule
Hogan, Timothy, M.D.	MManz@pauldingcountyhospital.com	Paulding CO. Hosp	Opposes ©(4)
Horen, Nicholas MD		University of Toledo	Opposes ©4); supports Pharmacy Bd Rule
Houmsse, Mahmoud , M.D.		OSU Medical	Opposes 4731-35-02(A)2) and ©(4)
James, Allen, M.D., Medical Dir	Melissa.Snider@osumc.edu	OSU Hospital, East	Oppose ©(4) and (A)(2). Suggests that another provider in the same group be able to assess patient.
Janzen, Amanda, PharmD candidate	janzenal@mail.uc.edu		Opposes all.
Jones, Ashley, NP	Ashley.Jones3@osumc.edu		Opposes ©(4) and requests exemption for team based in a provider's office.
Jones, Morgan, PharmD candidate	jones5mm@mail.uc.edu		Opposes ©(4) and (D)(1)
Kaczor, Chet, PharmD, Chief Pharmacy Officer, and Patel, Anup, M.D., Chief of Neurology	Chet.Kaczor@nationwidechildrens.org	Nationwide Childrens	Objections to numerous provisions, offers suggested langauge
Kadia, Niyati Ketan, Pharm.D.	Niyati.Kadia@utoledo.edu	University of Toledo Medical	Opposes ©(4)
Kanwal, Neeraj, M.D., Interim President	Janet.VanNest@ProMedica.org	Promedica Toledo Hosp	Same as Dr. Bishop
Kapraly, Pamela, M.D.	Ashleigh.Dible@memorialohio.com	Memorial Family Medicine	Opposes ©(4) and (D)(1)
Kauser, Heidi, RPh	HKauser@pauldingcountyhospital.com		Opposes ©(4); supports Pharmacy Bd rule
Kayyali, Ammar, MD		University of Toledo	Opposes D1; supports Pharmacy bd rule

Khatibi, Hamid, M.D.	KLShepherd@mercy.com	Mercy Health - St. Rita's	Opposes ©4); supports Pharmacy Bd Rule
King, Philip Pharm D.	phil.king.pharmd@gmail.com	SUMMA, Akron Hospital	Opposes. Agrees with Russell, Everly, Arendt, and Nichol
Kirschner, Eric, M.D.	eskirschner1@mercy.com	Mercy Health - St. Rita's	requirement for the managing pharmacist to notify the consulting physician ***prior to any drug therapy action*** would greatly impede the timeliness of patient care being provided by the pharmacist.
Klautky, Stephen A, M.D.	klautkys@summahealth.org	– Summa Health Heart and Vascular Institute	Opposes ©(4); supports Pharmacy Bd rule
Laroque, Barbara, MD, Interim Chief Clinical Officer, 3 other physicians and 5 pharmacists	Alexa.Valentino@primaryonehealth.org	Primary One Health	Oppose (A)3) and ©(4)
Larry, John, M.D.	Diana.Venci@osumc.edu	OSU Medical	Opposes 4731-35-02(A)2) and ©(4)
Lemon, Michael, M.D.	LemonM@woodcountyhospital.org		Opposes ©(4)
Leopold, Todd, Pharm. D.	LeopoldT@woodcountyhospital.org	Wood Co. Hospital	Are different agreements needed for each type of service? Contacting providers on every one of these current routine processes by pharmacists. It will have a severe impact on delivering medication therapy to our patients in a timely and appropriate manner.
LePoire, Aaron D, Pharm.D.	ADLePoire@mercy.com		Opposes ©(4); supports Pharmacy Bd rule
Lomax, Jacob, Pharm student	j-lomax.1@onu.edu	Ohio Northern University National Community Pharmacists Association Student Chapter	would be detrimental to the future careers of pharmacy students. may also prove harmful for the public.
MacKinnon, Neil, PhD., Dean, College of Pharmacy	MACKINNJ@ucmail.uc.edu	University of Cincinnati	Objections to numerous provisions; supports Pharmacy Bd rule
Malone, Meghan, Pharm D.	Meghan.Malone@ProMedica.org	ProMedica Health Systems	Opposes ©(4) and (D)(1). Communication within 72 hours more reasonable. Should include PAs and APRNs.
Marar, U Krishman, M.D.	Margie.Hevezi@osumc.edu	OSU Medical	Opposes (A)(2) and ©(4).
Martin, Steve, Pharm.D. Dean, College of Pharmacy	s-martin.11@onu.edu	Ohio Northern University	Opposes numerous provisions; references Pharmacy Board rule
Masone, Kristine, Pharm. D.	mason.516@osu.edu		(C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as a member of the healthcare team.
Maugel, Les L., R.Ph., Pharmacy Mgr	llmaul66@buckeye-express.com	Mercy Health - St. Charles	4731-35-02 C-4) will impede the process to the point all patient care improvements will be negated
McConaghy, John, M.D.	<John.McConaghy@osumc.edu>	OSU Medical	proposed rules are burdensome, and are a big step back from the patient-centered, team based care
McConnell, Erin, M.D.	Erin.McConnell@osumc.edu	OSU Medical	Should not put more restrictions on the pharmacist. They are important part of team.
McGlone, Sean, VP and General Counsel	Sean.McGlone@ohiohospitals.org	OHA	Opposes numerous provsions; Refers to Pharmacy Board rule language
Megerian, Cliff, M.D., President UH Physicians and Brien, William Warren, M.D., Chief Medical and Quality OFficer	Daniel.Bucci@UHhospitals.org	University Hosptials	Objections to numerous provisions.
Mehta, Bella, Pharm.D.	mehta.6@osu.edu	OSU College of Pharmacy	Opposes ©(4) an (D)(1)
Menkhaus, Tara, PharmD Candidate	menkhata@mail.uc.edu		Opposes rule as would like pharmacist's scope of practice.
Milks, Michael Wesley, M.D.	Diana.Venci@osumc.edu	OSU Medical	Opposes (A)(2) and ©(4).
Millhon, Judson,Jr., M.D.	Laura.Welsh@ohiohealth.com	Ohio Health	Opposes ©(4) and (D)(1)
Mitchell, Ginny, Pham.D.	Virginia.Mitchell@osumc.edu	OSU Medical	Opposes ©(4) and (D)(1)
Monarch, Kristen, Pharm.D., Clinical Pharmacy Mgr	Kristen.Monarch@ProMedica.org	ProMedica - Flowers Hospital	Opposes ©(4); supports Pharmacy Bd rule
Montgomery, James, Pharm.D.	jmont13273@gmail.com		(C)(4) of rule 4731-35-02. This section would be a significant step back, essentially reversing course with the law that was passed 3 years ago. Requiring a physician to review every decision made and essentially require them to sign off on all orders is not only an undue burden to the physician, but it worsens quality of care by delaying treatment for the patient.
Murphy, E. Michael, Pharm. D	murphy.981@osu.edu		Opposes ©(4) and (D)(1).
Myers, Adam, M.D., Chief Population Health	barnhab@ccf.org	Cleveland Clinic	Objections to numerous provisions of the rules. Suggests language mimic the Pharmacy Bd. Rules.

Myers, Andrew J, PharmD candidate on behalf of pharm students	myers.1292@buckeyemail.osu.edu		Oppose ©(4) and (D)(1)
Nichol, Allen, Pharm. D.	allennichol@aol.com	CeutiCare Inc	The rule is trying to regulate the practice of pharmacy and is a restraint of trade.
O'Connell, Bryan, M.D.	oconnellb@summahealth.org		Opposes ©(4) and (D)(1)
Oehler, John L, D.O.	John.Oehler@ohiohealth.com	Ohio Health	Opposes ©(4) and (D)(1).
Olaes, Tricia, M.D.	Tricia.Olaes@ohiohealth.com	Ohio Health	the requirements for notification and consent prior to action by a pharmacist, as well as the requirement for regular meetings to review a written consult report represent my greatest concerns
Parker, Kyle, RPh	k-parker.4@onu.edu	Ohio Northern College of Pharmacy	Opposes numerous provisons as need amended to reflect current practice by both institutional and community pharmacy practices consult agreements with physicians; Consent language should mirror PHarmacy Board rule; physiican prior approval hinders pharmacist ability to assist physician.
Planisek, Stephanie, Pharm. D	PLANISS@ccf.org		a discussion with a physician prior to making a change, this would limit the number of consults that pharmacist could complete , increase the number of pages, phone calls, and pull physicians away from patient care. (to discuss a change to a medication that they had placed pharmacy on to dose).
Provenzano, Joel, M.D.	Joel.Provenzano@ohiohealth.com		Opposes the requirements for notification and consent prior to action by a pharmacist, as well as the requirement for regular meetings to review a written consult report.
Qiu, Shuhao, M.D., PhD		University of Toledo	Oposes ©(4) and (D)(1)
Ram, Uma, RPh	rxuma444@gmail.com		requesting your full support for the Collaborative Practice Agreement between a Physician and a Pharmacist
Randy Runyon, President and CEO	jdirossi@ohiochc.org	OH Association of Community Health Centers	The complexity of the proposed rules will diminish the opportunity for Ohio's multidisciplinary provider teams to positively impact the health of our state
Rentsch, Tiffany, Pharmacy resident	trentsch@axesspointe.org		Proposed rules would ultimately result in greater burden of documentation to physicians, reduced time for patient care, and reduce the benefit consult agreements already provide.
Ridge, Shelli, D.O.	mhartzler@cedarville.edu	Western Med. Family Physicians	Rule should mirror the Pharmacy Board rule; includes a chart comparing Pharm Bd rules with proposed Medical Bd rules
Riepenhoff, Chuck, RPh	Chuck.Riepenhoff@ProMedica.org	ProMedica Health Systems	I hope that the proposed requirement for notification and physician consent before a pharmacist can take action be removed, and further that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).
Roberts, Beckie, patient	care2come@yahoo.com		Afraid of losing her blood thinning care.
Roby, James, M.D.	RobyJ@woodcountyhospital.org		Supports the Pharmacy Bd rules
Rodis, Jennifer, Pharm.D.	rodis.2@osu.edu	OSU College of Pharmacy	C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care. Additionally, I believe this change does not align with the skills and competencies our PharmD students possess upon graduation. Participated in a CDC demonstration project for collaboration that showed improvement in blood pressure and diabetis compliance.
Rosko, Nathaniel, Pharm.D.	nathaniel.rosko@gmail.com		strongly oppose section (C)(4) of rule 4731-35-02. This section would be a significant step back, essentially reversing course with the law that was passed 3 years ago. Requiring a physician to review every decision made and essentially require them to sign off on all orders is not only an undue burden to the physician, but it worsens quality of care by delaying treatment for the patient. I help manage side effects from chemotherapy, ensure appropriate monitoring, and provide supportive care for our hematology and oncology patients in an environment that changes monthly with new medication approvals
Rossfeld, Zach, M.D.	zachrossfeld@gmail.com	Ohio Health	Opposes ©(4) and (D)(1). The current regulations allow physicians and pharmacists to reach mutually agreeable terms that ensure adequate collaboration, expertise, oversight, and quality assurance mechanisms exist within the consult agreement. Physicians already have the flexibility to engage in a consult agreement that addresses training, communication, and quality assurance mechanisms that are appropriate for the medication management that is being performed.
Russell, Nathaniel, M.D.	nathanielhrussell@yahoo.com		4731-35-02©(4) will place hardship on physicians by them having to approve changes in advance. It essentially negates the process.
Ryan, Thomas, M.D.	Thomas.Ryan@osumc.edu	OSU Medical	Opposes (A)(2) and ©(4).

Sabatino, Jennifer, Pharm D.	Jennifer.Sabatino@osumc.edu	OSU Medical	Opposes ©(4) and (D)(1)
SAMENUK, Paul, RPh	Paul.Samenuk@utoledo.edu	Univ Toledo Medical Center	Opposes ©(4) and (D)(1); supports Pharmacy Bd rule
Schroeder, Michelle, Pharm. D.	Michelle.Mangan@utoledo.edu	Univ of Toledo, Pharm	(C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.
Schwartz, Sarah Boehmer, MD	Sarah.Schwartz2@ohiohealth.com	Ohio Health	Same as Dr. Rossfeld
Scott, E. Demond, M.D., Chief Medical Officer	mloughney@axesspointe.org	AxessPointe Community Health Centers	Opposes ©(4)
Shah, Mayank, M.D.	Kimberly.Haviland@ohiohealth.com	Marion General	Same as Dr. White
Shah, Mrunal, M.D.	Kimberly.Haviland@ohiohealth.com	Marion General	Same as Dr. White
Shanker, Kirti, M.D.	Kirti.Shanker@osumc.edu	OSU Medical	Opposes. Agrees with Russell, Everly, Arendt, and Nichol
Shipman, Allie Jo, Pharm. D., Associate Director	alliejo.shipman@ncpanet.org	National Community Pharmacists Association	Opposes numerous provisons; respectfully encourage the Board to ensure that any and all rules related to physician-pharmacist consult agreements are promulgated in consultation with the state board of pharmacy and are focused on the regulation of physician actions
Shoukair, Sirine, Pharm.D.	<Sirine.Shoukair@utoledo.edu>	Univ Toledo Medical Center	Opposes ©(4)(a) and (b)
SILVERIO, TONDA, NP	TONDA.SILVERIO@osumc.edu		Agrees with Ashley Jones
Singrey, Amanda, Pharm.D.	amanda.singrey@gmail.com		**please consider removing section (C)(4) and section (D)(1). (D)(1) would be a large amount of administrative work that seems unnecessary as the decision criteria the pharmacist uses to justify a medication change would be documented in their progress notes which can be made available to the physicians. I believe that having a separate consult report containing all this information would be repetitive and cumbersome**
Smith, Mary, Pharm.D.	Mary.Jochum@utoledo.edu	Univ Toledo Medical Center	Oppose ©(4) and (D)(1)
Smith, Russell, Pharm.D., Dir. Of Pharmacy	Russell.Smith@utoledo.edu	Univ Toledo Medical Center	Opposes ©(4)(a) and (b)
Spangler, Wendell, M.D.	WSpangler@pauldingcountyhospital.com	Paulding CO. Hosp	Opposes ©(4)
Stacy, Beth	Beth.Stacy@UCHealth.com	Greater Cincinnati Society of Health System Pharmacists	current language may reduce the overall feasibility of pharmacy consults for inpatient practice; Opposes numerous provisions
Stansbery, Shawn, D.O.	shawnstansberydo@gmail.com		Opposes ©(4); supports Pharmacy Bd rule
Stewart, Laura, RPh, Clinical Mgr, Pharmaceutical Services	Laura Stewart <LStewart@genesishcs.org>	Genesis Healthcare System	Opposes ©(4); concerns re requirement for access to patient records
Sullivan, Dennis, M.D, and Pinkerton, Mark, M.D.	wepinkertons@gmail.com		Rules written from perspective of pharmacist in traditional community setting, which is not the case; Opposes ©(4) and (D)(1).
Sutton, John, M.D.	John.Sutton@aultman.com	My Community Health Center	Opposes without specifying specific provisions. suggested changes will greatly limit the existing process and established care that has been demonstrably successful in our office
T. Laurence Blosser M.D., Corporate Medical Director	lblosser@COPCP.com	Central OH Primary Care	Oppose ©(4)
Tasma, Brian, MD		University of Toledo	Opposes D1; supports Pharmacy bd rule
Tayal, Neeraj H., M.D., Div. Director Internal Med and Geriatics	Alicia.Powers@osumc.edu	OSU Medical	Opposes ©(4) and (D)(1).
Taylor, Diana L, M.D.	Diana.Taylor@ohiohealth.com	Ohio Health	Agrees with Dr. Bullock
Teegla, Yamini, M.D., Medical Director	astraw@cedarville.edu	Rocking Horse Community Health Center	Opposes ©(4)
Thomas, Andrew, M.D., Chief Clinical Officer	Trisha.Jordan@osumc.edu	OSU Medical	Objections to numerous provisions, with suggested language.
Thomas, Julia, RPh	jam2570@gmail.com	Ohio Health	Opposes ©(4) and (D)(1)
Thompson, Craig, M.D.	Tasha.White@ohiohealth.com	Ohio Health	Opposes ©(4) and (D)(1).
Tobias, Ben PA		Univ of Toledo	Opposes D1

Tuckerman, Chad, Pharm.D.	Chad.Tuckerman@utoledo.edu	Univ Toledo Medical Center	Opposes (D)(1); Supports current Pharmacy Bd rule.
Tumbush, John, D.O., RPh	John.Tumbush@Uhhospitals.org		Although proposed rules are similar to Pharmacy Board rules, the modifications nullify the pharmacist's ability to provide care independently, which is needed in rural areas. Specifically ©(4) and (D)(1).
Vanderoff, Bruce, M.D., Sr. VP and Chief Medical Officer, and McCluskey III, Charles F., Pharm.D., VP Pharmacy Services	Charles.McCluskeyIII@ohiohealth.com	Ohio Health	Should be congruent with Pharmacy Bd rules; opposes (A)(5)(b) and (A)5)©, ©(4); (D)(1)
vonGunten, Charles, M.D.	Charles.vonGunten@ohiohealth.com	Ohio Health	Distressed by the requirements for notification and consent prior to action by a pharmacist, as well as the requirement for regular meetings to review a written consult report. The current regulations allow physicians and pharmacists to reach mutually agreeable terms that ensure adequate collaboration, expertise, oversight, and quality assurance mechanisms exist within the consult agreement.
Vora, Sanjay, M.D.	Sanjay.Vora@ohiohealth.com	Ohio Health	Agrees with Dr. Bullock
Walters, Matthew, RN, Dir. Of Clinical Services	mwalters@specialcarecorp.com	Special Care Hospital Management	Provides contract services in hospitals; Opposes ©(4); Supports Pharmacy Board rules.
Wang, Tzu-Fei, M.D.,	Aaron.Dush@osumc.edu	OSU Medical	Opposes (A)(2) and ©(4).
Wexler, Randy, M.D.	Randy.Wexler@osumc.edu	OSU Medical	Opposes requirement for pharmacist to get pre-approval; one size fits all policies have unintended consequences, I would respectfully request an exception for pharmacists who practice in a team-based environment, within a providers office, such that the provider is available in real-time during all hours for which the pharmacist is managing patients
Wheeler, Derek, M.D., Chief of Staff	came by US mail	Cincinnati Children's	The proposed rules are too cumbersome for in-patient care at a large institution. Opposes numerous provisions and suggests language mirror Pharmacy Board rules.
Wheeler, Sarah, Pharm. D.	sarahwheeler2018@gmail.com		remove in entirety section (A)(I)(i) from 4731-35-01 and sections (C)(4) and (D)(I) from 4731-35-02. Will likely result in delays in therapy and therapeutic goal attainment for patients managed under consult agreements and simultaneously detract from physicians' ability to provide care for more patients.
White, Matthew, M.D., and 5 other TeamHealth ED physicians	Kimberly.Haviland@ohiohealth.com	Marion General	Oppose ©(4) and (D)(1)
Williams, Leanne, PharmD. Candidate	willi2l3@mail.uc.edu		Opposes all.
Wunsch, Kaitlin, PharmD student	wunschke@mail.uc.edu	University of Cincinnati	Opposes ©(4)
Xu, Katie, Doctor of Pharm candidate	xu.947@buckeyemail.osu.edu		(C)-4 and (D)-1 will limit the pharmacist's ability to effectively manage patient's care. Pharmacist-run clinics have been shown to increase adherence for patients and to reduce adverse effects and hospitalizations.
Zeedyk, Janet, PA-C	JZeedyk@pauldingcountyhospital.com		Opposes ©4); supports Pharmacy Bd Rule
Mbaso, Chiamaka, M.D.		University of Toledo	Opposes ©(4); supports Pharmacy Bd rule
Akpunonu, Basil, M.D.		University of Toledo	Opposes ©(4); supports Pharmacy Bd rule
Cooper, Christopher, M.D.		University of Toledo	Opposes ©(4); supports Pharmacy Bd rule

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

OSU Heart and Vascular Center
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Fax: (614) 366-2175

February 6, 2019

To: Sallie Debolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

To Whom It May Concern:

As a practicing physician in the state of Ohio, I would like to thank you for your service to the State Medical Board of Ohio and for all you do to enhance the care of our fellow Ohioans. I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a physician that currently utilizes the services of pharmacists as independent practitioners through collaborative practice agreements, I am in favor of pharmacists continuing to provide patient care in this manner as a means to improve quality, safety, and efficiency in our health system. The utilization of consult agreements between physicians and pharmacists at The Ohio State University Wexner Medical Center has improved patient outcomes and helped control healthcare costs. I believe pharmacists are a vital part of the interdisciplinary team and are vital for successful provision of high quality clinical services and improving access to care. I am supportive of the continued incorporation of pharmacist services into my day to day practice. I have appreciated the updates by the Board of Pharmacy over the last few years. The rules proposed by the Medical Board are generally acceptable and in line with current pharmacy rules.

However, I feel several provisions are converse to current practice and limit the utility of consult agreements. Sections (A)(2) and (C)(4) of 4731-35-02, in current form, would increase provider burden and decrease efficiency of the current system, significantly impacting the business of healthcare. Furthermore, (C)(4) would reduce quality of care by discrediting pharmacists' clinical decision making capabilities already authorized under agreed collaborative practice agreements and accompanying scope of practice. We are asking this language regarding "at least one time per year" in (A)(2) and the entirety of (C)(4) be removed (this is covered in (A)(1) of 4731-35-01).

If you have any questions, please do not hesitate to contact me. Thank you for your consideration.

Sincerely,

Rami Kahwash, MD
Wexner Medical Center at the Ohio State University Medical Center
OSU Heart and Vascular Center
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Columbus, OH 43210
Office: 614-293-1965
Fax: 614-366-2175

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February 7, 2019

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State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

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If you have any questions, please do not hesitate to contact me. Thank you for your consideration.

Sincerely,

Raul Weiss, M.D. FACC
Professor of Internal Medicine, Department of Cardiology
Wexner Medical Center at the Ohio State University Medical Center
OSU Heart and Vascular Center
452 W 10th Avenue
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If you have any questions, please do not hesitate to contact me. Thank you for your consideration.

Sincerely,

Ralph S. Augostini, M.D., FACC, FHRS
Bob and Corrine Frick Chair in Cardiac Electrophysiology
Associate Professor of Internal Medicine
Ohio State University Medical Center
ph 614.293.4967
fax 614.293-5614

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February 7, 2019

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State Medical Board of Ohio
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If you have any questions, please do not hesitate to contact me. Thank you for your consideration.

Sincerely,

John D Hummel, MD
Associate Professor of Internal Medicine
Ohio State University Medical Center
ph 614.293.4967
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THE OHIO STATE UNIVERSITY
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OSU Heart and Vascular Center
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February 7, 2019

To: Sallie Debolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

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Sincerely,

Toshimasa Okabe MD
Assistant Professor of Medicine
Cardiac Electrophysiology, Division of Cardiovascular Medicine
The Ohio State University Wexner Medical Center
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February 7, 2019

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State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
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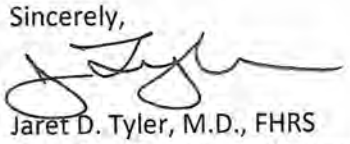

Jaret D. Tyler, M.D., FHRS
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February 7, 2019

To: Sallie Debolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

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If you have any questions, please do not hesitate to contact me. Thank you for your consideration.

Sincerely,

Steven J Kalbfleisch, MD
Professor of Internal Medicine, Department of Cardiology
Wexner Medical Center at the Ohio State University Medical Center
OSU Heart and Vascular Center
452 W 10th Avenue
Columbus, OH 43210
ph 614.293.4967
fax 614.293-5614

From: Ahmad, Faraz
To: Debolt, Sallie
Subject: State Medical Board of Ohio Proposed Rules
Date: Saturday, February 2, 2019 8:10:18 AM

Dear Ms. Debolt,

I am writing to you to express my concern regarding the new proposal regarding collaborative arrangements between physicians and pharmacists (4731-35-01 Consult agreements 4731-35-02 Standards for managing drug therapy). More specifically, I am concerned about the proposal seeking to restrict a pharmacist's scope of practice within consult agreements with physicians.

I am a provider in the Department of Family Medicine at Ohio State University and Lead Physician at OSU CarePoint East and collaborating physician at OSU Total Health and Wellness. At both practices, I and other providers work very closely with the clinical pharmacist to help manage diabetic patients, patients with tobacco use dependence, and patients on anticoagulation medication. The clinic pharmacist plays a key role in helping us better manage and provide higher quality care to diabetic patients and patients who are interested in quitting smoking. For example, the pharmacist helps adjust insulin dosages for diabetic patients and initiating medication and/or tobacco replacement therapy for smokers. Although I am sure the intention of this proposal is to ensure patient safety, my concern is that by requiring prior approval it will serve as a barrier to proving quality timely care. Additionally, it would restrict pharmacists from practicing to their full potential and it does not appreciate the education and training they receive to attain their position. In our practice they are a valued member of the team. By having a pharmacist at our practice I am able to schedule my patients to have more frequent visits with the pharmacist to help monitor and adjust their medications when my schedule is over booked and I am unable to see the patient. This ability to rely on a pharmacist who is well trained and qualified actually ends up benefiting the patient because instead of having to wait a few weeks to months to be seen by me they can be seen by our pharmacist on a more frequent basis.

I hope you will reconsider this proposal due to the potential negative consequences it would have for the care provided to our patients in a team-based environment that relies on using our pharmacists to their full potential and taking advantage of their training. Thank you.

Faraz Ahmad MD,MPH

Department of Medicine
Chair: Lance D. Dworkin, M.D.
Admin.Vice-Chair: Basil E. Akpunonu, M.D.
Administrator: Beth Smotherman
Assistant to Chair: Maureen Gilmore

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Health Science Campus
3000 Arlington Ave., MS 1186
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COLLEGE OF MEDICINE AND LIFE SCIENCES
THE UNIVERSITY OF TOLEDO

Division Chiefs
Cardiovascular Medicine: Mark W. Burket, M.D.
Community Internal Med: Allen Markowicz, M.D.
Dermatology: Lorie D. Gottwald, M.D.
Endocrinology: Juan C. Jaume, M.D.
Gastroenterology: Ali Nawras, M.D.
General Internal Medicine: Basil E. Akpunonu, M.D.
Hematology/Oncology: John Nemunaitis, M.D.
Infectious Diseases: Joan Duggan, M.D.
Nephrology: Deepak Malhotra, M.D., Ph.D.
Pulmonary/Critical Care: Jeffrey R. Hammersley, M.D.
Rheumatology: M. Bashar Kahaleh, M.D.

February 8, 2019

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy

Dear Ms. Debolt:

I am writing in regards to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. Consult Agreements for Pharmacist Management of Patient's Drug Therapy is of interest to me due to my current collaborative practice with a pharmacist as a physician practicing at South Toledo Internist at 3355 Glendale Avenue, Toledo, Ohio, and The University of Toledo Medical Center at 3000 Arlington Avenue, Toledo, Ohio. Within my outpatient clinic, I work side by side with clinical pharmacists on a daily basis who provide unique value to our patients and improve overall quality of care.

Currently, consult agreements allow physicians to work collaboratively with pharmacists to manage chronic diseases. In my practice, we have pharmacists who independently manage diabetes, hypertension, and dyslipidemia through consult agreements. Pharmacists improve the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Additionally, our pharmacists serve as drug information experts and educators for both our residents, providers and patients. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

The proposed rule changes, specifically those that require pharmacists to notify the physician of any action prior to implementation (4731-35-02 C-4) would discourage collaborative practice and obstruct our current quality-based workflow. Pharmacists are the medication expert within the interdisciplinary patient care team making their expertise imperative to the care of patients. This expertise and evidence-based care can be managed independently within an agreed upon scope of practice. The removal of the autonomy afforded to pharmacists through consult agreements would lead to a tedious and inefficient process for chronic disease management that would negatively impact the pharmacist, provider and patient. Logistically, a

busy provider may not always be in clinic making it difficult for both the pharmacist and patient's to reach them. In this case the pharmacist is the best resource to manage chronic diseases and ensure timely care is provided. I recommend that this requirement be removed from the proposal.

Examples of collaborations include educating learners within the clinic (medical students, medical residents, PA students) -- teaching them about appropriate use of medications for disease states, working together to come up with a therapeutic plan moving forward -- in this instance, I may call a patient and get blood sugar readings and other pertinent information and then work through my thought process with the resident so they are also learning how to manage diabetes appropriately. Additionally, on the inpatient settings, pharmacists make recommendations during rounds including monitoring and dosing of warfarin, antibiotics and antibiotic stewardship.

In summary, I hope that the proposal be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,

Basil Akpunonu, M.D., MSC, FACP
Professor of Medicine

Sarah Aldrich, PharmD
University of Toledo College of Pharmacy and Pharmaceutical Sciences
3000 Arlington Ave
Toledo, OH 43614
2/5/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

Dear Ms. DeBolt:

I would like to thank you as a practicing pharmacist in the state of Ohio for your service to the State Medical Board of Ohio. I appreciate your effort in enhancing the care of our fellow Ohioans. Thank you for the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a clinical ambulatory care pharmacist practicing collaboratively in an internal medicine clinic, I am concerned about the language included in the 4731-35-02 Standards for managing drug therapy in sections (C)(4) and (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as part of the collaborative care model currently provided in my clinic.

I have seen other pharmacists and currently provide high quality and valuable care to patients through consult agreements. In my personal experience, patients are able to reach their therapeutic goals more quickly, are more adherent and engaged, and have overall better health outcomes when they have increased access to the healthcare team. The pharmacist helps increase access and is a beneficial resource to improve patient quality and safety. Additionally, I have seen physicians be able to provide care to more patients when they utilize a pharmacist as an extension of the care they provide.

Based on my personal experience, through practice and participation in these agreements, I feel that the citizens of Ohio deserve the highest level of care from all members of their healthcare team. I would ask the State Medical Board of Ohio to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

Sarah Aldrich

Sarah Aldrich, PharmD

UC Health

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

February 5, 2019

Dear Ms. Sallie Debolt,

On behalf of UC Health, we would like to formally submit comments on the proposed language for the new Medical Board of Ohio rules regulating consult agreements between physicians and pharmacists.

Although UC Health understands the need for guidance of pharmacist practice under a consult agreement, the proposed language changes to the current consult agreement rules (OAC 4729:1-6-01, -02, -03) significantly diminish the scope and role of the pharmacist in managing a patient's medication therapy under the provision of a consult agreement. It should be noted that a consult agreement as currently written is voluntarily entered into by a physician under well-defined 'procedures' and 'decision criteria' for the pharmacist. The diminished scope in the proposed language will negatively impact patients in Ohio by significantly restricting patient access to care requested by a physician to be provided by pharmacists as the medication therapy experts while also over-burdening physicians with administrative requirements to manage these consults agreements as outlined in the proposed rule changes.

At UC Health, the proposed changes to the rules will directly affect the safety and care provided to over 600 active ambulatory care patients and over 800 monthly acute care hospitalized patients all managed collaboratively under a consult agreement between a physician and pharmacist. Examples of areas in which consult agreements are vital include our anticoagulation (patients receiving high-alert blood thinning medicines) and pharmacotherapy (complex patients with diabetes; high blood pressure; smoking cessation needs) clinics as well as inpatients receiving high-risk antibiotics, high-alert anticoagulants, specialized nutrition support, and complex medications for pulmonary hypertension. Consult agreements also permit pharmacists to make important drug dosing adjustments to avoid adverse drug events for complex and high-alert medications. All consult agreements at UC Health are voluntarily requested by physicians and conducted under well-defined 'procedures' and 'decision criteria' as outlined in OAC 4729:1. Moreover, published medical literature demonstrates a pharmacist's role in medication management reduces medication error and improves patient outcomes.

We recommend the following changes to the proposed rule:

4731-35-01 Consult Agreements

- Removal of Section A-1-i – requirement for physician approval prior to adjustment to the dose of a controlled substance.
    - Given the current challenges in Ohio with management of opioids and opioid addiction, limiting the ability for pharmacists to manage controlled substances under a formal consult agreement from a physician will have the potential to perpetuate the problem of opioid overuse by preventing pharmacists from

adjusting doses down or discontinuing opioids that are no longer needed for the patient.

4731-35-02 – Standards for Managing Drug Therapy

- Modification of section A-3 – The language around physician communication to the patient is excessive and discourages patients from allowing a pharmacist to participate in their care through a consult agreement. We recommend sub-bullet (d) be removed from the rules.
- Removal of section A-6 – The requirement that the authorizing physician ensure the managing pharmacists' training and experience are adequate is an excessive burden on the physician. As pharmacists are extensively trained in pharmacology and pharmacotherapy through their prerequisite education in order to become licensed, further scrutiny of this training and experience by the authorizing physician is excessive. Moreover, the verification of pharmacist credentials and competency should remain with the employing institution or business.
- Clarification of section A-7 – Further clarification of "prompt review".
- Modification of section B-1 – Placing the responsibility of defining the extent and scope of the pharmacist on the physician is unclear. Recommend rewording to outline that scope of the pharmacist is defined by the policy/procedure established in the consult agreement.
- Modification of section C-4 – Recommend removal of requirement for pharmacist to notify primary physician prior to any action. This requirement is extremely onerous on both the physician and the managing pharmacist, and will discourage physicians from entering into consult agreements with pharmacists. This will negatively impact patients' access to the necessary care they could receive from a pharmacist to manage their medications under a consult agreement and the related details of pharmacist requirements for an approved consult agreement currently described in OAC 4729:1-6-02. As the medication therapy experts, pharmacists are qualified to perform these actions under a consult agreement. This rule will decrease access and quality of care. We recommend sub-bullet (b) be removed from the rules.
- Modification of section D-1 – Recommend removal of the requirement for primary physician and managing pharmacist to hold regular meetings. This requirement is onerous on both the physician and the managing pharmacist, and will discourage physicians from entering into consult agreements with pharmacists.

Thank you for your consideration of our comments for incorporation into these rules. Please feel free to contact me with any questions or clarifications.

Sincerely,

Evie Alessandrini, MD, MSCE
SVP, Chief Medical Officer, UC Health

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

University Hospital East
Medical Staff Office
181 Taylor Ave
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Columbus, OH 43203

Phone: 614-257-3634
Fax: 614-257-3636

February 7, 2019

To: Sallie Debolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

Dear Ms. Debolt:

As a practicing physician in the State of Ohio, I would like to thank you for your service to the State Medical Board of Ohio and for all you do to enhance the care of our fellow Ohioans. I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

In the ambulatory setting, I collaborate with our pharmacist-led anticoagulation clinic. Our pharmacists do point of care coagulation testing and then adjust the doses of anticoagulants, such as Coumadin, based on test results using established clinical protocols. I am concerned that the proposed provisions in 4731-35-02, Section C-4 could pose a barrier to efficient and safe care. As written, this provision would require prior approval by the collaborating physician for the pharmacist working in anticoagulation clinics to change doses of medications such as Coumadin. For protocol-driven dosage adjustment, prior approval of every dosage change by a collaborating physician is not only unnecessary and inefficient but it could place the patient at harm if the physician is not able to immediately respond to the pharmacist to approve dosage adjustments.

I have similar concerns in the inpatient setting where our pharmacists frequently adjust doses of high-risk medications based on blood testing of drug levels, again based on established clinical protocols. A very common example of this is vancomycin, an antibiotic that has to be dose-adjusted based on patients' fluctuating physiologic status. Once again, protocol-driven dosage adjustments by the pharmacists are essential to the safe use of medications such as vancomycin where an excessive dose can result in kidney failure. Adding a requirement that the pharmacist must first obtain permission of the physician to adjust doses of these drugs is inefficient and could potentially place the patient at harm if the physician is unable to respond immediately to the pharmacist (such as when the physician is in the midst of a surgical procedure, driving a vehicle on the way home, or in the midst of a sensitive counseling episode with a patient where interruption would be detrimental).

For these reasons, I recommend that provision 4731-35-02, Section C-4 be removed.

I additionally have concerns about 4731-35-02, Section A-2. As written, this provision requires that a specific collaborating physician assess each patient at least once per year. In our pharmacist-led anticoagulation clinic, there are different collaborating physicians on different days, depending on individual physicians' office schedules, physician vacations, etc. In order to meet the requirements of this provision, every physician who serves on a rotational basis as the collaborating physician would need to see all patients in the anticoagulation clinic annually; in our anticoagulation clinic, there are 10 different physicians covering the clinic in the month of February alone. Furthermore, our anticoagulation clinic serves patients referred for anticoagulation management from the more than 1,700 physicians who are employed by the Ohio State University Medical Center.

For this reason, I recommend that in 4731-35-02. Section A-2, the sentence "The physician shall periodically assess the patient, at least one time per year" be deleted. I further recommend that the wording, "The physician must have..." be re-phrased as "The physician <u>or another physician in the same medical group practice</u> must have...".

In the past 2 decades, medicine has changed significantly and the safe and efficient care of patients increasingly requires a team effort between doctors, nurses, and pharmacists. For the team to be effective, each member must be empowered to function within the scope of their training and skills. I believe that the modifications above will allow help ensure that our patients in Ohio get safer and more efficient care. If you have any questions, please do not hesitate to contact me. Thank you for your consideration.

Sincerely,

James Allen, MD
Medical Director, University Hospital East
Professor of Internal Medicine
The Ohio State University
Division of Pulmonary and Critical Care Medicine
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181 Taylor Ave.
Columbus, OH 43203

Phone: 614-257-3634
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February 8, 2019

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy

Dear Ms. Debolt:

I am writing in regards to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. Consult Agreements for Pharmacist Management of Patient's Drug Therapy is of interest to me due to my current collaborative practice with a pharmacist as a physician practicing at ProMedica Physicians Digestive Healthcare in Toledo, Ohio. Within my outpatient clinic, I work side by side with clinical pharmacists on a daily basis who provide unique value to our patients and improve overall quality of care.

Currently, consult agreements allow physicians to work collaboratively with pharmacists to manage chronic diseases. In my practice, we have pharmacists who independently manage diabetes, hypertension, and dyslipidemia through consult agreements. Pharmacists improve the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Additionally, our pharmacists serve as drug information experts and educators for both our residents, providers and patients. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

The proposed rule changes, specifically those that require pharmacists to notify the physician of any action prior to implementation (4731-35-02 C-4) would discourage collaborative practice and obstruct our current quality-based workflow. Pharmacists are the medication expert within the interdisciplinary patient care team making their expertise imperative to the care of patients. This expertise and evidence-based care can be managed independently within an agreed upon scope of practice. The removal of the autonomy afforded to pharmacists through consult agreements would lead to a tedious and inefficient process for chronic disease management that would negatively impact the pharmacist, provider and patient. Logistically, a busy provider may not always be in clinic making it difficult for both the pharmacist and patients to reach them. In this case the pharmacist is the best resource to manage chronic diseases and ensure timely care is provided. I recommend that this requirement be removed from the proposal.

In summary, I hope that the proposal be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,

S. Bashar Almadani, MD, MPH
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THE OHIO STATE UNIVERSITY
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2/6/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
Sallie.Debolt@med.ohio.gov

Dear Ms. DeBolt:

I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a physician that utilizes the services of pharmacists through collaborative practice agreements to provide care to my patients, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.

Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:
Aranguren
E685C30B62F5453...

Aranguren

MD

February 8, 2019

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy

Dear Ms. Debolt:

I am writing in regards to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. Consult Agreements for Pharmacist Management of Patient's Drug Therapy is of interest to me due to my current collaborative practice with a pharmacist as a Nurse Practitioner, practicing at Paulding County Hospital in a Family Practice office. Within my outpatient clinic, I work side by side with clinical pharmacists on a daily basis who provide unique value to our patients and improve overall quality of care.

Currently, consult agreements allow physicians to work collaboratively with pharmacists to manage chronic diseases. In my practice, we have pharmacists who independently manage diabetes, hypertension, and dyslipidemia through consult agreements. Pharmacists improve the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Additionally, our pharmacists serve as drug information experts and educators for both our residents, providers and patients. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

The proposed rule changes, specifically those that require pharmacists to notify the physician of any action prior to implementation (4731-35-02 C-4) would discourage collaborative practice and obstruct our current quality-based workflow. Pharmacists are the medication expert within the interdisciplinary patient care team making their expertise imperative to the care of patients. This expertise and evidence-based care can be managed independently within an agreed upon scope of practice. The removal of the autonomy afforded to pharmacists through consult agreements would lead to a tedious and inefficient process for chronic disease management that would negatively impact the pharmacist, provider and patient. Logistically, a busy provider may not always be in clinic making it difficult for both the pharmacist and patient's to reach them. In this case the pharmacist is the best resource to manage chronic diseases and ensure timely care is provided. I recommend that this requirement be removed from the proposal.

I value that PCH Pharmacy can dose and monitor my Coumadin clinic patients, as well as certain antibiotic dosing that is needed. They hold excellent knowledge and I trust in their skills and medical decision making. I do not feel the need to be notified of every action made. The pharmacy takes great consideration when making any decisions with my patients. Not only

would this change negatively impact my outpatient workflow as a provider, but my patients would be inconvenienced. With that being said, I have had the pharmacist contact me on occasion with any questions or concerns. Again, we have a mutual trust and they are more than capable of dosing medications, within their specified scope of practice.

In summary, I hope that the proposal be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,

Julie Arend, CNP
1035 W. Wayne St.
Paulding, OH 45879

From: Arendt, Daniel
To: Debolt, Sallie
Subject: Comments on the proposed rules for physician-pharmacist consult agreements
Date: Tuesday, January 22, 2019 9:52:36 AM

Dear Ms. Debolt,

I first wanted to thank you and the Ohio medical board for the time that you have spent assessing the current consult agreement policies and for working to improve the structure that we have in place here in Ohio.

My main comment and reason for concern relates to section 4731-35-02 (standards for managing drug therapy), Subsection C (Quality assurance mechanisms), point 4a and 4b. This sections suggests that pharmacists must notify the physician prior to any actions that they take and receive consent of the physician before enacting any change. I feel that this section in particular is not only impractical but that it disregards the very purpose of having a consult agreement.

For example, in our pharmacist run clinic, we see multiple patients back to back who are referred to us from different physicians. It is simply not feasible to reach out to and get a response from the physician in time to see our next patients. As soon as we are done seeing our patients we inform the providers of our actions but needing a response before sending a patient home with their new dosing plan would have a drastically negative impact on our patient care. Patients would be held up and a typically short appointment could be widely extended, physician offices would be quickly overwhelmed with the volume of calls they'd receive daily and pharmacists would have to limit the number of patients they can provide care to due to the new communication based time constraints.

In addition to being impractical, I believe that this section goes against the very nature of a consult agreements purpose. A consult agreement is a collaborative decision to improve patient care by allowing pharmacists to use their pharmacotherapy expertise to co-manage selected patient disease states. These consult agreements are in place to alleviate some of the burden physicians feel by having a large number of patients and their own set of time constraints. Pharmacists in these consult agreements can spend more time with patients and take more time to counsel them and improve outcomes. The decision to enlist in a consult agreement is a decision to utilize the pharmacotherapy expertise of the pharmacist as it relates to co-managing already diagnosed disease states. By requiring approval of all clinical decision making prior to enacting a change, the practice agreement becomes no different and no more beneficial to patients than when a pharmacist who is not covered by a consult agreement reaches out to a physician with a recommendation for one of their patients.

I feel strongly that this particular section in effect, cancels out the very nature of consult agreements and would have a negative impact on patient care in Ohio. As consult agreements have come into place, we have seen improved outcomes and better / more comprehensive patient care. This update to the consult agreement structure would be a drastic set back to the progress that we have seen here in Ohio and would be a detriment towards our collective goal of providing top quality, patient-centered care.

Thank you very much for your time, and don't hesitate to contact me with any questions you have

regarding my comments.

All the best,

Daniel Arendt

Daniel Arendt, Pharm.D.
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University Hospitals Geauga Medical Center
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Dr. Delilah Armstrong, MD
Site Medical Director
University Hospitals Green Road Primary Care
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1/24/2019

Sallie Debolt, Esq.
Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

Dear Sallie Debolt, Esq.:

My name is Delilah Armstrong and I am a primary care physician working in Cleveland, Ohio. I am writing to express my concerns about the proposed rules establishing standards and procedures for a physician who is entering into a consult agreement for pharmacist management of a patient's drug therapy. My practice manages the care of over 4,000 patients in suburban Cleveland. I practice with 4 other providers and a clinical pharmacist who works in our office under a consult agreement.

Collaborating with a pharmacist has been a part of our clinic since it was founded in April 2016. Our practice is a Comprehensive Primary Care Plus (CPC+) participating site with CMS and Ohio Medicaid, and is established with a founding principle to deliver the best care to the patients who need it most. Dr. Alexander Hoffman helps us achieve this goal through interdisciplinary care in our office. Dr. Hoffman is board certified in pharmacotherapy and manages chronic diseases such as diabetes, hypertension, hyperlipidemia, as well as runs our warfarin management service. The goal of having a pharmacist in our practice is to improve the patient's quality of care, improve their medication use, reduce poor outcomes, and lower risk of hospitalization or death due to chronic disease.

As you are aware, the State Pharmacy Board of Ohio has established rules for collaborating with pharmacists using a consult agreement. We currently follow the rules as set forth by the State Pharmacy Board in our practice. While the proposed rules from the State Medical Board are similar, I am concerned that some of the proposed rules would add burden to our patient care agreements and restrict Dr. Hoffman's ability to make clinical decisions in real time.

I am specifically concerned that Section 4731-35-02.C.4.a-b prevents a clinical pharmacist from making any changes to drug therapy or monitoring without an extensive notification and consent process. This process puts undue burden on the consulting relationship and reduces its effectiveness in delivering timely and appropriate patient care. I am also concerned that Section 4731-35-02.D.1 adds burdensome paperwork to a process that is already working well in our office.

I appreciate the opportunity to express concerns regarding the proposed rules and would happily answer any questions you may have.

Sincerest Professional Regards,

Dr. Delilah Armstrong, MD
Site Medical Director

Kathleen Bahrey, PharmD
4088 Willow Hollow Drive
Columbus, OH 43230

February 5th, 2019

Sallie Debolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, Ohio 43215

Dear Ms. Debolt:

I would like to thank you, both as a pharmacist and patient advocate, for the opportunity to comment on the board's draft of rules pertaining to 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a student and thus far into my career as a pharmacist, I have been passionate about the laws and regulations that govern our ability as healthcare professionals to care for our patients. I have visited my representatives multiple times, both at the state house in Columbus and on Capital Hill, to express my support or opposition of bills I felt would impact my current and future patients. Witnessing the passing of HB 188, which provided new consult agreement provisions for pharmacists, was a monumental milestone in this journey. Being granted the ability to manage medications and utilize lab tests to monitor safety and efficacy of therapy for chronic conditions was a small step toward the endless possibilities of collaboration with physicians and increasing patient access to care.

In the short time this law has been in place, collaborative practice agreements have allowed for pharmacists to take responsibility for chronic disease state management, subsequently providing physicians the flexibility to focus time on more complicated conditions and concerns. Overall, this law has helped to strengthen pharmacist-physician relationships and create a more patient centered, team-based care model.

As they currently stand, the statements listed in section (C)(4) and (D)(1) of 4731-35-02 Standards for managing drug therapy will effectively demolish this capability and revoke the opportunity for pharmacists to effectively share in chronic disease state management. Given this, I ask that these sections be removed in entirety as to prevent the reverse of strides made towards advancing patient care.

I sincerely appreciate your consideration given this extremely important matter and hope pharmacists will continue to be provided the opportunity to serve patients to the best of our ability.

Sincerely,

Kathleen Bahrey

Kathleen Bahrey, PharmD

MERCYHEALTH

St. Charles Hospital
Inpatient Pharmacy

2600 Navarre Ave.
Oregon, OH 43616
mercy.com

February 8, 2019

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy

Dear Ms. Debolt:

I am writing in regard to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. Consult Agreements for Pharmacist Management of Patient's Drug Therapy is of interest to me due to my current collaborative practice with a pharmacist as a physician practicing at Mercy Health-Bay Meadows Family Medicine, 3851 Navarre Avenue, Suite 200, Oregon, OH 43616. Within my outpatient clinic, I work side by side with clinical pharmacists on a daily basis who provide unique value to our patients and improve overall quality of care.

Currently, consult agreements allow physicians to work collaboratively with pharmacists to manage chronic diseases. In my practice, we have pharmacists who independently manage diabetes, hypertension, and dyslipidemia through consult agreements. Pharmacists improve the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Additionally, our pharmacists serve as drug information experts and educators for both our residents, providers and patients. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

The proposed rule changes, specifically those that require pharmacists to notify the physician of any action prior to implementation (4731-35-02 C-4) would discourage collaborative practice and obstruct our current quality-based workflow. Pharmacists are the medication expert within the interdisciplinary patient care team making their expertise imperative to the care of patients. This expertise and evidence-based care can be managed independently within an agreed upon scope of practice. The removal of the autonomy afforded to pharmacists through consult agreements would lead to a tedious and inefficient process for chronic disease management that would negatively impact the pharmacist, provider and patient. Logistically, a busy provider may not always be in clinic making it difficult for both the pharmacist and patient's to reach them. In this case the pharmacist is the best resource to manage chronic diseases and ensure timely care is provided. I recommend that this requirement be removed from the proposal.

MERCYHEALTH

St. Charles Hospital
Inpatient Pharmacy

2600 Navarre Ave.
Oregon, OH 43616
mercy.com

In summary, I hope that the proposal be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,

Tanya R Baldwin, MD
3851 Navarre Avenue, Suite 200
Oregon, OH 43616

OhioHealth

TO: State Medical Board of Ohio

FROM: Michael Bang, MD

RE: Response to Proposed Rules 4731-35-01 and 4731-35-02: Consult Agreements

Thank you for the opportunity to provide comments on the Medical Board's recently proposed rules regarding consult agreements between pharmacists and physicians. Consult agreements have been an invaluable resource for physicians to expand access and improve quality, especially since the revision of the law in 2016. In general, I appreciate the added clarity that the medical board has provided specific to physician participation in a consult agreement. However, some of the new provisions outlined in the proposed rules create a significant burden that would outweigh many of the benefits of a consult agreement, and would negatively impact patient care.

Specifically, the requirements for notification and consent prior to action by a pharmacist, as well as the requirement for regular meetings to review a written consult report represent my greatest concerns. The current regulations allow physicians and pharmacists to reach mutually agreeable terms that ensure adequate collaboration, expertise, oversight, and quality assurance mechanisms exist within the consult agreement. Physicians already have the flexibility to engage in a consult agreement that addresses training, communication, and quality assurance mechanisms that are appropriate for the medication management that is being performed.

Requiring a physician's consent prior to each action adds significant time without providing any benefit to the patient. Consult agreements already require a "description of the procedures, decision criteria, and plan the managing pharmacist is to follow in acting under a consult agreement." Asking a physician to confirm that the decision criteria and plan are correct prior to every change is unnecessary and only adds burden to the pharmacist and physician. Adding complexity into a medication adjustment may also cause a patient to experience suboptimal care while consent is being obtained.

Similarly on the requirement for regular meetings, the law already requires "communication between a pharmacist and physician acting under a consult agreement shall take place at regular intervals specified by the primary physician acting under the agreement." Additional requirements for regular meetings and written consult reports only add complexity and administrative burden to an already safe collaborative.

Ultimately, I believe that these proposed rules run counter to the efficiencies that the law revision was intended to provide in 2016, and I recommend that the State Medical Board of Ohio reconsider adding any new requirements or barriers to care into the rules. I appreciate your consideration and the opportunity to provide feedback on the proposed rules. If you have any questions or would like to further discuss our comments, please reach out at the contact information below.

Sincerely,

Michael Bang MD

Michael Bang, MD
Hospitalist with Medone Hospital Physicians
Chair of the Pharmacy and Therapeutics Committee at Riverside Methodist Hospital
mbang@medonehp.com
614-255-6900

From:	Bartman, Veronique
To:	Debolt, Sallie
Cc:	Welker, Mary Jo
Subject:	VERY STRONG OBJECTION to proposed rules for pharmacist consult agreements and standards for managing drug therapy 4731-35-01 and 02
Date:	Friday, February 8, 2019 1:20:47 PM

We have been at level 3 certified patient medical home since 2011 and we participate in federal CPC+ and the Ohio version. **In order to improve patient's health, quality of care, and decrease barriers to care, we work with team of ancillary providers including dietician, nurse case manager, psychologist, social worker, and pharmacist. THESE ANCILLARY PROVIDERS ARE ESSENTIAL TO OUR HEALTH CARE MISSION, NOT TO MENTION THE QUALITY GOALS WE ARE REQUIRED TO MEET. TO MAKE PHARMACIST GET PROVIDER APPROVAL BEFORE MAKING CHANGES WILL PUT PATIENTS AT RISK BY INTRODUCING HARMFUL DELAYS IN CONDITION MANAGEMENT. MAKING THEM GENERATE AN ADDITIONAL "CONSULT REPORT" IS UNNECESSARILY BURDENSOME FOR THE PHARMACIST AND THE PROVIDER MONITORING THE CARE.**

We have worked in collaboration with pharmacists in our office since 2011 and have gradually expanded their role and increased time spent in our office. We have had 3 different pharmacists over that time and ALL have been INVALUABLE, especially with our patients with poorly controlled chronic medical conditions such as diabetes and hypertension. They have also been able to assist patients with smoking cessation interventions. They are able to spend 30-60 minutes with the patient educating them on their conditions and medication options and then do short-term monitoring of adjustments between physician/pcp appointment. This has been especially beneficial for our diabetic patients, especially those on insulin and new diabetics. If I have a patient out of control, they will interact with the pharmacist in person and thru electronic communication of their blood pressures, blood sugars, or progress numbers 3-5 times INBETWEEN their [at-most] every 3 month visits with me. This prevents dangerous highs and lows of pressures and sugars, allows control to be achieved much more quickly and much more safely, and side effects minimized. Complications and ER visits are prevented, thus reducing patient morbidity AND mortality, as well as health care costs. Pharmacists do NOT replace the physician-patient relationship, rather augment it and improve continuity of care.

The pharmacist ALREADY informs us of actions taken thru their visit progress note and NEVER goes outside of their scope of practice. They have recently been able to start sending prescriptions to pharmacy at time of visit that we cosign afterwards and that has improved patient's ability to make changes quickly and improve adherence.

With more providers out of office for teaching obligations or working part time, the provider may not be available when patient is seen. So implementation of changes will be delayed OR increase burden on covering partners who does NOT know the patient and thus disrupt continuity of care.

Our previously poorly controlled patients with collaborative management with pharmacist have improved outcomes, improved quality of life, and better health and functioning.

TO MAKE COLLABORATING PHARMACIST GET PROVIDER APPROVAL BEFORE MAKING MEDICATION CHANGES WILL PUT PATIENTS AT RISK BY INTRODUCING HARMFUL AND UNNECESSARY DELAYS IN CONDITION MANAGEMENT.
MAKING PHARMACIST GENERATE AN ADDITIONAL "CONSULT REPORT" IS UNNECESSARILY BURDENSOME FOR THE PHARMACIST AND THE PROVIDER MONITORING THE CARE. IT DOES NOT IMPROVE QUALITY, JUST WASTES VALUABLE TIME that could be spent addressing other important patient needs.

Sincerely,

Veronique Bartman, M.D.
Clinical Assistant Professor
OSU Family Medicine at Worthington
P 614-293-2850
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Rebecca Berg
AxessPointe Community Health Centers
1400 South Arlington Street, Suite 38 Akron, OH, 44306
rberg@axesspointe.org

State Medical Board of Ohio
30 East Broad Street, 3rd Floor Columbus, OH, 43215
Sallie.Debolt@med.ohio.gov

Dear Ms. Debolt,

My name is Rebecca Berg and I am a post-graduate year one pharmacy resident in Northeast Ohio specializing in ambulatory care. I'm writing to submit my comments on the proposed rule changes to 4731-35-01 and 4731-35-02.

I would first like to thank the State Medical Board of Ohio for its support thus far on the collaboration of physicians and pharmacists through consult agreements. This has allowed many Ohio pharmacists to take an active role on the patient care team. A study published by the American Medical Association (AMA) found that the work pharmacists do on the care team allows for reductions in medication therapy problems and improved patient outcomes[1] and the AMA has supported adding a pharmacist to the team to improve outcomes.[2]

I am concerned that the proposed rule changes, 4731-35-02(C)(4)(a,b), will increase burden on physicians, lead to delays in patient care, and, ultimately, reverse the benefit currently seen with consult agreements. To highlight these concerns, I will provide examples of how these changes could impact patient care in practice.

My first concern is that these changes will increase burden on physicians which will reduce patient access to care. In 2013, Ohio's patient to primary care provider ratio was 1482:1 and the need for additional providers was expected to rise by 8% by 2030.[3] This can be exaggerated in underserved areas where patients already have limited access to care. Under current consult agreements, pharmacists can help to alleviate this shortage of primary care. Pharmacists can manage a patient's disease state through the consult agreement without contacting the physician for approval of changes made to medication therapy. This allows the pharmacist to work as an extension of the physician, thus extending the amount of time a physician may place between patient follow-ups and allowing more time for more patients. With the proposed changes, the physician must review each pharmacist encounter, essentially increasing the workload of the physician to what it would have been had the consult agreement never been in place. Additionally, multiple pharmacists may be working under a consult agreement with one physician. This pharmacist to physician ratio may lead to the physician reviewing two or three times as many encounters in one week. Overall, this increased burden on physicians will lead to reduced time available for patient visits and further worsening of the shortage in primary care providers. Current consult agreements have expanded patient access to care by relieving some of the physician burden, but I fear these changes will reverse this progress.

1. Kaboli PJ, Hoth AB, McClimon BJ, Schnipper JL. Clinical pharmacists and inpatient medical care: A systematic review. *Arch Intern Med*. 2006;166: 955-964.
2. American Medical Association. Add a pharmacist to the team to see better outcomes. https://www.ama-assn.org/practice-management/payment-models/add-pharmacist-team-see-better-outcomes. Accessed January 29, 2019.
3. Petterson SM, Cai A, Moore M, Bazemore A. Ohio: Projecting primary care physician workforce. State-level projections of primary care workforce, 2010-2030. Robert Graham Center. Washington, DC. Robert Graham Center; 2013.

My second concern is that the proposed changes will lead to delays in patient care that will worsen patient outcomes. One patient population that currently benefits from consult agreements are patients with diabetes. Diabetic patients may only see their provider every three months but, through consult agreements, these patients can be seen weekly by a pharmacist. This allows the pharmacist to provide frequent adjustments to the patients' insulin dosing, therefore getting the patient to goal sooner. These closer follow-up visits improve glycemic control and result in better patient outcomes. With the proposed changes, patients would have to wait for the physician to approve any dosing changes which would increase time to control and worsen outcomes. Another patient population that benefits from current consult agreements are patients who receive frequent INR testing for warfarin therapy. Presently, pharmacists can perform INR testing and adjust warfarin doses accordingly. With the proposed changes, pharmacists would need physician approval to not only adjust the warfarin dose but also to perform the INR. Consider a patient who comes to a pharmacist run warfarin clinic on a Friday afternoon. The pharmacist performs the INR which reveals a subtherapeutic level. Under current consult agreements, the pharmacist may provide the patient with bridge therapy preventing the patient from having a life-threatening clot. With the proposed rules, the pharmacist would need to first get approval from a physician prior to providing therapy to the patient. Consider the patient's physician is on vacation and the covering physician has gone home for the weekend. The patient may not receive therapy until the following Monday putting him at risk for harm. These delays in care that may result from the proposed rule changes could significantly reduce patient outcomes.

My final concern is that the proposed rule changes will undo the progress that has been made on current consult agreements. For example, current agreements contain algorithms laid out by the physicians and pharmacists that dictate what changes pharmacists can make based on patient presentation. This allows the pharmacist to adjust patients' medication therapy in ways already approved by the physician with stipulation that the physician may override any changes made by the pharmacist. These current agreements keep the liability on whichever healthcare provider made the change whether it be pharmacist or physician. The proposed rules would require pharmacists to submit all changes to the physician for approval even if the change is outlined in the algorithm set forth in the agreement. This makes the algorithms redundant and essentially null and void. Additionally, this also shifts liability back to the physician as it is the physician who gives final approval of any changes made.

I feel strongly that the proposed rule changes would ultimately result in greater burden to physicians, delay in patient care, and a reduction in the benefit that current consult agreements already provide. I would like to thank you for your time and consideration. I can be reached for questions at the following email: rberg@axesspointe.org. I look forward to continuing the collaboration between physicians and pharmacists to better patient care.

Sincerely,
Rebecca Berg, PharmD

1. Kaboli PJ, Hoth AB, McClimon BJ, Schnipper JL. Clinical pharmacists and inpatient medical care: A systematic review. *Arch Intern Med.* 2006;165: 955-964.
2. American Medical Association. Add a pharmacist to the team to see better outcomes. https://www.ama-assn.org/practice-management/payment-models/add-pharmacist-team-see-better-outcomes. Accessed January 29, 2019.
3. Petterson SM, Cai A, Moore M, Bazemore A. Ohio: Projecting primary care physician workforce. State-level projections of primary care workforce, 2010-2030. Robert Graham Center. Washington, DC. Robert Graham Center; 2013.

MERCYHEALTH

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Inpatient Pharmacy

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February 8, 2019

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy

Dear Ms. Debolt:

I am writing in regard to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. Consult Agreements for Pharmacist Management of Patient's Drug Therapy is of interest to me due to my current collaborative practice with a pharmacist as a physician practicing at Toledo Clinic, 1661 Holland Road, Suite 200, Maumee, OH 43537. Within my outpatient clinic, I work side by side with clinical pharmacists on a daily basis who provide unique value to our patients and improve overall quality of care.

Currently, consult agreements allow physicians to work collaboratively with pharmacists to manage chronic diseases. In my practice, we have pharmacists who independently manage diabetes, hypertension, and dyslipidemia through consult agreements. Pharmacists improve the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Additionally, our pharmacists serve as drug information experts and educators for both our residents, providers and patients. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

The proposed rule changes, specifically those that require pharmacists to notify the physician of any action prior to implementation (4731-35-02 C-4) would discourage collaborative practice and obstruct our current quality-based workflow. Pharmacists are the medication expert within the interdisciplinary patient care team making their expertise imperative to the care of patients. This expertise and evidence-based care can be managed independently within an agreed upon scope of practice. The removal of the autonomy afforded to pharmacists through consult agreements would lead to a tedious and inefficient process for chronic disease management that would negatively impact the pharmacist, provider and patient. Logistically, a busy provider may not always be in clinic making it difficult for both the pharmacist and patient's to reach them. In this case the pharmacist is the best resource to manage chronic diseases and ensure timely care is provided. I recommend that this requirement be removed from the proposal.

MERCYHEALTH

St. Charles Hospital
Inpatient Pharmacy

2600 Navarre Ave.
Oregon, OH 43616
mercy.com

In summary, I hope that the proposal be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,

Dean M. Bernardo, MD
1661 Holland Road, Suite 200
Maumee, OH 43537

From:	Berning, Sarah (berninsn)
To:	Debolt, Sallie
Subject:	Comment on 4731-35-01 and 4731-35-02
Date:	Thursday, February 7, 2019 6:27:17 PM

Sallie Debolt,

Here are two different curriculums for two different doctorate level degrees

Degree 1:
Drug Delivery I
Principles of Medicinal Chemistry
Pharmacy Calculations
Principles of Pharmacology and Pharmacotherapy
Therapeutics I
Clinical Pharmacokinetics
Evidence-based Pharmacotherapy I
Case Studies in Therapeutics I
Therapeutics of nonprescription drugs
Therapeutics II
Case Studies in Therapeutics II
Pharmacy Practice Skills Development I
Therapeutics III Therapeutics IV
Evidence Based Pharmacotherapy II

Degree 2:
Healthcare Emergency management
Clinical Skills 101 and 102
Fundamentals of Molecular Medicine
Fundamentals of Cellular Medicine
Musculoskeletal – Integumentary
Brain, Mind and Behavior
Blood and Cardiovascular system
Renal and Pulmonary Systems
Gastoinstestinal/Endocrine/Reproduction
Multi-systems
Health Care Emergency Management II
Principles in Interprofessional Collaborative Practice

Degree 2 has no course dedicated specifically to pharmacology or therapeutics of medications.

Recipients of Degree 2 do not explicitly meet these benchmarks, however recipients of Degree 1 do:
Describe STANDARD therapeutic approaches to treat common diseases affecting each organ system.
Explain the BASIC science underlying the therapeutic benefits and adverse side effects of pharmacologic agents.

Which degree holder would you prefer to manage your medication therapy?

Degree 1 is the PharmD curriculum at UC and Degree 2 is the Doctor of Medicine curriculum, also at UC.

Degree 1 is dedicated to every aspect of drugs and their proper use. Degree 2 is dedicated to every aspect of the human body and how to heal it, with a small focus on the standard and basic therapeutic strategies of drugs.

Degree 2 can write for medications. Degree 1 must ask degree 2 about any and all changes to medications before making them.

Are you starting to see a problem? You do not have to be a pharmacist to understand that those must suitably trained in medications should have the most or at least equal authority in handling those medications.

Doctors only learn standards and basics of medications, and we're talking about over 1,000 approved drugs. Pharmacist and Doctors are not in a turf war, we are handling 2 completely separate roles; one in which the doctor is providing diagnoses and the pharmacist is providing drug therapy. This keeps the patient as the focus and ensures that they get the best and most comprehensive medical attention.

**Adapted from a colleague's submission.

Thank you for your time,

Sarah Berning

PharmD Candidate – Class of 2021
University of Cincinnati
berninsn@mail.uc.edu

Inpatient Pharmacy Intern
Good Samaritan Hospital - Cincinnati
Sarah_Berning@trihealth.com
513.545.7475

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February 8, 2019

Sallie Debolt, Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy

Dear Ms. Debolt:

I am writing in regards to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. Consult Agreements for Pharmacist Management of Patient's Drug Therapy is of interest to me due to my current role as Chief Medical Officer, Paramount Insurance. Within our health plan, we have active medication therapy management programs, that utilize clinical pharmacists.

Paramount encourages physicians to establish pharmacist consulting arrangements for the betterment of patient care. For example, I have encouraged physicians to work closely with Coumadin clinics, to better manage anticoagulants. Timely monitoring of lab results and dosing changes of anticoagulants is critically important.

Therefore, proposed rule changes, specifically those that require pharmacists to notify the physician of any action prior to implementation (4731-35-02 C-4) would discourage collaborative practice and obstruct workflow. Pharmacists following evidence-based care guidelines can manage independently within an agreed upon scope of practice. The removal of the autonomy afforded to pharmacists through proposed consult agreements would lead to a tedious and inefficient process for both acute and chronic disease management that would negatively impact the patient. Logistically, a busy provider may not always be in clinic making it difficult for both the pharmacist and patient's to reach them. In this case, the pharmacist is an excellent resource to manage chronic diseases, and ensure timely care is provided. I recommend that this requirement be removed from the proposal.

In summary, I hope that 4731-35-02 C-4 be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements). I urge you to remove the requirements for physician approval of each individual change.

Sincerely,

Dee Bialecki-Haase, MD, MBA, CPE
Chief Medical Officer, Paramount Insurance Company, a division of ProMedica

Steam Plant MSC S-39000 | 100 Madison Ave., 3rd Floor | Toledo, Ohio 43604 | 567-585-3894
Fax: 567-585-9650 | promedica.org

Our Mission is to improve your health and well-being.

February 7, 2019

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy

Dear Ms. Debolt:

I am writing in regards to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. Consult Agreements for Pharmacist Management of Patient's Drug Therapy is of interest to me due to my current role as Chief Medical Officer, ProMedica Physician Group (PPG) and Acute Care. Within our medical group, clinical prescribers work side by side with clinical pharmacists on a daily basis who provide unique value to our patients and improve overall quality of care. PPG is the largest non-academic group of physicians in Ohio.

Currently, consult agreements allow physicians to work collaboratively with pharmacists to manage acute inpatients and chronically ill outpatients. We have pharmacists who manage anticoagulants, diabetes, hypertension, and dyslipidemia through consult agreements. In these settings, pharmacists have improved the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Additionally, our pharmacists serve as drug information experts and educators for our providers and patients. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

The proposed rule changes, specifically those that require pharmacists to notify the physician of any action prior to implementation (4731-35-02 C-4) would discourage collaborative practice and obstruct our current workflow. Pharmacists following evidence-based care guidelines can manage independently within an agreed upon scope of practice.

The removal of the autonomy afforded to pharmacists through proposed consult agreements would lead to a tedious and inefficient process for both acute and chronic disease management that would negatively impact the patient. Logistically, a busy provider may not always be in clinic making it difficult for both the pharmacist and patient's to reach them. In this case, the pharmacist is an excellent resource to manage chronic diseases (for example, timely dosing of Coumadin), and ensure timely care is provided. I recommend that this requirement be removed from the proposal.

In summary, I hope that 4731-35-02 C-4 be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements). I urge you to remove the requirements for physician approval of each individual change.

Sincerely,

Kent E. Bishop MD

Kent E. Bishop, MD
Chief Medical Officer
Promedica Physician Group and Acute Care

Megan Bishop, PharmD Candidate 2019
37785 Davis Chapel Road
Logan, OH 43138

February 5, 2019

Sallie Debolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

Dear Ms. Debolt:

I would like to thank you as a student pharmacist in the state of Ohio for your time and service to the State Medical Board of Ohio and for your efforts to enhance the care provided to our Ohio citizens. I appreciate the opportunity to comment on the board's draft rules for 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a future pharmacist, I am concerned about the language that is included in 4731-35-01 in sections (A)(1)(i), (A)(1)(k), and (A)(1)(l). I have similar concerns for 4731-35-02 in sections (C)(4) and (D)(1). I fear that such requirements not only limit the pharmacist's ability to provide efficient and adequate patient care, but also warrant additional work to physicians within consult agreements. This language assumes that pharmacists must receive constant approval from their physician counterparts prior to making decisions rather than utilizing their knowledge base to practice in the best interest of their patients. I feel that these requirements will be a burden to all those involved in the agreement and will defeat the purpose of the consult agreement entirely.

In my professional experiences, I have witnessed pharmacists provide high quality care through consult agreements and it is evident that enhanced collaboration between healthcare professionals is associated with better patient outcomes. Under such agreements, physicians are given the opportunity to provide care to even more patients when they utilize pharmacists as an extension of the care they provide.

The citizens of Ohio deserve to receive the highest quality of care that their healthcare team can provide. With this being said, I suggest that the State Medical Board of Ohio remove in entirety sections (A)(1)(i), (A)(1)(k), and (A)(1)(l) from 4731-35-01 as well as sections (C)(4) and (D)(1) from 4731-35-02.

Again, I appreciate the opportunity to comment on the State Medical Board of Ohio's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

Megan L. Bishop

Megan Bishop, PharmD Candidate 2019

From: Laurence Blosser
To: Debolt, Sallie
Subject: draft rules on Consult agreements and Standards for managing drug therapy with Pharmacists
Date: Thursday, February 7, 2019 9:17:20 AM
Attachments: image001.png
image003.png

Central Ohio Primary Care Physicians
655 Africa Road
Westerville, Ohio 43082
Phone: (614) 326-2672
Fax: (614) 326-2685

February 7, 2019

To: Sallie Debolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

To Whom It May Concern:

As a practicing physician in the state of Ohio I would like to thank you for your service to the State Medical Board of Ohio and for all you do to enhance the care of our fellow Ohioans. I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

I am in favor of pharmacists providing patient care as independent practitioners through collaborative practice as a means to improve quality, safety, and efficiency in our medical group and have appreciated the updates by the Board of Pharmacy over the last few years. The rules proposed by the Medical Board are generally acceptable and in line with current pharmacy rules.

However, I feel Section (C)(4) of 4731-35-02 "Standards for managing drug therapy," are converse to current practice and limit the utility of consult agreements. In current form, the noted section would increase provider burden and decrease efficiency of patient care, significantly impacting the business of healthcare. Furthermore, it would reduce quality of care by discrediting pharmacists' clinical decision making capabilities already authorized under agreed collaborative practice agreements and accompanying scope of practice. As it is addressed in (A)(1) of Section 4731-35-01, we would ask that the entirety of (C)(4) be removed from 4731-35-02.

We at COPC believe pharmacists are a vital part of the interdisciplinary team and we are supportive of the continued incorporation of pharmacist services into daily practice. Again, I sincerely

appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy. If you have any questions, please do not hesitate to contact me. Thank you for your consideration.

Sincerely,

Larry Blosser

T. Laurence Blosser M.D.
Corporate Medical Director
Central Ohio Primary Care Physicians
655 Africa Road | Westerville, Ohio | 43082
Office: 614-865-8008 cell: 614-440-0673
lblosser@copcp.com | www.copcp.com

From: Sara Bonenfant
To: Debolt, Sallie
Subject: 4731-35-01 Consult agreements
Date: Tuesday, February 5, 2019 3:19:57 PM

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

Dear Ms. DeBolt,

My name is Sara Bonenfant and I am a third-year pharmacy student at Northeast Ohio Medical University (NEOMED). I am commenting in regards to the requested changes to pharmacist's consult agreements. I am in opposition to these changes because these changes will negatively impact patient care. This proposed rule would erase pharmacist's ability to act under a consult agreement unless the pharmacists gets prior approval for anything they want to do. I work at University Hospital's Parma Medical Center where we have a Coumadin Clinic that is run by pharmacists. If the pharmacists would have to call the physician each time they needed to order an INR, this would negatively impact patient care.

I am excited to work in Ohio as a pharmacist because our scope of practice would allow me to use all of the valuable knowledge I have learned in the 7 years of schooling. With this new agreement, it seems to be going backwards and would greatly impact patient care. As a student, advocating for my profession is important to me because I see the barriers that pharmacists face today, and I hope to change these so that when I am a pharmacist, I am practicing at the top of my license.

Thank you for your time,

Sara Bonenfant
Vice Chair American Society of Health-System Pharmacists (ASHP) Pharmacy Student Forum Executive Committee
PharmD Candidate 2020
Northeast Ohio Medical University

MetroHealth

February 7, 2019

Ms. Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 East Broad Street
3rd Floor
Columbus, OH 43215

Dear Ms. Sallie Debolt,

On behalf of MetroHealth, one of the largest and most comprehensive healthcare systems in Northeast Ohio, we would like to take this opportunity to respectfully comment on the rules regulating consult agreements and standards for managing drug therapy between physicians and pharmacists proposed by the State Medical Board of Ohio. The goal is to align these rules with the original intent of the consult agreement law, to improve patient safety and prevent onerous delays in medication therapy such as that experienced by Ohioan Kevin Houdeschell who tragically died as a direct result of his inability to obtain lifesaving insulin. We agree with the proposed rules for 4731-35-01; however, we are suggesting changes to the Standards for Managing Drug Therapy (4731-35-02) as they may impede the purpose of the consult agreement between physician, pharmacist, and patient.

Medical and Pharmacy Boards exist to improve the quality and safety of patient healthcare. If rules create barriers for pharmacists and physicians to meet these goals, they are likely to create barriers for patients as well. The MetroHealth System is a leader in expanding patient care by utilizing physician-pharmacist consult agreements. In 2018, over 200 unique MetroHealth physicians referred 3000 patients to specialty trained pharmacists for chronic disease state management including diabetes and anticoagulation. Pharmacists' care has proved a great investment for the current and future health of Cuyahoga County. Recent HgbA1c results of diabetic patients seen by pharmacists have decreased substantially as compared to those who had been managed by physicians alone.[1] Marked improvement has also been documented for hypertension and dyslipidemia. [2, 3]

Healthcare coverage for Ohioans is at an all-time high, but unfortunately there is a critical shortage of primary care providers to provide the care Ohioans need at the right time, in the right place and at the lowest cost. To this end, twenty-four Ohio counties are considered medically underserved where it is difficult for patients to receive primary care, including Cuyahoga County. The 2016 Ohio State Health Assessment cites an urgent need to improve health and wellbeing in Ohio. At MetroHealth, consult agreements have allowed pharmacists to help fill these gaps in patient care. A 2014 survey reported diabetes affected nearly 12% of Ohioans. That same study reported that hypertension affected nearly one-third of the Ohio population, which will likely increase with the implementation of the 2017 ACC/AHA Hypertension Guidelines for diagnosis. [4, 5] The mainstay of treatment for these disease states involves titrating medications to achieve optimal therapeutic outcomes. At MetroHealth, many common disease states are currently managed by highly trained clinical pharmacists under physician directed consult agreements including hypertension, diabetes, dyslipidemia, smoking cessation, anticoagulation, heart failure, asthma, COPD, GERD, vitamin D deficiency, and anemia.

In Ohio, seven colleges of pharmacy graduate a high number of qualified pharmacists who may be eligible to provide patient care under a physician-directed consult agreement. All pharmacists must now graduate with a Doctor of Pharmacy degree, which involves six to eight years of didactic and experiential education. Upon graduation, PharmDs often seek to complete one- or two-year post-graduate residencies focusing on

direct patient care training. Whereas there are workforce shortages in other health professions in Ohio, that is not the case with pharmacists. We should leverage this asset that is unique to Ohio.

The process by which a physician can refer a patient to a pharmacist is an "opt-in" action by the referring physician and patient. This is stated in the proposed rule 4731-35-02 (A), "A physician ***may elect*** to manage the drug therapy of an established patient entering into a consult agreement..." and we agree that the decision to refer a patient to a pharmacist should be directed by a physician. Patients and/or physicians may elect to discontinue the agreement at any time. The pharmacist is legally obligated to notify all involved parties including the patient and referring physician(s) if a consult agreement is discontinued. These are established in current Board of Pharmacy consult agreement rules. If a physician chooses not to utilize a pharmacist, they are free to do so, but the rules should not impede physicians who choose to use a pharmacist's services.

Concerns with proposed language include:

4731-35-02, Section B2: Scope of the managing pharmacist

The task of developing predetermined individualized decision criteria that encompasses all patient referrals yet are specific to individual patient management by the pharmacist is largely unobtainable. Individual patients are likely to have multiple circumstances including financial considerations and perceptions about medication use which must be addressed in the shared decision-making process. There are also many drug-drug interactions and drug-disease state interactions that arise, creating the need for very individualized patient care plans. As an alternative, national guidelines and current peer reviewed published literature are the sources of physician-approved decision criteria at MetroHealth and are used by pharmacists to adjust patient medication therapy versus adjusting according to a "predetermined plan". We would recommend that the term "decision criteria" be replaced with a more acceptable "national standards" or "accepted medical prescribing practices" which should be established within a global consult agreement policy as opposed to "decision criteria which the pharmacist must follow prior to an action and after conducting an action".

4731-35-02, Section C(4): Quality assurance mechanisms

Existing Board of Pharmacy rules require quality measures for consult agreements and we agree with this concept. At MetroHealth, medication decision making is reviewed by physicians at regular intervals. If deemed inappropriate, a remediation plan for the pharmacist is required. In addition, all pharmacists practicing under consult agreements are required to be licensed in the State of Ohio, have a residency or equivalent patient experience, and board certification in a relevant area of practice similar to credentialing of physicians. We support these mechanisms to ensure patient safety. All pharmacist decision making is made in writing in the electronic medical record and sent to the primary care provider for his/her review to create a timely quality assurance mechanism. Physicians may choose to alter any portion of pharmacist-directed medication changes after reviewing the plan. We oppose the requirement of physician notification and obtaining consent *prior to* a medication change as this is not in the interest of patient well-being and creates unnecessary barriers and delays to healthcare, defeating the purpose of reduced drug misadventures and improved drug adherence.

4731-35-02, Section D: Continuous quality improvement

We agree with the concept of patient safety and quality improvement; however, the term "regular meetings" is ambiguous and implies that all pharmacist-directed changes be reviewed prospectively and in-person or by phone between the physician and pharmacist. Pharmacists recognize the importance of decision-making review as a quality improvement measure. However, we recommend that review be conducted by the

MetroHealth

referring physician at an interval agreed upon by the referring provider and pharmacist using all currently available vehicles such as electronic documentation. At MetroHealth, documentation of the pharmacist decision making is required in the patient's electronic medical record which is immediately available for physician review and circumvents the need for a regular meeting with a very busy physician.

In conclusion, the physician-pharmacist consult agreement is an invaluable tool that has been shown to assist both physicians and patients in improving patient care. Our goal is to continue to provide this care in a safe and effective manner. Thank you for your time and consideration of these comments.

Sincerely,

Bernard Boulanger, MD, MBA
EVP Chief Clinical Officer

Sherrie D. Williams, MD, MHS
Medical Director & Chair, Pharmacy & Therapeutics Committee

Jay Kuhn RPh

Jay Kuhn, RPh
Director of Pharmacy

MetroHealth

2018 MetroHealth Physician-Pharmacist Consult Agreement Statistics/ References:

Statistics in 1,2 and 3 describe 2018 patients referred to the pharmacist for Diabetes, Hypertension, and Dyslipidemia. Quality information compares patients that were seen by the pharmacist and patients never evaluated by the pharmacist.

1. **Diabetes:** Average initial A1c for all patients referred to the pharmacist: 10.05%. Most recent A1c for patients referred to a pharmacist who have had a visit: 8.51% *(change in A1c for patients referred who had a visit: -1.53%)*. Most recent A1c for patients referred to a pharmacist who have **not** had a visit: 9.64% (change in A1c for Patients referred to a pharmacist who have **not** had a visit: -0.43%).
2. **Hypertension:** Initial Systolic for patients referred who had a visit with a pharmacist: 132.71. Initial Systolic for Patients referred to a pharmacist who have **not** had a visit with a pharmacist: 133.00. Initial Systolic for all Patients: 132.82. Initial Diastolic for Patients referred to a pharmacist who have had a visit: 72.27. Initial Diastolic for Patients referred who have **not** had a visit: 73.97. Initial Diastolic for all Patients: 72.92. Most Recent Systolic for patients referred to a pharmacist who have had a visit: 130.52. *Change in Systolic for Patients referred who have had a visit: -2.19.* Most Recent Systolic for Patients referred who have **not** had a visit: 132.44. Change in Systolic for Patients referred who have **not** had a visit: -0.56. Most Recent Diastolic for patients referred who had a visit: 70.58. *Change in Diastolic for Patients referred who have had a visit: -1.69.* Most Recent Diastolic for Patients referred who have **not** had a visit: 73.86. Change in Diastolic for Patients referred who have **not** had a visit: -0.11.
3. **Dyslipidemia:** Initial LDL for Patients referred to a pharmacist who have had a visit: 110.03. Initial LDL for patients referred who have **not** had a visit: 115.09. Initial LDL for all patients: 111.94. Initial TGs for patients referred who have had a visit: 192.86. Initial TGs for patients referred who have **not** had a visit: 200.16. Initial TGs for all patients: 195.61. Most Recent LDL for Patients referred who have had a visit: 100.91. *Change in LDL for patients referred who have had a pharmacist visit: -9.12.* Most Recent LDL for patients referred who have **not** had a visit: 114.02. Change in LDL for patients referred who have **not** had a visit: -1.07. Most Recent TGs for patients referred who have had a visit: 166.82. Change in TGs for patients referred who have had a visit: -26.04. Most Recent TGs for Patients referred who have **not** had a visit: 194.92. Change in TGs for Patients referred who have **not** had a visit: -5.24. Percentage of patients on statin therapy who had a pharmacist visit: 83%. Percentage of patients on statin therapy who have **not** had a visit: 73%
4. Ohio Department of Health 2016 State Health Assessment Executive Summary. https://odh.ohio.gov/wps/portal/gov/odh/about-us/sha-ship/media/ohio-2016-sha-executive-summary. Accessed 1.23.19.
5. Whelton PK, Carey RM, Aronow WS, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Hypertension. 2017.

From: Ernest Boyd
To: Harrell, Colleen
Cc: Debolt, Sallie; Antonio Ciaccia; Cecil, Tari
Subject: Re: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy
Date: Friday, February 8, 2019 6:03:53 PM

Excellent comments. Thanks!

Ernest Boyd, Pharm.D (hon), MBA
Ohio Pharmacists Assn
2674 Federated Blvd
Columbus, OH 43235
614-389-3236
Eboyd@ohiopharmacists.org

On Feb 8, 2019, at 5:27 AM, Harrell, Colleen <Colleen.Harrell@promedica.org> wrote:

> Ms. Debolt,
> Please see the attached correspondence regarding 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy. I hope that you will consider our comments before action is taken by the medical board.
> Thank you,
>
> **Colleen Harrell, PharmD, CDE, CACP**
> **Lead Clinical Pharmacist**
> **Residency Program Director (PGY-1)**
> ProMedica Toledo Hospital/Toledo Children's Hospital
> Wildwood Orthopaedic and Spine Hospital
> 2142 North Cove Blvd.
> Toledo, Ohio 43606
> Phone: 419-291-3766
>
> <image001.jpg>

<4731-35-01 consult agreements and Standards for managing drug therapy.pdf>

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

Department of Internal Medicine
Division of General Internal Medicine
Martha Morehouse Pavilion
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2/4/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
Sallie.Debolt@med.ohio.gov

Dear Ms. DeBolt:

I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a physician that utilizes the services of pharmacists through collaborative practice agreements to provide care to my patients, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.

The current collaborative practice agreement parameters have allowed me to improve chronic disease control and patient safety through supervised co-management with highly skilled clinical pharmacists. As a result of this collaboration, our clinic's population of over 5000 patients have seen marked improvement in quality and safety metrics for diabetes, hypertension, and polypharmacy.

Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:
8788AA57A657457...

Brill

MD

TO: State Medical Board of Ohio

FROM: Carolyn Bullock DO

RE: Response to Proposed Rules 4731-35-01 and 4731-35-02: Consult Agreements

Thank you for the opportunity to provide comments on the Medical Board's recently proposed rules regarding consult agreements between pharmacists and physicians. Consult agreements have been an invaluable resource for physicians to expand access and improve quality, especially since the revision of the law in 2016. In general, I appreciate the added clarity that the medical board has provided specific to physician participation in a consult agreement. However, some of the new provisions outlined in the proposed rules create a significant burden that would outweigh many of the benefits of a consult agreement, and would negatively impact patient care.

Specifically, the requirements for notification and consent prior to action by a pharmacist, as well as the requirement for regular meetings to review a written consult report represent my greatest concerns. The current regulations allow physicians and pharmacists to reach mutually agreeable terms that ensure adequate collaboration, expertise, oversight, and quality assurance mechanisms exist within the consult agreement. Physicians already have the flexibility to engage in a consult agreement that addresses training, communication, and quality assurance mechanisms that are appropriate for the medication management that is being performed.

Requiring a physician's consent prior to each action adds significant time without providing any benefit to the patient. Consult agreements already require a "description of the procedures, decision criteria, and plan the managing pharmacist is to follow in acting under a consult agreement." Asking a physician to confirm that the decision criteria and plan are correct prior to every change is unnecessary and only adds burden to the pharmacist and physician. Adding complexity into a medication adjustment may also cause a patient to experience suboptimal care while consent is being obtained.

Similarly on the requirement for regular meetings, the law already requires "communication between a pharmacist and physician acting under a consult agreement shall take place at regular intervals specified by the primary physician acting under the agreement." Additional requirements for regular meetings and written consult reports only add complexity and administrative burden to an already safe collaborative

Ultimately, I believe that these proposed rules run counter to the efficiencies that the law revision was intended to provide in 2016, and I recommend that the State Medical Board of Ohio reconsider adding any new requirements or barriers to care into the rules. I appreciate your consideration and the opportunity to provide feedback on the proposed rules. If you have any questions or would like to further discuss our comments, please reach out at the contact information below.

Carolyn Bullock DO
614-533-4000

Licking Memorial Hospital

February 8, 2019

Sallie Debolt
Sallie.Debolt@med.ohio.gov

Re: Comments to Proposed Rules 4731-35-01 and 4731-35-02

Dear Ms. Debolt:

Since 2003, Licking Memorial Hospital's Medication Therapy Clinic (LMH-MTC) has managed patient's anticoagulation therapy. Over the last sixteen years LMH-MTC successfully expanded its clinic to include anemia, heart failure and diabetes medication management. Because of LMH-MTC good patient outcomes its pharmacists provide direct patient care for the majority of physicians in Licking County. LMH-MTC has received referrals from 152 physicians and currently has 1,204 active patients for disease state medication management. In 2018 LMH-MTC had over 15,000 clinic visits. During visits, on average, LMH-MTC pharmacists spend 30 minutes with a patient. That equals approximately 7,584 hours of direct patient care in 2018 for medication therapy provided by pharmacists for physicians. Discussed more fully below, as proposed, the regulatory burdens created by these rules will negatively impact patient care at pharmacist-led medication therapy clinics, including LMH-MTC and the Licking County community.

Proposed rule 4731-35-02(C)(4) requires physician notification that includes the pharmacist's decision making rational and the physician's approval *before* the managing pharmacist can make *any* change to the patient's drug treatment or even order a simple urine screen. This language renders R.C. 4729.39 and proposed rule 4731-35-01 meaningless. *See* R.C. 4729.39(B)(1) which expressly permits physicians to authorize such prescribing authority under a pharmacist consult agreement.

Proposed rule 4731-35-02(C)(4) not only narrows the legislative authority of a pharmacist to manage a patient's drug therapy, but detrimentally effects a pharmacist's ability to manage a patient's drug therapy. For example, the notification and approval process will reduce the amount of time pharmacist can spend with their patients as more time will be needed to comply with these steps. The notification and approval process shifts medication therapy back to the physician defeating the purpose of having a consult agreement. And the notification and approval process will negatively impact patient care and outcomes. Patients will immediately suffer negative outcomes because of unnecessary delays in getting recommended blood or urine screens or may experience adverse drug reactions caused by dangerous delays in medication adjustments or changes.

Evidence shows that pharmacist-led clinics have better patient outcomes. In regards to anticoagulation management alone, a systematic review of 6 different studies

from 2011-2016 published in *Biomedical Research 2018; 29(7):1327-1332*, determined the following benefits of a pharmacist-led clinic compared to physician managed care:

- Patients were 3.66 times more likely to be within range in pharmacist-led coagulation clinics compared to the physicians managed group.
- Significant improvement in quality of life of patients managed by pharmacists.
- Reduction in burden of hospitalization and ED visits.
- Reduction of time required for monitoring.
- Less INR testing with potential cost-benefit over physician-led clinic.
- Achieved targeted therapeutic INR, increased satisfaction, reduced diagnostic costs, reduced supra-therapeutic INR in pharmacist-led clinics.

These findings were attributed in part to the pharmacist's knowledge of drug and herbal interactions.

Therefore, LMH-MTC recommends that 4731-35-02(C)(4) be deleted in its entirety. If you wish to discuss this matter or my recommendations please do not hesitate to reach me by phone at (220) 564-4010 or by email at Ccairns@lmhealth.org .

Sincerely,

Craig B. Cairns, M.D., M.P.H
Vice President, Medical Affairs

THE OHIO STATE UNIVERSITY
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Division of General Internal Medicine
Martha Morehouse Pavilion
Suite 2335
2050 Kenny Road
Columbus, OH 43221
614-293-4953 Phone
614-293-6890 Fax

2/6/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
Sallie.Debolt@med.ohio.gov

Dear Ms. DeBolt:

I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a physician that utilizes the services of pharmacists through collaborative practice agreements to provide care to my patients, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.

Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:
Caligiuri
2EB6F7CE792B458...

Caligiuri

md

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

Division of Hematology & Oncology
460 W. 10th Ave
Columbus OH 43210
Phone: (614) 293-9441
Fax: (614) 293-6420

February 7, 2019

To: Sallie Debolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

To Whom It May Concern:

As a practicing physician in the state of Ohio, I would like to thank you for your service to the State Medical Board of Ohio and for all you do to enhance the care of our fellow Ohioans. I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a physician that currently utilizes the services of pharmacists as independent practitioners through collaborative practice agreements, I am in favor of pharmacists continuing to provide patient care in this manner as a means to improve quality, safety, and efficiency in our health system. The utilization of consult agreements between physicians and pharmacists at The Ohio State University Wexner Medical Center has improved patient outcomes and helped control healthcare costs. I believe pharmacists are a vital part of the interdisciplinary team and are vital for successful provision of high quality clinical services and improving access to care. I am supportive of the continued incorporation of pharmacist services into my day to day practice. I have appreciated the updates by the Board of Pharmacy over the last few years. The rules proposed by the Medical Board are generally acceptable and in line with current pharmacy rules.

However, I feel several provisions are converse to current practice and limit the utility of consult agreements. Sections (A)(2) and (C)(4) of 4731-35-02, in current form, would increase provider burden and decrease efficiency of the current system, significantly impacting the business of healthcare. Furthermore, (C)(4) would reduce quality of care by discrediting pharmacists' clinical decision making capabilities already authorized under agreed collaborative practice agreements and accompanying scope of practice. We are asking this language regarding "at least one time per year" in (A)(2) and the entirety of (C)(4) be removed (this is covered in (A)(1) of 4731-35-01).

If you have any questions, please do not hesitate to contact me. Thank you for your consideration.

Sincerely,

Spero Cataland, MD
Wexner Medical Center at the Ohio State University Medical Center
Division of Hematology & Oncology
460 W 10th Avenue
Columbus, OH 43210
Office: 614-293-9441
Fax: 614-293-6420

From: Chaffee, Roger
To: Debolt, Sallie
Cc: Godios, Rhianna
Subject: Collaborative Medication Agreements
Date: Friday, February 8, 2019 11:59:43 AM

Dear Dr. Debolt,

As Chairman of Cardiovascular Disease and Director of the Summa Health Heart and Vascular Institute I oversee our Summa Anti-coagulation Management Service. This service has improved standardization of anti-coagulation. It has made the time in therapeutic range better, approximately 75%, and bleeding complications less. The pharmacists oversee our medication protocols and provide an efficient, timely, point-of-care service. The changes proposed in the Standards for Managing Drug Treatment, Section C-4 and D-1 would prohibit us from being able to provide a timely service. This change would require us to make over 100 communications per day to receive approval prior to making alterations in therapy. We simply could not do this. It would essentially end a very successful program. I believe that this would result in more expensive, less safe care. This change seems regressive and would end what has become a very well-functioning collaborative environment that really makes great use of our highly skilled PharmD professionals. I sincerely appreciate your consideration in this issue. Please do not make this change.

Sincerely,

Roger B. Chaffee, MD
Chairman, Department of Cardiovascular Disease
Medical Director, Summa Health Heart & Vascular Institute

Summa Health Medical Group - Cardiology
95 Arch Street | Suite 300 | Akron, OH 44304
p: 330.253.8195 f: 234.312.2308
chaffeer@summahealth.org

TO: State Medical Board of Ohio

FROM: Ashley Chambers, MD

RE: Response to Proposed Rules 4731-35-01 and 4731-35-02: Consult Agreements

Thank you for the opportunity to provide comments on the Medical Board's recently proposed rules regarding consult agreements between pharmacists and physicians. Consult agreements have been an invaluable resource for physicians to expand access and improve quality, especially since the revision of the law in 2016. In general, I appreciate the added clarity that the medical board has provided specific to physician participation in a consult agreement. However, some of the new provisions outlined in the proposed rules create a significant burden that would outweigh many of the benefits of a consult agreement, and would negatively impact patient care.

Specifically, the requirements for notification and consent prior to action by a pharmacist, as well as the requirement for regular meetings to review a written consult report represent my greatest concerns. The current regulations allow physicians and pharmacists to reach mutually agreeable terms that ensure adequate collaboration, expertise, oversight, and quality assurance mechanisms exist within the consult agreement. Physicians already have the flexibility to engage in a consult agreement that addresses training, communication, and quality assurance mechanisms that are appropriate for the medication management that is being performed.

Requiring a physician's consent prior to each action adds significant time without providing any benefit to the patient. Consult agreements already require a "description of the procedures, decision criteria, and plan the managing pharmacist is to follow in acting under a consult agreement." Asking a physician to confirm that the decision criteria and plan are correct prior to every change is unnecessary and only adds burden to the pharmacist and physician. Adding complexity into a medication adjustment may also cause a patient to experience suboptimal care while consent is being obtained.

Similarly on the requirement for regular meetings, the law already requires "communication between a pharmacist and physician acting under a consult agreement shall take place at regular intervals specified by the primary physician acting under the agreement." Additional requirements for regular meetings and written consult reports only add complexity and administrative burden to an already safe collaborative

Ultimately, I believe that these proposed rules run counter to the efficiencies that the law revision was intended to provide in 2016, and I recommend that the State Medical Board of Ohio reconsider adding any new requirements or barriers to care into the rules. I appreciate your consideration and the opportunity to provide feedback on the proposed rules. If you have any questions or would like to further discuss our comments, please reach out at the contact information below.

Ashley E. Chambers, MD
Internal Medicine Physician
Ohio Health Primary Care, Endocrinology and Pulmonary Physicians
7630 Rivers Edge Drive
Worthington, Ohio 43235

MERCYHEALTH

St. Charles Hospital
Inpatient Pharmacy

2600 Navarre Ave.
Oregon, OH 43616
mercy.com

February 8, 2019

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy

Dear Ms. Debolt:

I am writing in regard to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. Consult Agreements for Pharmacist Management of Patient's Drug Therapy is of interest to me due to my current collaborative practice with a pharmacist as a physician practicing at Mercy Health - Oregon Clinic, 3841 Navarre Avenue, Oregon, OH 43616. Within my outpatient clinic, I work side by side with clinical pharmacists on a daily basis who provide unique value to our patients and improve overall quality of care.

Currently, consult agreements allow physicians to work collaboratively with pharmacists to manage chronic diseases. In my practice, we have pharmacists who independently manage diabetes, hypertension, and dyslipidemia through consult agreements. Pharmacists improve the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Additionally, our pharmacists serve as drug information experts and educators for both our residents, providers and patients. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

The proposed rule changes, specifically those that require pharmacists to notify the physician of any action prior to implementation (4731-35-02 C-4) would discourage collaborative practice and obstruct our current quality-based workflow. Pharmacists are the medication expert within the interdisciplinary patient care team making their expertise imperative to the care of patients. This expertise and evidence-based care can be managed independently within an agreed upon scope of practice. The removal of the autonomy afforded to pharmacists through consult agreements would lead to a tedious and inefficient process for chronic disease management that would negatively impact the pharmacist, provider and patient. Logistically, a busy provider may not always be in clinic making it difficult for both the pharmacist and patient's to reach them. In this case the pharmacist is the best resource to manage chronic diseases and ensure timely care is provided. I recommend that this requirement be removed from the proposal.

MERCYHEALTH

St. Charles Hospital
Inpatient Pharmacy

2600 Navarre Ave.
Oregon, OH 43616
mercy.com

In summary, I hope that the proposal be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,

Riaz N. Chaudhary, MD
3841 Navarre Avenue
Oregon, OH 43616

THE OHIO STATE UNIVERSITY
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Division of General Internal Medicine
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2/5/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
Sallie.Debolt@med.ohio.gov

Dear Ms. DeBolt:

I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a physician that utilizes the services of pharmacists through collaborative practice agreements to provide care to my patients, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.

We have been working with pharmacy through our collaborative agreement on a variety scenarios including coumadin management, diabetes management and inpatient discharge transitions. In each of these cases, I have found pharmacy's ability to provide immediate care as very beneficial and vital to providing excellent care for my patients. I am very much against the proposed changes to the pharmacist consult agreement law and if passed, will greatly affect care of patients for the worst.

Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:
Christopher Chiu
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Christopher Chiu

Dr

OHIO PHARMACISTS ASSOCIATION
2674 Federated Blvd., Columbus, OH 43235 • Phone: (614) 389-3236 • Fax: (614) 389-4582

February 8, 2019

Sallie Debolt
State Medical Board of Ohio
30 E. Broad St., 3rd Floor
Columbus, Ohio 43215

Sallie,

On behalf of the Ohio Pharmacists Association, we thank you for the opportunity to comment on the State Medical Board's proposed draft rules (4731-35-01, 4731-35-02) on physician-pharmacist consult agreements. As the organization that led the push for unanimous passage of HB 188 in the 131st General Assembly, our member pharmacists – who practice in a variety of practice settings across the state – are well aware of the law, its intent, and its impact on healthcare delivery in Ohio.

Now that the law has been in effect for nearly three years, we have learned a lot about the value and challenges associated with consult agreements. In many ways, the new laws have expanded patient access to treatment for chronic disease management, improved patient outcomes by better focusing care delivery, and removed several regulatory hurdles that made pharmacist utilization cumbersome for physicians. With that said, we have serious concerns with a number of provisions in the Medical Board's proposed rules that would take this progress backwards and in some instances, directly conflict with the intent of the law, which was passed with the support of the Ohio State Medical Association and every voting member of the 131st General Assembly.

In 4731-35-01(A)(b), 4731-35-02(3)(b-d), the proposed informed consent requirements would put pharmacists outside the norms of other healthcare providers. These proposed rules would add unnecessary administrative paperwork hassles, as well as feed an unjust stigma regarding pharmacist-rendered care. We believe the philosophical concepts are currently contained in OAC 4729:1-6-01(H-I), and we would recommend adopting similar language in the medical board rules that focus on informed consent.

In 4731-35-01(A)(i), the proposed requirement would render key components of the consult agreement law useless. The purpose of the law was to allow for thoughtful delegation of care from physicians to pharmacists when appropriate and when mutually agreed upon. Any requirement for a pharmacist to seek prior approval from a physician before adjusting a dose for any drug would revert back to the old laws that the legislature sought to change, would severely inhibit pharmacist-delivered medication management in needed practice settings like palliative care, and create administrative barriers that would heavily discourage utilization of pharmacists in consult agreements. Just as the legislature and DEA have opened the door for pharmacists to prescribe controlled substances when appropriate, we believe this proposed requirement would be an unreasonable step backwards. We ask for this subsection to be removed.

In 4731-35-01(B), we believe that while the primary physician is ultimately in charge of the agreement, recordkeeping is a task that can be delegated or handled under the umbrella of the institution. We would recommend broadening the language to go beyond the primary physician.

In 4731-35-01(C)(1), we also believe this language should be broadened beyond the primary physician. We recommend adapting the following language to go beyond the primary physician and extended to the practice group or institution.

In 4731-35-02(A)(1), similar to the comments above, we believe that the practice group or institution can transmit the patient record, as well as ensure the record's confidentiality while transmitting it to the pharmacist.

In 4731-35-02(A)(7), we believe this subsection should be removed or modified to reflect the rules that govern delegation with other mid-level practitioners. Communication and record-checking requirements should be similar for all healthcare providers, and this language would add unnecessary, costly administrative burdens for physicians who wouldn't be delegating authority if they didn't trust the actions of their consulting pharmacist. We believe these expectations should be set by the physician, rather than the state.

In 4731-35-02(B)(2)(b-c), we recommend making this language less specific. A physician and pharmacist should be trusted to develop an overall plan for care delivery, and should not necessarily have to delineate separate plans for before and after actions.

In 4731-35-02(C)(1-2), we are concerned how verification of an ongoing physician-patient relationship and a physician's appropriate scope of practice can occur. This onus is ultimately on the physician, and we do not believe a pharmacist should be held liable if a physician misrepresents the nature of their patient relationship or their scope of practice. We support the concepts, but do not believe these are reasonable expectations for the consulting pharmacists. We recommend adjusting this language to put the onus on the physician to not delegate if they are outside the bounds of the law's requirements.

In 4731-35-02(C)(4), this language runs directly contrary to the will of the legislature, who through HB 188 in the 131st General Assembly explicitly removed language that required pharmacists to seek physician approval prior to taking actions under a consult agreement. This language would render the law change largely useless. We believe this subsection is excessively burdensome, usurps the wishes of the physician, administratively costly, and in direct conflict with Ohio law. This language should be removed.

In 4731-35-02(D), we believe that if the pharmacist is documenting actions appropriately and sharing them with the physician in addition to undergoing continuous quality improvement programs, then developing separate, formal consult reports is unnecessarily duplicative and administratively burdensome. In lieu of a report, we believe the ongoing recordkeeping, dialogue, and meetings are enough to ensure effective communication. If not, the physician is free to require a report if they so choose, but we do not believe it should be mandated every time.

In 4731-35-02(D)(1), while we believe regular meetings are a good way to ensure ongoing communication, we believe these meetings should be organic in nature, meaning that the topics of those meetings and logistics should be set and agreed upon by the physicians and pharmacists. Collaboration is not a new concept for physicians, and they should be trusted to track pharmacist care management just as they would for any other health care provider. We recommend removing the detail requirements delineated in 4731-35-02(D)(1)(a-e).

In 4731-35-02(D)(2)(c), not every pharmacist will require a DEA number. This subsection should be amended to apply only to pharmacists who are prescribing controlled substances.

We understand that considerable time and effort went into these rule proposals, and we appreciate the opportunity to comment. As mentioned above, the intent of the legislation was to tear down barriers that

previously stood in the way of physicians who want to utilize pharmacists to care for patients and improve their outcomes. Respectfully, we feel many of these rules will roll current progress backwards. As the current laws have been on the books for nearly three years, we are not aware of any emerging issues or patient safety threats that have arose since enaction, and we have heard nothing but positive feedback from physicians, pharmacists, and patients who have come to appreciate the new flexibility of deploying pharmacists to tackle complicated drug therapy challenges.

In the spirit of the collaborative goals of the law, we would welcome further discussion on the rule proposals if so desired. On behalf of our 4,000+ members that practice in a variety of practice settings across the state, we thank you for considering our comments and recommendations on how to ensure that patients can maximize the benefits that HB 188 provides.

Antonio Ciaccia
Ohio Pharmacists Association
aciaccia@ohiopharmacists.org

From:	Clark, Aaron
To:	Debolt, Sallie
Subject:	4731-35-01 Consult agreements 4731-35-02 Standards for managing drug therapy).
Date:	Friday, February 8, 2019 9:09:17 AM

To the State Medical Board,

I am writing to express my concerns with new language proposed with respect to collaborative arrangements between physicians and pharmacist's (4731-35-01 Consult agreements 4731-35-02 Standards for managing drug therapy). These proposed rules are not only burdensome, but are actually antithetical to where primary care has evolved with respect to patient-centered team-based primary care. This model of care is not only the preferred model of care not only within the primary care community, but the payer community as well. This preference is demonstrated by the growth of value based contracts, and primary care team based models of support such as Comprehensive Primary Care Plus from the Centers for Medicare and Medicaid Services, as well as the Ohio Department of Medicaid's Ohio CPC.

In particular I am concerned with the proposed new requirement that the pharmacist notify the physician prior to any action which includes changing or discontinuing a drug, ordering tests such as urine or blood and that the pharmacist include a detailed description of the proposed action, and obtain the consent of the primary care physician.

I have worked with a clinical pharmacist for the past 5 years. She manages the insulin on my diabetic patients, provides bridging recommendations for patients on anticoagulation who need invasive interventions, and smoking cessation education just to name a few. I receive a detailed report from her for review following each patient encounter. Any test or pharmaceutical that she orders is cosigned by me. The requirement of prior approval essentially constructs barriers to good patient care.

Primary care, especially in the current environment of value based healthcare is a team support. Pharmacist's are highly educated licensed professionals. In addition, during a routine clinical day, it is quite deleterious to care to implement the prior authorization review requirements as proposed as it not only negatively impacts the patient the pharmacist is managing, but the patient the clinician is caring for at the same time.

The offices of Ohio State University Family Medicine require all patients with a hemoglobin A1c greater than 9 to see the pharmacist for medication management and diabetes education. The clinical pharmacist with whom I work has taken patients with A1c's above 9, and brought their diabetes under control. Our pharmacist spends an hour with them at the first visit, and 30 minutes at subsequent visits. No clinician has that amount of time and this in depth visit along with the pharmacists expertise is what provides the benefit.

Given the variety of environment's in which pharmacists collaborate, and the reality that one size fits all policies have unintended consequences, I would respectfully request an exception for pharmacists who practice in a team-based environment, within a providers office, such that the provider is available in real-time during all hours for which the pharmacist is managing patients

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

Aaron D. Clark, DO
Associate Professor – Clinical
Associate Chair
Department of Family Medicine
2231 North High Street, Room 273, Columbus, OH 43201

614-293-2653 Office / 614-293-2715 Fax

February 7, 2019

Sallie Debolt, JD, Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy

Dear Ms. Debolt:

I am writing in regards to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. Consult Agreements for Pharmacist Management of Patient's Drug Therapy is of interest to me due to my current collaborative practice with a physician Ambulatory Care Pharmacist practicing at The University of Toledo General Internal Medicine Clinics and a Clinical Lecturer at The University of Toledo College of Pharmacy and Pharmaceutical Sciences. Within my outpatient clinic, I work side by side physicians on a daily basis to provide unique value to our patients and improve overall quality of care.

Currently, consult agreements allow me to work collaboratively with physicians to manage chronic diseases. In my practice I manage diabetes, hypertension, and dyslipidemia through consult agreements. I also serve as a drug information expert and educator for both our residents, providers and patients. Pharmacists improve the continuity of care, level of care and overall quality of the patients' healthcare experience. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

The proposed rule changes, specifically those that require pharmacists to notify the physician of any action prior to implementation (4731-35-02 C-4) would discourage collaborative practice and obstruct our current quality-based workflow. As the medication expert within the interdisciplinary patient care team, my expertise is imperative to the care of patients. By utilizing evidence-based medicine, chronic disease can be managed independently within an agreed upon scope of practice. The removal of this autonomy through the restriction of consult agreements would lead to a tedious and inefficient process for chronic disease management that would negatively impact the pharmacist, provider and patient. Logistically, a busy provider may not always be in clinic making it difficult for both myself and/or a patient to reach them. In this case I am the best resource to manage chronic diseases and ensure timely care is provided. I recommend that this requirement be removed from the proposal.

Since beginning in my position in July 2018, I have managed chronic disease in over 70 patients through consult agreements. Recently a patient stated that if it wasn't for my availability and close follow up of her chronic disease, she does not feel she would be close to achieving her healthcare goals. Her physician has become one of my biggest supporters and encourages my involvement in the majority of his panel of patients.

In summary, I hope that the proposal be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,

Marilee Clemons, PharmD, RPh
Ambulatory Care Pharmacist
Clinical Lecturer

From:	Columber, Heather
To:	Debolt, Sallie
Subject:	recently proposed changes to be adopted regarding Consult Agreements and Standards for managing drug therapy.
Date:	Thursday, February 7, 2019 1:19:00 PM

TO: State Medical Board of Ohio

FROM: Heather Columber, D.O.

RE: Response to Proposed Rules 4731-35-01 and 4731-35-02: Consult Agreements

Thank you for the opportunity to provide comments on the Medical Board's recently proposed rules regarding consult agreements between pharmacists and physicians. Consult agreements have been an invaluable resource for physicians to expand access and improve quality, especially since the revision of the law in 2016. In general, I appreciate the added clarity that the medical board has provided specific to physician participation in a consult agreement. However, some of the new provisions outlined in the proposed rules create a significant burden that would outweigh many of the benefits of a consult agreement, and would negatively impact patient care.

Specifically, the requirements for notification and consent prior to action by a pharmacist, as well as the requirement for regular meetings to review a written consult report represent my greatest concerns. The current regulations allow physicians and pharmacists to reach mutually agreeable terms that ensure adequate collaboration, expertise, oversight, and quality assurance mechanisms exist within the consult agreement. Physicians already have the flexibility to engage in a consult agreement that addresses training, communication, and quality assurance mechanisms that are appropriate for the medication management that is being performed.

Requiring a physician's consent prior to each action adds significant time without providing any benefit to the patient. Consult agreements already require a "description of the procedures, decision criteria, and plan the managing pharmacist is to follow in acting under a consult agreement." Asking a physician to confirm that the decision criteria and plan are correct prior to every change is unnecessary and only adds burden to the pharmacist and physician. Adding complexity into a medication adjustment may also cause a patient to experience suboptimal care while consent is being obtained.

Similarly on the requirement for regular meetings, the law already requires "communication between a pharmacist and physician acting under a consult agreement shall take place at regular intervals specified by the primary physician acting under the agreement." Additional requirements for regular meetings and written consult reports only add complexity and administrative burden to an already safe collaborative

Ultimately, I believe that these proposed rules run counter to the efficiencies that the law revision was intended to provide in 2016, and I recommend that the State Medical Board of Ohio reconsider adding any new requirements or barriers to care into the rules. I appreciate your consideration and the opportunity to provide feedback on the proposed rules. If you have any questions or would like to further discuss our comments, please reach out at the contact information below.

Sincerely,

Heather Columber, D.O.
Associate Medical Director of Primary Care for OhioHealth Physicians Group
OhioHealth Primary Care Physicians, Mallard Square
1713 Marion Mount Gilead Road, Suite 108
Marion, Ohio 43302
(740) 383-7080 office
(740) 386-2824 fax
(614) 746-8432 cell

FORTUNE 100 Best Companies to Work For 2007-2018

OhioHealth

TO: State Medical Board of Ohio

FROM: Glen E. Cooke, MD, FACC

RE: Response to Proposed Rules 4731-35-01 and 4731-35-02: Consult Agreements

Thank you for the opportunity to provide comments on the Medical Board's recently proposed rules regarding consult agreements between pharmacists and physicians. Consult agreements have been an invaluable resource for physicians to expand access and improve quality, especially since the revision of the law in 2016. In general, I appreciate the added clarity that the medical board has provided specific to physician participation in a consult agreement. However, some of the new provisions outlined in the proposed rules create a significant burden that would outweigh many of the benefits of a consult agreement, and would negatively impact patient care.

Specifically, the requirements for notification and consent prior to action by a pharmacist, as well as the requirement for regular meetings to review a written consult report represent my greatest concerns. The current regulations allow physicians and pharmacists to reach mutually agreeable terms that ensure adequate collaboration, expertise, oversight, and quality assurance mechanisms exist within the consult agreement. Physicians already have the flexibility to engage in a consult agreement that addresses training, communication, and quality assurance mechanisms that are appropriate for the medication management that is being performed.

Requiring a physician's consent prior to each action adds significant time without providing any benefit to the patient. Consult agreements already require a "description of the procedures, decision criteria, and plan the managing pharmacist is to follow in acting under a consult agreement." Asking a physician to confirm that the decision criteria and plan are correct prior to every change is unnecessary and only adds burden to the pharmacist and physician. Adding complexity into a medication adjustment may also cause a patient to experience suboptimal care while consent is being obtained.

Similarly on the requirement for regular meetings, the law already requires "communication between a pharmacist and physician acting under a consult agreement shall take place at regular intervals specified by the primary physician acting under the agreement." Additional requirements for regular meetings and written consult reports only add complexity and administrative burden to an already safe collaborative

Ultimately, I believe that these proposed rules run counter to the efficiencies that the law revision was intended to provide in 2016, and I recommend that the State Medical Board of Ohio reconsider adding any new requirements or barriers to care into the rules. I appreciate your consideration and the opportunity to provide feedback on the proposed rules. If you have any questions or would like to further discuss our comments, please reach out at the contact information below.

Glen E. Cooke, MD, FACC

From: Cooper, M.D., Cathy
To: Debolt, Sallie
Subject: Pharmacists- changes in prescribing and ordering labs
Date: Wednesday, February 6, 2019 10:46:53 AM

Good morning,

I am hoping to see a continuation of the pharmacists who help manage patient care as prescribe and order medications. Our pharmacist have been invaluable in seeing our patients and making great changes in the management in my area of diabetes and hypertension. It's unfortunate that we need to cosign for these highly educated folks- whom we use as a resource and guide in managing rx. Please reconsider- this has been seamless and now that changes are coming- it will once again complicate and delay patient care.

Cathy L Cooper MD

THE UNIVERSITY OF
TOLEDO
1872

Christopher J. Cooper, M.D.
Executive Vice President for Clinical Affairs
Dean of the College of Medicine & Life Sciences

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February 5, 2019

Sallie Debolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

Dear Ms. Debolt,

Thank you for the opportunity to review and provide comments on the proposed draft Medical Board Rules 4731-35-01 Consult Agreements and 4731-35-02 Standards for Managing Drug Therapy.

Our physicians partner with our pharmacists as the medication experts within the interdisciplinary patient care team. The pharmacists' expertise is imperative to assisting us with the care of our patients. The medication management provided to our patients can be managed within an agreed upon scope of the Consult Agreement through the combined rules of the Ohio Medical and Pharmacy Board.

In 2018, The University of Toledo credentialed and privileged board certified pharmacists partnered with our medical staff to perform about 36,000 actions (approx. 100 per day) under the current consult law. These pharmacists are reviewed by the Medical Staff processes of FPPE and OPPE for quality assurance and their partnering physicians retrospectively review and acknowledge the activities of the pharmacist as a quality measure in compliance with current rules and regulations. The current consult agreement, in conjunction with our approved Medical Executive Committee policies, have allowed us to currently have over 300 days since the last medication related harm event. The proposed language requiring advanced notification and consent would take time from both the physician and pharmacist away from other patient care duties and decrease the number of lifesaving and quality of care improving interventions our physicians and pharmacists can make for our patients.

Consult agreements allow physicians to work collaboratively with pharmacists to manage chronic diseases in the ambulatory setting. Physicians and pharmacists partner to manage patients in primary care and in anticoagulation. In 2018, our pharmacists provided over 6000 patient encounters that demonstrated improved outcomes, such as, compliance, fewer adverse reactions, and quicker achievement of therapeutic goals similar to the Impact Trial and other similar studies. The U.S. Department of Health and Human Services (HHS) in December 2018 published Reforming America's Healthcare System Through Choice and Competition, recognizes that pharmacists improve the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

Our recommendation would be to delete C-4 a and b from proposed rule 4731-35-02 (C-4) that indicates prior to any action a pharmacist can perform, the pharmacist must notify the physician and obtain consent.

In summary, the proposed changes would discourage collaborative practice and obstruct our current quality-based workflow for both the medical and pharmacy teams. Within the current consult agreements, physicians and pharmacists work closely together to ensure the best patient care for our patients. If the proposed changes occur, there will be more unnecessary phone calls, longer time to patient care, and potential related harm to patients. We are pleased the Medical Board has provided physicians additional guidance on managing consult agreements, but we would ask the Medical Board to consider removing 4731-35-2 C-4 a and b from the proposed draft Medical Rules.

Sincerely,

CJ Cooper

Christopher J. Cooper, M.D.
Executive Vice President for Clinical Affairs
Dean of the College of Medicine and Life Sciences

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

Department of Internal Medicine
Division of General Internal Medicine
Martha Morehouse Pavilion
Suite 2335
2050 Kenny Road
Columbus, OH 43221
614-293-4953 Phone
614-293-6890 Fax

2/4/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
Sallie.Debolt@med.ohio.gov

Dear Ms. DeBolt:

I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a physician that utilizes the services of pharmacists through collaborative practice agreements to provide care to my patients, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.

I have practiced in a multitude of settings over the past twelve years, including both military and civilian hospital and clinic settings, that have relied heavily on - and benefited immensely from - collaborative practice agreements with pharmacists. In my experience, clinical pharmacists make sound clinical decisions in accordance with best evidence and guidelines, provide excellent medication counseling, and are prone to making fewer prescribing mistakes than physicians. Moreover, their efforts decrease physician workload, allowing us to meet patient needs in ways that others cannot.

Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:
Shawn Patrick Corcoran
DBCF7B45C0AE4C7...

Shawn Patrick Corcoran

Internal Medicine Physician

Sallie DeBolt

State of Ohio
Medical Board
sallie.debolt@med.ohio.gov

Dear Ms. DeBolt

I am writing to the Medical Board about the proposed changes to the physician/clinical pharmacist, consult agreement.
As a patient of the system I can attest to the benefits of having a Pharm. D, assist the primary care physician especially in the management of patients with poorly controlled hypertension and diabetes, requiring multiple medications.
The collaborative effort by my primary care physician and the clinical pharmacist has resulted in a multiple medication regimen which has converted my poorly controlled blood pressure levels to normal readings. I have benefited from the current system.

I am a professor at The Ohio State University College of Medicine, Department of Ophthalmology; I have spent my career, practicing medicine, teaching medical students, residents and fellows. I believe the purpose of our health care system is to be focused on what is best for the patients. This is what I teach my students.

The current rules allow the physician to delegate to the clinical pharmacist medication decisions that he or she deems appropriate. The proposed change requiring multiple signatories the patient, the physician, and the clinical pharmacist is not practical. What if the doctor is not available to sign the form? I see on a daily basis, retinal complications cases of poorly controlled blood pressure and diabetes. For example I refer those patients who are in urgent need of blood pressure medication to a practice of a primary care physician with a clinical pharmacist. My patients are treated quickly, especially important, with patients with a retinal bleed, with blood pressure of 200/100.

The current system works, I do not feel the proposed rule changes, are in our patients best interest.

Yours truly,

Frederick H. Davidorf, M.D.
Professor Department of Ophthalmology
The College of Medicine
The Ohio State University

From: Davis, Melissa
To: Debolt, Sallie
Subject: collaboration with pharmacists
Date: Friday, February 1, 2019 12:54:38 PM

Dear Ms. Debolt,

I am concerned about the proposed changes to OH law that would affect pharmacist collaboration with physicians. I work closely with pharmacists in my primary care office and at one of our family medicine residency program training sites and they are invaluable with regard to improving patient adherence with diabetes treatment, smoking cessation, etc. I have seen diabetic patients improve quite a bit and patients quit smoking successfully with participation of the pharmacists. It would cause a major quality issue at our office if the pharmacist had to stop and verify every dose adjustment with a physician before it could go into effect. it would cause delays for the patients and add to our administrative burden which is already out of control.

Melissa Davis, MD
Clinical Assistant Professor
Department of Family Medicine
The Ohio State Wexner Medical Center
CarePoint East, 2nd Floor, 543 Taylor Avenue, Columbus, OH, 43203
614-688-6490 Office / 614-688-6491 Fax

Western Medicine, Inc.
Family Physicians
7774 Dayton-Springfield Road
Fairborn, Ohio 45324
Phone: 937-864-7363

State Medical Board of Ohio
30 East Broad Street, 3rd Floor
Columbus, Ohio 43215

To whom it may concern,

I am writing to express my concerns regarding the proposed rules for consult agreements with pharmacists. As the business owner of a successful Comprehensive Primary Care Plus family medicine practice and as a practicing physician, I feel that these new rules are burdensome to my practice and ultimately, a hindrance to providing high quality patient care.

These rules state that the pharmacist in a consult agreement with a physician must consult the physician prior to any action that is taken in a patient's care. The point of the updated law approved in 2016 was to do away with this requirement. Returning to this practice, will add unnecessary time to the process of patient care. I have chosen to enter into a consult agreement with the clinical pharmacists I work with because I recognize that their education, training, and skill set is well suited for management of chronic conditions. If I wanted them to ask me for permission, I would not choose to have this relationship. If the pharmacist has to confirm each decision that they want to make with the physician, it inhibits their ability to operate fully within the pharmacist's scope. The purpose of the consult agreement is to share patient care responsibility, and the consult agreement/referral to the pharmacist for disease state management is essentially reversed if the pharmacist is unable to make changes with their own clinical decision making.

Furthermore, the proposed rules suggest that the pharmacist and physician within the consult agreement develop a continuous quality improvement program that requires regular meetings with the physician and pharmacist as well as consult report detailing for changes made underneath the pharmacist's care. If a pharmacist and physician have a good relationship, they will have regular communication regarding patient care. This does not mean that an extensive formal quality improvement program is needed. This should be left up to the pharmacist and physician in the consult agreement to determine how they want to stay in regular communication, and how they want to handle patient care. In our practice, I review our pharmacists' chart notes weekly, and respond if there are any concerns with therapy changes, which typically, there are none. Our clinical pharmacy team has drastically improved our "diabetes in control" quality metrics by targeting our at risk diabetes population. Medicare's Comprehensive Care Program is

calling for more physicians to engage with clinical pharmacists in their practice, and these rules would hinder the expansion of comprehensive quality primary care efforts.

The pharmacist should not be required to verify a patient-physician ongoing relationship. This should be the responsibility of the physician to ensure that they are regularly having contact with the patient. The pharmacist and physician can discuss what the physician's preferences are for continued patient-physician relationship allowing the pharmacist to make recommendations to the patient as needed for follow-up with their physician. However, this should not be a requirement for the pharmacist. This is a responsibility that the physician shall maintain and that the pharmacist may help with as warranted.

Lastly, there is no need for ongoing consult reports in addition to our chart notes. Our pharmacist documents in the patient chart the same way I do and forwards her notes to the collaborating physician for review. Additional consult reports are labor intensive, unnecessary, and will not improvement patient care

I have been very pleased with the work that our clinical pharmacists have done to improve patient care. I hope to continue this excellent and comprehensive level of patient care through utilization of a pharmacist without the hindrance of these specific restrictive rules on our consult agreement. For pharmacists and physicians alike, the proposed rules for consult agreements by your board between pharmacists and physicians needs to be re-evaluated and mirror the rules we are currently following that were already set forth by the Board of Pharmacy

Sincerely,

Jacob Dean, MD

Owner and Physician

Western Medicine Family Physicians

www.WesternMedicineInc.com

From: Scott Deering
To: Debolt, Sallie
Subject: Proposed Pharmacy Rules
Date: Friday, February 8, 2019 2:35:09 PM

February 8, 2019

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult Agreements and 4731-35-02 Standards for Managing Drug Therapy

Dear Ms. Debolt:

I am writing in regards to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. The suggested rule changes, specifically those that require pharmacists to notify the physician of any action prior to implementation (4731-35-02 C-4) would discourage collaborative practice and obstruct our current quality-based workflow. Pharmacists are the medication expert within the interdisciplinary patient care team making their expertise imperative to the care of patients. This expertise and evidence-based care can be managed independently within an agreed upon scope of practice. The removal of the autonomy afforded to pharmacists through consult agreements would lead to a tedious and inefficient process for chronic disease management and patient care for hospitalized patients. It would definitely have a negative impact on the pharmacist, provider and patient. Logistically, a busy provider may not always be available - making it difficult for both the pharmacist and patient's to reach them; thereby delaying care and conceivably causing harm in certain circumstances.

I recommend that the proposal requiring affirmation from a physician prior to dosing adjustment be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,

Dr. Scott J. Deering, MD

Bowling Green Orthopaedics
1215 Ridgewood, Suite A
Bowling Green, OH 43402

From: Deichstetter, Kaley (deichsky)
To: Debolt, Sallie
Subject: Comment on Ohio Medical Board Decisions
Date: Friday, February 8, 2019 1:01:19 PM

Sallie Debolt,

Here are two different curriculums for two different doctorate level degrees

Degree 1:
Drug Delivery I
Principles of Medicinal Chemistry
Pharmacy Calculations
Principles of Pharmacology and Pharmacotherapy
Therapeutics I
Clinical Pharmacokinetics
Evidence-based Pharmacotherapy I
Case Studies in Therapeutics I
Therapeutics of nonprescription drugs
Therapeutics II
Case Studies in Therapeutics II
Pharmacy Practice Skills Development I
Therapeutics III Therapeutics IV
Evidence Based Pharmacotherapy II

Degree 2:
Healthcare Emergency management
Clinical Skills 101 and 102
Fundamentals of Molecular Medicine
Fundamentals of Cellular Medicine
Musculoskeletal – Integumentary
Brain, Mind and Behavior
Blood and Cardiovascular system
Renal and Pulmonary Systems
Gastoinstestinal/Endocrine/Reproduction
Multi-systems
Health Care Emergency Management II
Principles in Interprofessional Collaborative Practice

Degree 2 has no course dedicated specifically to pharmacology or therapeutics of medications.

Recipients of Degree 2 do not explicitly meet these benchmarks, however recipients of Degree 1 do:
Describe STANDARD therapeutic approaches to treat common diseases affecting each organ system.
Explain the BASIC science underlying the therapeutic benefits and adverse side effects of pharmacologic agents.

Which degree holder would you prefer to manage your medication therapy?

Degree 1 is the PharmD curriculum at UC and Degree 2 is the Doctor of Medicine curriculum, also at UC.

Degree 1 is dedicated to every aspect of drugs and their proper use. Degree 2 is dedicated to every aspect of the human body and how to heal it, with a small focus on the standard and basic therapeutic strategies of drugs.

Degree 2 can write for medications. Degree 1 must ask degree 2 about any and all changes to medications before making them.

Are you starting to see a problem? You do not have to be a pharmacist to understand that those must suitably trained in medications should have the most or at least equal authority in handling those medications.

Doctors only learn standards and basics of medications, and we're talking about over 1,000 approved drugs. Pharmacist and Doctors are not in a turf war, we are handling 2 completely separate roles; one in which the doctor is providing diagnoses and the pharmacist is providing drug therapy. This keeps the patient as the focus and ensures that they get the best and most comprehensive medical attention.

**Adapted from a colleague's submission.

Kaley Deichstetter
PharmD Candidate 2021
University of Cincinnati
James L. Winkle College of Pharmacy

Department of Medicine
Chair: Lance D. Dworkin, M.D.
Admin.Vice-Chair: Basil E. Akpunonu, M.D.
Administrator: Beth Smotherman
Assistant to Chair: Maureen Gilmore

Department of Medicine
Health Science Campus
3000 Arlington Ave., MS 1186
Toledo, Ohio 43614-2598
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COLLEGE OF MEDICINE AND LIFE SCIENCES
THE UNIVERSITY OF TOLEDO

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Community Internal Med: Allen Markowicz, M.D.
Dermatology: Lorie D. Gottwald, M.D.
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Infectious Diseases: Joan Duggan, M.D.
Nephrology: Deepak Malhotra, M.D., Ph.D.
Pulmonary/Critical Care: Jeffrey R. Hammersley, M.D.
Rheumatology: M. Bashar Kahaleh, M.D.

February 8, 2019

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy

Dear Ms. Debolt:

I am writing in regards to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. Consult Agreements for Pharmacist Management of Patient's Drug Therapy is of interest to me due to my current collaborative practice with a pharmacist as a physician practicing at South Toledo Internist at 3355 Glendale Avenue, Toledo, Ohio, and The University of Toledo Medical Center at 3000 Arlington Avenue, Toledo, Ohio. Within my outpatient clinic, I work side by side with clinical pharmacists on a daily basis who provide unique value to our patients and improve overall quality of care.

Currently, consult agreements allow physicians to work collaboratively with pharmacists to manage chronic diseases. In my practice, we have pharmacists who independently manage diabetes, hypertension, and dyslipidemia through consult agreements. Pharmacists improve the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Additionally, our pharmacists serve as drug information experts and educators for both our residents, providers and patients. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

The proposed rule changes, specifically those that require pharmacists to notify the physician of any action prior to implementation (4731-35-02 C-4) would discourage collaborative practice and obstruct our current quality-based workflow. Pharmacists are the medication expert within the interdisciplinary patient care team making their expertise imperative to the care of patients. This expertise and evidence-based care can be managed independently within an agreed upon scope of practice. The removal of the autonomy afforded to pharmacists through consult agreements would lead to a tedious and inefficient process for chronic disease management that would negatively impact the pharmacist, provider and patient. Logistically, a

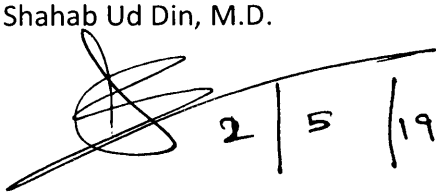
busy provider may not always be in clinic making it difficult for both the pharmacist and patient's to reach them. In this case the pharmacist is the best resource to manage chronic diseases and ensure timely care is provided. I recommend that this requirement be removed from the proposal.

Examples of collaborations include educating learners within the clinic (medical students, medical residents, PA students) -- teaching them about appropriate use of medications for disease states, working together to come up with a therapeutic plan moving forward -- in this instance, I may call a patient and get blood sugar readings and other pertinent information and then work through my thought process with the resident so they are also learning how to manage diabetes appropriately. Additionally, on the inpatient settings, pharmacists make recommendations during rounds including monitoring and dosing of warfarin, antibiotics and antibiotic stewardship.

In summary, I hope that the proposal be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,

Shahab Ud Din, M.D.



Yana Doughty, PharmD, CACP
Clinical Pharmacist
University of Toledo Medical Center
3000 Arlington Ave MS 1131
Toledo, OH 43614

February 8, 2019

Sallie Debolt, Esq., Senior Counsel

State Medical Board of Ohio

30 E. Broad Street, 3rd Floor

Columbus, OH 43215

Dear Ms Debolt,

Thank you for the opportunity to review the proposed draft Medical Board Rules 4731-35-01 Consult Agreements and 4731-35-02 Standards for Managing Drug Therapy. As a clinical pharmacist specializing in anticoagulation at The University of Toledo Medical Center, I have had the opportunity to work directly with physicians under the current consult law to provide patients with timely and outcome driven anticoagulation therapy. Physicians collaborate with pharmacists as the medication experts within the interdisciplinary patient care team making their expertise imperative to assisting us with the care of our patients. This knowledge of evidence-based care can be managed within an agreed upon scope of the Consult Agreement through the combined rules of the Ohio Medical and Pharmacy Board.

My request for the proposed consult agreement change would be to delete 4731-35-02 (C-4) a &b from proposed rule that indicates prior to any action a pharmacist can perform, the pharmacist must notify the physician and obtain consent.

The UTMC anticoagulation clinic oversees the management of roughly 700 patients. Pharmacists work under consult agreements and have specific training, credentialing, privileging, and board certifications in the area of anticoagulation. The work we do daily in this clinic has shown to have successful outcomes in terms of fewer bleeds and thromboembolism while maintaining higher percentage of patients in therapeutic range than standard of care management. Pharmacists are reviewed by the Medical Staff processes of FPPE and OPPE for quality assurance and their partnering physicians retrospectively reviews and acknowledges the activities of the pharmacist as a quality measure in compliance with current rules and regulations. The proposed language requiring advanced notification and consent would take the physician and pharmacist away from other patient care duties and decreasing the number of lifesaving and quality of care improving interventions our physicians and pharmacists can make for our patients.

Consult agreements allow physicians to work collaboratively with pharmacists to manage chronic diseases in the ambulatory setting. Physicians and pharmacists collaborate to manage patients in primary care and in anticoagulation. Our pharmacists provided over 6000 patient encounters in 2018 demonstrating improved outcomes such as compliance, fewer adverse reactions, and quicker achievement of therapeutic goals similar to the Impact Trial and other similar studies. Additionally, Pharmacists have been recognized by the U.S. Department of Health and Human Services (HHS) to improve the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

In summary: the proposed changes would discourage collaborative practice and obstruct our current quality-based workflow for both the medical and pharmacy teams. With the current consult agreements, the physicians and pharmacists work closely together to ensure the best patient care happens to patients. If the proposed changes occur, there will be more unnecessary phone calls, longer time to patient care, and potential harm to patients. We are pleased the Medical Board has provided physicians additional guidance on managing consult agreements although we would ask the Medical Board to consider removing 4731-35-2 C-4 a and b from the proposed draft Medical Rules

Sincerely,

Yana Doughty, PharmD, CACP

Memorial FAMILY MEDICINE | RICHWOOD

TO: State Medical Board of Ohio

FROM: [David R. Dunkin, D.O.]

RE: Response to Proposed Rules 4731-35-01 and 4731-35-02: Consult Agreements

Thank you for the opportunity to provide comments on the Medical Board's recently proposed rules regarding consult agreements between pharmacists and physicians. Consult agreements have been an invaluable resource for physicians to expand access and improve quality, especially since the revision of the law in 2016. In general, I appreciate the added clarity that the medical board has provided specific to physician participation in a consult agreement. However, some of the new provisions outlined in the proposed rules create a significant burden that would outweigh many of the benefits of a consult agreement, and would negatively impact patient care.

Specifically, the requirements for notification and consent prior to action by a pharmacist, as well as the requirement for regular meetings to review a written consult report represent my greatest concerns. The current regulations allow physicians and pharmacists to reach mutually agreeable terms that ensure adequate collaboration, expertise, oversight, and quality assurance mechanisms exist within the consult agreement. Physicians already have the flexibility to engage in a consult agreement that addresses training, communication, and quality assurance mechanisms that are appropriate for the medication management that is being performed.

Requiring a physician's consent prior to each action adds significant time without providing any benefit to the patient. Consult agreements already require a "description of the procedures, decision criteria, and plan the managing pharmacist is to follow in acting under a consult agreement." Asking a physician to confirm that the decision criteria and plan are correct prior to every change is unnecessary and only adds burden to the pharmacist and physician. Adding complexity into a medication adjustment may also cause a patient to experience suboptimal care while consent is being obtained.

Similarly on the requirement for regular meetings, the law already requires "communication between a pharmacist and physician acting under a consult agreement shall take place at regular intervals specified by the primary physician acting under the agreement." Additional requirements for regular meetings and written consult reports only add complexity and administrative burden to an already safe collaborative

Ultimately, I believe that these proposed rules run counter to the efficiencies that the law revision was intended to provide in 2016, and I recommend that the State Medical Board of Ohio reconsider adding any new requirements or barriers to care into the rules. I appreciate your consideration and the opportunity to provide feedback on the proposed rules. If you have any questions or would like to further discuss our comments, please reach out at the contact information below.

Sincerely:

David R. Dunkin, DO

David R. Dunkin, D.O.

☎ 740 943 2354

740 943 5068

memorialohio.com

19 West Ottawa St., Richwood, OH 43344

Garrett Eggers, PharmD, MS
Director – OSHP Legal Affairs Division

February 8, 2019

Sallie Debolt
State Medical Board of Ohio
30 E. Broad St., 3rd Floor
Columbus, Ohio 43215

Dear Ms. Sallie Debolt,

On behalf of the Ohio Society of Health-System Pharmacists (OSHP), I would like to formally submit comments on the proposed language for the new Medical Board of Ohio rules regulating consult agreements between physicians and pharmacists.

Although OSHP understands the need for guidance of pharmacist practice under a consult agreement, our organization feels the current language in the proposed rules significantly diminishes the scope and role of the pharmacist in managing a patient's medication therapy under the provision of a consult agreement. This diminished scope will have significant negative impact on patients in Ohio by restricting access to care by medication experts, and over-burdening physicians with administrative requirements to manage these consults agreements as is outlined in the proposed rules. As such, we recommend the following changes:

4731-35-01 Consult Agreements

Overall, OSHP is in general agreement with this section and feel it meets the intent of the consult agreement law as written. Recommend only the following change:

- Removal of Section A-1-i – requirement for physician approval prior to adjustment to the dose of a controlled substance.
    - Given the current challenges in Ohio with management of opioids and opioid addiction, limiting the ability for pharmacists to manage controlled substances will have the potential to perpetuate the problem of opioid overuse by preventing pharmacists from adjusting doses down or discontinuing opioids that are no longer needed for the patient.

4731-35-02 – Standards for Managing Drug Therapy

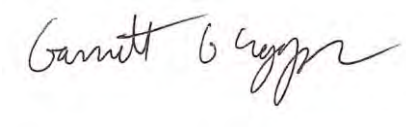
Overall, OSHP feels this section restricts the pharmacist's role in patient care and is in conflict with the consult agreement law and Ohio Board of Pharmacy rules as are currently written. Under the current consult agreement law and rules which have been in place since 2016, patients have seen improved access and quality of care without experiencing adverse events as a result of the expanded role of pharmacists in their care. Below are our specific recommendations:

Garrett Eggers, PharmD, MS
Director – OSHP Legal Affairs Division

- Modification of section A-3 – The language around physician communication to the patient is excessive and discourages patients from allowing a pharmacist to participate in their care through a consult agreement. We recommend sub-bullet (d) be removed from the rules.
- Removal of section A-6 – The requirement that the authorizing physician ensure the managing pharmacists' training and experience are adequate is an excessive burden on the physician. As pharmacists are extensively trained in pharmacology and pharmacotherapy through their prerequisite education in order to become licensed, further scrutiny of this training and experience by the authorizing physician is excessive.
- Clarification of section A-7 – Further clarification of "prompt review".
- Modification of section B-1 – Placing the responsibility of defining the extent and scope of the pharmacist on the physician is unclear. Recommend rewording to outline that scope of the pharmacist is defined by the policy/procedure established in the consult agreement.
- Modification of section C-4-a – Recommend removal of requirement for pharmacist to notify primary physician prior to any action. This requirement is extremely onerous on both the physician and the managing pharmacist, and will discourage physicians from entering into consult agreements with pharmacists. This will negatively impact patients' access to the necessary care they could receive from a pharmacist to manage their medications under a consult agreement. As the medication experts, pharmacists are qualified to perform these actions under a consult agreement. For physicians who do enter into consult agreements, these rules will have the effect of delaying necessary patient care while pharmacists await physician approval prior to implementing medication therapy modifications as appropriate. Overall, the net result is this rule will decrease both access and quality of care for patients in Ohio.
- Modification of section D-1 – Recommend removal of the requirement for primary physician and managing pharmacist to hold regular meetings. This requirement is onerous on both the physician and the managing pharmacist, and will discourage physicians from entering into consult agreements with pharmacists.

Thank you for your consideration of our comments for incorporation into these rules. Please feel free to contact me with any questions or clarifications.

Sincerely,



Garrett Eggers, PharmD, MS
Director – OSHP Legal Affairs Division
eggersg@ccf.org
(216) 618-2479

February 7, 2019

Lindsey Eitniear, PharmD, BCPS, AAHIVP, CDCA
Assistant Director of Pharmacy
The University of Toledo Medical Center
3000 Arlington Ave, MS 1060
Toledo, OH 43614

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy

Dear Ms. Debolt:

I am writing in regards to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. Consult Agreements for Pharmacist Management of Patient's Drug Therapy is of interest to me due to my current collaborative practice with our medical staff as a licensed, board certified, credentialed, and privileged pharmacist practicing at the University of Toledo Medical Center. Within our hospital, I work side by side with physicians on a daily basis who provide unique value to our patients and improve overall quality of care.

Currently, consult agreements allow physicians to work collaboratively with pharmacists to dose antibiotics, anticoagulants, discontinue duplicate medications, and renally adjust medications. In my practice, we have pharmacists who independently change doses, frequencies, routes, and order labs through consult agreements. Pharmacists improve the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Additionally, our pharmacists serve as drug information experts and educators for both our residents, providers and patients. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

The proposal includes unnecessary additions (4731-35-02 D-1) requiring the pharmacist to have a detailed description of a continuous quality improvement project including regular meetings with the physician. This should not be outlined by the rules, but should be dependent on the practice allowing variation from site to site. I recommend this be removed from the proposal.

I have personally been able to positively influence patient care beyond what our physicians are able to do with consult agreements. From providing smoking cessation assistance to patients to dosing life-saving medications such as KCentra and Tobramycin. Pharmacists have the time to cater to education and condition management that hospital and primary care physicians do not. We also have the expertise to dose and manage complicated medications that require substantial monitoring and adjustment. Removing pharmacists' ability to manage these

conditions and medications would impact patient care globally wherever pharmacists are available as an extension of physicians.

In summary, I hope that the proposal be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,

Lindsey Eitniear, PharmD, BCPS, AAHIVP, CDCA
Assistant Director of Pharmacy
The University of Toledo Medical Center
3000 Arlington Ave, MS 1060
Toledo, OH 43614

February 8, 2019

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy

Dear Ms. Debolt:

I am writing in regard to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. Consult Agreements for Pharmacist Management of Patient's Drug Therapy is of interest to me as I routinely consult the services of inpatient pharmacists to manage antibiotics and anticoagulants.

Using consults, I am able to ensure my patients are quickly assessed for appropriate dosing using consistent dosing methods. The pharmacists leave notes to let me know what therapy changes are happening. I have the opportunity to opt out of the consults if I feel it is necessary but I appreciate the added expertise I can provide to my patients with the pharmacists as collaborators.

The proposed rule changes, specifically those that require pharmacists to notify the physician of any action prior to implementation (4731-35-02 C-4) would discourage collaborative practice and obstruct our current quality-based workflow. Pharmacists are the medication experts within the interdisciplinary patient care team making their expertise imperative to the care of patients. This expertise and evidence-based care can be managed independently within an agreed upon scope of practice. The removal of the autonomy afforded to pharmacists through consult agreements would lead to a tedious and inefficient process for medication management that would negatively impact the pharmacist, provider, and patient. I am truly concerned regarding the need for contact before any change in therapy will be a significant impediment to my workflow. Timeliness of antibiotics and anticoagulants I routinely consult a pharmacist to complete is essential to improve outcomes for my critically ill patients. Please remove this requirement from the proposal.

In summary, I strongly advise the proposed rule change not be approved and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,

Hesham El Gamal, MD
960 W. Wooster Street, #107
Bowling Green, OH 43402

THE UNIVERSITY OF TOLEDO
MEDICAL CENTER

February 5, 2019

Sallie Debolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

Dear Ms. Debolt:

Thank you for the opportunity to review the proposed draft Medical Board Rules 4731-35-01 Consult Agreements and 4731-35-02 Standards for Managing Drug Therapy. Physicians partner with pharmacists as the medication experts within the interdisciplinary patient care team making their expertise imperative to assisting us with the care of our patients. This knowledge of evidence-based care can be managed within an agreed upon scope of the Consult Agreement through the combined rules of the Ohio Medical and Pharmacy Board. Our recommendation would be to delete C-4a and b from proposed rule 4731-35-02 (C-4) that indicates prior to any action a pharmacist can perform, the pharmacist must notify the physician and obtain consent.

University of Toledo Medical Center credentialed and privileged board certified pharmacists in 2018 partnered with our medical staff to perform about 36,000 actions (approx. 100 per day) under the current consult law. Pharmacists are reviewed by the Medical Staff processes of FPPE and OPPE for quality assurance and their partnering physicians retrospectively review and acknowledge the activities of the pharmacist as a quality measure in compliance with current rules and regulations. The current consult agreement, in conjunction with our approved Medical Executive Committee policies, has allowed us to currently have over 300 days since the last medication-related harm event. The proposed language requiring advanced notification and consent would take the physician and pharmacist away from other patient care duties and decreasing the number of lifesaving and quality of care improving interventions our physicians and pharmacists can make for our patients.

Consult agreements allow physicians to work collaboratively with pharmacists to manage chronic diseases in the ambulatory setting. Physicians and pharmacists partner to manage patients in primary care and in anticoagulation. Our pharmacists provided over 6,000 patient encounters in 2018 demonstrating improved outcomes such as compliance, fewer adverse reactions, and quicker achievement of therapeutic goals similar to the Impact Trial and other similar studies. Pharmacists have been recognized by the U.S. Department of Health and

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Human Services (HHS) to improve the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

In summary: the proposed changes would discourage collaborative practice and obstruct our current quality-based workflow for both the medical and pharmacy teams. With the current consult agreements, the physicians and pharmacists work closely together to ensure the best patient care happens to patients. If the proposed changes occur, there will be more unnecessary phone calls, longer time to patient care, and potential harm to patients. We are pleased the Medical Board has provided physicians additional guidance on managing consult agreements, although we would ask the Medical Board to consider removing 4731-35-2 C-4 a and b from the proposed draft Medical Rules

Sincerely,

Michael Ellis, M.D.
Chief Medical Officer

Taylor Engelhart, PharmD, RPh
AxessPointe Community Health Centers
143 Gougler Ave, Kent, Ohio, 44240
tengelhart@neome.edu

State Medical Board of Ohio
30 E. Broad St., 3rd Floor
Columbus, Ohio 43215
(614) 466-3934
Sallie.Debolt@med.ohio.gov

Dear Ms. Debolt,

My name is Taylor Engelhart and I am a post-graduate year one pharmacy resident in Northeast Ohio. After completing my doctorate program and becoming a pharmacist, I have elected to pursue further education and specialize in ambulatory care. I'm writing you to explain my concerns regarding the proposed rule changes to 4731-35-01 and 4731-35-02, which will be making changes to consult agreements and standards for managing drug therapy.

Firstly, I would like to acknowledge and thank the State Medical Board of Ohio for the support we have received in the recent years. There has been great progress made regarding collaboration of physicians with pharmacists through consult agreements. Through my years of training to become a pharmacist, I have had the pleasure of working with many physicians and pharmacists to improve the healthcare and lives of patients in Northeast Ohio. I have seen firsthand, as a member of those teams, the benefit of having a collaborative practice agreement. In collaboration, these two professions can improve patient centered outcomes, reduce drug therapy problems, and bridge the gap in preventative medicine during a time where we are seeing a shortage of primary care providers. The benefits I have seen could be greatly reduced, if not eliminated if these proposed rules are approved.

One of the greatest benefits of physician-pharmacist consult agreements is the increased access to care. A patient who may have to wait months to get in to see his/her provider can now get in to see a pharmacist within the next week. The patient can then have their medication adjusted at the pharmacist visits at a faster rate. Along with this, closer follow-up is possible, and outcomes can be achieved at a faster rate. One of the groups I see benefit most from the consult agreement is individuals with diabetes. This population is at a high risk for amputation, kidney dysfunction, blindness and more if their diabetes remains uncontrolled. For this reason, it is crucial that the patient be seen so that medications can be adjusted to help them meet goals and minimize the risk of complications related to diabetes. While high blood sugar is a huge concern, so is low blood sugar, which can lead to death. For this reason, diabetes medications, specifically insulin, must be adjusted slowly, precisely, and with close

monitoring. A physician is commonly limited to only seeing their patients once a month or once every two months, due to scheduling requirements. This limitation then only allows for insulin adjustments to happen every couple months, delaying the control of their disease. More aggressive adjustments without close monitoring would put the patient at risk of low blood sugar. With a collaborative practice agreement, the patient can see a pharmacist, having the pharmacist adjust every week or two, helping to achieve goals at a significantly quicker pace, along with allowing for close monitoring. Achieving these goals sooner isn't just a matter of hitting a goal number sooner, it is a matter of helping the patient keep their limbs, stay off dialysis, or maintain their eye site.

Many physicians have been depending on the pharmacists to help in matters such as these to allow them to free up their schedules for other patients. If the proposed rules are approved, the time that physicians were gaining to provide more care as a result of our current consult agreement, will be limited once again. Not only will they have their notes to complete, but now they will also be having to review the changes being made by the pharmacists working along with them. Physicians who have been trusting and utilizing pharmacists on their team to provide services, will have a greater time burden and regress in time allowed to spend caring for patients. In addition, having to wait for the approval by the physician, will serve as another delay in therapy for the patients, therefor delaying therapy benefits.

The progress that has been made over the past several years was all with the patients' health and wellbeing in mind. Both pharmacists and physicians have the same goal, and that is to improve the health of our patients. I believe that the proposed rule changes to 4731-35-01 and 4731-35-02 will be a great disservice to the patients as well as to the physicians. These changes will burden the physicians, limit access to care and delay therapy benefits. With the progress in consult agreements, we have made great improvements in patient care. I hope to see this progress not only continue, but also grow as these two professions continue to work together to provide care.

If you have any questions or would like to reach me, feel free to email me at tengelhart@axesspointe.org. Thank you for your time and consideration in this matter.

Taylor Engelhart, PharmD, RPh
January 30, 2019

From:	Esber, Heather
To:	Debolt, Sallie
Subject:	Comments on State Medical Board's proposed draft rules (4731-35-01, 4731-35-02) on physician-pharmacist consult agreements
Date:	Friday, February 8, 2019 2:54:52 PM

Dear Sallie,
Thank you for the opportunity to comment on the State Medical Board's proposed draft rules on physician-pharmacist consult agreements.

Over the past three years, HB188 has expanded patient access to treatment for chronic disease management, improve patient outcomes by focusing on care delivery and removed regulatory hurdles that made pharmacist utilization cumbersome for physicians.

Here at OhioHealth, we have seen tremendous improvements in patient care as a result of this law. I am the Program Manager of OhioHealth's Comprehensive Diabetes Program, a program developed to serve high-risk uncontrolled diabetics with an HbA1C>=9. As part of this program, OhioHealth has instituted a consult agreement between pharmacists and Primary Care physicians which gives pharmacists the ability to manage and evaluate the drug therapy of patients for comprehensive diabetes management. In the six months since this program has been implemented, pharmacists, through the consult agreement, have been able to engage and care for hundreds of patients. We have seen improved clinical outcomes that would not have been possible without this consult agreement.

I am concerned with a number of provisions in the Medical Board's proposed rules that would take this progress backwards and dismantle the programs that we have put in place at OhioHealth. These proposed rules directly conflict with the intent of the law.

- Specifically, the requirements for notification and consent prior to action by a pharmacist, as well as the requirement for regular meetings to review a written consult report represent my greatest concerns. The current regulations allow physicians and pharmacists to reach mutually agreeable terms that ensure adequate collaboration, expertise, oversight, and quality assurance mechanisms exist within the consult agreement. Physicians already have the flexibility to engage in a consult agreement that addresses training, communication, and quality assurance mechanisms that are appropriate for the medication management that is being performed.

- Requiring a physician's consent prior to each action adds significant time without providing any benefit to the patient. Consult agreements already require a "description of the procedures, decision criteria, and plan the managing pharmacist is to follow in acting under a consult agreement." Asking a physician to confirm that the decision criteria and plan are correct prior to every change is unnecessary and only adds burden to the pharmacist and physician. Adding complexity into a medication adjustment may also cause a patient to experience suboptimal care while consent is being obtained.

- Similarly on the requirement for regular meetings, the law already requires "communication

between a pharmacist and physician acting under a consult agreement shall take place at regular intervals specified by the primary physician acting under the agreement." Additional requirements for regular meetings and written consult reports only add complexity and administrative burden to an already safe collaborative

Ultimately, I believe that these proposed rules run counter to the efficiencies that the law revision was intended to provide in 2016, and I recommend that the State Medical Board of Ohio reconsider adding any new requirements or barriers to care into the rules. I appreciate your consideration and the opportunity to provide feedback on the proposed rules. If you have any questions or would like to further discuss our comments, please reach out at the contact information below.

Thank you for your consideration.

Sincerely,
Heather Esber, MBA
Program Manager: OhioHealth Comprehensive Diabetes Program
Heather.esber@ohiohealth.com
201-618-5443

From:	Lukas Everly
To:	Debolt, Sallie
Subject:	Comments for proposed changes to 4731-35-02
Date:	Tuesday, January 22, 2019 9:28:21 AM

Dear Ms. Debolt,

In reviewing the most recent proposed changes to rules governing the design and conduct of physician-pharmacist consult agreements I have major concerns. First and foremost being that this proposal forces pharmacists to contact a physician for final approval before implementing any changes as outlined in the agreement. This unnecessary restriction cripples the ability of pharmacists to utilize their expertise as the medication experts to provide care to patients and removes the ability of physicians to utilize pharmacists to their appropriate potential. This change effectively guts any ability for a consult agreement to exist outside of niche ambulatory care centers and will restrict patients from receiving care. Should a physician desire final approval of any changes to a patient's therapy prior to implementation, they may stipulate this within the current rules for consult agreements.

Countless studies have shown that enabling pharmacists to provide direct patient care through their clinical expertise improves healthcare outcomes and decreases costs in the long term. Restricting a physician's ability to establish and recognize the autonomy of the pharmacists they choose to consult adds unnecessary barriers for patients seeking optimal drug therapy management.

Thank you,
Lukas Everly

Lukas Everly, Pharm.D., BCPS
Assistant Professor
Department of Pharmacy Practice

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2/5/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
Sallie.Debolt@med.ohio.gov

Dear Ms. DeBolt:

I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a physician that utilizes the services of pharmacists through collaborative practice agreements to provide care to my patients, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.

I have had many of my patients benefit from working directly with our clinical pharmacists to improve their hypertension and diabetes. When looking at diabetic patients specifically, my patients have the opportunity to have an individual appointment with our pharmacist where they can discuss the best medication options and make immediate changes that will directly impact their blood sugar and health. It is because of this pharmacy collaboration that my patients can have medications adjusted and review of their blood sugars even when they are not personally seeing me in clinic. These patient have improved blood sugars and blood pressure and hugely benefit from this added consultation.

Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:
Farris
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Farris

Attending MD

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February 8, 2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

Dear Ms. DeBolt:

As a practicing pharmacist in the state of Ohio, I would like to thank you for your service to the State Medical Board of Ohio and for all you do to enhance the care of our fellow Ohioans. I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a pharmacist practicing under current collaborative practice rules, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.

During my residency training and in the early part of my career, I have been fortunate to work in a collaborative practice model that allowed pharmacists to work at the highest level of their licensure. I've witnessed the powerful impact that pharmacists can provide to patients while working in a practice that incorporates pharmacist collaborative practice agreements. Through my personal experience, patients benefit vastly by pharmacist's involvement in chronic condition management (diabetes, hypertension, hyperlipidemia, anticoagulation, etc.) through collaborative practice. Patients are able to quickly reach and maintain therapeutic goals through the pharmacist's guidance and ability to provide frequent contact and medication adjustments. Additionally, I feel that physicians are able to provide a higher level of care for more patients when pharmacists in a collaborative practice model are utilized as an extension of their care.

Based on my personal experience through practice and that I feel that the citizens of Ohio deserve the highest level of care from members of their healthcare team I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

Phillip Farwig, Pharm.D.
Clinical Pharmacy Specialist – Ambulatory Care
OSU Division of General Internal Medicine

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Admin.Vice-Chair: Basil E. Akpunonu, M.D.
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COLLEGE OF MEDICINE AND LIFE SCIENCES
THE UNIVERSITY OF TOLEDO

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February 8, 2019

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy

Dear Ms. Debolt:

I am writing in regards to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. Consult Agreements for Pharmacist Management of Patient's Drug Therapy is of interest to me due to my current collaborative practice with a pharmacist as a physician practicing at South Toledo Internists at 3355 Glendale Avenue, Toledo, Ohio, and The University of Toledo Medical Center at 3000 Arlington Avenue, Toledo, Ohio. Within my outpatient clinic, I work side by side with clinical pharmacists on a daily basis who provide unique value to our patients and improve overall quality of care.

Currently, consult agreements allow physicians to work collaboratively with pharmacists to manage chronic diseases. In my practice, we have pharmacists who independently manage diabetes, hypertension, and dyslipidemia through consult agreements. Pharmacists improve the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Additionally, our pharmacists serve as drug information experts and educators for both our residents, providers and patients. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

The proposed rule changes, specifically those that require pharmacists to notify the physician of any action prior to implementation (4731-35-02 C-4) would discourage collaborative practice and obstruct our current quality-based workflow. Pharmacists are the medication expert within the interdisciplinary patient care team making their expertise imperative to the care of patients. This expertise and evidence-based care can be managed independently within an agreed upon scope of practice. The removal of the autonomy afforded to pharmacists through consult agreements would lead to a tedious and inefficient process for chronic disease management that would negatively impact the pharmacist, provider and patient. Logistically, a

busy provider may not always be in clinic making it difficult for both the pharmacist and patient's to reach them. In this case the pharmacist is the best resource to manage chronic diseases and ensure timely care is provided. I recommend that this requirement be removed from the proposal.

Examples of collaborations include educating learners within the clinic (medical students, medical residents, PA students) -- teaching them about appropriate use of medications for disease states, working together to come up with a therapeutic plan moving forward -- in this instance, I may call a patient and get blood sugar readings and other pertinent information and then work through my thought process with the resident so they are also learning how to manage diabetes appropriately. Additionally, on the inpatient settings, pharmacists make recommendations during rounds including monitoring and dosing of warfarin, antibiotics and antibiotic stewardship.

In summary, I hope that the proposal be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,

Douglas Federman MD

Douglas J. Federman, MD, FACP
Associate Professor of Medicine
Division of General Internal Medicine

From:	File, Thomas
To:	Debolt, Sallie
Cc:	Jennifer Hayhurst; Monica Hueckel; Politis, Paula A.
Subject:	Restricting pharmacists
Date:	Friday, February 1, 2019 8:03:03 AM
Attachments:	89871D0B-8A29-4567-A35E-F6E3AB16D99F[7].png AD81E723-8CAA-4138-9C6C-ADAB0A9DD791[7].png

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Dear Ms. Debolt
I wish to comment and respond to the proposed rule for pharmacist management of patient's drug therapy.
I am an infectious diseases physician practicing at Summa Health in Akron. I am Chair of the Division of Infectious Diseases at Summa and Chair of the Infectious Disease Section At Northeast Ohio Medical University. In addition I am presently President-Elect of the Infectious Diseases Society of America.
I Co-direct an antimicrobial stewardship program along with a lead pharmacist here at Summa. Our stewardship program has had great impact on improving patient outcomes and safety. I had just become aware of a potential policy which might restrict our stewardship pharmacists in their role of appropriately monitoring antimicrobial dosing:
https://med.ohio.gov/Laws-Rules/Newly-Adopted-and-Proposed-Rules/Consult-Agreements-for-Pharmacist-Management-of-a-Patients-Drug-Therapy
The part of concern is section C4 of 4731-35-01 Consult agreements. See below:

4) When the managing pharmacist changes the duration of treatment for the

current drug therapy; adjusts a drug's strength, dose, dosage form, frequency

of administration, route of administration, discontinues a drug, prescribes a

new drug, or orders urine or blood tests, as authorized under section B)(1)(a),

and (B)(1)(b) of this rule, the managing pharmacist must:

(a) Notify the primary physician prior to any action. The notification shall

include a description of:

(i) The decision criteria considered by the managing pharmacist in

deciding to conduct an authorized action; and

(ii) A description of the proposed authorized action the managing

pharmacist intends to conduct.

(b) Obtain the consent of the primary physician to conduct the proposed

authorized action.

Presently our stewardship pharmacists have the authority to monitor and change doses of antimicrobials based on factors that include creatinine clearance, antimicrobial levels, type of pathogen and infection, MIC, etc. As an example if a vancomycin level is very high, they can withhold doses and appropriately change the frequency. If the pharmacist was required to obtain consent from the primary physician this may take hours to days and an additional dose of vancomycin might automatically be administered which would be detrimental to the patient. Actually the stewardship pharmacists have the best expertise as compared to most physicians to optimally monitor drug dosing.
I am concerned the proposed policy would have a significant detrimental impact on optimal dosing of antimicrobial agents which may lead to decreased patient outcomes and jeopardize patient safety.

Thank you your consideration. I am CCing contacts at the Ohio State Medical Association and our Lead Stewardship Pharmacist here at Summa.

Sincerely

Tom File

Thomas M File, Jr. MD MSc MACP FIDSA FCCP
Chair, Infectious Disease Division
Summa Health
Akron, OH
Professor, Internal Medicine; Master Teacher; Chair, Infectious Disease Section
Northeast Ohio Medical University (NEOMED)
Rootstown, Ohio;
President-Elect, Infectious Diseases Society of America

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[cid:95DECC79-D91A-4056-82C4-6D91AFF2FE1A]
[cid:C4C43450-4208-401B-813A-25D51E04835E]

February 8, 2019

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy

Dear Ms. Debolt:

I am writing in regards to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. Consult Agreements for Pharmacist Management of Patient's Drug Therapy is of interest to me due to my current collaborative practice with a pharmacist as a medical director and physician practicing at ProMedica Jobst Vascular. Within my outpatient clinic, I work side by side with clinical pharmacists on a daily basis who provide unique value to our patients and improve overall quality of care.

Currently, consult agreements allow physicians to work collaboratively with pharmacists to manage chronic diseases. In my practice, we have pharmacists who independently manage anticoagulation, smoking cessation, and diabetes through consult agreements at Jobst Anticoagulation Service. In addition, our pharmacists are hoping to expand their services to other chronic disease states. Pharmacists improve the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Additionally, our pharmacists serve as drug information experts and educators for both our residents, providers and patients. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

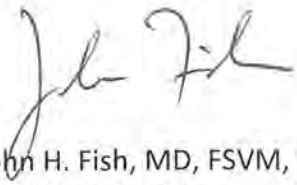
The proposed rule changes, specifically those that require pharmacists to notify the physician of any action prior to implementation (4731-35-02 C-4) would discourage collaborative practice and obstruct our current quality-based workflow. Pharmacists are the medication expert within the interdisciplinary patient care team making their expertise imperative to the care of patients. This expertise and evidence-based care can be managed independently within an agreed upon scope of practice. The removal of the autonomy afforded to pharmacists through consult agreements would lead to a tedious and inefficient process for chronic disease management that would negatively impact the pharmacist, provider and patient. Logistically, a busy provider may not always be in clinic making it difficult for both the pharmacist and patient's to reach them. In this case the pharmacist is the best resource to manage chronic diseases and ensure timely care is provided. I recommend that this requirement be removed from the proposal.

- Our pharmacists are able to provide quicker access to care through our consult agreement. Particularly by providing on call services for critical INR results after hours in addition to point-of-care services.

- We have a bridging protocol which allows pharmacists to assist with peri-operative anticoagulation which decreases response time to clearance requests.
- Our pharmacists have improved transitions of care with high risk anticoagulants by providing patient education, making interventions on dosing, and coordinating care.
- Through a pilot program in our Jobst Vascular Wound Care Center, pharmacists have shown to improve diabetes management which in turn helped assist with healing time.
- Jobst Anticoagulation Service is continuing to grow both in terms of patient volume and disease state management. We have a total of nine clinics servicing over 2,500 patients since 2014.
- As a physician, I agree with the existing rules as established by the Board of Pharmacy. These newly proposed rule changes would result in physician contact about every dosing decision by the pharmacist, which would be a tremendous burden on our physician practice and would create significant and potentially dangerous delays in patient care. I find that the consult agreement provides sufficient detail to ensure excellent communication between the physicians and pharmacists to provide best patient care.

In summary, I hope that the proposal be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,



John H. Fish, MD, FSVM, FACP
2109 Hughes Drive
Suite 450
Toledo, OH 43606

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2/4/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
Sallie.Debolt@med.ohio.gov

Dear Ms. DeBolt:

I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a physician that utilizes the services of pharmacists through collaborative practice agreements to provide care to my patients, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.

Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:
Matthew J Flanigan
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Matthew J Flanigan

MJF

From: Julie Foglio
To: Debolt, Sallie
Subject: Consult Agreements for Pharmacists Management of a Patient"s Drug Therapy- Comments
Date: Friday, February 1, 2019 3:28:00 PM

Ms. Debolt,

Good afternoon. I wanted to reach out for comments regarding 4731-35-02. My concern is with section C-4(a). The requirement to notify a physician prior to any action taking place by the pharmacist would dramatically reduce the potential impact pharmacist provider status can have on patient care in the state of Ohio. My preference would be to continue with the existing rules as written. Please let me know if you would like any further clarification on this matter.

Thank you in advance.

Julie E. Foglio, PharmD, BCPS
440.813.4762

From: Alan Fox
To: Debolt, Sallie
Subject: Ohio Medical Board Pharmacist Collaboration
Date: Friday, February 8, 2019 6:40:10 AM
Attachments: Comment Collaboration ASCP.docx

Hello,

We are writing to you as the Board of Ohio's American Society of Consultant Pharmacists. It is the opinion of the Ohio ASCP board that the legislation is too confining in its current form in order to benefit The Patient, The Physician or The Pharmacist.

Our interpretation is that this draft allows Collaborating Pharmacists to continue to make recommendations, but does not allow them to practice collaboratively. The proposed rules requires a consultation prior to any change of medication as well an overly stringent quality review on behalf of the Physician. Many of my colleagues have seven year Doctorates that include at least one year of hospital clinical practice. Several have a certification in specific areas of Pharmacy Practice such as Geriatrics. Physician Assistants are required to have Masters level degree and to have a "quality assurance program" in place for monitoring. The PA rules only require direct consultation "when necessary." The Nurse Practitioner's standard care arrangement requires a match in specialties, and a process for resolution of clinical disagreements. The Nurse Practitioner is required 45 hours of medication training and 36 hours of single provider training in order to manage medications. Ohio NPs must have periodic random chart review and a semiannual review of prescribing practices. It is clear that our NP and PA peers are qualified to collaborate with Physicians in order to streamline care in Ohio. It is our position that Ohio's Pharmacists are also qualified by education, training and credentialing to extend the Physician's practice in order to best meet the needs of Ohio's residents.
Our comments are attached to this email.

Your time and consideration are greatly appreciated,

The Ohio Board of ASCP:

Alan S. Fox	Kaylee Mehlman	Scott Amick
President	President Elect	Treasurer

Executive Board Members:

Sarah Brett	Angela Edmonds	Erin M. Foti
Drew Harmon	Greg Milanich	

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2/4/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
Sallie.Debolt@med.ohio.gov

Dear Ms. DeBolt:

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Our pharmacists at Ohio State Wexner Medical Center are the most clinically knowledgeable pharmacists I've worked with. They are crucial to my management of opioid use disorder, and limiting their scope of practice will harm the functioning of our integrated addiction clinic. Please reconsider this change.

Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:
Martin C Fried
E9396E032F25411...

Martin C Fried

Dr. Martin Fried

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2/4/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
Sallie.Debolt@med.ohio.gov

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As a physician that utilizes the services of pharmacists through collaborative practice agreements to provide care to my patients, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.

I have seen tremendous improvements in diabetes control for my patients with the help of our pharmacists at our clinic through a collaborative practice agreement at The Ohio State University. Taking this away would have a direct, negative effect on my patients, and it is critical that section C4 & D1 be removed.

Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:
Aaron Friedberg, MD
311DB2C7F51D4B9...

Aaron Friedberg, MD

MD

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2/6/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
Sallie.Debolt@med.ohio.gov

Dear Ms. DeBolt:

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Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:
Friedman
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Friedman

MD

TO: State Medical Board of Ohio

FROM: Matthew Fuerst

RE: Response to Proposed Rules 4731-35-01 and 4731-35-02: Consult Agreements

Thank you for the opportunity to provide comments on the Medical Board's recently proposed rules regarding consult agreements between pharmacists and physicians. Consult agreements have been an invaluable resource for physicians to expand access and improve quality, especially since the revision of the law in 2016. In general, I appreciate the added clarity that the medical board has provided specific to physician participation in a consult agreement. However, some of the new provisions outlined in the proposed rules create a significant burden that would outweigh many of the benefits of a consult agreement, and would negatively impact patient care.

Specifically, the requirements for notification and consent prior to action by a pharmacist, as well as the requirement for regular meetings to review a written consult report represent my greatest concerns. The current regulations allow physicians and pharmacists to reach mutually agreeable terms that ensure adequate collaboration, expertise, oversight, and quality assurance mechanisms exist within the consult agreement. Physicians already have the flexibility to engage in a consult agreement that addresses training, communication, and quality assurance mechanisms that are appropriate for the medication management that is being performed.

Requiring a physician's consent prior to each action adds significant time without providing any benefit to the patient. Consult agreements already require a "description of the procedures, decision criteria, and plan the managing pharmacist is to follow in acting under a consult agreement." Asking a physician to confirm that the decision criteria and plan are correct prior to every change is unnecessary and only adds burden to the pharmacist and physician. Adding complexity into a medication adjustment may also cause a patient to experience suboptimal care while consent is being obtained.

Similarly on the requirement for regular meetings, the law already requires "communication between a pharmacist and physician acting under a consult agreement shall take place at regular intervals specified by the primary physician acting under the agreement." Additional requirements for regular meetings and written consult reports only add complexity and administrative burden to an already safe collaborative

Ultimately, I believe that these proposed rules run counter to the efficiencies that the law revision was intended to provide in 2016, and I recommend that the State Medical Board of Ohio reconsider adding any new requirements or barriers to care into the rules. I appreciate your consideration and the opportunity to provide feedback on the proposed rules. If you have any questions or would like to further discuss our comments, please reach out at the contact information below.

Matthew Fuerst, MD

Regann Geise
University of Toledo APhA-ASP
Vice President of Policy
1114 4 Seasons Dr. Apt 5
Toledo, OH 43615

February 4, 2019

Sallie DeBolt
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

Ms. DeBolt,

In recent weeks, new rule changes were proposed regarding sections 4731-35-01 (Consult agreements) and 4731-35-02 (Standards for Managing Drug Therapy). On behalf of the student pharmacists with the American Pharmacist Association Academy of Student Pharmacist chapter at the University of Toledo, we are writing to recommend that these rule changes not be implemented by the State Medical Board.

As students, we see first-hand the role our professors and senior pharmacists play in the lives of patients through these collaborative practice agreements. As students, we know the rigorous curriculum, education and training that comes with being a pharmacist; these collaborative practice agreements allow us to utilize this training to the top of our license, ultimately making the largest impact on patient care. As students, we know pharmacists are highly qualified to have an active, clinical role through collaborative practice agreements.

The new rule changes to the sections stated above would ultimately change the ability of a pharmacist working under a collaborative practice in such a way that their role would almost be nonexistent; with these changes, the extent of physician oversight in the agreement prevents the pharmacist from using their clinical knowledge and education to provide patient care. The suggested rule changes restrict the abilities of the pharmacist in these agreements, demonstrated in the proposed requirement for the physician to review the agreement with the patient, and even allowing the patient to opt out of seeing the pharmacist in the agreement. Wouldn't it be in the best interest of the patient to have the opportunity to see a pharmacist, and speak with them regarding their drug therapies? With the amount of training and education that goes into a doctorate of pharmacy, a pharmacist is capable and knowledgeable to make choices regarding therapy without having to seek the physician's' approval before making any and all changes. Collaborative practice agreements enable Ohioans across the state to have increased access to healthcare; we urge you to consider the impact of these rule changes on the practice of the pharmacist, and the patients of the great state of Ohio.

In conclusion, please consider removing the proposed changes to section (C)(4) and (D)(1) in 4731-35-02, and 4731-35-01. As you receive comments in support and disagreement over these proposed changes, the students would like you to consider the impact pharmacists are able to make on patient health-care. Thank you for considering our statements, and we hope a decision regarding these rule changes will be made with the pharmacist in mind.

Thank you,

University of Toledo College of Pharmacy APhA-ASP students

February 8, 2019

Andrew P. Schachat, M.D.
President
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

Subject: Letter Regarding the Proposed Rules on Consult Agreements for Pharmacist Management of a Patient's Drug Therapy (4731-35-01 and 4731-35-02)

Dear Dr. Schachat:

On behalf of ASHP (American Society of Health-System Pharmacists), I am writing to express our concerns over the proposed rules on consult agreements for pharmacist management of a patient's drug therapy (4731-35-01 and 4731-35-02) and to request that the State Medical Board of Ohio consider changes to its proposed rules.

ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's nearly 50,000 members include pharmacists, student pharmacists, and pharmacy technicians. For more than 75 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety.

ASHP is concerned that the proposed rules severely diminish the scope and role of the pharmacist in managing a patient's medication therapy under the provisions of a consult agreement. The diminished scope of practice will have significant negative impact on patients by limiting patient access to the care of medication experts and burdening physicians with onerous administrative requirements to manage these consult agreements. We recommend the following changes to the proposed rules:

4731-35-01 — Consult Agreements

- Removal of Section A-1-i — Requirement for physician approval prior to adjustment to the dose of a controlled substance.
    - Given the current national opioid crisis, limitations on the ability of pharmacists to manage controlled substances could exacerbate the problem of opioid overuse by preventing pharmacists from adjusting doses down or discontinuing opioids that are no longer needed for the patient.

4731-35-02 — Standards for Managing Drug Therapy

- Modification of section A-3 — The language concerning physician communication with the patient is excessive and could discourage patients from allowing a pharmacist to participate in their care through a consult agreement. We recommend that sub bullet (d) be removed from the rules.
- Removal of section A-6 — The requirement that the authorizing physician ensure that the managing pharmacist's training and experience are adequate is an excessive burden on the physician. In order to be licensed in Ohio, pharmacists are extensively trained in pharmacology and pharmacotherapy in

pharmacy school and through the process of continuing education, further scrutiny of this training and experience by the authorizing physician is redundant and over burdensome.

- Clarification of section A-7 — The term "prompt review" is subjective as written and should be more clearly defined.
- Modification of section B-1 —The responsibility of defining the extent and scope of the pharmacist on the physician is unclear in this section. We recommend rewording this section to outline that the scope of practice for the managing pharmacist is defined by the policy/procedure established in the consult agreement.
- Modification of section C-4-a — We recommend removal of the requirement for a pharmacist to notify a primary physician prior to any action. This requirement goes against the spirit and purpose of the consult agreement. It is an extra layer of regulation that is extremely onerous on the physician as well as the managing pharmacist, and it could discourage physicians from entering into consult agreements with pharmacists. This rule will negatively impact patients' access to the necessary care they could receive from a pharmacist to manage their medications under a consult agreement. As the medication experts, pharmacists are qualified to perform these actions under a consult agreement. This rule will decrease both access to and quality of care.
- Modification of section D-1 — We recommend removal of the requirement for the primary physician and managing pharmacist to hold regular meetings. Meetings held between physicians and pharmacists under a consult agreement should be held as needed on a case-by-case basis, directed by either the physician or pharmacist.

Patients receive better care when pharmacists are able to fully and efficiently work with physicians and other providers on the healthcare team. These proposed rules as written will limit the many current positive and beneficial collaborations between physicians and pharmacists in the state of Ohio, and will not be in the best interest of the patients that we all, as members of the interdisciplinary healthcare team, are seeking to serve.

We appreciate the opportunity to offer our comments on the proposed rules. If you have any questions regarding this letter, or if we can be of any assistance, please contact Nicholas Gentile, Director of State Grassroots Advocacy and Political Action, at ngentile@ashp.org or 301-664-8687.

Sincerely,

Kasey K. Thompson, Pharm.D., M.S., M.B.A.
ASHP
Chief Operating Officer & Senior Vice President for Policy and Planning

From: Godios, Rhianna
To: Debolt, Sallie
Subject: Response to Proposed New Rules to Restrict Collaborative Practice
Date: Friday, February 8, 2019 12:42:27 PM
Attachments: image002.png

Dear Ms. Debolt and Ohio Medical Board:

I wish to comment and respond to the proposed rule for pharmacist management of patient's drug therapy. I am the Pharmacist Program Coordinator for the Anticoagulation Management Service at Summa Health in Akron. I am a Clinical Assistant Professor of Pharmacy Practice for Northeast Ohio Medical University, College of Pharmacy. In addition I am a Board Certified Ambulatory Care Pharmacist, as well as, a Certified Anticoagulation Care Provider.

I co-direct the anticoagulation management service along with a board certified cardiologist here at Summa. Our program has had a positive impact on patient outcomes and safety. Our pharmacist- directed program has been designated as an Anticoagulation Center of Excellence by the Anticoagulation Forum. Only approximately 1 out of 5 programs that complete the assessment meet the necessary standards to achieve this recognition. Within our health system the anticoagulation management service has become the standard of care and patients are enrolled only after an attending physician consults us. Having us involved in their patient's care frees their time to focus on more complicated patients.

Recently I have become aware of a potential policy which might restrict our anticoagulation pharmacists in their role of appropriately monitoring anticoagulation therapy: https://med.ohio.gov/Laws-Rules/Newly-Adopted-and-Proposed-Rules/Consult-Agreements-for-Pharmacist-Management-of-a-Patients-Drug-Therapy. The part of concern is section C4 of 4731-35-01 Consult agreements. See below:
(4) When the managing pharmacist changes the duration of treatment for the current drug therapy; adjusts a drug's strength, dose, dosage form, frequency of administration, route of administration, discontinues a drug, prescribes a new drug, or orders urine or blood tests, as authorized under section B)(1)(a), and (B)(1)(b) of this rule, the managing pharmacist must: (a) **Notify the primary physician prior to any action**. The notification shall include a description of: (i) The decision criteria considered by the managing pharmacist in deciding to conduct an authorized action; and (ii) A description of the proposed authorized action the managing pharmacist intends to conduct. (b) Obtain the consent of the primary physician to conduct the proposed authorized action.

Presently our anticoagulation pharmacists have the authority to monitor and change doses of anticoagulants based on factors that include INR, drug interactions, preparation for surgery, creatinine clearance, side effects, etc. Our outpatient clinic has around 850 patients enrolled and our pharmacists manage anticoagulation for about 80 - 100 patients per day either face to face or via telephone. Our inpatient anticoagulation pharmacists receives multiple referrals from physicians throughout the hospital and typically manages the anticoagulation for about 20 - 30 patients per day. If the pharmacist was required to obtain consent from the primary physician this may take hours to days and delay the ability to make timely dose adjustments which would be detrimental to the patient. This change would create a business model that is not sustainable resulting in the closure of this valuable service.

Primary literature supports the role of pharmacists in providing direct care to patients on anticoagulation, as well as, other chronic diseases. Our anticoagulation pharmacists are specially trained and have the expertise necessary to optimally monitor drug dosing. I am concerned the proposed policy would have

a significant detrimental impact on optimal dosing of anticoagulation agents which may lead to negatively impact patient outcomes and jeopardize patient safety.

Thank you for your consideration.

Sincerely,

Rhianna Godios, PharmD, BCACP, CACP
Pharmacist Program Coordinator
Summa Health Anticoagulation Management Service (SAMS)
95 Arch Street|Suite 100 |Akron, OH 44304
phone 330.375.7110 pager 330.971.0922 fax 330.375.3229
godiosr@summahealth.org

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2/6/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
Sallie.Debolt@med.ohio.gov

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In my experience, working with our clinical pharmacists significantly enhances patient care, improves patient safety and outcomes, and improves physician satisfaction. We are able to provide more care between visits, adjust medications more readily, and improve health in much more rapid fashion. Preventing pharmacists from working in this capacity could be devastating to this progress and for our patients.

Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:
Kevin J. Goist MD
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Kevin J. Goist MD

MD

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2/6/2019

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Pharmacy services can streamline care with directed protocols while having adequate patient safeguards.

Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

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Sincerely,

DocuSigned by:
Gordish
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Gordish

MD

Department of Medicine
Chair: Lance D. Dworkin, M.D.
Admin.Vice-Chair: Basil E. Akpunonu, M.D.
Administrator: Beth Smotherman
Assistant to Chair: Maureen Gilmore

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COLLEGE OF MEDICINE AND LIFE SCIENCES
THE UNIVERSITY OF TOLEDO

Division Chiefs
Cardiovascular Medicine: Mark W. Burket, M.D.
Community Internal Med: Allen Markowicz, M.D.
Dermatology: Lorie D. Gottwald, M.D.
Endocrinology: Juan C. Jaume, M.D.
Gastroenterology: Ali Nawras, M.D.
General Internal Medicine: Basil E. Akpunonu, M.D.
Hematology/Oncology: John Nemunaitis, M.D.
Infectious Diseases: Joan Duggan, M.D.
Nephrology: Deepak Malhotra, M.D., Ph.D.
Pulmonary/Critical Care: Jeffrey R. Hammersley, M.D.
Rheumatology: M. Bashar Kahaleh, M.D.

February 8, 2019

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy

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I am writing in regards to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. Consult Agreements for Pharmacist Management of Patient's Drug Therapy is of interest to me due to my current collaborative practice with a pharmacist as a physician practicing at South Toledo Internist at 3355 Glendale Avenue, Toledo, Ohio, and The University of Toledo Medical Center at 3000 Arlington Avenue, Toledo, Ohio. Within my outpatient clinic, I work side by side with clinical pharmacists on a daily basis who provide unique value to our patients and improve overall quality of care.

Currently, consult agreements allow physicians to work collaboratively with pharmacists to manage chronic diseases, identifying drug interactions that had potential to be a patient safety event and mitigating it before it occurs. In my practice, we have pharmacists who independently manage diabetes, hypertension, and dyslipidemia through consult agreements. Pharmacists improve the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Additionally, our pharmacists serve as drug information experts and educators for both our residents, providers and patients. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

The proposed rule changes, specifically those that require pharmacists to notify the physician of any action prior to implementation (4731-35-02 C-4) would discourage collaborative practice and obstruct our current quality-based workflow. Pharmacists are the medication expert within the interdisciplinary patient care team making their expertise imperative to the care of patients. This expertise and evidence-based care can be managed independently within an agreed upon scope of practice. The removal of the autonomy afforded to pharmacists through consult agreements would lead to a tedious and inefficient process for chronic disease management that would negatively impact the pharmacist, provider and patient. Logistically, a

busy provider may not always be in clinic making it difficult for both the pharmacist and patient's to reach them. In this case the pharmacist is the best resource to manage chronic diseases and ensure timely care is provided. I recommend that this requirement be removed from the proposal.

In summary, I hope that the proposal be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,

Rashmi Goyal, M.D.
Professor of Medicine

THE OHIO STATE UNIVERSITY
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Division of General Internal Medicine
Martha Morehouse Pavilion
Suite 2335
2050 Kenny Road
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2/5/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
Sallie.Debolt@med.ohio.gov

Dear Ms. DeBolt:

I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a physician that utilizes the services of pharmacists through collaborative practice agreements to provide care to my patients, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.

The addition of pharmacy staff to our clinics has enhanced the quality and safety of care delivered to our patients at OSUWMC. For example, they participate directly in the care of our most medically complex patients by providing contact between patient visits to assist with medication adjustments. As medicine becomes more a team sport and we are asked to care for larger numbers of medically complex patients, the pharmacy team's ability to collaborate while making independent decisions will be imperative to our operations and to quality care delivery. Collaborative agreements make this possible.

Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:
Jod M. Grandominico
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Jod M. Grandominico

MD

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2/6/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
Sallie.Debolt@med.ohio.gov

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Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:
Grever
6332B976A752456...

Grever

MD

From: Grimm, Abbey
To: Debolt, Sallie
Subject: Regarding the proposal for consult agreements for pharmacist management of drug therapy
Date: Tuesday, February 5, 2019 2:02:05 PM

To whom it may concern,

I am writing this email to comment that I am concerned about the new proposed rules for consult agreements for pharmacist management of drug therapy. I am currently a third year pharmacy student at Ohio State University. Through my experiences as an intern pharmacist, I have both observed and participated in the many benefits that the current consult agreements between pharmacists and physicians provide. These benefits include (but are not limited to) a decreased burden on physicians in regards to minor therapeutic changes (i.e. changes from intravenous to oral medications for patient comfort, dose changes for patient taking warfarin, etc.), increased communication between physicians and pharmacists in regards to better patient care, and the ability of pharmacists to utilize clinical skills in practice.

Personally, I have seen patients receive comprehensive diabetes education, management of warfarin therapy, and smoking cessation counseling from an experienced pharmacist without the need for a physicians visit. This significantly lifts burden from physicians and provides patients with convenient access to more direct disease management from an expert in drug therapy. Additionally, I have only heard positive remarks from physicians who have entered into consult agreements with pharmacists, who I believe VERY much appreciate the work that pharmacists do in regards to this matter.

I feel that the current proposed rule changes will move these improvements in healthcare backwards -- possibly back to square one -- and I feel that this will not only increase burden on both pharmacists and physicians, but it will delay care to patients.

I appreciate your time in considering my concerns.

Sincerely,
Abbey J. Grimm

Abbey J. Grimm
PharmD Candidate, Class of 2020
The Ohio State University College of Pharmacy
grimm.232@buckeyemail.osu.edu

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2/5/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
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Sallie.Debolt@med.ohio.gov

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Pharmacists are an essential member of the medical team. Their role in chronic disease management helps to enhance the quality of care that my patients need.

Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:
Tanya R. Gure, MD
39AEA779EC774CD...

Tanya R. Gure, MD

Section Chief, Geriatrics

From: Gustafson, Kyle
To: Debolt, Sallie
Subject: Ohio Medical Board- Draft Consult Agreement
Date: Wednesday, February 6, 2019 2:27:35 PM

Ms Debolt,

My name is Kyle Gustafson, and I am a practicing pharmacist at a hospital in Cleveland, Ohio. I have spent a significant amount of time looking over the proposed consult agreement and comparing it to the existing documents in the Ohio Board of Pharmacy, and HB 188 which went into effect in October of 2017.

I have concerns regarding the proposed wording in the medical boards draft, specifically as it relates to the implementation of a consult agreement and its value to the patient and healthcare setting. As a pharmacist, I always have the ability to call a physician and suggest changes to a medications dosage, dosage form, etc. The real value of a consult agreement to the patient, and to the physician, is the ability for medications to be adjusted, changed, and titrated without placing an additional demand on the physician's time. This arrangement allows the physician to focus care on their more acutely ill patients and the pharmacist to use their professional expertise to ensure the best possible management of chronic medical conditions for the patient. As currently proposed, the medical boards wording jeopardizes these benefits.

Specifically, the restriction for physician contact prior to any action (such as increase the dose, changing medications, or even changing a medication for a tablet) means that a consult agreement would increase the time demands of the authorizing physician, and place the patient in a scenario where they may be forced to wait extended periods of time while the pharmacist contacts the physician. At its core, this is no different than a pharmacist currently practicing outside of a consult agreement who is capable of making direct contact with a physician to suggest a medication change, or in the case of some changes (such as dosage form) is allowed by law to change a prescription without contacting the physician. In this circumstance specifically, a pharmacist practicing under a consult agreement is more restricted than a pharmacist practicing outside of such an agreement.

I understand the need for professional and legal oversight when it comes to pharmacists practicing under a consult agreement. It is important for all three of the provider, pharmacist, and the patient to be on the same page in terms of expectations, quality assurance, and communication. However, consult agreements are still an 'opt in' agreement between the prescriber and pharmacist, where the pharmacist has likely already demonstrated their competency to the physician and has an established relationship with the prescriber long before any consult agreement has been signed. In that sense, the prescriber choosing to enter into such an agreement is a vote of confidence for the skills and expertise of the pharmacist.

I believe that it would be worth the Medical Boards time to review the regulations in this document in light of the voluntary nature of these agreements, and provide their individual providers more flexibility to determine the scope, content, and independence of these agreements- such as what actions necessitate prior contact from the pharmacist. The current draft appears to undermine that professional relationship and reduces the value of the consult agreement to being as (or more)

restrictive than a pharmacist's baseline professional responsibility.

I would be happy to discuss these concerns in follow-up communications. Please do not hesitate to reach out if you have additional questions or seek clarification. I appreciate you taking the time to read and consider these points.

Have a wonderful day,
Kyle

Kyle A. Gustafson, Pharm.D., BCPS, BCCCP
Residency Program Director, PGY-1
Pharmacy Clinical Specialist
Southwest General Hospital

Assistant Professor of Pharmacy Practice
Northeastern Ohio Medical University

Cell: (330) 466-8640
Office: (440) 816-4496

D.V.

BON SECOURS MERCY HEALTH

February 8, 2019

Sallie Debolt, Senior Counsel
State Medical Board of Ohio
30 East Broad Street, 3rd Floor
Columbus, OH 43215

RE: Proposed Rules: 4731-35-01, 4731-35-02

Dear Ms. Debolt,

Bon Secours Mercy Health (BSMH), formerly Mercy Health serving throughout Ohio, appreciates the opportunity to formally submit comments on the proposed language for the Medical Board's rules regulating consult agreements between physicians and pharmacists (4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy).

For Ohio based BSMH locations, the proposed changes to the rules will directly affect the safety and care provided annually at over 72,000 ambulatory care patient visits operating under a consult agreement between a physician and pharmacist. Areas in which consult agreements are vital include management of anticoagulation, patients with complex disease states (diabetes, congestive heart failure, hypertension, hyperlipidemia, chronic obstructive pulmonary disease), and smoking cessation. Consult agreements also permit pharmacists to make important drug dosing adjustments to avoid adverse drug events for complex and high-alert medications. All consult agreements at BSMH are voluntarily requested by physicians and conducted under well-defined 'procedures' and 'decision criteria' as outlined in OAC 4729:1. Moreover, published medical literature demonstrates a pharmacist's role in medication management reduces medication errors and improves patient outcomes.

Our organization feels that the language as proposed significantly diminishes the scope and role of the pharmacist in managing a patient's medication therapy under the provision of a consult agreement. This will negatively impact patients in Ohio by significantly restricting access to care by pharmacists as medication therapy experts (as requested by a physician) while also over-burdening physicians with administrative requirements to manage these consult agreements. Lastly, we believe it would be helpful to both physicians and pharmacists for there to be consistency between the Medical Board and the Pharmacy Board rules. As such, we recommend the following changes:

4731-35-01 Consult Agreements

- Removal of Section A-1-i – requirement for physician approval prior to adjustment to the dose of a controlled substance.
    - Given the current challenges in Ohio with management of opioids and opioid addiction, limiting the ability for pharmacists to manage controlled substances will have the potential to perpetuate the problem of opioid overuse by preventing pharmacists from adjusting doses down or discontinuing opioids that are no longer needed for the patient. In addition, new prescribing rules passed in December 2018 (OAC 4731-11-14) specifically recommend an option for consultation of a pharmacist medication review for patients prescribed opioid doses greater than fifty morphine equivalent dose.

BON SECOURS MERCY HEALTH

4731-35-02 – Standards for Managing Drug Therapy

- Modification of section A-3 – The language around physician communication to the patient is excessive and discourages patients from allowing a pharmacist to participate in their care through a consult agreement. We recommend sub-bullet (d) be removed from the rules.
- Removal of section A-6 – The requirement that the authorizing physician ensure the managing pharmacists' training and experience are adequate is an excessive burden on the physician. As pharmacists are extensively trained in pharmacology and pharmacotherapy through their prerequisite education in order to become licensed, further scrutiny of this training and experience by the authorizing physician is excessive.
- Clarification of section A-7 – Further clarification of "prompt review".
- Modification of section B-1 – Placing the responsibility of defining the extent and scope of the pharmacist on the physician is unclear. Recommend rewording to outline that scope of the pharmacist is defined by the policy/procedure established in the consult agreement.
- Modification of section C-4 – Recommend removal of requirement for pharmacist to notify primary physician prior to any action. This requirement is extremely onerous on both the physician and the managing pharmacist, and will discourage physicians from entering into consult agreements with pharmacists. This will negatively impact patients' access to the necessary care they could receive from a pharmacist to manage their medications under a consult agreement. As the medication experts, pharmacists are qualified to perform these actions under a consult agreement. This rule will decrease access and quality of care.
- Modification of section D-1 – Recommend removal of the requirement for primary physician and managing pharmacist to hold regular meetings. This requirement is onerous on both the physician and the managing pharmacist, and will discourage physicians from entering into consult agreements with pharmacists.

Thank you for conducting a thoughtful process that allows us to provide input on such important issues. Should you need any further information, please don't hesitate to contact me.

Sincerely,

W. Haidar MD

Wael Haidar, MD
Chief Clinical Officer
Bon Secours Mercy Health

To whom it may concern,

My name is Matt Haldiman, and I have been a pharmacist for 10 years in the state of Ohio. During that time, I have had the privilege of directly participating in and experiencing the significant contribution that a pharmacist can provide as a member of the healthcare team and the ways they can impact patient education and adherence with regards to their medication regimens.

I want to thank you for the opportunity to provide feedback to the proposed changes within the State Medical Board of Ohio legal sections 4731-35-01 and 4731-35-02 regarding consult agreements and standards for managing drug therapy.

Pharmacists play a unique role in the healthcare team. They are able to quickly assess a medication regimen, use evidence-based guidelines to provide recommendations to guide therapy, and educate patients on those changes to ensure a high level of understanding and compliance at home. This work has been proven to very successfully relieve unnecessary burdens on providers. Pharmacists have specialized training with regards to areas such as pharmacokinetic dosing, anticoagulation monitoring, and patient counseling. With those skills, we provide excellent patient care throughout the state utilizing consults agreements effectively.

The language proposed would not only slow down or prevent the pharmacist from providing this incredibly valuable service, but it would also place an enormous burden of work back on the shoulders of the providers we were originally put in place to assist. With every recommendation, rather than following a previously vetted and established treatment guideline or algorithm, we would be required to make unnecessary and time-consuming phone calls to providers to review and approve each step. We feel this is unnecessary and will lead to delays in patient care causing adverse events due to those delays.

With all of this, I ask that you please consider removing the proposed language that would place a restriction on the level of patient care we are currently able to provide. I ask that you please revisit this section and consider the patient first and foremost. Allowing the pharmacist to function at the top of her/his license utilizing previously approved protocols within a consult agreement will allow us to continue to provide guideline-based, time-sensitive, and patient-centered care through our partnership in consult agreements.

Thank you for your consideration,

Matt Haldiman
9388 Jerome Road
Dublin, Ohio 43017
Phone 330-421-4813

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2/4/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
Sallie.Debolt@med.ohio.gov

Dear Ms. DeBolt:

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As a physician that utilizes the services of pharmacists through collaborative practice agreements to provide care to my patients, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.

I have personally worked directly with a clinical pharmacist in my practice for the past 6 years. By utilizing their unique skillset, we have seen marked improvement in our patients' health, particularly in control of chronic conditions such as diabetes and high blood pressure. The proposed language will significantly limit a pharmacist's ability to assist in improving the long-term health of my patients.

Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:
Christopher Hanks
E957E30BC87A4D6...

Christopher Hanks

MD

Our Mission is to improve your health and well-being.

February 8, 2019

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy

Dear Ms. Debolt:

I am writing in regards to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. Consult Agreements for Pharmacist Management of Patient's Drug Therapy is of interest to me due to my current collaborative practice with physicians as pharmacists practicing at ProMedica. Every day, pharmacists manage medication therapy for vancomycin, aminoglycosides, warfarin, and others.

Currently, consult agreements allow physicians to work collaboratively with pharmacists to manage medication therapy. In our practice, we have pharmacists who independently manage warfarin, vancomycin, aminoglycoside and other therapies through consult agreements. Pharmacists improve the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Additionally, as pharmacists, we serve as drug information experts and educators for both our providers and patients. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

The proposed rule changes, specifically those that require pharmacists to notify the physician of any action prior to implementation (4731-35-02 C-4) would discourage collaborative practice and obstruct our current quality-based workflow. Pharmacists are the medication expert within the interdisciplinary patient care team making their expertise imperative to the care of patients. This expertise and evidence-based care can be managed independently within an agreed upon scope of practice. The removal of the autonomy afforded to pharmacists through consult agreements would lead to a tedious and inefficient process for medication management that would negatively impact the pharmacist, provider and patient. Logistically,

busy providers may not always be available, making it difficult for the pharmacist to reach them. For example, if antibiotic dosing is delayed in a septic patient because a pharmacist cannot confirm the dose with the prescriber, there is an increased risk of death. Timeliness of antibiotics is essential to improve outcomes. In this case the pharmacist is the best resource to manage treatment and ensure timely care is provided. We recommend that this requirement be removed from the proposal.

At ProMedica Toledo Hospital/Toledo Children's Hospital, we manage 1700 days of therapy a month (antibiotics, anticoagulants, TPN, and medication weaning). Each consult is documented in the medical record with a progress note, and any changes are documented in subsequent progress notes. In addition, pharmacists adjust the dose of medications (400-500/month) as outlined in policy for weight or renal function. The physicians trust our care and would not want an additional 2200 calls per month for therapy adjustments. The prescribers understand our role as medication experts.

In summary, we hope that the proposal be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,

Tari S Cecil RPh

Tari Cecil, RPH
Pharmacy Director, Metro Division
ProMedica Toledo Hospital/Toledo Children's Hospital
Promedica Flower Hospital
ProMedica Bay Park Hospital
Promedica Wildwood Orthopaedic and Spine Hospital

Colleen Harrell

Colleen Harrell, PharmD, CDE
Lead Clinical Pharmacist
ProMedica Toledo Hospital/Toledo Children's Hospital
ProMedica Wildwood Orthopaedic and Spine Hospital

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Admin.Vice-Chair: Basil E. Akpunonu, M.D.
Administrator: Beth Smotherman
Assistant to Chair: Maureen Gilmore

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COLLEGE OF MEDICINE AND LIFE SCIENCES
THE UNIVERSITY OF TOLEDO

Division Chiefs
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Community Internal Med: Allen Markowicz, M.D.
Dermatology: Lorie D. Gottwald, M.D.
Endocrinology: Juan C. Jaume, M.D.
Gastroenterology: Ali Nawras, M.D.
General Internal Medicine: Basil E. Akpunonu, M.D.
Hematology/Oncology: John Nemunaitis, M.D.
Infectious Diseases: Michael Ellis, M.D.
Nephrology: Deepak Malhotra, M.D., Ph.D.
Pulmonary/Critical Care: Jeffrey R. Hammersley, M.D.
Rheumatology: M. Bashar Kahaleh, M.D.

February 8, 2019

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

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Currently, consult agreements allow physicians to work collaboratively with pharmacists to manage chronic diseases. In my practice, we have pharmacists who independently manage diabetes, hypertension, and dyslipidemia through consult agreements. Pharmacists improve the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Additionally, our pharmacists serve as drug information experts and educators for both our residents, providers and patients. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

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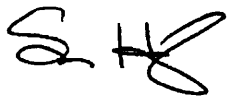
busy provider may not always be in clinic making it difficult for both the pharmacist and patient's to reach them. In this case the pharmacist is the best resource to manage chronic diseases and ensure timely care is provided. I recommend that this requirement be removed from the proposal.

Examples of collaborations include educating learners within the clinic (medical students, medical residents, PA students) -- teaching them about appropriate use of medications for disease states, working together to come up with a therapeutic plan moving forward -- in this instance, I may call a patient and get blood sugar readings and other pertinent information and then work through my thought process with the resident so they are also learning how to manage diabetes appropriately. Additionally, on the inpatient settings, pharmacists make recommendations during rounds including monitoring and dosing of warfarin, antibiotics and antibiotic stewardship.

In summary, I hope that the proposal be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely yours,



Srinivas K Hejeebu, DO, FACP, FACOI
Professor of Medicine
Division of General Internal Medicine
Secretary, University of Toledo, Board of Directors

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Rheumatology: M. Bashar Kahaleh, M.D.

February 8, 2019

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

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busy provider may not always be in clinic making it difficult for both the pharmacist and patient's to reach them. In this case the pharmacist is the best resource to manage chronic diseases and ensure timely care is provided. I recommend that this requirement be removed from the proposal.

Examples of collaborations include educating learners within the clinic (medical students, medical residents, PA students) -- teaching them about appropriate use of medications for disease states, working together to come up with a therapeutic plan moving forward -- in this instance, I may call a patient and get blood sugar readings and other pertinent information and then work through my thought process with the resident so they are also learning how to manage diabetes appropriately. Additionally, on the inpatient settings, pharmacists make recommendations during rounds including monitoring and dosing of warfarin, antibiotics and antibiotic stewardship.

In summary, I hope that the proposal be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,

Bryan T Hinch, MD, FACP, FAAP
Associate Professor of Internal Medicine
Associate Director, Internal Medicine Residency Program
Chief Medical Information Officer

From: Barb Hoersten
To: Debolt, Sallie
Subject: 4731-35- proposed rule change concerns
Date: Friday, February 8, 2019 11:38:13 AM
Importance: High

February 8, 2019

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy

Dear Ms. Debolt:

I am writing in regards to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. Consult Agreements for Pharmacist Management of Patient's Drug Therapy is of interest to me due to my current services provided as a Clinical Pharmacist at Paulding County Hospital.

Currently, consult agreements allow physicians to work collaboratively with pharmacists to manage chronic diseases. It allows pharmacists to independently manage diabetes, hypertension, and dyslipidemia through consult agreements. Pharmacists improve the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Additionally, our pharmacists serve as drug information experts and educators for both our residents, providers and patients. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

The proposed rule changes, specifically those that require pharmacists to notify the physician of any action prior to implementation (4731-35-02 C-4) would discourage collaborative practice and obstruct our current quality-based workflow. Pharmacists are the medication expert within the interdisciplinary patient care team making their expertise imperative to the care of patients. This expertise and evidence-based care can be managed independently within an agreed upon scope of practice. The removal of the autonomy afforded to pharmacists through consult agreements would lead to a tedious and inefficient process for chronic disease management that would negatively impact the pharmacist, provider and patient. Logistically, a busy provider may not always be in clinic making it difficult for both the pharmacist and patient's to reach them. In this case the pharmacist is the best resource to manage chronic diseases and ensure timely care is provided. I recommend that this

requirement be removed from the proposal.

Coming from a rural small community hospital, providers depend on my services. The volume of our patient load cannot support an on-site provider. Providing anticoagulation management services not only assists the patients, but also helps providers to utilize their time more efficiently. The proposed changes would not allow me to provide timely dosing to patients, putting them at risk of having an adverse event.
In summary, I hope that the proposal be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,

Barbara I Hoersten, RPh
17759 State Route 66
Fort Jennings, OH 45844

Barbara I Hoersten, RPh
VP Pharmacy, Radiology
Paulding County Hospital
bhoersten@pauldingcountyhospital.com
419-399-4080, ext 320

TIMOTHY HOGAN, M.D.
109 North First Street
Oakwood, OH 45873

Telephone: (419) 594-3520
Fax: (419) 594-3530

February 8, 2019

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy

Dear Ms. Debolt:

I am writing in regards to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. Consult Agreements for Pharmacist Management of Patient's Drug Therapy is of interest to me due to my current collaborative practice with a pharmacist as a physician practicing at Oakwood Medical Center in Oakwood, Ohio. Within my outpatient clinic, I work side by side with clinical pharmacists on a daily basis who provide unique value to our patients and improve overall quality of care.

Currently, consult agreements allow physicians to work collaboratively with pharmacists to manage chronic diseases. In my practice, we have pharmacists who independently manage diabetes, hypertension, and dyslipidemia through consult agreements. Pharmacists improve the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Additionally, our pharmacists serve as drug information experts and educators for both our residents, providers and patients. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

The proposed rule changes, specifically those that require pharmacists to notify the physician of any action prior to implementation (4731-35-02 C-4) would discourage collaborative practice and obstruct our current quality-based workflow. Pharmacists are the medication expert within the interdisciplinary patient care team making their expertise imperative to the care of patients. This expertise and evidence-based care can be managed independently within an agreed upon scope of practice. The removal of the autonomy afforded to pharmacists through consult agreements would lead to a tedious and inefficient process for chronic disease management that would negatively impact the pharmacist, provider and patient. Logistically, a busy provider may not always be in clinic making it difficult for both the pharmacist and patient's to reach them. In this case the pharmacist is the best resource to manage chronic diseases and ensure timely care is provided. I recommend that this requirement be removed from the proposal.

TIMOTHY HOGAN, M.D.
109 North First Street
Oakwood, OH 45873
Telephone: (419) 594-3520
Fax: (419) 594-3530

I run a very busy practice and the services that the pharmacist provides at the Coumadin Clinic is most invaluable and allows me to focus on other aspects of patient care. If these proposals take effect, it would be a needless burden on my office workflow. My patients have enjoyed the personal care they get from the pharmacist.

In summary, I hope that the proposal be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,

Timothy H. Hogan MD CCFP

Department of Medicine
Chair: Lance D. Dworkin, M.D.
Admin.Vice-Chair: Basil E. Akpunonu, M.D.
Administrator: Beth Smotherman
Assistant to Chair: Maureen Gilmore

Department of Medicine
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3000 Arlington Ave., MS 1186
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COLLEGE OF MEDICINE AND LIFE SCIENCES
THE UNIVERSITY OF TOLEDO

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Pulmonary/Critical Care: Jeffrey R. Hammersley, M.D.
Rheumatology: M. Bashar Kahaleh, M.D.

February 8, 2019

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy

Dear Ms. Debolt:

I am writing in regards to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. Consult Agreements for Pharmacist Management of Patient's Drug Therapy is of interest to me due to my current collaborative practice with a pharmacist as a physician practicing at South Toledo Internists at 3355 Glendale Avenue, Toledo, Ohio, and The University of Toledo Medical Center at 3000 Arlington Avenue, Toledo, Ohio. Within my outpatient clinic, I work side by side with clinical pharmacists on a daily basis who provide unique value to our patients and improve overall quality of care.

Currently, consult agreements allow physicians to work collaboratively with pharmacists to manage chronic diseases. In my practice, we have pharmacists who independently manage diabetes, hypertension, and dyslipidemia through consult agreements. Pharmacists improve the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Additionally, our pharmacists serve as drug information experts and educators for both our residents, providers and patients. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

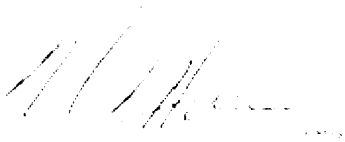
The proposed rule changes, specifically those that require pharmacists to notify the physician of any action prior to implementation (4731-35-02 C-4) would discourage collaborative practice and obstruct our current quality-based workflow. Pharmacists are the medication expert within the interdisciplinary patient care team making their expertise imperative to the care of patients. This expertise and evidence-based care can be managed independently within an agreed upon scope of practice. The removal of the autonomy afforded to pharmacists through consult agreements would lead to a tedious and inefficient process for chronic disease management that would negatively impact the pharmacist, provider and patient. Logistically, a

busy provider may not always be in clinic making it difficult for both the pharmacist and patient's to reach them. In this case the pharmacist is the best resource to manage chronic diseases and ensure timely care is provided. I recommend that this requirement be removed from the proposal.

Examples of collaborations include educating learners within the clinic (medical students, medical residents, PA students) -- teaching them about appropriate use of medications for disease states, working together to come up with a therapeutic plan moving forward -- in this instance, I may call a patient and get blood sugar readings and other pertinent information and then work through my thought process with the resident so they are also learning how to manage diabetes appropriately. Additionally, on the inpatient settings, pharmacists make recommendations during rounds including monitoring and dosing of warfarin, antibiotics and antibiotic stewardship.

In summary, I hope that the proposal be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,



Nicholas Horen, MD, Assistant Professor,Internal Medicine
Associate Director, Internal Medicine Residency Program
Associate Director, Internal Medicine Clerkship
Director, Internal Medicine Resident Clinics
Director, Primary Care Residency Program

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

OSU Heart and Vascular Center
452 W. 10th Avenue
Columbus OH 43210
Phone: (614) 293-1965
Fax: (614) 366-2175

February 7, 2019

To: Sallie Debolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

To Whom It May Concern:

As a practicing physician in the state of Ohio, I would like to thank you for your service to the State Medical Board of Ohio and for all you do to enhance the care of our fellow Ohioans. I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a physician who currently utilizes the services of pharmacists as independent practitioners through collaborative practice agreements, I am in favor of pharmacists continuing to provide patient care in this manner as a means to improve quality, safety, and efficiency in our health system. The utilization of consult agreements between physicians and pharmacists at The Ohio State University Wexner Medical Center has improved patient outcomes, expanded healthcare accessibility, and helped control healthcare costs. I believe pharmacists are a vital part of the interdisciplinary team and are vital for successful provision of high quality clinical services and improving access to care. I am supportive of the continued incorporation of pharmacist services into my day to day practice. I have appreciated the updates by the Board of Pharmacy over the last few years. The rules proposed by the Medical Board are generally acceptable and in line with current pharmacy rules.

However, I feel several provisions are converse to current practice and limit the utility of consult agreements. Sections (A)(2) and (C)(4) of 4731-35-02, in current form, would increase provider burden and decrease efficiency of the current system, significantly impacting the business of healthcare. Furthermore, (C)(4) would reduce quality of care by discrediting pharmacists' clinical decision making capabilities already authorized under agreed collaborative practice agreements and accompanying scope of practice. We are asking this language regarding "at least one time per year" in (A)(2) and the entirety of (C)(4) be removed (this is covered in (A)(1) of 4731-35-01).

If you have any questions, please do not hesitate to contact me. Thank you for your consideration.

Sincerely,

Mahmoud Houmsse, MD
Director, Anti-Arrhythmic Clinic
Wexner Medical Center at the Ohio State University Medical Center
OSU Heart and Vascular Center
452 W 10th Avenue
Columbus, OH 43210
Office: 614-293-1965
Fax: 614-366-2175

Department of Medicine
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COLLEGE OF MEDICINE
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Nephrology: Deepak Malhotra, M.D., Ph.D.
Pulmonary/Critical Care: Jeffrey R. Hammersley, M.D.
Rheumatology: M. Bashar Kahaleh, M.D.

February 8, 2019

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy

Dear Ms. Debolt:

I am writing in regards to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. Consult Agreements for Pharmacist Management of Patient's Drug Therapy is of interest to me due to my current collaborative practice with a pharmacist as a PA practicing at South Toledo Internist, 3355 Arlington Avenue, Toledo, Ohio. Within my outpatient clinic, I work side by side with clinical pharmacists on a daily basis who provide unique value to our patients and improve overall quality of care.

Currently, consult agreements allow physicians to work collaboratively with pharmacists to manage chronic diseases. In my practice, we have pharmacists who independently manage diabetes, hypertension, and dyslipidemia through consult agreements. Pharmacists improve the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Additionally, our pharmacists serve as drug information experts and educators for both our residents, providers and patients. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

The proposal includes unnecessary additions (4731-35-02 D-1) requiring the pharmacist to have a detailed description of a continuous quality improvement project including regular meetings with the physician. This should not be outlined by the rules, but should be dependent on the practice allowing variation from site to site. I recommend this be removed from the proposal.

Our collaborative model has allowed us to work towards a path of achieving improvement in HbA1C control.

In summary, I hope that the proposal be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,

Cletus Iwuagwu, M.D. 2/5/19

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

Department of Internal Medicine
Division of General Internal Medicine
Martha Morehouse Pavilion
Suite 2335
2050 Kenny Road
Columbus, OH 43221
614-293-4953 Phone
614-293-6890 Fax

2/5/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
Sallie.Debolt@med.ohio.gov

Dear Ms. DeBolt:

I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a physician that utilizes the services of pharmacists through collaborative practice agreements to provide care to my patients, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.

I work with several pharmacists under collaborative practice agreements. Through this we have been able to titrate our patients diabetes medications, sometimes on a weekly basis. We are able to get patient off unnecessary medications such as proton pump inhibitors. We are able to provide real time warfarin management. The current language would negate all these efforts.

Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:
Harrison Lee Jackson, MD
562822E31A5A4A7...

Harrison Lee Jackson, MD

Assitant Professor - Clinical

From: Janzen, Amanda (janzenal)
To: Debolt, Sallie
Subject: Commentary on 4731-35-01 Consult Agreements
Date: Friday, February 8, 2019 12:18:01 AM

To whom it may concern:

I write to you out of concern for the changes that the Board of Medicine is trying to propose by revising the following rule:

4731-35-01 Consult agreements

Allow me to give you some educational background on pharmacists licensed in the state of Ohio. Pharmacists spend 3-4 years in undergraduate level education, many graduating with a bachelors in chemistry, biology, or other advanced science degrees. They continue on to a 4 year graduate program where they are actively out in the community working, shadowing, and volunteering throughout their program. Pharmacists graduate with a Pharm.D. degree - that is, a Doctor of Pharmacy. The American Society of Health-Systems Pharmacists along with the American Pharmacists Association also set the goal that all pharmacists graduating from year 2020 and on should be mandated to complete residency training after graduation. Although it is not mandated yet, it is likely pharmacy will head in this direction. Presently, pharmacists can choose to do 1-2 years of residency training or go down the fellowship path which has a heavy focus in research amongst other options. Pharmacists also may further specialize their training by becoming board certified in their area of specialty like oncology, ambulatory care, critical care, etc.

Throughout schooling, pharmacists learn drug kinetic parameters. They learn what the drug does to the body and what the body does to the drug. They study in-depth details about side effect profiles, black box warnings, precautions, ways for the medicine to be best absorbed, etc. This profession requires an extensive understanding of chemistry, mathematics, and physiology. The education pharmacists receive is un-replicated in any other medical profession, including that of physicians.

We know that we are running into a shortage of physicians and the profession of pharmacy has been working diligently in preparation to help fill that gap. Pharmacists are completely capable of medication management. In other states like California, Montana, North Carolina, and New Mexico, pharmacists have an even more-so expanded scope of practice, duties such as prescribing maintenance medication and performing physical examinations.

Pharmacists are ready, willing, and already an integral component of a patient's medical team. Under current collaborative practice agreements, pharmacists have already been adjusting medication and interchanging therapy as needed. It makes no sense to stop a streamlined process to have the pharmacist stop and make calls back to a physician, who is generally never

readily available, leave a message, wait a hour for a phone call back just for the physician to agree with the change the pharmacist was going to make. This is a waste of time, resources, and money. So many physicians out there have a deep appreciation and relationship with their pharmacy team members. It allows them to take time to conduct thorough examinations and make non-rushed diagnoses while they hand off medication related concerns to the medication experts - pharmacists.

I am a third year student pharmacist at the University of Cincinnati and a 9 year cancer survivor. I decided to become a pharmacist because without medication I would not be here today and I wanted to use knowledge of medicine to save the lives of others. I also wouldn't be here today if a physician did not properly diagnose the type of cancer I had. Pharmacists and physicians are two different types of doctors that need to work hand in hand, amongst an interprofessional team, to achieve optimal patient outcomes. Let's not take steps backwards when we should be moving forward.

I appreciate the opportunity to share my thoughts.

Thank you,

Amanda Janzen
PharmD Candidate 2020
University of Cincinnati
SSHP President
Member, ASHP Advancement of Pharmacy Practice Advisory Group
UCMC OP Pharmacy Intern
e: janzenal@mail.uc.edu I c: 513.592.8699

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

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Division of General Internal Medicine
Martha Morehouse Pavilion
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2050 Kenny Road
Columbus, OH 43221
614-293-4953 Phone
614-293-6890 Fax

2/7/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
Sallie.Debolt@med.ohio.gov

Dear Ms. DeBolt:

I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

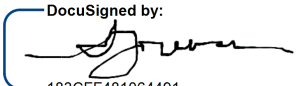
As a physician that utilizes the services of pharmacists through collaborative practice agreements to provide care to my patients, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.

Sections (C)(4) and (D)(1) are in direct conflict with the goal of the State Medical Board of Ohio which is "To protect and enhance the health and safety of the public through effective medical regulation", and I ask that you remove them in their entirety. We have a universally beneficial collaborative practice at our Upper Arlington General Internal Medicine site. Because of the collaboration we've had with our pharmacist, our patients have seen dramatic improvement in the diabetic control with average A1c measurements dropping from an average of over 10 to under 7.6. Research has clearly established that improvements like these translate into better outcomes for our patients.

Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:

183CFF481064491...

Jonaus

Sarah Jonaus MD

From: Jones, Morgan (jones5mm)
To: Debolt, Sallie
Subject: Comments on proposal
Date: Friday, February 8, 2019 11:54:23 PM

Dear Ms. DeBolt:

I would like to thank you for your service to the State Medical Board and for all you do for the care of our state's citizens. We appreciate the opportunity to comment on the board's draft rules on 4731-35-01 consult agreements and 4731-35-02 standards for managing drug therapy. We, as the student body of the University of Cincinnati College of Pharmacy, represent our individual voices.

As student-pharmacists, we are concerned about language included in 4731-35-02 standards for managing drug therapy in section (C)(4) and section (D)(1). Our curriculum is largely based on our ability to provide quality, individualized patient care as it pertains to the management of patient's disease states and medications. We spend several years learning the same guidelines and treatment options that physicians learn with additional training in pharmacology and pharmacotherapy. We practice the application of this knowledge through a variety of experiences on rotations and at work.

As proposed, this language would limit pharmacists' ability to assist patients with their medication management, and thus inhibit our ability as students to learn valuable skills we will use to improve patient health in our role as healthcare professionals. Through current collaborative practice opportunities, the students at Ohio State have already been learning how to collaborate with physicians though experiential rotations and have witnessed first-hand how beneficial a pharmacist is to the patient care process and healthcare team. To enhance patient outcomes, the continued collaboration between pharmacists and physicians through collaborative practice is necessary, not the further fragmentation of patient care that would likely take place with the way the rules are being proposed to be re-written

With everything we have learned about the opportunities to improve health outcomes in our state and the vigor of our developed Pharm.D. curriculum, we believe the citizens of Ohio deserve access to the highest level of care from all members of their healthcare team. We ask the State Medical Board of Ohio remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 standards for managing drug therapy.

Again, we sincerely appreciate the State Medical Board of Ohio providing us with the opportunity to comment on the board's draft rules on 4731-35-01 consult agreements and 4731-35-02 standards for managing drug therapy.

Regards,

Morgan Jones
PharmD Candidate | Class of 2021
James L. Winkle College of Pharmacy
Cincinnati Children's Hospital Medical Center | Pharmacy Intern
jones5mm@mail.uc.edu | (513) 746-6537

PROMEDICA

Your health. Our mission.

Our Mission is to improve your health and well-being.

February 8, 2019

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy

Dear Ms. Debolt:

I am writing in regards to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. Consult Agreements for Pharmacist Management of Patient's Drug Therapy is of interest to me due to my current role as SVP Pharmacy, ProMedica Health System and interim President, ProMedica Toledo Hospital. Within our hospital, and health system, clinical prescribers work side by side with clinical pharmacists on a daily basis who provide unique value to our patients and improve overall quality of care.

Currently, consult agreements allow physicians to work collaboratively with pharmacists to manage acute inpatients and chronically ill outpatients. We have pharmacists who manage anticoagulants, diabetes, hypertension, and dyslipidemia through consult agreements. In these settings, pharmacists have improved the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Additionally, our pharmacists serve as drug information experts and educators for our medical residents, providers and patients. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

The proposed rule changes, specifically those that require pharmacists to notify the physician of any action prior to implementation (4731-35-02 C-4) would discourage collaborative practice and obstruct our current workflow. Pharmacists following evidence-based care guidelines can manage independently within an agreed upon scope of practice. The removal of the autonomy afforded to pharmacists through proposed consult agreements would lead to a tedious and inefficient process for both acute and chronic disease management that would negatively impact the patient. Logistically, a busy provider may not always be in clinic making it difficult for both the pharmacist and patient's to reach them. In this case, the pharmacist is an excellent resource to manage chronic diseases and ensure timely care is provided. I recommend that this requirement be removed from the proposal.

In summary, I hope that 4731-35-02 C-4 be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements). I urge you to remove the requirements for physician approval of each individual change.

Sincerely,

Neeraj Kanwal, MD

Neeraj Kanwal, M.D.
Sr. Vice President, Pharmacy
Vice President, Medical Affairs ProMedica Toledo Hospital
Interim President, ProMedica Toledo Hospital and ProMedica Toledo Children's Hospital

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Fax: 567-585-9650 | promedica.org

TO: State Medical Board of Ohio

FROM: Pamela Kapraly, M.D.

RE: Response to Proposed Rules 4731-35-01 and 4731-35-02: Consult Agreements

Thank you for the opportunity to provide comments on the Medical Board's recently proposed rules regarding consult agreements between pharmacists and physicians. Consult agreements have been an invaluable resource for physicians to expand access and improve quality, especially since the revision of the law in 2016. In general, I appreciate the added clarity that the medical board has provided specific to physician participation in a consult agreement. However, some of the new provisions outlined in the proposed rules create a significant burden that would outweigh many of the benefits of a consult agreement, and would negatively impact patient care.

Specifically, the requirements for notification and consent prior to action by a pharmacist, as well as the requirement for regular meetings to review a written consult report represent my greatest concerns. The current regulations allow physicians and pharmacists to reach mutually agreeable terms that ensure adequate collaboration, expertise, oversight, and quality assurance mechanisms exist within the consult agreement. Physicians already have the flexibility to engage in a consult agreement that addresses training, communication, and quality assurance mechanisms that are appropriate for the medication management that is being performed.

Requiring a physician's consent prior to each action adds significant time without providing any benefit to the patient. Consult agreements already require a "description of the procedures, decision criteria, and plan the managing pharmacist is to follow in acting under a consult agreement." Asking a physician to confirm that the decision criteria and plan are correct prior to every change is unnecessary and only adds burden to the pharmacist and physician. Adding complexity into a medication adjustment may also cause a patient to experience suboptimal care while consent is being obtained.

Similarly on the requirement for regular meetings, the law already requires "communication between a pharmacist and physician acting under a consult agreement shall take place at regular intervals specified by the primary physician acting under the agreement." Additional requirements for regular meetings and written consult reports only add complexity and administrative burden to an already safe collaborative

Ultimately, I believe that these proposed rules run counter to the efficiencies that the law revision was intended to provide in 2016, and I recommend that the State Medical Board of Ohio reconsider adding any new requirements or barriers to care into the rules. If you have any questions or would like to further discuss our comments, please reach out at the contact information below.

Pamela Kapraly M.D. pkapaly@gmail.com
740 943 2354
740 943 5068
memorialohio.com
19 West Ottawa St., Richwood, OH 43344

February 8, 2019

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy

Dear Ms. Debolt:

I am writing in regards to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. Consult Agreements for Pharmacist Management of Patient's Drug Therapy is of interest to me due to my current services provided as a Clinical Pharmacist at Paulding County Hospital.

Currently, consult agreements allow physicians to work collaboratively with pharmacists to manage chronic diseases. It allows pharmacists to independently manage diabetes, hypertension, and dyslipidemia through consult agreements. Pharmacists improve the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Additionally, our pharmacists serve as drug information experts and educators for both our residents, providers and patients. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

The proposed rule changes, specifically those that require pharmacists to notify the physician of any action prior to implementation (4731-35-02 C-4) would discourage collaborative practice and obstruct our current quality-based workflow. Pharmacists are the medication expert within the interdisciplinary patient care team making their expertise imperative to the care of patients. This expertise and evidence-based care can be managed independently within an agreed upon scope of practice. The removal of the autonomy afforded to pharmacists through consult agreements would lead to a tedious and inefficient process for chronic disease management that would negatively impact the pharmacist, provider and patient. Logistically, a busy provider may not always be in clinic making it difficult for both the pharmacist and patient's to reach them. In this case the pharmacist is the best resource to manage chronic diseases and ensure timely care is provided. I recommend that this requirement be removed from the proposal.

Coming from a rural small community hospital, providers depend on my services. The volume of our patient load cannot support an on-site provider. Providing anticoagulation management services not only assists the patients, but also helps providers to utilize their time more efficiently. The proposed changes would not allow me to provide timely dosing to patients, putting them at risk of having an adverse event.

In summary, I hope that the proposal be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,

Heidi D Kauser, RPh
10146 State Route 500
Paulding, OH 45879

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February 8, 2019

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy

Dear Ms. Debolt:

I am writing in regards to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. Consult Agreements for Pharmacist Management of Patient's Drug Therapy is of interest to me due to my current collaborative practice with a pharmacist as a PA practicing at South Toledo Internist, 3355 Arlington Avenue, Toledo, Ohio. Within my outpatient clinic, I work side by side with clinical pharmacists on a daily basis who provide unique value to our patients and improve overall quality of care.

Currently, consult agreements allow physicians to work collaboratively with pharmacists to manage chronic diseases. In my practice, we have pharmacists who independently manage diabetes, hypertension, and dyslipidemia through consult agreements. Pharmacists improve the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Additionally, our pharmacists serve as drug information experts and educators for both our residents, providers and patients. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

The proposal includes unnecessary additions (4731-35-02 D-1) requiring the pharmacist to have a detailed description of a continuous quality improvement project including regular meetings with the physician. This should not be outlined by the rules, but should be dependent on the practice allowing variation from site to site. I recommend this be removed from the proposal.

Our collaborative model has allowed us to work towards a path of achieving improvement in HbA1C control.

In summary, I hope that the proposal be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,

Ammar Kayyali, M.D.

NATIONWIDE CHILDREN'S

When your child needs a hospital, everything matters.℠

February 5, 2019
State Medical Board of Ohio
Sallie Debolt, Senior Counsel
30 E Broad Street, 3rd Floor
Columbus, OH 43215

Comments on Proposed Medical Board Rules on Consult Agreements

Dear Ms. Debolt,

On behalf of medical and pharmacy leadership at Nationwide Children's Hospital, thank you for the opportunity to comment on proposed rules 4731-35-01 Consult Agreements and 4731-35-02 Standards for managing drug therapy. These proposed rules would regulate the use of consult agreements between physicians and pharmacists. It is exciting to see the legislature in the State of Ohio recognize the collaborative practice opportunities that exist between physicians and pharmacists, who are experts in medication therapy management.

Nationwide Children's Hospital employs a patient-centered care approach utilizing the skillsets of many disciplines to create best outcomes for patients, including the role of the pharmacist in optimizing medication use for patients. The proposed rules as written would severely limit the ability for patients and physicians to benefit from the collaborative practice of pharmacists. The rules are written from the standpoint of managing a single patient with a single physician and single pharmacist. From an enterprise standpoint, patient care cannot be managed in this manner. Instead, systems must be built which allow for consistency of care delivery from myriad providers and pharmacists for our patient populations. Furthermore, rules as constructed do not account for the typical practice of medicine and pharmacy in an institutional setting and these rules would significantly frustrate and unnecessarily burden physicians. For example, antimicrobial stewardship programs are highly encouraged and a core element of such programs are conversions from intravenous to oral antimicrobial therapy. Given changes to the consult agreement law, institutional practice now often utilizes credentialing and privileging processes to enable pharmacists to make these changes and optimize patient medication regimens. As the rules are currently constructed, it would be too cumbersome to operationalize such a program in a complex, large institutional setting.

It is also important to consider the potential positive impact that community-based pharmacists can have on patient care in outpatient / ambulatory settings and the many underserved areas of Ohio which stand to benefit from an optimally designed consult agreement.

We respectfully request that the State Medical Board of Ohio revise these rules to mirror the State of Ohio Board of Pharmacy rules on consult agreements and rules governing the practice of physician assistants (4730-2-07 and 4730-2-07). Specific recommendations for edits are provided below.

NATIONWIDE CHILDREN'S

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Proposed Rule 4731-35-01 – Consult Agreements

It is recommended to strike (A)(1)(b) and replace with language from OAC 4729:1-6-01(H) and 4729:1-06-01(I). This will provide the necessary guidelines around consent while also exempting inpatient management of patient care and will align with the State of Ohio Board of Pharmacy rules.

It is recommended to strike (A)(1)(i). Pharmacists are able to obtain DEA numbers and the intent of the law is to allow for consult agreements to be used for the management of many disease states, including those managed in part by prescribing of controlled substances including epilepsy disorders and behavioral health diseases (e.g. attention-deficit/hyperactivity disorder), amongst others.

It is recommended to change the language in (A)(2) to state, "...requirements of paragraphs (A)(1)(b) through (A)(1)(f)..." This will align the language with the State of Ohio Board of Pharmacy. This is necessary since (A)(1)(b) has been added and does not exist in this place in the OAC 4729:1-6-02.

It is recommended to strike (A)(5)(b) through (A)(5)(d) as (A)(1)(a) already accounts for the pharmacists and physicians in the agreement and takes into account the consult agreement may be executed on behalf of physician or pharmacist practice groups or through institutional credentialing and privileging. It may be advisable to restructure (A)(5) to state, "Amendments to the consult agreement are required when there are changes to (A)(1)(c) through (A)(1)(f)."

It is recommended to add section (A)(8) stating the same language as 4729:1-6-02(A)(2), "Institutional or ambulatory outpatient facilities may implement a consult agreement and meet the requirements of paragraphs (A)(1)(c) through (A)(1)(f) and (A)(5) (if adopted as recommended in the preceding paragraph) of this rule through institutional credentialing standards or policies. Such standards or policies shall be referenced as part of the consult agreement and available to an agent of the board upon request.

It is recommended to edit (B) Recordkeeping to state, "The primary physician, physician practice group, or institution as defined in rule 4729-17-01 of the administrative code..." in order to allow for recordkeeping to be maintained by the institution as are all other medical records.

It is recommended to edit (C)(1) to add the following language, "...the primary physician, physician practice group, or institution as defined in rule 4729-17-01 must:." It is also recommended to delete the first sentence of (C)(1)(ii), "An agent of the primary physician" as this is replicated in the following sentence. Sections (C)(1)(c) and (C)(1)(d) are redundant based on paragraph (A)(1)(c) through (A)(1)(f) and are recommended to be deleted.

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Proposed Rule 4731-35-02 Standards for Managing Drug Therapy

It is recommended to align this rule more closely with 4729:1-6-03 and physician assistant rules 4730-2-06 and 4730-2-07 of the administrative code. This will allow for the collaborative practice of pharmacists and physicians to function in a more seamless, optimized manner.

It is recommended to delete (A)(3) and replace with language from OAC 4729:1-6-01(H) and 4729:1-06-01(I). This will provide the necessary guidelines around consent while also exempting inpatient management of patient care and will align with the State of Ohio Board of Pharmacy rules. Alternatively, if 4730-35-01(A)(1)(b) is modified as above, this entire paragraph may not be necessary.

It is recommended to delete (A)(6) as this is redundant and covered in 4731-35-01(A)(1)(m). Additionally, pharmacists receive training in doctoral degree programs and take licensure exams. Physicians ought not to be burdened by additional requirements when these are already otherwise met.

It is recommended to either delete or align (A)(7) with rules for nurse practitioners and/or physician assistants. Communication is often documented in the medical record and discussed amongst care teams. It is recommended to allow for each physician practice or institution to determine what, if any requirements should exist around review of records.

It is recommended to delete or modify (B)(1) and (B)(2) and instead refer to the consult agreement requirements in 4731-35-01(A)(c-f). This provides enough context while allowing for the clinical practice of medication optimization to appropriately occur.

It is recommended to delete (C)(4) in its entirety and instead refer to 4731-35-01(A)(1)(g-h). It is impractical to require notification and consent of the primary physician before taking any action. If left unchanged, this language would render all consult agreements ineffectual. This clause is essentially reversing the intent of the consult agreement legislation.

It is recommended to modify (D)(1) to remove the requirement of regular meetings and make the guidance broad enough to apply to physician practices and institutions. Continuous Quality Improvement (CQI) programs are often managed via tracking populations of patients who receive interventions (e.g. pharmacist-managed patients) to appreciate outcomes. Also, privileging programs in institutions require peer-review or similar reviews which are then approved by the governing medical committee and may appropriately serve this purpose.

It is recommended to modify (D)(2)to state, "Notifications to primary physician. If prescribing controlled substances, the managing pharmacist..."

Thank you for the opportunity to comment on the proposed consult agreement rules and consideration for inclusion of the recommendations listed above.

NATIONWIDE CHILDREN'S
When your child needs a hospital, everything matters.℠

Respectfully submitted,

Chester Kaczor, PharmD, MBA
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Nationwide Children's Hospital
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Section Chief of Neurology
Interim Division Chief of Neurology
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Associate Professor Neurology and Pediatrics
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The Ohio State University College of Medicine
Director, Antimicrobial Stewardship Program
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February 6, 2019

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy

Dear Ms. Debolt:

I am writing in regards to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. Consult Agreements for Pharmacist Management of Patient's Drug Therapy is of interest to me due to my current collaborative practice with a pharmacist as a physician practicing at Mercy Health St. Rita's Medical Center. Within the hospital, I work side by side clinical pharmacists daily who provide unique value to our patients and improve overall quality of care.

Currently, consult agreements allow physicians to work collaboratively with pharmacists to manage specific inpatient drug therapy. In the hospital, we have pharmacists who independently make renal adjustments to medications, order specific labs, and manage medication consults (antibiotics, TPNS, anticoagulants, etc). Pharmacists improve the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Additionally, our pharmacists serve as drug information experts and educators for both our residents, providers and patients. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

The proposed rule changes, specifically those that require pharmacists to notify the physician of any action prior to implementation (4731-35-02 C-4) would discourage collaborative practice and obstruct our current quality-based workflow. Pharmacists are the medication experts within the interdisciplinary patient care team making their expertise imperative to the care of patients. This expertise and evidence-based care can be managed independently within an agreed upon scope of practice. The removal of the autonomy afforded to pharmacists through consult agreements would lead to a tedious and inefficient process for medication management that would negatively impact the pharmacist, provider and patient. Logistically, a busy provider may not always be available, making it difficult for the pharmacist to implement timely changes to medications. In this case, the pharmacist is the best resource to manage medication consults and other medication adjustments to ensure timely care is provided. I recommend that this requirement be removed from the proposal.

In summary, I hope that the proposal be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,

Hamid R Khatibi, MD
Hospitalist
Mercy Health St. Rita's Medical Center
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Lima, Ohio 45801
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From:	Philip King
To:	Debolt, Sallie
Subject:	Opposition to 4731-35-01 Consult agreements : proposed languge
Date:	Thursday, January 24, 2019 5:04:35 PM

To whom it may concern:

I am in stark opposition (as are many of my physician peers) of the newly proposed language presented by the State Medical Board of Ohio. I find it appalling. This is the EXACT opposite of good patient care.

"When the managing pharmacist changes the duration of
treatment for the current drug therapy; adjusts a drug's strength, dose, dosage form, frequency of administration, route of administration, discontinues a drug, prescribes a new drug, or orders urine or blood tests, as authorized under section (B)(1)(a), and (B)(1)(b) of this rule, the managing pharmacist must:

(a) Notify the primary physician PRIOR to any action.

The notification shall include a description of:

(i) The decision criteria considered by the managing pharmacist in deciding to conduct an authorized action; and
(ii) A description of the proposed authorized action the managing pharmacist intends to conduct.

(b) Obtain the consent of the primary physician to conduct the proposed authorized action."

This is what the proposal states (I am paraphrasing):

If a pharmacist wants to do something that was ALREADY agreed upon in an initial contract between a pharmacist (group) and a physician (group), the pharmacist needs to ask for permission EVERY SINGLE TIME they are going to do something that was ALREADY agreed upon in their unique pharmacist and physician contract.

This obstructs direct patient care that has already been shown to be safe and effective. Not only that, this type of care provided by pharmacists LOWERS healthcare costs.

The new proposal does NOT put patients' needs first. It puts physicians' wants first. And that want appears to be full control of pharmacists and the unique services pharmacists are trained to provide as true medication experts.

Dr. Philip King

--

Philip K. King, PharmD, BCPS
Clinical Lead Pharmacist, Neurology/Cardiovascular
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From: Kirschner, Eric S
To: Debolt, Sallie
Subject: 4731-35-01 & 4731-35-02 Proposed Rule Changes
Date: Monday, February 4, 2019 4:33:18 PM

February 4, 2019

Ms. Diebolt and Ohio Medical Board:

I am writing regarding the proposed State Medical Board Rules for consulting agreements involving pharmacists. Specifically, **4731-35-01** for consult agreements and **4731-35-02** regarding standards for managing drug therapy. I am concerned that the requirement for the managing pharmacist to notify the consulting physician ***prior to any drug therapy action*** would greatly impede the timeliness of patient care being provided by the pharmacist. Hospital consult agreements already define the scope of the pharmacist's practice and the requirements for follow-up communication. Pharmacists' primary purview is that related to medications and as a matter of course, they undergo extensive training and certification prior to clinical practice. Those of us in the clinical practice arena consider them to be our medication experts and often look to them for guidance, rather than the converse. Our pharmacists already possess specialty certifications to further support their role in medication management. As a physician, I am entirely comfortable in allowing medication adjustment to be done by my clinical pharmacist staff and they, in turn, provide feedback and monitoring of therapy, allowing me to focus on other vital patient care responsibilities.

The language specifying the requirement for a pharmacist to notify a physician prior to any action would not allow a pharmacist to dose a medication in "real-time", instead requiring two-way communication with the cooperating physician provider before even the most rudimentary change in drug dose. This would inevitably result in inefficiencies of care, inconveniencing the patient and likely disrupting physician workflow, possibly numerous times daily. Please note that physician response to such calls is seldom instantaneous, often with time delays of many minutes to hours, depending upon clinical schedules and procedures in which the doctor may be involved. This would add unnecessary burden to the patient in terms of waiting for medication change confirmation, as well as to the pharmacist in terms of need to contact the patient to verify the dose change. (Indeed, not all of our pharmacist-managed patients have telephones or easy means of contact.)

The requirement of the consulting physician and pharmacist to meet on a regular basis to discuss patient care and review detailed reports of actions may prove to be onerous for both the pharmacist and physician. Such requirements may more than offset any hoped-for efficiencies of the

cooperative management schema. Current consult agreements and ready access to electronic medical records from virtually any internet connected site already allow for open communication without the time constraints that this would place on both parties.

Rules have already been established in the Ohio Administrative Code which reflect requirements, limitations and care processes when pharmacists and physicians enter a consultative relationship. Numerous such consulting agreements reflecting the current OAC are already in place. The proposed rules do not add improvements to the established OAC rules, but instead impede patient care further by adding inefficiencies as noted above. While I am certain that the intent of the proposed changes was to benefit patient care, for the reasons noted, I fear that they will have the opposite effect. For these reasons, I oppose the proposed changes.

I remain available to further discuss this issue as you may desire.

Sincerely,

Eric S. Kirschner, MD
ICU Medical Director
Internal Medicine Program Director
Mercy Health St. Rita's Medical Center
730 W Market St
Lima, Ohio 45801
Email: eskirschner@mercy.com
Phone: 419-226-9584

From:	Klautky, Stephen A.
To:	Debolt, Sallie
Subject:	Proposed State Medical Board Rules interfering with pharmacy and physician care of patients
Date:	Friday, February 8, 2019 1:27:56 PM

Ms. Diebolt and Ohio Medical Board:

I am writing regarding the proposed State Medical Board Rules for consulting agreements involving pharmacists. Specifically, **4731-35-01** for consult agreements and **4731-35-02** regarding standards for managing drug therapy. I am concerned that the requirement for the managing pharmacist to notify the consulting physician ***prior to any drug therapy action*** would greatly impede the timeliness of patient care being provided by the pharmacist.

This proposal will interfere in the quality of care and make patients less safe. This is the biggest issue and complaint about the proposed changes. Please do not allow a decline in the quality that we have all worked so hard to achieve.

Hospital consult agreements already define the scope of the pharmacist's practice and the requirements for follow-up communication. Pharmacists' primary purview is that related to medications and as a matter of course, they undergo extensive training and certification prior to clinical practice. Those of us in the clinical practice arena consider them to be our medication experts and often look to them for guidance, rather than the converse. Our pharmacists already possess specialty certifications to further support their role in medication management. As a physician, I am entirely comfortable in allowing medication adjustment to be done by my clinical pharmacist staff and they, in turn, provide feedback and monitoring of therapy, allowing me to focus on other vital patient care responsibilities.

The language specifying the requirement for a pharmacist to notify a physician prior to any action would not allow a pharmacist to dose a medication in "real-time", instead requiring two-way communication with the cooperating physician provider before even the most rudimentary change in drug dose. This would inevitably result in inefficiencies of care, inconveniencing the patient and likely disrupting physician workflow, possibly numerous times daily. Please note that physician response to such calls is seldom instantaneous, often with time delays of many minutes to hours, depending upon clinical schedules and procedures in which the doctor may be involved. This would add unnecessary burden to the patient in terms of waiting for medication change confirmation, as well as to the pharmacist in terms of need to contact the patient to verify the dose change. (Indeed, not all of our pharmacist-managed patients have telephones or easy means of contact.)

The requirement of the consulting physician and pharmacist to meet on a

regular basis to discuss patient care and review detailed reports of actions will be onerous for both the pharmacist and physician. Such requirements may more than offset any hoped-for efficiencies of the cooperative management schema. Current consult agreements and ready access to electronic medical records from virtually any internet connected site already allow for open communication without the time constraints that this would place on both parties.

Rules have already been established in the Ohio Administrative Code which reflect requirements, limitations and care processes when pharmacists and physicians enter a consultative relationship. Numerous such consulting agreements reflecting the current OAC are already in place. The proposed rules do not add improvements to the established OAC rules, but instead impede patient care further by adding inefficiencies as noted above. While I am certain that the intent of the proposed changes was to benefit patient care, for the reasons noted, I fear that they will have the opposite effect. For these reasons, I oppose the proposed changes.

I remain available to further discuss this issue as you may desire.

Sincerely,

Stephen Klautky, M.D.
Cardiologist
NEOCS – Summa Health Heart and Vascular Institute

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2/7/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
Sallie.Debolt@med.ohio.gov

Dear Ms. DeBolt:

I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a physician that utilizes the services of pharmacists through collaborative practice agreements to provide care to my patients, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.

I rely often on my pharmacy colleagues to assist me in medication evaluations and recommendations for managing my patients' medications. The pharmacists with which I work are very knowledgeable and have my patient's best health and interests in mind. Their expertise and recommendations definitely provide a benefit to the care that I provide and definitely give my patients the best pharmaceutical options for treating their medical problems.

Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:
Konfala
42C1D62FD046420...

Konfala

MD

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

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2/6/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
Sallie.Debolt@med.ohio.gov

Dear Ms. DeBolt:

I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a physician that utilizes the services of pharmacists through collaborative practice agreements to provide care to my patients, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.

I have had several patients (one in particular comes to mind with head and neck cancer who depends on a feeding tube and has diabetes mellitus and is on insulin) whom our pharmacists helped manage their insulin needs and nutritional needs in such a way as to prevent life threatening complications. Without their collaborative care, many of my patients would be at risk for adverse outcomes.

Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:
Cynthia Kreger
D92869BA917C4F9...

Cynthia Kreger

MD

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

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2/5/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
Sallie.Debolt@med.ohio.gov

Dear Ms. DeBolt:

I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a physician that utilizes the services of pharmacists through collaborative practice agreements to provide care to my patients, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.

With truly collaborative care between pharmacist and physician I have been able to achieve tremendous improvement in my most challenging diabetics. I have had several diabetic go from A1c > 10 to a controlled A1c through collaborative practice. This proposed language referenced will be detrimental to this continued success. It will erode the true ability to collaborate and negatively impact patient care. It would completely undermine collaboration as it currently exists and simply return care of patients to a previously unsuccessful model.

Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:
Michael S Langan
A59384F47FAF43A...

Michael S Langan

MD

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February 7, 2019

Sallie Debolt
State Medical Board of Ohio
30 E Broad St, 3rd Floor
Columbus, OH 43215

Sallie,

Thank you for the opportunity to comment on the proposed rules establishing standards and procedures for a physician who is entering into a consult agreement for pharmacist management of a patient's drug therapy. We, a group of practitioners from PrimaryOne Health, have been practicing collaboratively under consult agreements since December 2017 and we have some concerns with the rules as they have been proposed by the State Medical Board of Ohio. PrimaryOne Health is a Federally Qualified Health Center (FQHC) recognized as a National Committee for Quality Assurance (NCQA) Tier 3 patient-centered medical home. PrimaryOne Health has 10 health centers throughout central Ohio and serves more than 46,000 culturally and socioeconomically diverse patients. The pharmacy department at PrimaryOne Health consists of 5 clinical pharmacists, including a post-graduate year 2 (PGY2) ambulatory care pharmacy resident. Pharmacists at PrimaryOne Health complete rigorous training to ensure they are equipped to perform pharmacist duties. All pharmacists have received their Doctorate of Pharmacy degree, completed 1-2 years of residency training prior to hire, and are highly encouraged and supported to receive board certification in specialty areas. Furthermore, pharmacists undergo internal credentialing similar to physicians, before they are able to operate within the Consult Agreements (CA) established between physicians and pharmacists.

Pharmacists at PrimaryOne Health provide disease state management, population health management, patient education, and serve as a drug information resource to other healthcare providers. Currently pharmacists and physicians at PrimaryOne Health have CAs in place for smoking cessation and COPD management. Pharmacists operating under the CA has helped streamline patient care, increase access to care, and decrease provider burden. The proposed changes to sections 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy, intrude upon physician-pharmacist collaboration, are onerous and would negatively impact how we at PrimaryOne Health currently care for our patients.

Along with the current CA for smoking cessation and COPD, PrimaryOne Health is looking to expand CAs. Within the upcoming months, the organization plans to implement CAs for pharmacist management of diabetes and pharmacist provided Medication-Assisted Treatment (MAT) for substance use disorders. Pharmacists who have been trained to administer Vivitrol injections will help manage MAT patients after the patient has their initial visit with a managing physician. Under the current CA rules, pharmacists

would be able to expand access to a much-needed service. If the proposed changes are made, it would significantly limit our ability to expand access to the MAT service for this vulnerable patient population. The following proposed rules concern us because we believe, if enacted, they would negatively impact current and future patient care at PrimaryOne Health.

Please consider removing the following language:

4731-35-02 Section (C)(4): When the managing pharmacist changes the duration of treatment for the current drug therapy; adjusts a drug's strength, dose, dosage form, frequency of administration, route of administration, discontinues a drug, prescribes a new drug, or orders urine or blood tests, as authorized under section B)(1)(a), and B)(1)(b) of this rule, the managing pharmacist must:
(a) Notify the primary physician prior to any action. The notification shall include a description of:
(i) The decision criteria considered by the managing pharmacist in deciding to conduct an authorized action; and
(ii) A description of the proposed authorized action the managing pharmacist intends to conduct.
(b) Obtain the consent of the primary physician to conduct the proposed authorized action.
Rationale: The requirement to notify and obtain consent from the primary physician prior to any action regarding therapy changes would cause a burden upon the primary physician, increase fragmentation of care, and may lead to clinical inertia. If enacted, this rule would directly impact the efficiency that a CA is supposed to allow, resulting in patients' not obtaining blood/urine tests in a timely manner and delayed medication changes, which detracts from the quality of care that can be provided if this rule were not in place.

Please consider revising the following language to allow either the physician or the pharmacist to communicate the content of the proposed CA to the patient and obtain consent:

4731-35-02 Section (A)(3): Requiring that the physician prior to the effective date of the consult agreement and prior to a pharmacist managing the patient's drug therapy shall communicate the content of the proposed consult agreement to each patient whose drug therapy is managed under the agreement.
Rationale: Requiring physicians to obtain consent from patients would increase administrative burden and decrease efficiency and effectiveness of consult agreement. Pharmacists at PrimaryOne Health explain the CA to patients, including the information outlined in proposed rules 4731-35-02 (A)(3)(a-d) and obtain patient consent to participate in the physician-pharmacist CA. Pharmacists also check to ensure that the patient maintains an ongoing physician-patient relationship and will terminate the CA if the physician included in the CA leaves the practice or if the patient transitions care to a non-physician primary care provider.

PrimaryOne Health

Your first choice for quality care®

PrimaryOne Health's mission is to provide access to services that improve the health status of families –including people experiencing financial, social or cultural barriers to health care.

Physicians at PrimaryOne Health rely on pharmacists to act as care extenders and help streamline care. One physician said, " I enjoy and value the pharmacy team here at PrimaryOne Health and their impact on patient care. When working in a very busy clinic, the pharmacist is able to further patient care through our current consult agreements. Patient care would be interrupted if those services were restricted as outlined in these proposed rules." Please consider implementing the edits outlined above to help us continue to serve our vulnerable patients through pharmacists' practicing at the top of their licenses.

Sincerely,

Barbara Laroque, MD
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2/6/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
Sallie.Debolt@med.ohio.gov

Dear Ms. DeBolt:

I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a physician that utilizes the services of pharmacists through collaborative practice agreements to provide care to my patients, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.

Working collaboratively with the pharmacist in my office has improved my quality of care and my patient's satisfaction with their care. He is knowledgeable and definitely brings a different skill set to the care team. We are tracking metrics and his participation in the care of our diabetes patients has resulted in significant improvements in their diabetes control.

Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:
Kristina M Lehman, MD, IBCLC
C52F9260D3554D9...

Kristina M Lehman, MD, IBCLC

Assistant Professor

From: Dr. Michael Lemon
To: Debolt, Sallie
Subject: Proposed rules establishing standards and procedures for a physician who is entering into a consult agreement for pharmacist management of a patient's drug therapy
Date: Friday, February 8, 2019 9:42:46 AM
Attachments: image001.png
pharmacy Consult Agreement Proposal Letter Template v3.docx

Dear MS Debolt:

Please add my concerns and objections in my letter to the - I am sure - ever growing pile of similar concerns and objections from Pharmacists and Physicians who are alarmed at the potential to harm patient care. These awkwardly designed regulations will impede the efforts of all of us to improve patient care and reduce the timeliness of same. The true heart of the matter is to interfere with agreed to policies and parameter with the below verbiage :

(a) Notify the primary physician prior to any action. The notification shall include a description of:
i. The decision criteria considered by the managing pharmacist in deciding to conduct an authorized action; and
ii. A description of the proposed authorized action the managing pharmacist intends to conduct.
(b) Obtain the consent of the primary physician to conduct the proposed authorized action.

Sincerely,

Mike Lemon

Michael J Lemon, MD FAAP
Pediatrician – Wood County Medical Associates
Medical Director, Wood Health Company / Wood County Hospital

"The good thing about Science is that it's true whether or not you believe in it."
-Neil deGrasse Tyson

From:	Todd Leopold
To:	Debolt, Sallie
Subject:	New regulations related to consult agreements and standards for managing drug therapy
Date:	Tuesday, February 5, 2019 4:32:13 PM

Sallie,

We currently have policies that address automatic therapeutic substitution, renal adjustment, dosing services, and discontinuation of duplicate orders – Do we need separate Consult Agreements for each of these services provided? I am also concerned about contacting providers on every one of these current routine processes by pharmacists. It will have a severe impact on delivering medication therapy to our patients in a timely and appropriate manner.

Could you please clarify?

Thanks,

Todd

Todd M. Leopold, RPh, PharmD
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2/6/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
Sallie.Debolt@med.ohio.gov

Dear Ms. DeBolt:

I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a physician that utilizes the services of pharmacists through collaborative practice agreements to provide care to my patients, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.

Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:
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Li

Internal Medicine MD., PHD

CONSULT AGREEMENTS COMMENTS --ONU NCPA Student Chapter 2/4/19

The proposed rules set forth by the State Medical Board of Ohio on consult agreements for pharmacist management of a patient's drug therapy would be detrimental to the future careers of pharmacy students. While the Medical Board and the Board of Pharmacy both share the common purpose of protecting the public, these self-serving rules would not only limit the current practice of pharmacy but may also prove harmful for the public. More specifically, proposals such as to "Notify the primary physician prior to any action and obtain the consent of the primary physician to conduct the proposed authorized action" decrease the current scope of pharmacy practice and demean the value of collaboration. By limiting the care pharmacists can provide to patients in a time when medically underserved areas encompass swaths of Ohio and physician shortages grow exponentially, the rules set forth by the State Medical Board of Ohio do not put the patients' well-being first or offer additional patient safety in comparison to current legislation.

As soon to be practicing pharmacists, we hope to have a relationship with prescribers that allows for meaningful collaboration. Through this collaboration, we will lessen the strain on primary care physicians and other practitioners by providing care directly to their patients. If patients wanting pharmacist care can no longer receive care from pharmacists with these newly proposed rules, their quality of care could be greatly impacted when patients have to seek out these overburdened prescribers. Again, the proposed rules set forth by the Medical Board do not offer any additional protection to the public and would limit the care we may provide to patients as future pharmacists.

The James L. Winkle
College of Pharmacy

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Phone (513) 558-3784
Fax (513) 558-4372

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

February 8, 2019

Dear Ms. Sallie Debolt,

On behalf of the University of Cincinnati James L. Winkle College of Pharmacy, I would like to formally submit comments on the proposed language for the new Medical Board of Ohio rules that would significantly interrupt current and future consult agreements between physicians and pharmacists for managing complex medication therapies for Ohio patients. The impact of these changes could have negative implications on patient safety and clinical outcomes related to acute and chronic illness. The changes will also negatively impact my faculty who have a clinical practice in the state of Ohio.

As OAC 4729:1-6-01, -02, -03 are currently written, a consult agreement is voluntarily entered into by a physician requesting a collaborative approach to managing their patients' medication therapy under well-defined 'procedures' and 'decision criteria' for the pharmacist that are understood by the physician. Although our profession understands the need for guidance of pharmacist practice under a consult agreement, the proposed language changes will significantly diminish the scope and role of the dully trained and credentialed pharmacist – as well as expectations of the consulting physician – in managing a patient's medication therapy under the provision of a consult agreement.

Moreover, the diminished scope in the proposed language will negatively impact patients by significantly restricting patient access to care requested by a physician to be provided by pharmacists as the medication therapy experts while also over-burdening physicians with administrative requirements to manage these consults agreements as outlined in the proposed rule changes.

Please see below a series of recommendations to the proposed rules changes.

4731-35-01 Consult Agreements

- Removal of Section A-1-i – requirement for physician approval prior to adjustment to the dose of a controlled substance.
    - Given the current challenges in Ohio with management of opioids and opioid addiction, limiting the ability for pharmacists to manage controlled substances under a formal consult agreement from a physician will have the potential to perpetuate the problem of opioid overuse by preventing pharmacists from adjusting doses down or discontinuing opioids that are no longer needed for the patient.

4731-35-02 – Standards for Managing Drug Therapy

- Modification of section A-3 – The language around physician communication to the patient is excessive and discourages patients from allowing a pharmacist to participate in their care through a consult agreement. We recommend sub-bullet (d) be removed from the rules.
- Removal of section A-6 – The requirement that the authorizing physician ensure the managing pharmacists' training and experience are adequate is an excessive burden on the physician. As pharmacists are extensively trained in pharmacology and pharmacotherapy through their prerequisite education in order to become licensed, further scrutiny of this training and experience by the authorizing physician is excessive. Moreover, the verification of pharmacist credentials and competency should remain with the employing institution or business.
- Clarification of section A-7 – Further clarification of "prompt review".
- Modification of section B-1 – Placing the responsibility of defining the extent and scope of the pharmacist on the physician is unclear. Recommend rewording to outline that scope of the pharmacist is defined by the policy/procedure established in the consult agreement.
- Modification of section C-4 – Recommend removal of requirement for pharmacist to notify primary physician prior to any action. This requirement is extremely onerous on both the physician and the managing pharmacist, and will discourage physicians from entering into consult agreements with pharmacists. This will negatively impact patients' access to the necessary care they could receive from a pharmacist to manage their medications under a consult agreement and the related details of pharmacist requirements for an approved consult agreement currently described in OAC 4729:1-6-02. As the medication therapy experts, pharmacists are qualified to perform these actions under a consult agreement. This rule will decrease access and quality of care. We recommend sub-bullet (b) be removed from the rules.
- Modification of section D-1 – Recommend removal of the requirement for primary physician and managing pharmacist to hold regular meetings. This requirement is onerous on both the physician and the managing pharmacist, and will discourage physicians from entering into consult agreements with pharmacists.

Thank you for your consideration of our comments for incorporation into these rules. Please feel free to contact me with any questions or clarifications.

Sincerely,

Neil J MacKinnon, BSc(Pharm), MSc(Pharm), PhD, Dean and Professor
James L Winkle College of Pharmacy
University of Cincinnati

From:	Malone, Meghan
To:	Debolt, Sallie
Cc:	apalcic@ohiopharmacists.org
Subject:	4731-35-02 Standards for managing drug therapy proposed rule comments
Date:	Wednesday, February 6, 2019 4:58:23 PM

Ms. Debolt,

I would like to provide some comments regarding the proposed rule 4731-35-02 Standards for managing drug therapy. For section C (4), requiring a pharmacist to notify and obtain permission from the primary physician before modifying a patient's drug therapy would severely impede patient care. I think notifying a physician within 72 hours (such as is included in Pennsylvania law https://www.pacode.com/secure/data/049/chapter27/s27.302.html) about a change is much more practical. Also, for section D (1), I don't think regular meetings (at least if this means face to face) is going to very practical especially when a pharmacist group has consult agreements with several physicians. Additionally, I would ask to consider adding that a physician assistant or nurse practitioner be able to enter a consult agreement with a pharmacist since this would also help to improve patient care.

Thank you for your consideration,

Meghan Malone, PharmD, BCPS, BCACP
Clinical Pharmacist
Jobst Anticoagulation Service
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2/5/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
Sallie.Debolt@med.ohio.gov

Dear Ms. DeBolt:

I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a physician that utilizes the services of pharmacists through collaborative practice agreements to provide care to my patients, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.

By utilizing our pharmacist through the collaborative practice agreements, we have seen our patients with high blood pressure receive improved care. They are getting the proper monitoring labs they need, we are better assessing for side effects and their blood pressure is better controlled. We have recently started to use this in patients with diabetes and have already seen a big difference. Curbing pharmacists' ability to provide collaborative care would be a great step backwards in providing patients with comprehensive personalized care.

Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:
Shengyi Mao
018CA7525D964C4...

Shengyi Mao

MD

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February 7, 2019

To: Sallie Debolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

To Whom It May Concern:

As a practicing physician in the state of Ohio, I would like to thank you for your service to the State Medical Board of Ohio and for all you do to enhance the care of our fellow Ohioans. I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a physician that currently utilizes the services of pharmacists as independent practitioners through collaborative practice agreements, I am in favor of pharmacists continuing to provide patient care in this manner as a means to improve quality, safety, and efficiency in our health system. The utilization of consult agreements between physicians and pharmacists at The Ohio State University Wexner Medical Center has improved patient outcomes and helped control healthcare costs. I believe pharmacists are a vital part of the interdisciplinary team and are vital for successful provision of high quality clinical services and improving access to care. I am supportive of the continued incorporation of pharmacist services into my day to day practice. I have appreciated the updates by the Board of Pharmacy over the last few years. The rules proposed by the Medical Board are generally acceptable and in line with current pharmacy rules.

However, I feel several provisions are converse to current practice and limit the utility of consult agreements. Sections (A)(2) and (C)(4) of 4731-35-02, in current form, would increase provider burden and decrease efficiency of the current system, significantly impacting the business of healthcare. Furthermore, (C)(4) would reduce quality of care by discrediting pharmacists' clinical decision making capabilities already authorized under agreed collaborative practice agreements and accompanying scope of practice. We are asking this language regarding "at least one time per year" in (A)(2) and the entirety of (C)(4) be removed (this is covered in (A)(1) of 4731-35-01).

If you have any questions, please do not hesitate to contact me. Thank you for your consideration.

Sincerely,

Dr. U. Krishnan Marar
Clinical Assistant Professor of Medicine
Division of Cardiovascular Medicine
Ohio State University Medical Center
Ph 614.293.4967
Fax 614.293.5614

From:	Steven Martin
To:	Debolt, Sallie
Subject:	Draft rules for consult agreements with pharmacists
Date:	Friday, February 8, 2019 3:27:54 PM
Attachments:	SMB Comments on Draft Consult Agreement Language.pdf

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Ms. Debolt,

Please see attached my comments on the draft rules for consult agreements with pharmacists. I'll be happy to discuss any of these with you or others if you'd like.

My best,

Steve

Steven J. Martin, PharmD, BCPS, FCCP, FCCM
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4731-35-01 Consult Agreements.

(A) Requirements of a consult agreement.

(1) A consult agreement shall include all of the following:

A1b. A description of the patient's informed consent to drug therapy management pursuant to the consult agreement.

- Informed consent is onerous and reduces the patient's access to care.
- Duplicative as its already in the pharmacy regs…..4729 1-6-02 (H) "Communicated" as used in division (B)(4) of section 4729.39, means consent shall be obtained from each individual patient participating in a consult agreement.

A1i. A requirement for physician approval prior to adjustment to the dose of a controlled substance.

- This reduces access to care for the patient. The purpose of the consult agreement is to improve access to care and provide the patient with the medication management expertise of the pharmacist.

A1k. An appropriate quality assurance mechanism to ensure that managing pharmacists only act within the scope authorized by the consult agreement.

- Duplicative. 4729 -1-6-02 A (i) An appropriate quality assurance mechanism to ensure that managing pharmacists only act within the scope authorized by the consult agreement.
- This is onerous and unlikely to affect quality of patient care. Pharmacists must act with their scope of their practice, which is regulated by the Board of Pharmacy.

(A) Requirements of a consult agreement

(5) Amendments to the consult agreement are required when:

A5a. The scope of the managing pharmacist's permitted procedures expands past what was contemplated within the agreement; or

b. The subtraction, or addition of an authorized pharmacist; or

c. The subtraction or addition of an authorized physician; or

d. Other significant changes to the existing agreement.

- The physician can revoke authorization for the collaborative practice agreement at any time. This obviates the need to amend the agreement whenever minor changes are made to practice scope, or practitioners in the group practices change. All of this language seems to indicate lack of trust of the pharmacist. There is a lack of data to substantiate this mistrust.

- Pharmacists regulations already cover this issue in 4729-1-6-03 (B) The pharmacist's prescriptive authority shall not exceed what is specified in the consult agreement.
- Not necessary as they would need to work through the Pharmacy Board anyway to take action on the RPh license.

(C) Managing Drug Therapy

(1) For the purpose of implementing the management of a patient's drug therapy by an authorized managing pharmacist acting pursuant to a consult agreement, the primary physician must:

C1a. Provide for the managing pharmacist with access to the patient's medical record;

- This is a great concept; access to the physician medical record system for the pharmacist will improve communication and the dissemination of accurate information.
- It is not clear what *access* to the patient's medical record means

C1c. Specifically authorize the managing pharmacist's ability to:

(i) Change the duration of treatment for the current drug therapy; adjust a drug's strength, dose, dosage form, frequency of administration, route of administration, discontinue a drug, or to prescribe new drugs; and or

(ii) (Order blood, urine and other tests related to the drug therapy being managed and to evaluate those results, and

(d) Extent to which, and to whom, the managing pharmacist may delegate drug therapy management to other authorized pharmacists under the agreement.

- The purpose of the consult agreement is to improve the patient access to the pharmacists' scope of practice. By entering into the agreement with the pharmacist, these aspects of the pharmacist's scope are accepted by the physician. This language creates a redundant authorization process, is onerous, and is unnecessary.

4731-35-02 Standards for managing drug therapy.

A. A physician may elect to manage the drug therapy of an established patient by entering into a consult agreement with a pharmacist. The agreement is subject, but not limited to, the following standards:

3. The physician, prior to the effective date of the consult agreement, and prior to a pharmacist managing the patient's drug therapy, shall communicate the content of the proposed consult agreement to each patient whose drug therapy is managed under the

agreement, in such a manner that the patient or the patient's representative understands scope and role of the managing pharmacist, which includes the following:

(a) That participation in the consult agreement is voluntary and that the patient may choose not to participate;

(b) That the agreement will not be utilized unless the patient or the patient's authorized representative consents to the consult agreement;

(c) That the consent can be revoked by the patient at any time; and

(d) That the consult agreement and the patient's consent will be disclosed to the patient's primary care physician and any other treating physician or healthcare provider.

- These are onerous provisions, with unnecessary opt-op language that will reduce access to care. It interferes with the pharmacist-patient relationship by inserting the physician in the middle. The patient always has the option of choosing the practitioner with whom they wish to interact.

B. Scope of managing pharmacist.

(1) Based on the managing pharmacist's training and education, the physician must establish the extent and scope of the managing pharmacist's authority to:

(a) Change the duration of treatment for the current drug therapy; adjust a drug's strength, dose, dosage form, frequency of administration, route of administration, discontinue a drug, or to prescribe new drugs, including that prior physician approval is required before an adjustment to the dose for controlled substances; and

(b) Order blood, urine and other tests related to the drug therapy being managed and to evaluate those results.

(2) The primary physician must also establish:

(a) Decision criteria the managing pharmacist is to consider when acting pursuant to sections (B)(1)(a), and (B)(1)(b) of this section; and

(b) A plan the managing pharmacist is to follow prior to conducting an authorized action pursuant to sections (B)(1)(a), and (B)(1)(b) of this section; and

(c) A plan the managing pharmacist is to follow after having conducted an authorized action pursuant to sections (B)(1)(a), and (B)(1)(b) of this section.

- The physician does not establish the pharmacists' scope of practice. That is the responsibility of the State Board of Pharmacy. This language is not legal or necessary.

(C) Quality assurance mechanisms. The following quality assurance mechanisms shall be implemented to verify information contained within the consult agreement, and ensure the managing pharmacist's actions are authorized and meet the standards listed in sections (A) and (B) of this rule:

(1) Verification of ongoing physician-patient relationship. A physician-patient relationship can be established by detailing criteria set forth in section (A)(2) of this rule, within the consult agreement.

(2) Verification that physician diagnosis is within the physician's scope of practice. Establishing that a diagnosis is within the physician's scope of practice may be established by detailing the criteria set forth in section (A)(4) of this rule, within the consult agreement.

(3) Verification that pharmacist's training and experience is related to the drug therapy. Establishing that a pharmacist's requisite training and experience with a particular drug therapy is related to the diagnosis for which the drug therapy is prescribed, may be established by detailing the criteria set forth in section (A)(6) of this rule, within the consult agreement.

- These are unnecessary and onerous requirements that do not affect the quality of patient care but instead seek to limit the access of patients to pharmacist services.
- Again, duplicative as this is already a pharmacy board regulations.

From: llmaul66@buckeye-express.com
To: Debolt, Sallie
Subject: Consult Agreement Rules
Date: Friday, February 8, 2019 12:37:58 PM
Attachments: Baldwin T State Med Board Consult agreement comments.pdf
Bernardo D State Med Board Consult agreement comments.pdf
Chaudhary R State Med Board Consult agreement comments.pdf

Dear Ms. Debolt,

I am the Pharmacy Manager for Mercy Health St. Charles Hospital in Oregon, Ohio. We have an extensive Medication Management Program where we monitor anticoagulation therapy and Diabetes management through Consult Agreements. With over 500 patients utilizing our services and multiple Physicians, the proposed Medical Board rules for Consult Agreement basically eliminates any benefits for patients and physicians that we gain through the current Pharmacy Board Rules for Consult Agreements. Patients really enjoy their visits with the Pharmacists and take pride in their achievements as they see the improvements in their therapies. Our Pharmacists are consistently above National benchmarks for achieving INRs within range and our results in lowering A1Cs in diabetic patients are remarkable. lowering A1Cs by over 2 with in 3-6 months. These patient achievements are directly a result of the Consult Agreement rules as they exist today under the Ohio Board of Pharmacy- OAC 4729:1-6-02 Consult Agreements. Our Services greatly extend our Physicians' care of their patients by closely monitoring therapies, quickly making appropriate changes as agreed upon in the agreement, educating and coaching patients , and communicating results back to the provider. I have many examples of success and much support from Medical Staff and Administration at Mercy Health - St. Charles Hospital. Attached are three letters from Physician who utilize our Services, including our Chief Medical Officer, Dr. Riaz N. Chaudhary.

I feel the proposed Medical Board rules as written (4731-35-02 C-4) will impede the process to the point all patient care improvements will be negated. I ask for consideration of removing the language to communicate with Physicians prior to making changes in therapy.

Sincerely,

Les L. Maugel, R.Ph.

Mercy Health - St. Charles Pharmacy Manager

2600 Navarre Avenue

Oregon, Ohio 43616

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COLLEGE OF MEDICINE AND LIFE SCIENCES
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Nephrology: Deepak Malhotra, M.D., Ph.D.
Pulmonary/Critical Care: Jeffrey R. Hammersley, M.D.
Rheumatology: M. Bashar Kahaleh, M.D.

February 8, 2019

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy

Dear Ms. Debolt:

Please see my concerns regarding the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. Consult Agreements for Pharmacist Management of Patient's Drug Therapy affects me personally as a physician practicing at South Toledo Internist, 3355 Glendale Avenue, Toledo, Ohio. Within my outpatient clinic, I work side by side with clinical pharmacists on a daily basis who provide unique value to our patients and improve overall quality of care.

Currently, consult agreements allow physicians to work collaboratively with pharmacists to manage chronic diseases. In my practice, we have pharmacists who independently manage diabetes, hypertension, and dyslipidemia through consult agreements. Pharmacists improve the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Additionally, our pharmacists serve as drug information experts and educators for both our residents, providers and patients. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

The proposed rule changes, specifically those that require pharmacists to notify the physician of any action prior to implementation (4731-35-02 C-4) would discourage collaborative practice and obstruct our current quality-based workflow. Pharmacists are the medication expert within the interdisciplinary patient care team making their expertise imperative to the care of patients. This expertise and evidence-based care can be managed independently within an agreed upon scope of practice. The removal of the autonomy afforded to pharmacists through consult agreements would lead to a tedious and inefficient process for chronic disease management that would negatively impact the pharmacist, provider and patient. Logistically, a busy provider may not always be in clinic making it difficult for both the pharmacist and patient's to reach them. In this case the pharmacist is the best resource to manage chronic

diseases and ensure timely care is provided. I recommend that this requirement be removed from the proposal.

Collaborations include medication regimens through polypharmacy visits -- discontinuing un-needed medications, educating patients on the medications they are taking, making sure patients are getting appropriate lab monitoring for medications.

I hope that the proposal be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,

Chiamaka Mbaso, M.D.

OHIO HOSPITAL ASSOCIATION

Collaborating to
Ensure a Healthy Ohio

(Sent via e-mail to Sallie.Debolt@med.ohio.gov)

February 8, 2019

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 East Broad Street, 3rd Floor
Columbus, OH 43215

Re: Proposed Rules re: Physician-Pharmacist Consult Agreements
OAC 4731-35-01 and 4731-35-02

Dear Ms. Debolt:

On behalf of its 237 member hospitals and 13 health systems, the Ohio Hospital Association (OHA) appreciates the opportunity to provide comments on the above-referenced draft rules regarding physician-pharmacist consult agreements. OHA values being invited to participate in this process while the rules are in the draft phase, prior to introduction into the formal rulemaking process.

In short, Ohio's hospitals are concerned that the proposed rules will greatly restrict the usefulness of consult agreements as a patient care model, discourage physicians from entering consult agreements with pharmacists, and impede the delivery of safe, effective, and efficient care for patients. In addition, OHA believes some of the draft rules are a significant departure from the statutory framework, and related rules from the Ohio Pharmacy Board that have been in effect since 2016, permitting consult agreements.

Hospitals throughout the state have been using physician-pharmacist consult agreements as an important element of providing care to patients in a way that maximizes the expertise of all members of the care team. For example, consult agreements are used to manage the medication therapy of patients dealing with a variety of conditions, including diabetes, renal disease, blood clots, sepsis, hypertension, and many others. These consult arrangements are safe and effective because the care is delivered in accordance with clear parameters and standards for the escalation and de-escalation of care. These standards are developed in collaboration with the physician and other members of the care team, are consistent with best practices in institutional and other care settings, and supported by a robust base of evidence in the medical literature. OHA believes many of these benefits will be negated, patients will be adversely impacted, and physicians and pharmacists will be unnecessarily burdened with administrative tasks if the restrictions on consult agreements contemplated by the draft rules become effective.

OHA received feedback from numerous member hospitals, many of which we believe will submit comment letters of their own. The following specific comments highlight several themes from the feedback we received from members, but do not include all comments we received from members that they may address in their separate letters:

Proposed Rule 4731-35-01

Subsection (A)(1)(b) is inconsistent with the Pharmacy Board's consult agreement rules, as the Pharmacy Board rule exempts institutional facilities from the requirement to obtain patient consent for inpatient management of patient care. See OAC 4729:1-6-01(H). To avoid confusion, and to ensure the continued management of inpatient care according to recognized best practices, OHA recommends aligning the Medical Board rule with the Pharmacy Board rule on this issue.

Subsection (A)(1)(i) would require physician approval prior to a pharmacist adjusting the dose of a controlled substance. Many patient conditions, including epilepsy disorders and behavioral health diseases (ADHD, for example), are safely and effectively managed under consult agreements authorizing the management of controlled substances. In addition, as Ohio continues to deal with the opiate crisis, limiting pharmacists' efforts to manage controlled substances will prevent them from adjusting doses of opiates down or discontinuing opiates that are no longer needed by the patient. Requiring physician approval prior to adjusting doses for these drugs will impose significant barriers to the treatment of these conditions and also creates patient safety concerns, as appropriate and routine adjustments to medications would be delayed while the pharmacist waits for the physician's approval. For these reasons, OHA urges the Medical Board to delete subsection (A)(1)(i).

Subsections (A)(5)(b) and (c) require amendments to a consult agreement if an authorized pharmacist or physician is added or removed. This provision appears to be inconsistent with subsection (A)(1)(a) of this rule, which permits the consult agreement to identify the physicians and pharmacists authorized to enter the consult agreement not only by their individual name, but also by their practice group or based on institutional credentialing and privileging. If the consult agreement identifies the participating physicians and/or pharmacists by practice group or credentialing and privileging, it is unclear when an amendment would be required. Furthermore, in large institutions, where changes in staffing occur frequently, amendments could be required on a weekly, or, in some cases, more frequent, basis. The administrative burden associated with doing so would be significant without any corresponding increase in patient safety. OHA recommends deletion of this subsection.

Proposed Rule 4731-35-02

Subsection (A)(3) imposes very broad requirements regarding what a physician must communicate to a patient regarding the consult agreement. This language is significantly different from the Pharmacy Board's related rule, which not only exempts inpatient management of patient care, but also more narrowly defines what must be communicated to a patient when obtaining consent. See OAC 4729:1-6-01(H). Not only might the proposed language dissuade patients from allowing a pharmacist to participate in their care in a manner that is widely accepted as safe and effective, but it will create confusion regarding compliance with the inconsistent rules. For these reasons, OHA recommends that the language of this subsection mirror the language of the Pharmacy Board's rule, which requires patients to be notified that a pharmacist may be used in the management of their care and that the patient has the right to withdraw from the consult agreement.

Subsection (A)(6) requires the physician to ensure the pharmacist's training and experience. OHA believes this requirement imposes an unnecessary burden on physicians that will not improve patient care. Pharmacists complete rigorous training in pharmacology and pharmacotherapy during their education and

preparation for licensure, and they must complete continuing education requirements to maintain their licenses. OHA recommends deletion of this subsection.

Subsection (A)(7) requires physicians to "promptly review" the records of services provided to patients under the consult agreement, which we believe is a nebulous standard that creates administrative burden without improving patient care. The Pharmacy Board's rules already require that communication between the pharmacist and physician take place at regular intervals, and we believe this approach serves the physician, pharmacist, and other members of the care team well.

Subsection (B)(1)(a) requires physician approval prior to adjusting a dosage for controlled substances. For the same reasons noted above regarding proposed rule 4731-35-01(A)(1)(i), OHA urges the Medical Board to delete this requirement.

Subsection (B)(2) addresses the same issue that is addressed in Pharmacy Board rule 4729:1-6-02(A)(1)(d) but with different language. To avoid confusion and promote consistency, OHA recommends this subsection be replaced with the language from the existing Pharmacy Board rule.

Subsection (C)(4) would require the pharmacist to both notify, and obtain consent from, the physician before changing the duration of a treatment, adjusting a drug's strength, dose, frequency of administration, or route of administration, discontinuing a drug, prescribing a new drug, or ordering blood or urine tests. OHA believes this provision renders consult agreements completely useless and is contrary to the purpose for using consult agreements, which is to best utilize highly trained and skilled pharmacists to manage a patient's care, in partnership with the physician. This provision will result in significant interruptions in care, reduced access to care, and sub-optimal outcomes. OHA recommends this subsection be deleted.

Subsection (D)(1) would require the physician and pharmacist to meet on a regular basis and for the pharmacist to provide a detailed written report. OHA believes these requirements are an unnecessary administrative burden on physicians and pharmacists that will not improve patient care. The law and Pharmacy Board rules already require the physicians and pharmacists subject to a consult agreement to communicate at "regular intervals specified by the primary physician acting under the agreement" and to prepare a written report, if required by the physician. See ORC 4729.39(B)(6) and OAC 4729:1-6-02(A)(1)(g). OHA believes this subsection is overly prescriptive and recommends it be deleted.

Thank you again for the opportunity for OHA to share hospitals' perspective on these draft rules early in the process. We look forward to continuing to work with the Medical Board and other stakeholders to craft rules that align with those of other regulatory bodies and that continue to support and promote appropriate use of consult agreements, which are very effective tools to manage patient care.

Please feel free to contact me if you have any questions about OHA's comments.

Sincerely,

Sean McGlone
Sr. V.P. & General Counsel

From: McConaghy, John
To: Debolt, Sallie
Subject: Medical Board changes to pharmacist consultative agreements
Date: Friday, February 8, 2019 12:23:01 PM
Attachments: image001.png

To the State Medical Board,

I am writing to express my concerns with new language proposed with respect to collaborative arrangements between physicians and pharmacist's (4731-35-01 Consult agreements 4731-35-02 Standards for managing drug therapy). These proposed rules are burdensome, and are a big step back from the patient-centered, team based care that we have developed over the past several years. This is also the focus of CMS, Medicaid and the commercial payors. This team-based care is better for physicians and patients with better outcomes.

The proposed new requirement that the pharmacist notify the physician prior to any action which includes changing or discontinuing a drug, ordering tests such as urine or blood and that the pharmacist include a detailed description of the proposed action, and obtain the consent of the primary care physician essentially stops and reverses the progress we've made in improving the value of the care we deliver and it's quality.

I have worked with a clinical pharmacist for the past 5-6 years. She manages the insulin on my diabetic patients (she's also a certified diabetes educator) , provides bridging recommendations for patients on anticoagulation who need invasive interventions, and smoking cessation education just to name a few. I receive a detailed report from her for review following each patient encounter. Any test or pharmaceutical that she orders is cosigned by me. The new proposals will essentially remove these efficiencies, remove the expertise of critical members of the team and erode care.

Given the variety of environment's in which pharmacists collaborate, and the reality that one size fits all policies have unintended consequences, I would respectfully request an exception for pharmacists who practice in a team-based environment, within a providers office, such that the provider is available in real-time during all hours for which the pharmacist is managing patients.

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

John R McConaghy MD CPE FAAFP
Professor, Clinical Family Medicine
Vice Chair, Quality
Associate Director, Family Medicine Residency
Rardin Family Practice, 2231 N High St, Columbus, OH, 43201
614-293-2700 Office

john.mcconaghy@osumc.edu

From:	McConnell, Erin
To:	Debolt, Sallie
Cc:	Christ, Melissa; Farwig, Phillip
Subject:	proposed rule to pharmay collaboration changes
Date:	Wednesday, January 30, 2019 10:58:36 AM

Hello Ms Debolt and other committee members,

I am writing to share my experience with collaborating with pharmacy and my request NOT to tighten restrictions on the pharmacist's ability to collaborate with physicians and other APP. I work with Melissa Christ at OSU Wexner Medical Center at the satellite location of carepoint Lewis Center. The help that Melissa has provided in caring for my patients has been extremely valuable. She is quite knowledgeable in the management of hypertension / diabetes and also able to answer any question I have with regard to medication interactions, side effects, efficacy, etc. She has been instrumental in helping several of our diabetics regain control of their disease. She is extremely conscientious in her recommendations and I trust her implicitly. I feel similarly about the other clinical pharmacist with whom I have frequent contact, Phillip Farwig, with whom I collaborate at OSU Wexner Medical Center Martha Morehouse outpatient care facility. Phil has also been an excellent collaborator with our care of patients in the resident clinic, and this is a very high risk population who experience multiple barriers to care, financially, socially and medically. I am happy to discuss my positive experiences with any one involved in enacting this new legislation. I feel that additional restrictions would severely limit the benefit this has had for our patients

Sincerely

Erin E. McConnell MD
Internal medicine / pediatrics
OSU Wexner Medical Center
Carepoint Lewis Center
2250 Pullman Dr Ste 22
Lewis Center OH 43015

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

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Division of General Internal Medicine
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Columbus, OH 43221
614-293-4953 Phone
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2/5/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
Sallie.Debolt@med.ohio.gov

Dear Ms. DeBolt:

I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a physician that utilizes the services of pharmacists through collaborative practice agreements to provide care to my patients, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.

Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:
Erin E McConnell
E6658AF9B10F48C...

Erin E McConnell

MD

University Hospitals

February 7, 2019

Ms. Sallie DeBolt, Esq.
Senior Counsel, State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

Dear Ms. Debolt,

On behalf of University Hospitals' physicians, pharmacists, nurses, employees, and most importantly, the community we serve, we appreciate the opportunity to submit the following comments regarding proposed Ohio Administrative Code sections 4731-35-01 and 4731-35-02 regarding consult agreements for pharmacist management of a patient's drug therapy.

University Hospitals is a Cleveland-based super-regional health system that serves more than 1.2 million patients in 15 Northeast Ohio counties. The hub of our 18-hospital system is University Hospitals Cleveland Medical Center, a 1,032-bed academic medical center that encompasses UH Rainbow Babies & Children's Hospital; UH Seidman Cancer Center; and a medical-surgical complex boasting world-renowned excellence in every specialty. Our physician leaders and other experts are widely sought sources of thoughtful commentary and expertise on a host of medical and health-care topics.

While we appreciate the Medical Board's effort to ensure efficiency and efficacy, we are concerned that the rules, as drafted, may incentivize physicians to not enter into consult agreements with pharmacists and diminishes the role of the pharmacist in managing a patient's medication. Therefore, we respectfully submit the following comments for your consideration.

4731-35-01(A)(1)(i)
We recommend the requirement that a physician provide prior approval to adjustment to the dose of a controlled substance be removed. While some progress has been made, Ohio continues to struggle with the opioid epidemic, and particularly, managing the number of opioid prescriptions. Efforts to limit pharmacists' ability to manage controlled substances could potentially perpetuate the problem of opioid overuse by preventing pharmacists from adjusting doses down or discontinuing opioids that are no longer needed for the patient.

4731-35-01(A)(5)(b) and (c)
This section requires a consult agreement be amended every time a physician or pharmacist is added or removed. Such a requirement is overly burdensome and unnecessary as such names are usually included in an addendum, not the consult agreement itself.

4731-35-02(A)(3)(b), (c) and (d)
The proposed language regarding what and how a physician must communicate to a patient is overly broad and may discourages patients from allowing a pharmacist to participate in their care

through a consult agreement. This runs contrary to what is the best and the most efficient mode of care for the patient. We recommend sub-bullets (b), (c), and (d) be removed from the rules. Alternatively, the Medical Board could consider language similar to Ohio Pharmacy Board rule 4729:1-6-01(H) which requires patients be notified that a pharmacist may be utilized in the patient's care and that the patient maintains the right to withdraw from the consult agreement.

4731-35-02(A)(6)
The requirement that the authorizing physician ensure the managing pharmacist's training and experience are adequate is an excessive burden on the physician. Pharmacists are extensively trained in pharmacology and pharmacotherapy during their prerequisite education to become licensed. Additionally, a pharmacist must satisfy continuing education requirements to maintain his or her license. Therefore, further scrutiny of this training and experience by the authorizing physician is redundant and not the highest and best use of clinical time.

4731-35-02(C)(4)(a) and (b)
University Hospitals recommends this proposed section be removed from the rules. This section requires a pharmacist to notify and obtain consent of the physician prior to taking any action involving: duration of treatment, adjustment to a drug's strength, dose, dosage form, frequency of administration or route of administration; discontinuation of a drug; prescription of a new drug; or, ordering urine or blood tests. University Hospitals is concerned that this requirement seems to run counter to the very purpose and goal of the consult agreement, which is to establish when a pharmacist can adjust medical therapy without prior consultation. This requirement would demand additional, unnecessary interaction between a pharmacist and physicians that will delay care and lead to inefficiencies for the patient. It would likely discourage physicians from entering into consult agreements with pharmacists.

4731-35-02(D)(1)
The requirements of 4731-35-02(D)(1) would have a similar impact as those included in 4731-35-02(C)(4)(a) and (b) as described above. Therefore, we recommend removal of the section from the draft rules. Such a requirement runs counter to the purpose of a consult agreement and would likely result in fewer physicians entering into consult agreements with pharmacists.

Thank you once again for the opportunity to comment. UH remains ready and willing to be an active partner to assist as the Medical Board continues in the rulemaking process.

Sincerely,

Cliff Megerian, M.D.
President, University Hospitals Physician Network and System Institutes

William Warren Brien, M.D.
Chief Medical & Quality Officer, University Hospitals

THE OHIO STATE UNIVERSITY

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February 8, 2019

Sallie DeBolt, Esq, Senior Counsel
State Medical Board of Ohio
30 E. Broad St., 3rd floor
Columbus, OH 43215

Dear Ms. DeBolt:

As a practicing pharmacist in the State of Ohio and a faculty member at The Ohio State University, I appreciate the opportunity to provide comments on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

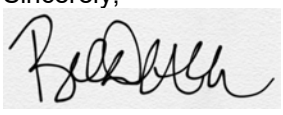
Over my pharmacy career spanning more than two decades, I have had the opportunity to provide care as part of health care teams in a variety of community-based practices including patient centered medical homes and in ambulatory care clinics that provided care to underserved populations. I also provided direct patient care within the very first anticoagulation management service at OSU. In these practice settings, consult agreements were critical to the provision of the team-based care and in affording health care access to patients.

I am concerned about the language included in 4731-35-02 Standards for managing drug therapy in section (C) (4) and section (D) (1). This language will limit the team-based approach to care that I have seen where pharmacists utilizing consult agreements achieved patient health outcomes that far exceeded traditional clinical outcomes and this language will hinder efficient and effective models of patient-centered practice due to the prohibitive requirements placed on physicians and pharmacists. Ohio currently ranks in the bottom quartile for chronic health outcomes and the language proposed will limit our ability to provide care to those Ohioans who don't have access to primary care.

Based on my practice experience and roles in advancing team based models of care, I ask that the State Medical Board of Ohio remove in entirety section (C) (4) and section (D) (1) from 4731-35-02 Standards for managing drug therapy.

Thank you for the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,



Bella Mehta, PharmD, FAPhA

From: Menkhaus, Tara (menkhata)
To: Debolt, Sallie
Subject: Collaborative practice agreements
Date: Thursday, February 7, 2019 12:20:21 PM

Ms. Debolt,

I hope you are having a great day. I just wanted to reach out to you about the proposal that will address the recent passing of provider status in Ohio for pharmacists.

I am graduating from the University of Cincinnati in April, and I was so excited when that bill was signed, knowing that my future as a pharmacist just became infinitely brighter. I work at Kroger pharmacy and every single day, I see changes that I could make to improve the quality of my patients' care. These changes are rarely radical and and frequently revolve around published guidelines or landmark trials. But they would make a very significant difference for the quality and even longevity of these patients' lives.

I have also seen minors mistakes in prescriptions or dealt with insurance rejections that do not require a quorum to resolve, but legally require the pharmacist to call the issuing provider to verify a change. I know physicians do not wish to hear from the pharmacist when we change from ProAir HFA to Ventolin HFA because of cost for the patient. A pulmonologist recently complained to me of this very thing. But what could I say? The law grants me no autonomy with my license, no right to use the specialized knowledge I have accumulated from my years of school and practice. I must always ask permission from a physician, as if I am not equally responsible under the law for a patient's care.

Physicians and pharmacists are on the same team: the patient's team. I have been looking forward to the day when we can practice together with trust. This proposal, like the medical board's resistance to pharmacist provided immunizations, worries me that the medical profession does not trust their pharmacists and I am here to assure you that pharmacists are devoted to providing excellent patient care. I am astounded on a daily basis by the determination my fellow pharmacists exemplify in practice, even when there are phones, and faxes and lines of people with unhappy faces and unkind words. This is a profession that does not buckle under pressure or meanness, and it never fails to show up even when its efforts are so rarely recognized. This is a profession that manages its role with severity - we are stalwart in ensuring the proper use of medication, and we do not grant that privilege to simply anyone who seeks it. The profession of pharmacy is as exacting of its members as that of medicine, and the appropriate training and credentialing will and has been occurring to allow pharmacists to move into new roles.

In addition to our doctorate degree, one and two year residency programs, board certifications and a multitude of training modalities, safeguard the care of patients. The

profession is exacting in the degree of expertise it requires of its pharmacists and in what roles they can attain.

I don't know how the profession of pharmacy and the marketplace will unfold with provider status. It will certainly take years for it to adjust to its new role. But I ask you not to limit my profession. I ask you to not determine the fate of a beautiful profession that has so much to offer to patients and to physicians. Pharmacists can and will be the bridge in knowledge that physicians need. Pharmacists can and will be the answer to physician burnout. Pharmacists can and will be the answer to lower costs of care and easier access for patients. Pharmacists can and will be the solution for the gaps in care common with heart failure with reduced ejection fraction, chronic obstructive pulmonary disease, diabetes mellitus, post-myocardial infarction management, and many other. We know the drugs, the guidelines, the conditions, the costs, and we know the patients. We know more than is sufficient to practice under a collaborative practice agreement and we deserve respect and trust to make these decisions without asking permission. If the profession of medicine trusts the judgment of physician assistants, then pharmacists have more than earned the same.

Please, I ask you, to allow us to live up to the role that we have been training for, to allow us the right to practice according to the clinical judgement we have developed, to allow us to provide the best possible care we can to patients, and to allow us to support the medical profession to the best of our abilities. Please, allow us to help you. I want our professions to work together in harmony and goodwill, with mutual respect for our respective areas of expertise.

When considering again your proposal, please inquire as to the nature of the motivation behind it. And once you have elaborated on its exact concerns with the potential new role for pharmacists, please seek out those who can address them best - the pharmacists themselves from various backgrounds - community, institutional, long-term care, etc. Kelly Epplen, Associate Dean of my college, I know would be thrilled to speak with you. She has supported and led many pharmacist initiatives, as well as expanded new frontiers for pharmacist roles in multiple states. Additionally, pharmacists or even the State Medical Board in North Carolina can allay your fears, for pharmacists have the greatest scope of practice within that state.

Our profession is often misunderstood as one that simply spent years in school to learn how to count by fives. Please, confirm your impressions before proceeding with this proposal. I love my profession and the members of it; I love what my profession contributes to the care of my patients, but I am so looking forward to what we can do in the future. Please help us to unfurl our wings and stand on the front lines with you, not behind you.

Thank you so much for your time.

Tara Menkhaus
PharmD Candidate 2019
University of Cincinnati
James L. Winkle College of Pharmacy
Kroger Pharmacy Intern

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

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February 7, 2019

To: Sallie Debolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

To Whom It May Concern:

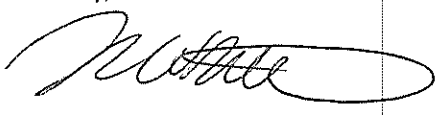
As a practicing physician in the state of Ohio, I would like to thank you for your service to the State Medical Board of Ohio and for all you do to enhance the care of our fellow Ohioans. I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a physician that currently utilizes the services of pharmacists as independent practitioners through collaborative practice agreements, I am in favor of pharmacists continuing to provide patient care in this manner as a means to improve quality, safety, and efficiency in our health system. The utilization of consult agreements between physicians and pharmacists at The Ohio State University Wexner Medical Center has improved patient outcomes and helped control healthcare costs. I believe pharmacists are a vital part of the interdisciplinary team and are vital for successful provision of high quality clinical services and improving access to care. I am supportive of the continued incorporation of pharmacist services into my day to day practice. I have appreciated the updates by the Board of Pharmacy over the last few years. The rules proposed by the Medical Board are generally acceptable and in line with current pharmacy rules.

However, I feel several provisions are converse to current practice and limit the utility of consult agreements. Sections (A)(2) and (C)(4) of 4731-35-02, in current form, would increase provider burden and decrease efficiency of the current system, significantly impacting the provision of healthcare. Furthermore, (C)(4) would reduce quality of care by discrediting pharmacists' clinical decision making capabilities already authorized under agreed collaborative practice agreements and accompanying scope of practice. We are asking this language regarding "at least one time per year" in (A)(2) and the entirety of (C)(4) be removed (this is covered in (A)(1) of 4731-35-01).

If you have any questions, please do not hesitate to contact me. Thank you for your consideration.

Sincerely,



M. Wesley Milks, MD
Assistant Professor of Clinical Medicine
Division of Cardiovascular Medicine, Department of Internal Medicine
The Ohio State University Wexner Medical Center Heart and Vascular Center
452 W 10th Avenue
Columbus, OH 43210
Office: 614-366-1256

OhioHealth

TO: State Medical Board of Ohio

FROM: Dr. Judson Millhon

RE: Response to Proposed Rules 4731-35-01 and 4731-35-02: Consult Agreements

Thank you for the opportunity to provide comments on the Medical Board's recently proposed rules regarding consult agreements between pharmacists and physicians. Consult agreements have been an invaluable resource for physicians to expand access and improve quality, especially since the revision of the law in 2016. In general, I appreciate the added clarity that the medical board has provided specific to physician participation in a consult agreement. However, some of the new provisions outlined in the proposed rules create a significant burden that would outweigh many of the benefits of a consult agreement, and would negatively impact patient care.

Specifically, the requirements for notification and consent prior to action by a pharmacist, as well as the requirement for regular meetings to review a written consult report represent my greatest concerns. The current regulations allow physicians and pharmacists to reach mutually agreeable terms that ensure adequate collaboration, expertise, oversight, and quality assurance mechanisms exist within the consult agreement. Physicians already have the flexibility to engage in a consult agreement that addresses training, communication, and quality assurance mechanisms that are appropriate for the medication management that is being performed.

Requiring a physician's consent prior to each action adds significant time without providing any benefit to the patient. Consult agreements already require a "description of the procedures, decision criteria, and plan the managing pharmacist is to follow in acting under a consult agreement." Asking a physician to confirm that the decision criteria and plan are correct prior to every change is unnecessary and only adds burden to the pharmacist and physician. Adding complexity into a medication adjustment may also cause a patient to experience suboptimal care while consent is being obtained.

Similarly on the requirement for regular meetings, the law already requires "communication between a pharmacist and physician acting under a consult agreement shall take place at regular intervals specified by the primary physician acting under the agreement." Additional requirements for regular meetings and written consult reports only add complexity and administrative burden to an already safe collaborative

Ultimately, I believe that these proposed rules run counter to the efficiencies that the law revision was intended to provide in 2016, and I recommend that the State Medical Board of Ohio reconsider adding any new requirements or barriers to care into the rules. I appreciate your consideration and the opportunity to provide feedback on the proposed rules. If you have any questions or would like to further discuss our comments, please reach out at the contact information below.

Judson S. Millhon Jr. MD, FACC, FSCAI

Jud Millhon

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

Department of Internal Medicine
Division of General Internal Medicine
Martha Morehouse Pavilion
Suite 2335
2050 Kenny Road
Columbus, OH 43221
614-293-4953 Phone
614-293-6890 Fax

February 7, 2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

Dear Ms. DeBolt:

I would like to thank you as a practicing pharmacist in the state of Ohio for your service to the State Medical Board of Ohio and for all you do to enhance the care of our fellow Ohioans. I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As an ambulatory care pharmacist who has been involved in collaborative practice agreements to provide care to patients, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.

For multiple years, I have been managing patient's anticoagulation therapy through collaborative practice agreement. During these appointments for anticoagulation management the patient's warfarin dose has been adjusted as deemed necessary based upon INR and potential or current medication interactions. Collaborative practice agreements have made it possible for patients to leave their anticoagulation appointment in a timely manner with in hand warfarin dosing instructions which can greatly improve the adherence and understanding to this new warfarin dosing regimen. The proposed language would not allow for patients to leave with dosing instructions in hand in timely manner and would likely result in possible inadvertent incorrect warfarin dosing instructions if it becomes necessary to contact patients by phone with dosing instructions after it has been reviewed with the physician.

Based on my personal experience through practice and that I feel that the citizens of Ohio deserve the highest level of care from members of their healthcare team I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

Ginny Mitchell, PharmD, BCPS, CLS
Clinical Pharmacist
OSU General Internal Medicine

February 8, 2019

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy

Dear Ms. Debolt:

I am writing in regard to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. Consult Agreements for Pharmacist Management of Patient's Drug Therapy is of interest to me due to my current collaborative practice with physicians as a pharmacist practicing inside the ProMedica Health System in the metro Toledo area. Every day, pharmacists manage medication therapy for vancomycin, aminoglycosides, warfarin, and other medications based on consult orders from our physician care team partners.

Currently, consult agreements allow physicians to work collaboratively with pharmacists to manage medication therapy. In our practice, we have pharmacists who independently manage warfarin, vancomycin, aminoglycoside and other therapies through consult agreements. Pharmacists improve the continuity of care, level of care and overall quality of the patients' health and healthcare experiences. Additionally, as pharmacists, we serve as drug information experts and educators for both our providers and patients. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

The proposed rule changes, specifically those that require pharmacists to notify the physician of any action prior to implementation (4731-35-02 C-4) would discourage collaborative practice and obstruct our current quality-based workflow. Pharmacists are the medication experts within the interdisciplinary patient care team making their expertise imperative to the care of patients. This expertise and evidence-based care can be managed independently within an agreed upon scope of practice. The removal of the autonomy afforded to pharmacists through consult agreements would lead to a tedious and inefficient process for medication management that would negatively impact the pharmacist, provider and patient. Logistically, busy providers may not always be available, making it difficult for both the pharmacist to reach them. For example, if antibiotic dosing is delayed in a septic patient because a pharmacist cannot confirm the dose with the prescriber, there is an increased risk of death. Timeliness of antibiotics is essential to improve outcomes. In this case the pharmacist is the best resource to manage treatment and ensure timely care is provided. We recommend that this requirement be removed from the proposal.

At ProMedica Flower Hospital, we manage 650 to 900 consults each month (antibiotics, anticoagulants, TPN, and medication weaning). Each consult is documented in the medical

record with a progress note, and any changes are documented in subsequent progress notes. These consults are voluntary from our physicians who trust our services. Without these consults, the physicians could expect thousands of additional calls each month which would interrupt their workflow and potentially cause errors. The prescribers understand our role as medication experts.

In summary, I strongly advise the proposed rule change not be approved and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,

Kristen Monarch-Mocek, PharmD, RPh
Clinical Pharmacy Manager, ProMedica Flower Hospital
5200 Harroun Road
Sylvania, OH 43560
419-824-1018

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2/6/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
Sallie.Debolt@med.ohio.gov

Dear Ms. DeBolt:

I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a physician that utilizes the services of pharmacists through collaborative practice agreements to provide care to my patients, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.

Current consult agreements allow physicians to determine patients who are best suited for this valuable intervention and still allow for physician oversight of care. Through our practice, and through the collaborative relationships that we've developed with our pharmacy team, I have seen patients benefit significantly from consult agreements. I feel comfortable with this arrangement as I still have control over which patients are included in the collaborative agreement and I still have the ability to oversee and change plans if needed. However, increased flexibility in allowing well trained pharmacists to make adjustments to established treatment plans makes sense in our current environment of utilizing members of the inter-professional team to the greatest degree possible.

Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:
Jared Moore
91DF67835F574BD...

Jared Moore

Internal Medicine

THE OHIO STATE UNIVERSITY
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2/7/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
Sallie.Debolt@med.ohio.gov

Dear Ms. DeBolt:

I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a physician that utilizes the services of pharmacists through collaborative practice agreements to provide care to my patients, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.

I heavily utilize a clinical pharmacist in my practice. I have seen several benefits to this, but the greatest benefit is in the outcomes in my diabetic patients. The pharmacist follows them in between my visits with the patients, and adjusts medications as needed. As a result, the diabetic control in my most difficult patients is markedly improved. If the pharmacist did not have the ability to make these changes independently, my patients would be deprived of a resource that is changing their lives, and we would be taking a great step backwards in the provision of medical care.

Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:
Robert A Murden
6B7D807A3FAD464...

Robert A Murden

MD

E. Michael Murphy, PharmD
5470 Cameron Ellis Dr.
Apt. 107
Westerville, OH 43081

February 3, 2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

Dear Ms. DeBolt:

I would like to thank you as a practicing pharmacist in the state of Ohio for your service to the State Medical Board of Ohio and for all you do to enhance the care of our fellow Ohioans. I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

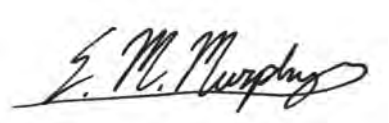
As a pharmacist, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.

I have seen pharmacists provide high quality and valuable care to their patients through consult agreements. In my personal experience patients are able to reach their therapeutic goals more quickly when they have more access points to members of their healthcare team. Additionally, I have seen physicians be able to provide care to more patients when they utilize the pharmacist as an extension of the care that they provide.

Based on my personal experience, through practice and that I feel that the citizens of Ohio deserve the highest level of care from members of their healthcare team I would ask the State Medical Board of Ohio to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,



E. Michael Murphy, PharmD

Cleveland Clinic

Adam L. Myers, M.D.
Chief, Population Health
Director, Cleveland Clinic Community Care

February 7, 2019

Ms. Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 East Broad Street
3rd Floor
Columbus, OH 43215

RE: Proposed Rules: 4731-35-01, 4731-35-02

Submitted electronically via:Sallie.Debolt@med.ohio.gov

Dear Ms. Debolt:

Cleveland Clinic is a not-for-profit, integrated healthcare system dedicated to patient-centered care, teaching and research. Our health system is comprised of a main campus, 13 community hospitals, 19 family health centers and 3 wellness centers with over 3,600 salaried physicians and scientists. Last year, our system had over seven million patient visits and more than 229,000 hospital admissions

We appreciate the opportunity to comment on the Medical Board's proposed rules governing consult agreements between physicians and pharmacists. We believe it would be helpful to both the physicians and pharmacists, the parties to the consult agreements, for there to be consistency between the Medical Board and the Pharmacy Board rules.

Pharmacists have become an integral part of our clinical care team. We work together at top of competency to meet our patients' needs. We share your commitment to promoting safe and reliable care for the all patients and appreciate the opportunity to provide comments to the proposed changes. This letter will delineate our respective input on each proposed change. However, I want to first express that if implemented as proposed, these changes would constitute a dramatic step backward in how we work as a team. The changes would disrupt what has proven to be a safe, efficient, and thoughtful sharing of responsibility for medication management.

Our detailed comments on specific sections of each of the rule are below.

4731-35-02 (C)(4)(a) and (b)
Proposed language: When the managing pharmacist changes the duration of treatment for the current drug therapy; adjusts a drug's strength, dose, dosage form, frequency of administration, route of administration, discontinues a drug, prescribes a new drug, or orders urine or blood tests, as authorized under section B)(1)(a), and (B)(1)(b) of this rule, the managing pharmacist must:

The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195
Tel 216 444-9660
myersa8@ccf.org

(a) Notify the primary physician prior to any action. The notification shall include a description of:

(i) The decision criteria considered by the managing pharmacist in deciding to conduct an authorized action; and

(ii) A description of the proposed authorized action the managing pharmacist intends to conduct.

(b) Obtain the consent of the primary physician to conduct the proposed authorized action.

Cleveland Clinic Comments

We are concerned with the language in this section as the purpose of consult agreement is to establish the conditions and criteria under which a pharmacist can adjust a patient's medical therapy without consulting the physician prior to the change.

The proposed language will require a pharmacist to notify a physician prior to any action and obtain consent of the primary physician prior to any action. If adopted as written, we are concerned with the significant increases in workload that physicians will face. For example, Cleveland Clinic pharmacists have operated warfarin clinics for decades. Currently, the pharmacist team cares for over 5,000 patients. Pharmacists see patients every 10-15 minutes at a volume of over 500 encounters per day across the team. The proposed rules would require the pharmacist to contact an individual physician before adjusting the therapy to receive permission to adjust, resulting in substantial interruptions in our primary care and cardiology physicians' schedules. Even assuming efficient discussion and decisions are made (5 minutes per case), the proposed rules will add over 40 hours of unnecessary work to our physicians each day.

Additionally, Cleveland Clinic has invested in our patients' health by embedding clinical pharmacists into primary care practice settings and multiple specialties. These pharmacists see patients with highly challenging medication regimens where our primary care and specialty care teams identify they need help to achieve the patient's clinical goals. When our physicians choose to partner with pharmacists to manage these patients, they are seen more quickly and achieve better outcomes. Additionally, the pharmacist is a valuable resource, permitting the physicians to see patients with needs outside the pharmacists' scope of practice. The current proposed rules will require physicians to review and determine therapy adjustments for over 180 patients per day on top of their current workload, resulting in an added 30 hours of physician workload per day.

In both cases above, the added requirement to obtain permission prior to action will result in longer patient visits and fewer total visits available to patients each day. The proposed rules will decrease patient access to both physicians and pharmacists, resulting in lower-quality, less efficient care

Therefore, we suggest that the language of this rule mirror that of the current Pharmacy Board Rule 4729:1-6-02(g) which reads "A description of how communication between a managing pharmacist and physician acting under a consult agreement shall take place at regular intervals specified by the physician who authorized the agreement. The agreement may include a requirement that a managing pharmacist send a consult report to each consulting physician."

4731-35-01(A)(1)(b)

Proposed Language: A consult agreement shall include all of the following:

(1)(b)A description of the patient's informed consent to drug therapy management pursuant to the consult agreement.

Cleveland Clinic Comments
For consistency between the rules, we suggest the language be changed to mirror the current pharmacy board rule listed below.

Pharmacy Board Rule 4729:1-6-01 (H)
"Communicated" as used in division (B)(4) of section 4729.39, means consent shall be obtained from each individual patient participating in a consult agreement. With the exception of inpatient management of patient care at an institutional facility as defined in rule 4729-17-01 of the Administrative Code, consent shall be obtained prior to a pharmacist managing a patient's drug therapy and shall communicate all of the following:
(1) A pharmacist may be utilized in the management of the patient's care; and
(2) The patient's or an individual authorized to act on behalf of a patient's right to elect to participate in and withdraw from the consult agreement

4731-35-01 (A)(5)(a)(b) and (c)
Proposed Language: Amendments to the consult agreement are required when:
(a) The scope of the managing pharmacist's permitted procedures expands past what was contemplated within the agreement; or
(b) The subtraction, or addition of an authorized pharmacist; or
(c) The subtraction or addition of an authorized physician; or
(d) Other significant changes to the existing agreement

Cleveland Clinic Comments
We agree with (a) that a new agreement should be written and signed if the pharmacist's procedures expand past what is contemplated within the agreement. However, we recommend that both (b) and (c) be eliminated from the rule because the names of physicians and pharmacists are kept as an addendum to the agreement. We believe that writing and signing a new agreement each time there is a staff change is unduly burdensome to the process.

4731-35-02 (A)(2)
Proposed language: The physician must have an ongoing physician-patient relationship with the patient whose drug therapy is being managed, including an initial assessment and diagnosis by the physician prior to the commencement of the consult agreement. The physician shall periodically assess the patient, at least one time per year.

Cleveland Clinic Comments
We believe the Medical Board should strike the language "at least one time per year" above and instead allow the physician to determine the frequency of periodic assessment based on clinical judgment.

Ohio Revised Code 4729.39(A)(1)
Each physician has an ongoing physician-patient relationship with each patient whose drug therapy is being managed.

4731-35-02 (A)(3) Standards for managing drug therapy
Proposed Language: The physician, prior to the effective date of the consult agreement, and prior to a pharmacist managing the patient's drug therapy, shall communicate the content of the proposed consult agreement to each patient whose drug therapy is managed under the agreement, in such a

manner that the patient or the patient's representative understands scope and role of the managing pharmacist, which includes the following:
(a) That participation in the consult agreement is voluntary and that the patient may choose not to participate;
(b) That the agreement will not be utilized unless the patient or the patient's authorized representative consents to the consult agreement;
(c) That the consent can be revoked by the patient at any time; and
(d) That the consult agreement and the patient's consent will be disclosed to the patient's primary care physician and any other treating physician or healthcare provider

Cleveland Clinic Comments
We believe that the Medical Board should mirror the language of the Pharmacy Board to promote consistency. Below is the Pharmacy Board rule.

Pharmacy Board Rule 4729:1-6-01 (H)
"Communicated" as used in division (B)(4) of section 4729.39, means consent shall be obtained from each individual patient participating in a consult agreement. With the exception of inpatient management of patient care at an institutional facility as defined in rule 4729-17-01 of the Administrative Code, consent shall be obtained prior to a pharmacist managing a patient's drug therapy and shall communicate all of the following:
(1) A pharmacist may be utilized in the management of the patient's care; and
(2) The patient's or an individual authorized to act on behalf of a patient's right to elect to participate in and withdraw from the consult agreement

4731-35-02(B)(2)(b)
Proposed Language: The primary physician must also establish:
(a) Decision criteria the managing pharmacist is to consider when acting pursuant to sections (B)(1)(a), and (B)(1)(b) of this section; and
(b) A plan the managing pharmacist is to follow prior to conducting an authorized action pursuant to sections (B)(1)(a), and (B)(1)(b) of this section; and
(c) A plan the managing pharmacist is to follow after having conducted an authorized action pursuant to sections (B)(1)(a), and (B)(1)(b) of this section.

Cleveland Clinic Comments
We suggest that the Medical Board adopt the language of 4727:1-60-02 (below) that the Pharmacy Board put into place to address this issue.

Pharmacy Board Rule 4727:1-6-02 Consult Agreement
(A)(1)(d) A description of the procedures, decision criteria, and plan the managing pharmacist is to follow in acting under a consult agreement. Such a description should provide a reasonable set of parameters of the activities a managing pharmacist is allowed to perform under a consult agreement

4731-35-02 (A)(3) (d)
Proposed Language: That the consult agreement and the patient's consent will be disclosed to the patient's primary care physician and any other treating physician or healthcare provider.

Cleveland Clinic Comments

We are concerned with this language because it is not always feasible for physicians to be aware of all of the other treating physicians or healthcare providers unless the patients specifically identifies them and asks that their records be submitted to them.

Therefore, we suggest that the language be changed to state "the information will be included in the patient's medical record and available to other treating providers as well as other providers as requested."

4731-35-02 (A)(7)

Proposed Language: The physician shall promptly review the records of all services provided to the patient under the consult agreement

Cleveland Clinic Comments

We suggest the Medical Board adopt the same language used in OAC 4729:1-6-02(A)(1)(g) -- A description of how communication between a managing pharmacist and physician acting under a consult agreement shall take place at regular intervals specified by the physician who authorized the agreement. The agreement may include a requirement that a managing pharmacist send a consult report to each consulting physician

4735-05(C)(2)

Proposed Language: Verification that physician diagnosis is within the physician's scope of practice.

Cleveland Clinic Comments

We are concerned with this language as it appears to put the responsibility for determining a physician's scope of practice on the pharmacist. We believe this determination should be made by the institution's privileging and credentialing body rather than the pharmacist.

4731-35-02 (D)(1)(a)(b)(c)(d) and (e)

Proposed Language: (D) Continuous quality improvement program. The following should be included in the development of a continuous quality improvement program in order to evaluate the effectiveness of patient care and ensure positive patient outcomes:

(1) Regular meetings. The primary physician and managing pharmacist must meet on a regular basis as established in the consult agreement, during which the managing pharmacist is to provide the primary physician with a written consult report, detailing:

(a) Changes or modifications made to patient's drug therapy and the decision criteria used by the managing pharmacist;

(b) Urine or blood tests authorized by the managing pharmacist, and the decision criteria used by the managing pharmacist;

(c) Evaluations made by the managing pharmacist;

(d) A summary of the managing pharmacist's annual follow-up consultation with patient;

Cleveland Clinic Comments

We are concerned that this section would create a tremendous burden for physicians as they would have to review each intervention completed by the pharmacist. Similar to our comment above, we feel that the language below addresses this situation by requiring physicians to establish in advance how pharmacist practice is reviewed.

Pharmacy Board Rule OAC 4729:1-6-02(A)(1)(g) -- A description of how communication between a managing pharmacist and physician acting under a consult agreement shall take place at regular

intervals specified by the physician who authorized the agreement. The agreement may include a requirement that a managing pharmacist send a consult report to each consulting physician

Thank you for conducting a thoughtful process that allows us to provide input on such important issues. Should you need any further information, please don't hesitate to contact me.

Sincerely,

Adam Myers, MD

Dear Ms. DeBolt:

We would like to thank you for your service to the State Medical Board and for all you do for the care of our state's citizens. We appreciate the opportunity to comment on the board's draft rules on 4731-35-01 consult agreements and 4731-35-02 standards for managing drug therapy. We, as the student body of The Ohio State University College of Pharmacy, represent our individual voices and not that of The Ohio State College of Pharmacy or The Ohio State University.

As student-pharmacists, we are concerned about language included in 4731-35-02 standards for managing drug therapy in section (C)(4) and section (D)(1). Our curriculum is largely based on our ability to provide quality, individualized patient care as it pertains to the management of patient's disease states and medications. We spend several years learning the same guidelines and treatment options that physicians learn with additional training in pharmacology and pharmacotherapy. We practice the application of this knowledge through a variety of experiences on rotations and at work.

As proposed, this language would limit pharmacists' ability to assist patients with their medication management, and thus inhibit our ability as students to learn valuable skills we will use to improve patient health in our role as healthcare professionals. Through current collaborative practice opportunities, the students at Ohio State have already been learning how to collaborate with physicians though experiential rotations and have witnessed first-hand how beneficial a pharmacist is to the patient care process and healthcare team. To enhance patient outcomes, the continued collaboration between pharmacists and physicians through collaborative practice is necessary, not the further fragmentation of patient care that would likely take place with the way the rules are being proposed to be re-written

With everything we have learned about the opportunities to improve health outcomes in our state and the vigor of our developed Pharm.D. curriculum, we believe the citizens of Ohio deserve access to the highest level of care from all members of their healthcare team. We ask the State Medical Board of Ohio remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 standards for managing drug therapy.

Again, we appreciate the State Medical Board of Ohio providing us with the opportunity to comment on the board's draft rules on 4731-35-01 consult agreements and 4731-35-02 standards for managing drug therapy.

Sincerely,
Doctor of Pharmacy Students of The Ohio State University College of Pharmacy

The following personal stories were provided from students of The Ohio State University College of Pharmacy:

“At my ambulatory care rotation, I assisted my preceptor in calling patients who were recently started or had recent changes in insulin. The pharmacist was able to adjust their insulin regimens based on their fasting glucose levels without the immediate approval of a physician. With the new CPA policies, my preceptor would not be able to so quickly and diligently adjust regimens to improve patient outcomes and reduce the burden of care in their clinic that serves roughly 100 patients per day”. – Andrew M

“In institutional settings, these agreements are of great importance to providing care. For example, being able to adjust vancomycin or aminoglycoside doses based on levels for patients makes the patient care process safer and more effective, allotting more time for physicians to do other patient care measures and pharmacists to take care of things they are specifically trained to evaluate and handle. Language in the current draft would reverse much of this and would make these processes more cumbersome and inefficient for providers” – Cassie R

“During an overnight rotation at OSUWMC last semester, my preceptor (a pharmacist with IV antibiotic dosing privileges) asked me to help him work up a patient and call the nurse for a vanco trough at 0430. The trough value came back significantly below goal. The vancomycin was dosed too low with too long of an interval, based on the indication, trough goal, and patient’s kidney function. With his consult agreement, he was able to adjust the dose using his clinical judgement and pharmacology expertise. Once he adjusted it, the order was able to go through and be compounded and delivered to the patient by 0500. Under the new CPA rules proposed by the Ohio Medical Board, how would that scenario I described above change? If I understand the new rules correctly, first, we would need permission to access the patient’s medical records. Then, we would need permission by that same physician to approve the dose. I don’t have much confidence this would happen in a timely or efficient manner, especially at 0430. This is not good for physicians or pharmacists, and it is certainly not good for patients. Pharmacists, alongside physicians, are some of the most highly trained personnel in the hospital, and in the medical field in general. We go to school for 8 years, many with 1-2-year residences after graduation. Much of our training in school revolves around making therapeutic decisions using our pharmacological expertise. Our role in collaborative, evidenced-based patient care should not be reduced to archaic roles of pharmacists from decades ago. Furthermore, the present and future roles of pharmacists should not be defined by sweeping proposals from the State Medical Board. The profession of pharmacy should be defined by our addition to patient-centered care, ensuring drug therapy optimization and drug safety, and improving patient outcomes as a result. One thing you must ask yourself has a healthcare professional is, how is this helping my patients? I cannot find a sound answer to that question in regards to this proposal. I strongly urge the board to not pass these proposed changes to CPAs, and to continue to allow physicians and pharmacists to practice collaboratively in an efficient manner.” – Anonymous

“I was able to spend a month with a pharmacist during my November APPE rotation that was part of a CPA. The patients that he cared for were all very appreciative of the level of care he was able to provide. He was able to adjust their medication regimens based on objective and subjective findings and was able to order labs as appropriate. The level of autonomy that he had allowed him to have more time with his patients discussing their therapy and disease state as opposed to having to discuss every change with the doctor. He was up to date on all of the new therapies for diabetes and even spent time educating the providers he worked with on new insulin therapies and formulations. He was able to provide a level of expert care for these uncontrolled patients that they were not getting before. I was amazed at how over 90% of all the patients we saw together were hitting their target goals. Integrating a pharmacist into the care team does not take away from the vital work that physicians do to care for their patients, but it allows them to focus on diagnosing and more thoroughly evaluating patients while allowing the pharmacist to focus on the drug therapy. Working collaboratively together leads to better outcomes and better patient satisfaction. I have noticed that patients get very frustrated dealing with the complexity of the healthcare system and all the hoops that everyone involved has to jump through. Allowing pharmacists more autonomy to care for their patients will also allow things to function more smoothly for the patient. Overall, the level of patient satisfaction and patient outcomes I witnessed was a sign that we should be doing more to include pharmacists in the care team, not creating more barriers.” – Ryan S

“The collaborative practice agreement that I have operated under at the Columbus Free Clinic is one of the reasons that we were able to take wait times from 4 hours to 2 and increase the patient population each night to better aid the underserved population in our area.” – Sam S

“I've witnessed first-hand the beneficial effects of collaborative practice agreements (CPAs). In outpatient clinics, pharmacists are often more readily available to advise patients with chronic disease states than physicians. A pharmacist I have worked with manages patients at her practice site. While the physicians in her clinic are busy all day with scheduled appointments, she is able to follow-up with patients to discuss recent therapy changes or chronic care. Patients are able to express concerns and report adverse effects, which she is then able to help them manage. The physician is notified of any changes and the circumstances that warranted the changes. Patients receive more consistent quality care and receive greater benefits from medication therapy. The physicians are more likely to stay on schedule and uninterrupted in providing care for their patients during the day. The physicians always express their gratitude for the insights the pharmacist provides and for the quality care she provides to their patients. Patients express their gratitude for the close contact and regular monitoring they receive. The addition of a pharmacist with a CPA to the clinical care team is invaluable at this site.” –Steve M

“When I shadow the pharmacists at the hospital during a night shift, I saw pharmacists correcting doses for a few renally impaired patients and dosing vancomycin according protocol. This definitely allows the physicians work more efficiently. More importantly, it reduces the chances of overdosing or underdosing a patient because the patient has alternate pharmacokinetic profile because of disease condition.” – Xunjie Z

“Consult practice agreements are an integral part of the pharmacist’s role in a variety of practice settings including, but not limited to ambulatory care practices, inpatient hospital practices, and community pharmacies. I have had the wonderful opportunity of volunteering at La Clinica Latina through the Rardin family practice center with students in the college of medicine, pharmacists, and physicians. This setting functions much like an ambulatory care center and has sparked my interest in pursuing a career in this area of pharmacy. Consult practice agreements allow pharmacist to work together with physicians and other health care providers to help maximize the best possible outcomes for these patients who often face multiple chronic health conditions such as asthma, diabetes, hypertension, and hyperlipidemia, among others. It allows the pharmacist to make therapeutic decisions on a patient’s care in relationship to a disease state that has already been evaluated, diagnosed, and monitored intensively by a physician. Having the ability to make these decisions, pharmacists are able to empower patients to best manage their diseases with the best combination and dosage of medications approved for their disease state, which is unique to each patient. Consult practice agreements allow pharmacist to practice at the top of their license, formulate relationships with both physicians and the patients they see, and monitor patients more closely for adverse effects the medications may be having on their health, which is able to be done in a more comprehensive way than what we would have access to in a traditional community pharmacy, thanks to the current status of consult practice agreements. Without consult practice agreements, the quality of care patients are able to receive and the quantity of patients who have access to healthcare will be diminished. This will put more pressure on physicians to manage drug dosages, adverse effects, and complex medication regimens for patients with chronic disease states, which is an area that pharmacists have received extensive training in during their education. Putting more time pressures physicians will further limit the number of patients they are able to see, which can negatively impact access to care for many of our most vulnerable patient populations.”

- Stephanie B

“I spent a month in an anti-coagulation clinic at Riverside Hospital doing about 20 hours with a team of pharmacists who have been practicing with CPAs for some time now. One of the pharmacists explained to me how the evolution of expanding CPAs in the state of Ohio has made their practice much more efficient for pharmacists, patients, and physicians. I heard how difficult the process of providing these patients with excellent care was when CPAs were in their infant stages, such as when each patient needed to have a CPA with their physician. This process added layers of administrative burden on the pharmacists and physicians and the changes that are proposed take the regulation of CPAs with pharmacists and physicians back to the "stone ages". – Matt H

“I learned the value of the ambulatory care Pharmacist in primary care at my rural setting APPE rotation. The pharmacist is able to see patients in rooms as an extension of the physician to give follow up care to patients. In one case, as an APPE intern, I caught that the patient was struggling with shortness of breath upon minimal physical exercise and recommended a albuterol inhaler.” – Susan M

“Working on my 4th year rotations, I have seen the difference pharmacists make through collaborative practice agreements. The pharmacist in the diabetes clinic was able to make independent decisions after a referral from an endocrinologist in the practice. She was able to make a greater impact on A1C reduction and blood glucose control in comparison to the present standard of care. Pharmacists are also able to be particularly useful when it may take months for a patient to be seen by their specialist. A pharmacist may have an opening in a few weeks whereas it may take months to be seen by the endocrinologist. Pharmacists are highly trained to be the medication experts and need to be treated as such in order to provide the best patient care.” – Alyssa R

This statement was signed by the following OSU students:

Andrew Myers
Natalie Hagy
Kelsi Escobar
Katelyn McTaggart
Cameron Quan
Samantha Hochevar
Sarah Etling
Amjad Hussein
Mika Garrett
Ha Nguyen
Matthew Schultz
George W. Bell, I
Emily Harris
Shannon Halloran
Peter Tran
Meghanne White
Megan Kirkpatrick
Cassie Rush
Ariela Lopez
Hailey Baird
Hannah Nielsen
Brianna Noll
Kendra Lee
Stephanie VanHouten
Kait Sterns
Hailey Wolk
Derick Schmidt
McKenna McClure
Maggie Sturm
Alex
Emily Veach
Jenna Karajeh
Karlis Abuls
Vivian Pham
Marisa Yudasz
Surawee Charoenwongsak
Danica Liu
Helen Ghebremedhin
Ryan Stefanich
Julie Bolibrzuch
Tyler P Bogard
Jennifer Philippon
Shannon McCarthy
Joseph Villari
Lindsey Lee
Samuel Slayton
Karl Singer
John Clevenger
Bernard Quansah
Abigail Block
Steven McVey
Maggie Watson
Julia Zaksheske
Madison Palmer
Xunjie Zhang
Katie Julian
Allison Susin
Stephanie Yasechko
Stephanie Brokaw
Matthew Hamrick
Joy Ugwuanyi
Alexa Plutt
Kyle Rybicki
Amy Zheng
Bob Brenneman
Melissa Thomas
Alba Evans
Pia Georgette Ang
Denise Truong
Maisha Hossain
Susan Moon
Ian Rebenock
Megan Fleming
Austin Kurtz
Kyle Zanath
Rebecca Hyun
Lisa Giangardella
Burgandy Staley
Tom Kellett
Parichehr shoureshi
Samra Nageye
Bridgette Zickefoose
Kara Kelsh
Aniket Patel
Tyler Everhardt
Carma Berry
Abbey Grimm
Ethan Land
Morgan Celone
Dana Alhashimi
Alyssa Rinaldi
Kyoo Yeon Koh
Laura Hagy
Michael Itschner II
Molly Johnson
Kyle Beck
Alisha Bias
Egla Agolli
Vivian Nguyen
Ranelle Coffman
Tara Kidd
Jennifer chan
Ryan Peterson
Anna Dugovich
Sara Pham
Madison Wood
Christine A. Stearns
Maria Cho
Raymond Chu
Thomas Kacner
Sarah Compton

From: allennichol@aol.com
To: Debolt, Sallie
Subject: comments on suggestions for changing the collaborative practice agreements between the boards of medicine and pharmacy
Date: Tuesday, January 22, 2019 3:02:41 PM

Sallie Debolt
State of Ohio
Medical Board

Below are my comments as they relate to the suggested changes :

A: Requirements of a consult agreement
1.(iii) institutional credentialing or privileging:
I am unaware of any requirements or offerings of credentialing or privileging of pharmacists by institutions in Ohio. Therefore this request for amendment is entirely out of bounds in this request, as it asks to define something that does not exist.
1.b. :patient's informed consent to order drug therapy management...:
I am not aware that APN's and PA's have such a requirement and since this agreement operates in the exact same statutory process, it seems prejudicial against the collaborating pharmacist and in my opinion, therefor would treat the pharmacist differently from the nurses and physician assistants, it then would appear to violate anti-trust, not to mention that again would hamper good clinical care that the managing physician has given specific direction to occur.
1.g. Second sentence: All prescribing, administering and dispensing of drugs shall be documented using positive identification pursuant to paragraph N of rule 4729-5-01 of the Administrative Code.
The collaborative practice agreement has nothing to do with administering and the dispensing of drugs. The primary focus is to manage the drug therapy, as directed by the individual(s) physicians , assigning the pharmacist to be able to modify drug therapy or order lab work as it pertains to the patient whose chronic disease therapy is being managed by the pharmacist. This sentence is totally irrelevant to the rule and the purpose of the collaborative practice agreement and should not be considered as either helpful or relevant to the rule. Therefor I suggest this not be considered for change.
1.h. : a description of how communication between a managing pharmacist and physician acting under a consult agreement shall take place at regular intervals specified by the physician who authorized the agreement:
Currently that is left to each collaborating physician and pharmacist. To try and standardize this action impedes the physician's ability to fully assign tasks that the physician would specifically like to have the pharmacist provide. One of the main purpose's and benefits to having this agreement in place is so that the physician can spend more time with other patients and allow their trusted pharmacist to manage very specific patients in a way that the two professionals have agreed upon. This amendment would hamper the ability to deliver optimal patient care, which I am sure the Medical Board would not like to have occur , especially since it is charged with the protection of public health and safety.
1. i. Requirement for a physician approval prior to adjustment to the dose of a controlled substance
First , only if the pharmacist has a DEA license to order a controlled substance this could not occur. Secondly , if the pharmacist held that DEA license, that protocol , again would be clearly defined by the managing physician, therefor any change in this area would be superfluous and again would only hamper the collaborating professionals.
1.j. A provision that allows a physician to override a decision made by the managing pharmacist when appropriate.
Again, this interference would slow the best care of the patient , as these decisions have been agreed upon by the two collaborating professionals. The pharmacist can only do what is in their individual consult agreement which is directed by their collaborating physician. This is again superfluous.
1.k. An appropriate Q/A mechanism to ensure pharmacists actions are within the scope authorized by the consult agreement.

Again, superfluous. This is the purpose of the agreement to be as specific as to what actions, currently defined by law, statute and rule , what the pharmacist may or may not provide. The individual physician limits the actions of the pharmacist via the consult agreement. No alternative language is necessary.

1.l. CQI:

I currently provide a CQI, data gathering, data analysis and other software that is applied to each and every patient. I would suggest that anyone involved currently in the consult agreement arena most probably is using some form of software , possibly an EMR or modified EMR to assist in the management of the chronic disease patients being managed by the pharmacist, possibly even more so than previous to the consult agreement being initiated.

1.m. training and experience criteria for managing pharmacists:

1. This statement diminishes the integrity of the physician : It basically says we know you pharmacist, have a license to practice pharmacy and we did not bother to check beyond that , malpractice insurance, clinical experience etc. This statement is an affront to managing physicians saying that they do not have the capability of thoroughly vetting professional people that they engage in helping them manage patient care. Pharmacists are licensed by the Ohio State Board of Pharmacy and unless they continue to complete all the necessary requirements to maintain their license, it will be revoked. The ORC governing the practice of pharmacy is specific to what pharmacists can and cannot do. It is not within the jurisdiction of the board of medicine to delineate what pharmacy practice should or should not be. Continuing education requirements are clearly defined by the board of pharmacy . Pharmacists are currently not responsible to be credentialed , board certified or have institutional privileges. The board of medicine appears to be attempting, by these proposed changes, to regulate the practice of pharmacy, clearly outside of their scope of jurisdiction. Furthermore, what governs the practice of medicine and the terminology of such practice, does not cross over to the practice of pharmacy and its terminology.

Any mention of terminal distributor licensing has only to do with the dispensing of medications and it is not relevant to consult agreements. All suggestions with that specific language should not be considered.

These comments are made by me and only represent my thoughts as an individually, licensed to practice pharmacy in the state of Ohio since 1974.

Allen Nichol, Pharm.D.
COO/VP Clinical Operations CeutiCare Inc.
2014 APhA Daniel B. Smith Award Recipient
614 506 8128

Niyati Kadia, PharmD
Clinical Pharmacist
University of Toledo Medical Center
3000 Arlington Ave MS 1131
Toledo, OH 43614

February 8, 2019

Sallie Debolt, Esq., Senior Counsel

State Medical Board of Ohio

30 E. Broad Street, 3rd Floor

Columbus, OH 43215

Dear Ms Debolt,

Thank you for the opportunity to review the proposed draft Medical Board Rules 4731-35-01 Consult Agreements and 4731-35-02 Standards for Managing Drug Therapy. As a clinical pharmacist specializing in anticoagulation at The University of Toledo Medical Center, I have had the opportunity to work directly with physicians in our cardiology and ortho departments under the current consult law to provide patients with timely and outcome driven anticoagulation therapy. Physicians collaborate with pharmacists as the medication experts within the interdisciplinary patient care team making their expertise imperative to assisting us with the care of our patients. This knowledge of evidence-based care can be managed within an agreed upon scope of the Consult Agreement through the combined rules of the Ohio Medical and Pharmacy Board.

My request for the proposed consult agreement change would be to **remove 4731-35-02 (C-4) a &b** from proposed rule that indicates prior to any action a pharmacist can perform, the pharmacist must notify the physician and obtain consent.

The UTMC anticoagulation clinic oversees the management of roughly 700 patients via phone and face to face appointments under consult agreement with director Dr. Laura Murphy. Pharmacists work under consult agreements and have specific training, credentialing, privileging, and board certifications in the area of anticoagulation. The work we do daily in this clinic has proven successful outcomes in terms of fewer bleeds and thromboembolism while maintaining higher percentage of patients in therapeutic range than standard of care management. Pharmacists are reviewed by the Medical Staff processes of FPPE and OPPE for quality assurance and their partnering physicians retrospectively reviews and acknowledges the activities of the pharmacist as a quality measure in compliance with current rules and regulations. The proposed language requiring advanced notification and consent would take the physician and pharmacist away from other patient care duties and decreasing the number of lifesaving and quality of care improving interventions our physicians and pharmacists can make for our patients.

Consult agreements allow physicians to work collaboratively with pharmacists to manage chronic diseases in the ambulatory setting. Physicians and pharmacists collaborate to manage patients in providing primary care and anticoagulation services. Our pharmacists have provided over 6000 patient encounters in 2018 demonstrating improved outcomes such as compliance, fewer adverse reactions, and quicker achievement of therapeutic goals similar to the Impact Trial and other similar studies. Additionally, Pharmacists have been recognized by the U.S. Department of Health and Human Services (HHS) to improve the continuity of care, level of care and overall quality of the patients' health and

healthcare experience. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

In summary: the proposed changes would discourage collaborative practice and obstruct our current quality-based workflow for both the medical and pharmacy teams. With the current consult agreements, the physicians and pharmacists work closely together to ensure the best patient care happens to patients. If the proposed changes occur, there will be more unnecessary phone calls throughout the day, longer time to patient care, and potential harm to patients. We are pleased the Medical Board has provided physicians additional guidance on managing consult agreements although we would ask the Medical Board to consider removing 4731-35-2 C-4 a and b from the proposed draft Medical Rules

Sincerely,

Niyati Kadia, PharmD

Ms. Diebolt and Ohio Medical Board:

I am writing regarding the proposed State Medical Board Rules for consulting agreements involving pharmacists. Specifically, **4731-35-01** for consult agreements and **4731-35-02** regarding standards for managing drug therapy. I am concerned that the requirement for the managing pharmacist to notify the consulting physician ***prior to any drug therapy action*** would greatly impede the timeliness of patient care being provided by the pharmacist. Hospital consult agreements already define the scope of the pharmacist's practice and the requirements for follow-up communication. Pharmacists' primary purview is that related to medications and as a matter of course, they undergo extensive training and certification prior to clinical practice. Those of us in the clinical practice arena consider them to be our medication experts and often look to them for guidance, rather than the converse. Our pharmacists already possess specialty certifications to further support their role in medication management. As a physician, I am entirely comfortable in allowing medication adjustment to be done by my clinical pharmacist staff and they, in turn, provide feedback and monitoring of therapy, allowing me to focus on other vital patient care responsibilities.

The language specifying the requirement for a pharmacist to notify a physician prior to any action would not allow a pharmacist to dose a medication in "real-time", instead requiring two-way communication with the cooperating physician provider before even the most rudimentary change in drug dose. This would inevitably result in inefficiencies of care, inconveniencing the patient and likely disrupting physician workflow, possibly numerous times daily. Please note that physician response to such calls is seldom instantaneous, often with time delays of many minutes to hours, depending upon clinical schedules and procedures in which the doctor may be involved. This would add unnecessary burden to the patient in terms of waiting for medication change confirmation, as well as to the pharmacist in terms of need to contact the patient to verify the dose change. (Indeed, not all of our pharmacist-managed patients have telephones or easy means of contact.)

The requirement of the consulting physician and pharmacist to meet on a regular basis to discuss patient care and review detailed reports of actions may prove to be onerous for both the pharmacist and physician. Such requirements may more than offset any hoped-for efficiencies of the cooperative management schema. Current consult agreements and ready access to electronic medical records from virtually any internet connected site already allow for open communication without the time constraints that this would place on both parties.

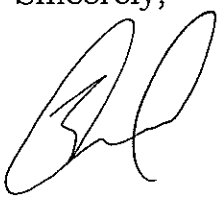
Rules have already been established in the Ohio Administrative Code which reflect requirements, limitations and care processes when pharmacists and physicians enter a consultative relationship. Numerous such consulting

agreements reflecting the current OAC are already in place. The proposed rules do not add improvements to the established OAC rules, but instead impede patient care further by adding inefficiencies as noted above. While I am certain that the intent of the proposed changes was to benefit patient care, for the reasons noted, I fear that they will have the opposite effect. For these reasons, I oppose the proposed changes.

Lastly, the pharmacist led standardization of treatment has improved outcomes and patient safety. These rule changes will inevitably cause physicians to abandon the pharmacist team approach and lead to more variability in care and less quality overall.

I remain available to further discuss this issue as you may desire.

Sincerely,



Bryan O'Connell MD
614-270-4412

From: Oehler, John L
To: Debolt, Sallie
Subject: response to proposed rules 4731-35-01 and 4731-35-02:Consult Agreements
Date: Wednesday, February 6, 2019 12:29:49 PM

TO: State Medical Board of Ohio

FROM: John Oehler, DO

RE: Response to Proposed Rules 4731-35-01 and 4731-35-02: Consult Agreements

Thank you for the opportunity to provide comments on the Medical Board's recently proposed rules regarding consult agreements between pharmacists and physicians. Consult agreements have been an invaluable resource for physicians to expand access and improve quality, especially since the revision of the law in 2016. In general, I appreciate the added clarity that the medical board has provided specific to physician participation in a consult agreement. However, some of the new provisions outlined in the proposed rules create a significant burden that would outweigh many of the benefits of a consult agreement, and would negatively impact patient care.

Specifically, the requirements for notification and consent prior to action by a pharmacist, as well as the requirement for regular meetings to review a written consult report represent my greatest concerns. The current regulations allow physicians and pharmacists to reach mutually agreeable terms that ensure adequate collaboration, expertise, oversight, and quality assurance mechanisms exist within the consult agreement. Physicians already have the flexibility to engage in a consult agreement that addresses training, communication, and quality assurance mechanisms that are appropriate for the medication management that is being performed.

Requiring a physician's consent prior to each action adds significant time without providing any benefit to the patient. Consult agreements already require a "description of the procedures, decision criteria, and plan the managing pharmacist is to follow in acting under a consult agreement." Asking a physician to confirm that the decision criteria and plan are correct prior to every change is unnecessary and only adds burden to the pharmacist and physician. Adding complexity into a medication adjustment may also cause a patient to experience suboptimal care while consent is being obtained.

Similarly on the requirement for regular meetings, the law already requires "communication between a pharmacist and physician acting under a consult agreement shall take place at regular intervals specified by the primary physician acting under the agreement." Additional requirements for regular meetings and written consult reports only add complexity and administrative burden to an already safe collaborative

Ultimately, I believe that these proposed rules run counter to the efficiencies that the law revision was intended to provide in 2016, and I recommend that the State Medical Board of Ohio reconsider adding any new requirements or barriers to care into the rules. I appreciate your consideration and the opportunity to provide feedback on the proposed rules. If you have any questions or would like to further discuss our comments, please reach out at the contact information below.

John L. Oehler, DO
Email:johnoehler@ohiohealth.com
Cell (740) 935-1145

FORTUNE 100 Best Companies to Work For 2007-2018

TO: State Medical Board of Ohio

FROM: Tricia Olaes, MD

RE: Response to Proposed Rules 4731-35-01 and 4731-35-02: Consult Agreements

Thank you for the opportunity to provide comments on the Medical Board's recently proposed rules regarding consult agreements between pharmacists and physicians. Consult agreements have been an invaluable resource for physicians to expand access and improve quality, especially since the revision of the law in 2016. In general, I appreciate the added clarity that the medical board has provided specific to physician participation in a consult agreement. However, some of the new provisions outlined in the proposed rules create a significant burden that would outweigh many of the benefits of a consult agreement, and would negatively impact patient care.

I have worked collaboratively with a pharmacist in my office to help manage my patients with uncontrolled diabetes and it was worked wonderfully as it currently stands. The pharmacist acts as a very useful flexible part of our outpatient diabetes management team and I find no need for her to run every medication change by me given we have a shared agreed upon disease protocol. I would not partake in such an agreement if I did not have professional confidence and trust in the pharmacist I am working with to follow an agreed upon protocol.

Specifically, the requirements for notification and consent prior to action by a pharmacist, as well as the requirement for regular meetings to review a written consult report represent my greatest concerns. The current regulations allow physicians and pharmacists to reach mutually agreeable terms that ensure adequate collaboration, expertise, oversight, and quality assurance mechanisms exist within the consult agreement. Physicians already have the flexibility to engage in a consult agreement that addresses training, communication, and quality assurance mechanisms that are appropriate for the medication management that is being performed.

Requiring a physician's consent prior to each action adds significant time without providing any benefit to the patient. Consult agreements already require a "description of the procedures, decision criteria, and plan the managing pharmacist is to follow in acting under a consult agreement." Asking a physician to confirm that the decision criteria and plan are correct prior to every change is unnecessary and only adds burden to the pharmacist and physician. Adding complexity into a medication adjustment may also cause a patient to experience suboptimal care while consent is being obtained.

Similarly on the requirement for regular meetings, the law already requires "communication between a pharmacist and physician acting under a consult agreement shall take place at regular intervals specified by the primary physician acting under the agreement." Additional requirements for regular meetings and written consult reports only add complexity and administrative burden to an already safe collaborative

Ultimately, I believe that these proposed rules run counter to the efficiencies that the law revision was intended to provide in 2016, and I recommend that the State Medical Board of Ohio reconsider adding any new requirements or barriers to care into the rules. I appreciate your consideration and the opportunity to provide feedback on the proposed rules. If you have any questions or would like to further discuss our comments, please reach out at the contact information below.

Tricia Olaes, MD
Family Medicine
Primary Care

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Fax (419) 772-1917

February 8, 2019

Sallie Debolt

State Medical Board of Ohio

30 E. Broad St., 3rd Floor

Columbus, Ohio 43215

Sallie,

Thank you for the opportunity to comment on your proposed rules regarding the Physician-Pharmacist Consult agreements. I have reviewed the proposed rules and have the following comments.

First, the proposed consult agreement language in general does not improve or ensure public safety, as compared to the current consult agreement language in place and practice in 4729:1-6-01-03. I understand that the proposed Medical Board rules must be created to support the legislative requirements for consult agreements, as well as the administrative Board of Pharmacy consult agreement language currently in place and in practice. As you are aware, the current consult agreement regulations in 4729:1-6-(01-03), were written and approved as a direct result of passage of HB 188 nearly 3 years ago. Since this legislative change, patient access to care has been improved under the direction of the physician via the consult agreement practice with the pharmacist. I fear that the unintended consequences that these proposed rules create will negatively impact patient care, pharmacist workflow and frankly, the physician's workflow, while adding no value to clinical care or patient safety.

Barring data that indicates the current consult agreement practice has negatively impacted Ohio patients, many of the proposed rules need amended to reflect current practice by both institutional and community pharmacy practices consult agreements with physicians. Our health care system is in vital need of more providers helping more patients. These rules as written will absolutely destroy the clinical care advancements made over the past few years via the consult agreement, which are currently benefitting Ohio patients. Adopting these rules as written will negatively impact patient access to care, impeding healthcare and thus worsening the health of Ohio patients, which is a direct contradiction of the Medical and Pharmacy Board's mission.

Specifically:

The proposed informed consent language in 4731-35-01(A)(b), 4731-35-02(3)(b-d) is much more restrictive and burdensome, as compared to any other mid-level practitioner's requirements. This needs removed and amended to reflect current practice and informed consent language requirements located in OAC 4729:1-6-01 (H-I).

Also 4731-35-01(A)(i): This requirement of contacting the physician prior to any dose change, reverts the practice back to prior HB 188. This language directly hinders the ability for the RPh and the physician to effectively work under the consult agreement. How dosage changes are handled clinically is spelled out within the consult agreements, so this is completely unnecessary, and undermines the intent of the consult agreement itself and truly needs removed.

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Also 4731-35-02(D): Additional reports required by the RPh is duplicative and burdensome, as the consult agreement language already covers the communication/reporting between the RPh and the physician.

In conclusion, I encourage you to consider these ideas to amend the current proposed Medical Board consult agreement language. The current language would stifle the ability for the RPh to assist the physician, and ultimately the patient in both the institutional and community setting. I also ask you to allow me to discuss this issue further with you and your Board staff and/or Board members. I think it would benefit the process if we could have a highly functioning physician who utilizes the pharmacist consult agreement speak with your Board. This may clarify the value that the current consult agreement regulations bring to our patients and may uncover some potential unintended consequences of your proposed consult agreement rules which I believe will hinder the pharmacist, the physician and the patient.

Thank you Sallie for the opportunity to comment and I hope to hear from you soon!

Kyle Parker, RPh, MBA

Asst Professor of Pharmacy Practice

Ohio Northern University, Raabe College of Pharmacy

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2/5/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
Sallie.Debolt@med.ohio.gov

Dear Ms. DeBolt:

I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a physician that utilizes the services of pharmacists through collaborative practice agreements to provide care to my patients, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.

Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:
Kruti Patel
0F5BF336343641C...

Kruti Patel

kp

From: Planisek, Stephanie
To: Debolt, Sallie
Subject: Consult Agreements for Pharmacist Management of a Patient's Drug Therapy
Date: Monday, February 4, 2019 11:35:47 AM

Hello,
I wanted to share my comments on how changes to the consult agreements would affect pharmacists and providers in the hospital setting.
We have consult agreements that are in place for warfarin dosing and vancomycin dosing currently that we act on daily. Under the current consult agreement, we can change doses, order necessary levels as needed for the management of either of these medications.
If changes were to require a discussion with a physician prior to making a change, this would limit the number of consults that pharmacist could complete , increase the number of pages, phone calls, and pull physicians away from patient care. (to discuss a change to a medication that they had placed pharmacy on to dose). Most consult agreements that are signed and agreed upon, are backed by current guidelines or follow the most up to date recommendations depending on the medication being managed.
If this change were to occur, would it not decrease or stop the number of consults that would be placed for pharmacy to manage medications (which is what we are specialized in). Would some physicians not think that it is a waste to have pharmacy dose it, as they are still gonna call me or talk to me daily about this medication anyway.

I believe there is data, (most definitely at each facility) of the benefits of pharmacy management vs provider management of medication therapy to improve patient care/ therapeutic levels, decrease Length of stay, and/or reduce readmissions.

Thank you and I appreciate your time,
Stephanie Planisek Pharm.D., MS, BCGP, RPH

TO: State Medical Board of Ohio

FROM: Joel Provenzano, MD
OPG Marion Area Physicians
1040 Delaware Ave.
Marion, OH 43302
740-375-8135

RE: Response to Proposed Rules 4731-35-01 and 4731-35-02: Consult Agreements

Thank you for the opportunity to provide comments on the Medical Board's recently proposed rules regarding consult agreements between pharmacists and physicians. Consult agreements have been an invaluable resource for physicians to expand access and improve quality, especially since the revision of the law in 2016. In general, I appreciate the added clarity that the medical board has provided specific to physician participation in a consult agreement. However, some of the new provisions outlined in the proposed rules create a significant burden that would outweigh many of the benefits of a consult agreement, and would negatively impact patient care.

I work very closely with my pharmacists in the ICU. We have two dedicated pharmacists that round with us specifically, every day. We rely on our pharmacists in a collaborative effort to help properly care for our patients. Requiring additional verification of an established relationship is superfluous and duplicative. They have the specific pharmacokinetics and medication risk training above and beyond what any medical doctor has, and we depend on that.

Specifically, the requirements for notification and consent prior to action by a pharmacist, as well as the requirement for regular meetings to review a written consult report represent my greatest concerns. The current regulations allow physicians and pharmacists to reach mutually agreeable terms that ensure adequate collaboration, expertise, oversight, and quality assurance mechanisms exist within the consult agreement. Physicians already have the flexibility to engage in a consult agreement that addresses training, communication, and quality assurance mechanisms that are appropriate for the medication management that is being performed.

Requiring a physician's consent prior to each action adds significant time without providing any benefit to the patient. Consult agreements already require a "description of the procedures, decision criteria, and plan the managing pharmacist is to follow in acting under a consult agreement." Asking a physician to confirm that the decision criteria and plan are correct prior to every change is unnecessary and only adds burden to the pharmacist and physician. Adding complexity into a medication adjustment may also cause a patient to experience suboptimal care while consent is being obtained.

Similarly on the requirement for regular meetings, the law already requires "communication between a pharmacist and physician acting under a consult agreement shall take place at regular intervals specified by the primary physician acting under the agreement." Additional requirements for regular meetings and written consult reports only add complexity and administrative burden to an already safe collaborative

Ultimately, I believe that these proposed rules run counter to the efficiencies that the law revision was intended to provide in 2016, and I recommend that the State Medical Board of Ohio reconsider adding

any new requirements or barriers to care into the rules. I appreciate your consideration and the opportunity to provide feedback on the proposed rules. If you have any questions or would like to further discuss our comments, please reach out at the contact information below.

Joel Provenzano, MD
OPG Marion Area Physicians
1040 Delaware Ave.
Marion, OH 43302
740-375-8135

Department of Medicine
Chair: Lance D. Dworkin, M.D.
Admin.Vice-Chair: Basil E. Akpunonu, M.D.
Administrator: Beth Smotherman
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Department of Medicine
Health Science Campus
3000 Arlington Ave., MS 1186
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COLLEGE OF MEDICINE AND LIFE SCIENCES
THE UNIVERSITY OF TOLEDO

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Community Internal Med: Allen Markowicz, M.D.
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Nephrology: Deepak Malhotra, M.D., Ph.D.
Pulmonary/Critical Care: Jeffrey R. Hammersley, M.D.
Rheumatology: M. Bashar Kahaleh, M.D.

February 8, 2019

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy

Dear Ms. Debolt:

Please see my concerns regarding the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. Consult Agreements for Pharmacist Management of Patient's Drug Therapy affects me personally as a physician practicing at South Toledo Internist, 3355 Glendale Avenue, Toledo, Ohio. Within my outpatient clinic, I work side by side with clinical pharmacists on a daily basis who provide unique value to our patients and improve overall quality of care.

Currently, consult agreements allow physicians to work collaboratively with pharmacists to manage chronic diseases. In my practice, we have pharmacists who independently manage diabetes, hypertension, and dyslipidemia through consult agreements. Pharmacists improve the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Additionally, our pharmacists serve as drug information experts and educators for both our residents, providers and patients. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

The proposed rule changes, specifically those that require pharmacists to notify the physician of any action prior to implementation (4731-35-02 C-4) would discourage collaborative practice and obstruct our current quality-based workflow. Pharmacists are the medication expert within the interdisciplinary patient care team making their expertise imperative to the care of patients. This expertise and evidence-based care can be managed independently within an agreed upon scope of practice. The removal of the autonomy afforded to pharmacists through consult agreements would lead to a tedious and inefficient process for chronic disease management that would negatively impact the pharmacist, provider and patient. Logistically, a busy provider may not always be in clinic making it difficult for both the pharmacist and patient's to reach them. In this case the pharmacist is the best resource to manage chronic

diseases and ensure timely care is provided. I recommend that this requirement be removed from the proposal.

Collaborations include medication regimens through polypharmacy visits -- discontinuing un-needed medications, educating patients on the medications they are taking, making sure patients are getting appropriate lab monitoring for medications.

I hope that the proposal be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,

Shuhao Qiu. M.D. (Feb/07/2019)

Shuhao Qiu, M.D., Ph.D.
Assistant Professor

From:	Uma Ram
To:	Debolt, Sallie
Cc:	aciaccia@ohiopharmacists.org
Subject:	Collaborative Practice Agreement between a MD/DO and a Pharmacist in the State of Ohio
Date:	Friday, February 8, 2019 4:57:36 PM

Ms. Sallie Debolt,

This is Pharmacist Uma Ram OH Lic# 03-1-19215 writing to you. I am a Registered Pharmacist with 27 years of work experience and been living in the Greater Columbus area for all these years. The independent Pharmacy that I worked for closed in June 2018 after 18 months. We were unable to keep our doors open for business after getting plundered by CVS Caremark, who reimbursed us way below cost for all the prescriptions we dispensed. At the same time, Express scripts closed their doors leaving 90 Pharmacists out of work. So it has been an uphill battle to find a job since June 2019 as I was the 91 st Pharmacist looking for one job.

But things are looking up for me after I met with Dr. Lisa Werner, DO , a Psychiatrist and Ms. Alicja Matusiak, her CNP. They are very impressed with my medication therapy management experience. They are willing to hire me as a Collaborative Practice Pharmacist.

I am sincerely hoping that you will support us Pharmacists in this new venture so we can fill the void created by shortage of MDs and CNPs. As a Pharmacist, I would be a perfect choice of health care provider who will do follow up visits and do a comprehensive medication review and free up the time for Physicians to do their diagnoses and initial consultations. With my vast knowledge of drug-drug interactions, drug-disease interactions, etc I would be a perfect fit to change our healthcare in Ohio.

I kindly requesting your full support for the Collaborative Practice Agreement between a Physician and a Pharmacist in the State of Ohio.

Thank you very much for giving me this opportunity to express my opinion

Sincerely,

Uma Ram RPh
OH Lic# 03-1-19215
(614)-208-0721

Sent from my iPhone

AxessPointe
Community Health Centers

January 30, 2019

State Medical Board of Ohio
30 East Broad Street, 3rd Floor
Columbus, OH, 43215
Sallie.Debolt@med.ohio.gov

Dear Ms. Debolt:

My name is Tiffany Rentsch and I am a post-graduate year two pharmacy resident in Northeast Ohio specializing in ambulatory care. I am writing to submit my comments on the proposed rules 4731-35-01 and 4731-35-02.

I would first like to thank the State Medical Board of Ohio for its work thus far on advancing the fields of medicine and pharmacy through collaboration between physicians and pharmacists. This has allowed many Ohio pharmacists, myself included, to take an active role on the patient care team. The work pharmacists do on the care team is essential to successful medication therapy management. Pharmacists close gaps in care, identify and resolve medication-related issues and promote the well-being of patients in conjunction with physicians.[1-2]

The concerns I would like to address regarding the proposed rules are as follows and mainly involve the regression of the progress made to date on consult agreements. To address these concerns, I will provide examples via scenarios of how the proposed rules may result in suboptimal patient outcomes and increased physician workload.

Firstly, I will provide an example of a pharmacist-run anticoagulation clinic within a primary care setting. Envision the newly diagnosed patient with a thromboembolic condition; if a vitamin K antagonist, such as warfarin, is used, many office visits, labs and dose adjustments are necessary to reach therapeutic levels. If the proposed rules are enacted, 4731-35-02(C)(4)(b) would require pharmacists to obtain consent of the primary physician for each lab and dosing adjustment made. With this requirement, the benefit of reducing physician workload with present consult agreements becomes null. If the physician is not available to approve such a request in a timely fashion, a delay of care, including delayed labs and delayed therapeutic levels may occur, which may, ultimately, result in patient harm.

AxessPointe
Community Health Centers

Next, consider pharmacists who manage patients with uncontrolled diabetes. These patients typically benefit from close follow-up, as often as weekly, to adjust therapy based on glycemic control.[2] With the proposed rules, each telephone or in-person encounter between the pharmacist and patient would need to be reviewed by the primary physician to obtain consent for the necessary changes, as minimal as a two-unit adjustment in the dose of insulin. As you might imagine, this burdens the provider with additional documentation and time spent away from direct patient care—time that is already of the essence. Under the current Ohio Administrative Code 4729:1-6-02(A)(1)(d), the decision criteria for adjustments in patients' therapies is required to be clearly outlined in consult agreements. The proposed rule results in additional and unnecessary documentation. The additional documentation would especially be of concern if a pharmacist sees multiple patients of a single physician in one day; the burden of responding to the requests of the pharmacist would add to the already formidable physician workload.

I would like to thank you for your time and consideration of my concerns regarding the proposed rules, 4731-35-01 and 4731-35-02. I hope it is evident from the aforementioned concerns that the proposed rules would ultimately result in greater burden of documentation to physicians, reduced time for patient care, and reduce the benefit consult agreements already provide. I can be reached for questions at the following email: trentsch@axesspointe.org. I look forward to continuing our collaborative work towards optimal patient outcomes.

Sincerely,

Tiffany Rentsch

Tiffany Rentsch, PharmD

---

[1] Touchette, D. R., Rao, S., Dhru, P.K., et al. (October 2012). Identification of and Intervention to Address Therapeutic Gaps in Care. The American Journal of Managed Care, 18(10), e364-71.
[2] Hughes, J. D., Wibowo, Y., Sunderland, B., & Hoti, K. (2017). The role of the pharmacist in the management of type 2 diabetes: current insights and future directions. Integrated pharmacy research & practice, 6, 15-27. doi:10.2147/IPRP.S103783

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

Department of Internal Medicine
Division of General Internal Medicine
Martha Morehouse Pavilion
Suite 2335
2050 Kenny Road
Columbus, OH 43221
614-293-4953 Phone
614-293-6890 Fax

2/6/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
Sallie.Debolt@med.ohio.gov

Dear Ms. DeBolt:

I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a physician that utilizes the services of pharmacists through collaborative practice agreements to provide care to my patients, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.

One of the biggest challenges for physicians is making timely titrations to medications in between office visits. This is where a skilled clinical pharmacist can have a great impact. In diabetes care for example, a pharmacist can communicate via phone or the EMR secure portal in between office visits to more rapidly titrate insulin and get patients' disease under control. We have utilized our pharmacist in this way and saw a marked improvement in our very poorly controlled diabetes patients. In those with an A1c > 9%, we were able to get two thirds of them to an A1c under 9% by utilizing our pharmacist in this way.

Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:
Richards
8F630A5A0EE444F...

Richards

MD

Western Medicine, Inc.
Family Physicians
7774 Dayton-Springfield Road
Fairborn, Ohio 45324
Phone: 937-864-7363

State Medical Board of Ohio

30 East Broad Street, 3rd Floor

Columbus, Ohio 43215

RE: Physician-Pharmacy Consult Agreement Proposed Rules

I joined Western Medicine Family Physicians about a year ago. Not only have I had the privilege to work with many clinical pharmacists during my residency training, but I was pleased to find this family medicine practice providing comprehensive and progressive care, that includes clinical pharmacist chronic disease state management.

Our clinical pharmacist is board certified in ambulatory care pharmacy and board certified in advanced diabetes management. We have established consult agreements for various chronic conditions, we (the physicians) diagnosis and refer to her for management, especially for the complicated patients who need intensive follow-up and education. Then she manages their therapy to improve their disease state. I have appreciated being able to provide these services in our office without referring out to various outside specialists who are not able to spend as much time with the patients as she is able to. We also have a close working relationship and I am able to access all of her notes in the same chart section where mine are found, so I am able to easily monitor her treatment plans as I see necessary.

I am writing to express my concerns with the recently proposed rules surrounding pharmacist-physician consult agreements. We are currently following the Ohio Board of Pharmacy rules and our practice is thriving and patient care is improving. The chart below highlights the differences in the Medical board rules vs. pharmacy board rules. As shown, the Medical board rules are essentially reversing my ability to allow the

pharmacist to use her clinical training to manage medications. The pharmacy board rules are adequate and allow for a pharmacist to use their clinical judgement within their scope of practice.

Sections of the proposed rules that would hinder patient care in our practice		
Ohio Board of Pharmacy Rules (OAC 4729:1-6-02; ORC 4729.39)	**Ohio Medical Board Proposed Rules**	**My Comments**
Appropriate quality assurance mechanism to ensure pharmacist's act within their scope authorized by agreement. Regular communication as determined by the managing pharmacist and physician in the agreement. **May** include a consult report to each consulting physician. Quality improvement program used to evaluate effectiveness of patient care and ensure positive patient outcomes – implement pursuant to agreement	Continuous Quality Improvement (CQI) Program – description of program to evaluate effectiveness of patient care and ensure positive patient outcomes & Quality assurance requirement to ensure pharmacist is operating in scope • Regular meetings – outlined in consult agreement • Consult report detailing – changes or modifications to patient's drug therapy with decision criteria, urine or blood tests by pharmacist and decision criteria used, evaluations made by pharmacist, summary of annual follow-up consultation with patient, and other information that may be relevant to evaluating effectiveness of drug therapy	We provide CQI by reviewing our pharmacists' notes after each visit, and co-sign their notes. Our medical director also has a process for reviewing these notes and monitoring patient care decisions by the pharmacist. There is no need for a time-intensive additional consult report.
ORC states patient can end consult agreement – no specific definitions for patient education on this process.	Physician requirement to review consult agreement details with patient & overboard opt-out communication with patients • Participation in agreement is voluntary	We communicate clearly with our patients about the referral to our clinical pharmacists. She has them sign a consent form at the first visit and reviews the process with them. There is no need to add additional time required by the physician to review this as well.

	• Agreement will not be utilized unless patient consents • Consent can be revoked at any time • Consult agreement and patient's consent will be disclosed to all other treating physicians	
Training and experience criteria for managing pharmacists – may include privileging or credentialing, board certification, continuing education or any other training requirements. Agreement shall contain a process to verify that the managing pharmacists meet the specified criteria	Medical Board rulemaking over the pharmacist scope • Physician must establish extent of pharmacist's authority to – change treatment and order blood, urine or other tests • Physician must establish - decision criteria pharmacist must consider, plan the pharmacist is to follow prior to conducting an action, and plan to follow after having conducted authorized action	We establish the pharmacist's authority in our consult agreement. We allow the pharmacist to make clinical decisions based on evidence-based medicine and national guidelines which is outlined in our agreement.
Agreement states diseases allowed to be managed, specific medications that can be managed, and decision criteria for the pharmacist	Detail requirements prior to and after any actions taken by the pharmacist • Notify physician prior to any action and gain consent • List decision criteria for deciding to conduct an authorized action • Description of proposed action the managing pharmacist intends to conduct	We absolutely do not want our pharmacist to have to ask us prior to making an action. This completely defeats the purpose of consulting the pharmacist to manage care. Pharmacist are capable providers of patient care with 7-8 years of education often with 1-2 of residency. We as physicians can choose to establish relationships and consult agreements with those that we have vetted and know are trained for the specialty in which we need. We need to work collaboratively to achieve comprehensive primary care and not expect that we have the capacity to approve every decision.

No specification on pharmacist involvement in maintaining physician-patient relationship	Pharmacist verification of patient-physician ongoing relationship • Must see patient at least once a year	While I want to see my patients yearly, I do not think this needs to be a legal issue for anyone. We have our patients follow-up yearly for a well visit already. We do not need this written in the rules.
Recordkeeping – record of each action taken for each patient whose drug therapy is managed under the agreement	Requirement to notify the physician prior to any action taken, detail of decision criteria and planned action and a prohibition on taking any action without consent of the physician	Please remove the "prior to" any action taken. Again this defeats the purpose of me choosing to consult a pharmacist to manage care. Please also remove the "prohibition on taking any action without consent of the physician." This is essentially reversing the law that was passed in 2016, and is not appropriate for rules set forth by your board.
May be an option if physician and pharmacist in consult agreement warrant it	Written, ongoing consult reports	Ongoing consult reports are unnecessary as we read each note written by our pharmacists. If a pharmacist was outside of our practice, a note/report from each visit is appropriate, but no additional reports beyond the encounter are necessary.

Sincerely,

Shelli Ridge, DO

Physician- Western Medicine, Inc

From: Riepenhoff, Chuck
To: Debolt, Sallie
Subject: Subject: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy
Date: Tuesday, February 5, 2019 4:57:00 PM

February 5, 2019

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Dear Ms. Debolt:

I would like to start by saying Thank You to the State Medical Board of Ohio and it's community of physicians as a whole for your progress throughout the years in working collaboratively with pharmacists. I have seen this progress first hand over the last decade while working with patients and physicians as part of Medication Therapy Management Programs I participate in.

For instance, I have always faxed physicians to request medication related labs for our mutual patients. As a pharmacist, part of my role is to use those lab values as a way to reinforce with patients the importance of taking the medications their provider prescribes. On one occasion in 2009, well before I participated in a Consult Agreement, a physician replied to my lab request with a written note that stated “Stick to counting pills”. During that same time period in 2009, another physician replied to one of my lab requests with a written note that stated “This is my patient. I will manage her medications”. Suffice to say, no lab values were included in their replies, and their notes were quite disappointing. However, fast forward 10 years to 2019, I am now working under a Consult Agreement with physicians, and here are a couple of comments I got back recently from physicians after I informed them of the medication adjustments I had already made for our mutual patients as part of our Consult Agreement: “Great, Thanks for your expertise”, and “Thanks for your help”. These recent comments from physicians are refreshing to see. I still have those notes written back in 2009 to remind me how far we've come. Progress indeed.

I have been working under a Consult Agreement with physicians in our health system for about 6 months now, so this type of experience is relatively new to me. In this short time though, it has proven to be a positive experience for myself, physicians, and patients alike. However, as pleased as I am with the progress I portrayed above thru physician comments then vs. now, I am equally concerned about some proposed rule changes to Consult Agreements and the Standards for Managing Drug Therapy.

Of particular concern would be the proposed requirement for pharmacists working under a Consult Agreement to notify the physician prior to any action taken, and a prohibition on taking any action without consent of the physician. I feel this requirement would inhibit the fluid and efficient patient care workflow I have experienced while collaborating with physicians as part of our Consult Agreement.

Currently the process for our Consult Agreement goes pretty much as follows: I get a referral from physicians for assistance in medication management. The physicians send me these referrals knowing that I can assist them in managing their patient within a specific scope of practice, which in my case is diabetes. I then meet with the patient to determine if any medication adjustments would be beneficial, and also determine if any diabetes related labs are necessary at that time. If so, I write, sign, and send prescriptions for any appropriate medication changes to the patient's pharmacy, and I order any labs I deem necessary. Since I currently have the authority to do all of this without first having to connect with the physician in order to get prior consent, I am able to confirm with the patient what I ordered and that the orders were sent - while the patient is still in front of me. Therefore, before the patient leaves our meeting, I am able to give the patient proper education and counseling on any medications and/or labs that I ordered. After the fact, I then communicate with the referring physicians to give them a summary of what changes I made and why I made them. I fear that having to get the physician consent prior to any action taken would be disruptive to the process described above, would therefore interrupt new medication therapy, and as a result would negate the original intention and key benefit of Consult Agreements for patients and physicians.

I feel the physicians I get referrals from trust and understand I'll make appropriate medication adjustments without their prior consent. Otherwise, I wouldn't get the referral for medication management to begin with. As long as I keep them properly informed, the physicians appear to appreciate the "behind the scenes" assistance I can give them in managing their higher risk patients with diabetes. It allows the physician to focus on the patients who are already in front of them day to day - while at the same time, at a separate appointment, I am able to provide a positive clinical impact on our mutual patients. I believe this appreciation is evidenced by comments such as "Great, Thanks for your expertise" that I mentioned above.

In summary, I hope that the proposed requirement for notification and physician consent before a pharmacist can take action be removed, and further that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

I look forward to continuing to work collaboratively with physicians in a productive manner as part of our Consult Agreements.

Professionally,

Chuck Riepenhoff, RPh, CDE
Clinical Pharmacist
ProMedica Health Systems
Diabetes and Nutrition Education Services
Toledo, OH
(P) 419.291.7045
(F) 419.480.6608

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From: Beckie Roberts
To: Debolt, Sallie
Subject: My inr.....
Date: Wednesday, February 6, 2019 11:16:01 AM

I Am so afraid of losing my blood thinning place where they keep up with my inr...if I don't have them then I might not be on blood thinners I wouldn't keep up if not for them at Summa health centers....in Akron Ohio am sorry but I had cancer and I had a stroke and I cant read a lot or write allot..here is my number if you need it...330-352-5462....

Thank You
Rebecca Roberts

Sent from Yahoo Mail on Android

From: Dr. James Roby
To: Debolt, Sallie
Subject: 4731-35-01 Consult Agreements and 4731-35-02 Standards for Managing Drug Therapy
Date: Friday, February 8, 2019 2:24:39 PM

February 8, 2019
Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215
Subject: 4731-35-01 Consult Agreements and 4731-35-02 Standards for Managing Drug Therapy
Dear Ms. Debolt:
I am writing in regards to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy.

I recommend that the proposal requiring affirmation from a physician prior to dosing adjustment be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,

James G Roby, MD
Member of the AAFP
4544 Crossfields Rd
Toledo, OH 43623

From: Rodis, Jennifer
To: Debolt, Sallie
Subject: Comments on 4731-35-01 and 4731-35-02
Date: Wednesday, February 6, 2019 11:01:27 AM
Attachments: image001.png

February 6, 2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

Dear Ms. DeBolt:

I would like to thank you for your service to the State Medical Board of Ohio and for all you do to improve the health of our fellow Ohioans. I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy. I submit these comments on behalf of myself.

As a pharmacist, administrator, and educator, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care. Additionally, I believe this change does not align with the skills and competencies our PharmD students possess upon graduation.

Our PharmD students complete a post-baccalaureate Doctor of Pharmacy degree, with three years of intense in-class, team-based learning on the science and therapeutics of medicines and disease; they engage in three years of patient care simulations in our patient care laboratory refining their communication and application skills, and they learn interprofessionally with physicians, nurses, physical and occupational therapists, nurse practitioners, social workers, and many other disciplines on and off-campus through immersive in-class and experiential training. The final year of the PharmD degree involves monthly rotations in a variety of practice settings. When our students leave campus, they are equipped with the knowledge and skills to optimize medications, communicate as a valuable member of a healthcare team, and manage acute and chronic diseases.

After graduation, pharmacists in our state are highly engaged in collaborative practice. I led over the past five years a Centers for Disease Control and Prevention funded demonstration project that provided access to pharmacist-provided care for patients in Federally-Qualified Health Centers with a focus on hypertension and diabetes. This project was a partnership among the Ohio Department of Health, Ohio Association of Community Health Centers, and the Ohio Pharmacists Association. As pharmacists became ingrained in the clinic's care models, collaborative practice agreements allowed these practitioners to streamline workflow and meaningfully engage with patients suffering from chronic disease. This project showed that, for patients with previously uncontrolled, out of range blood pressure, pharmacists helped bring 68 percent of these patients to goal. For patients with uncontrolled, out of range blood sugar due to diabetes, pharmacists helped bring 50 percent to goal.

Based on my experience in PharmD education and in working with pharmacists across the state, I feel that the citizens of Ohio deserve the highest level of care from members of their healthcare team through collaborative care. I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

THE OHIO STATE UNIVERSITY

Jennifer L. Rodis, PharmD, BCPS, FAPhA
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From:	Nathaniel Rosko
To:	Debolt, Sallie
Subject:	Feedback on Proposed Rule 4731-35-01 and 4731-35-02
Date:	Wednesday, February 6, 2019 10:46:35 AM

Good morning,

I am writing to provide feedback to the Medical Board's proposed rules 4731-35-01 and 4731-35-02 pertaining to consult agreements and standards for managing drug therapy between physicians and pharmacists.

Three years ago when Ohio passed the new legislation permitting physician-pharmacist consult agreements, this was a significant step forward in improving medication management for patients. Numerous studies have shown that interdisciplinary patient care significantly improves patient outcomes, specifically noting pharmacists as integral members of the care team. As the medication expert, we as pharmacists are best suited to manage drug therapy as we have extensive knowledge of minute differences in medication therapy, drug interactions, and required laboratory monitoring. **In my daily workflow, I help manage side effects from chemotherapy, ensure appropriate monitoring, and provide supportive care for our hematology and oncology patients in an environment that changes monthly with new medication approvals**. Beyond the direct benefits to the patient, our involvement also frees up physicians and advance practice providers to see more patients, particularly those in need of more acute care.

Given this, I strongly oppose section (C)(4) of rule 4731-35-02. This section would be a significant step back, essentially reversing course with the law that was passed 3 years ago. Requiring a physician to review every decision made and essentially require them to sign off on all orders is not only an undue burden to the physician, but it worsens quality of care by delaying treatment for the patient. I propose that this section be removed entirely from the rule.

Thank you for your time,

Nathaniel Rosko, PharmD, BCOP
Hematology/Oncology Clinical Specialist

TO: State Medical Board of Ohio

FROM: Zach Rossfeld, MD, FAAP

RE: Response to Proposed Rules 4731-35-01 and 4731-35-02: Consult Agreements

Thank you for the opportunity to provide comments on the Medical Board's recently proposed rules regarding consult agreements between pharmacists and physicians. Consult agreements have been an invaluable resource for physicians to expand access and improve quality, especially since the revision of the law in 2016. In general, I appreciate the added clarity that the medical board has provided specific to physician participation in a consult agreement. However, some of the new provisions outlined in the proposed rules create a significant burden that would outweigh many of the benefits of a consult agreement, and would negatively impact patient care.

In my inpatient palliative medicine practice, our team's pharmacist is a true resource. Our collaborative practice is additive. I am learning, communicating, and providing better care as a result of working closely with our pharmacist. I am in full support of the new provisions for a larger role within a consult agreement. At the same time, I am concerned with the proposed language for notification and consent prior to each action!

Specifically, the requirements for notification and consent prior to action by a pharmacist, as well as the requirement for regular meetings to review a written consult report represent my greatest concerns. The current regulations allow physicians and pharmacists to reach mutually agreeable terms that ensure adequate collaboration, expertise, oversight, and quality assurance mechanisms exist within the consult agreement. Physicians already have the flexibility to engage in a consult agreement that addresses training, communication, and quality assurance mechanisms that are appropriate for the medication management that is being performed.

Requiring a physician's consent prior to each action adds significant time without providing any benefit to the patient. This, to me, essentially invalidates the spirit of the new law. Consult agreements already require a "description of the procedures, decision criteria, and plan the managing pharmacist is to follow in acting under a consult agreement." Asking a physician to confirm that the decision criteria and plan are correct prior to every change is unnecessary and only adds burden to the pharmacist and physician. Adding complexity into a medication adjustment may also cause a patient to experience suboptimal care while consent is being obtained.

Similarly on the requirement for regular meetings, the law already requires "communication between a pharmacist and physician acting under a consult agreement shall take place at regular intervals specified by the primary physician acting under the agreement." Additional requirements for regular meetings and written consult reports only add complexity and administrative burden to an already safe collaborative

Ultimately, I believe that these proposed rules run counter to the efficiencies that the law revision was intended to provide in 2016, and I recommend that the State Medical Board of Ohio reconsider adding any new requirements or barriers to care into the rules. I appreciate your consideration and the opportunity to provide feedback on the proposed rules. If you have any questions or would like to further discuss our comments, please reach out at the contact information below.

Thanks for your efforts to improve access to and quality of care,

Zach Rossfeld, MD, FAAP zachrossfeld@gmail.com (419) 303-0627

February 8, 2019

Ms. Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, Ohio 43215

comments submitted via email

Dear Ms. Debolt,

The Ohio Association of Community Health Centers (OACHC) appreciates the opportunity to submit comments on proposed Rule 4731-35-01 "Consult Agreements" and proposed Rule 4731-35-02 "Standards for managing drug therapy" and their impact on the comprehensive model delivered by Ohio's Community Health Centers. While we appreciate and support guardrails and guidance to ensure patient-centered care – especially as more and more Ohioans seek drug therapy services at Community Health Centers – we believe these rules are overly burdensome and will actually be a hindrance to the stated objective of greater integration of clinical pharmacists to improve patient health outcomes.

OACHC represents all of Ohio's 54 FQHCs and FQHC Look-Alikes (more commonly referred to as Community Health Centers) which deliver accessible, affordable, high-quality primary and preventive health care to more than 751,000 Ohioans each year – regardless of their insurance status or ability to pay. Health Centers are leaders in integrating medical care, behavioral health, substance use treatment, dental, vision, pharmacy, and other services all under one roof. Ohio's Community Health Centers have a proven record of delivering high-quality, low-cost health care, coupled with a strong presence in impoverished urban neighborhoods and small towns and rural counties. The innovative health center team care model, including pharmacists, removes barriers and health disparities, lowers health system costs and allows communities to lead in the direction of their own care.

As such, we are very concerned that the complexity of the participating provider regulations contained in the proposed rules will result in neither our primary care physicians nor pharmacists electing to engage in consult agreements.

One example of such a potential missed opportunity as a result of the proposed rules, comes from Health Partners of Western Ohio (HPWO), an Ohio FQHC that participated in the Ohio KePRO Adverse Drug Events (ADE) and the Patient Safety Clinical Pharmacy Collaborative (PSPC) projects. HPWO achieved remarkable success by focusing on an integrated service delivery model to incorporate pharmaceutical considerations and referrals at key junctures. Under the leadership of then Director of Pharmacy Jenny Clark, HPWO dramatically reduced hospital admission and readmission rates in just three months. Specifically, this pharmacy-driven collaboration produced an impressive 67 percent relative improvement in hospital admissions, and 100 percent relative improvement in readmissions for its target patient population.

Make no mistake, the integrated, complementary relationship established between primary care providers and pharmacists at this health center provided these results. Initiatives such as this can only be sustained and replicated if physicians and pharmacists continue to co-manage patient care in a way that allows for practical checks and balances. As we think about reinventing our health care delivery system to emphasize prevention and team-based primary care, and push to deliver more cost-effective and patient-centered comprehensive care, Community Health Centers are uniquely positioned to continue to lead this transformation and make it a reality. The complexity of the proposed rules will diminish the opportunity for Ohio's multidisciplinary provider teams to positively impact the health of our state, especially at a time when critical issues like the opioid epidemic and so many other chronic illnesses that would benefit from improved medication therapy management threaten the health of our family, friends and neighbors.

On behalf of our member Health Centers, thank you for this opportunity to offer our concerns on the proposed Consult Agreement Rules. Please contact me or Julie DiRossi-King at 614.884.3101 if we can provide any additional information or clarification.

Sincerely,

Randy Runyon
President & CEO

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(614) 884-3101 (888) 884-3101 fax: (614) 884-3108
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From: Nathaniel Russell
To: Debolt, Sallie
Subject: 4731-35-01 Consult agreements
Date: Monday, January 21, 2019 10:35:16 PM

Sally,
I am emailing with some concerns regarding the language in this proposed change to pharmacist consult agreements.

Section "C" subgroup "4" is of particular concern as I have highlighted below. Unless I am interpreting this incorrectly, the language indicates that a pharmacist that is managing drug therapy under a consult agreement will have to explain proposed changes to therapy and receive the physician approval in prior to making any changes. This is of concern as this essentially negates the ability of a pharmacist to manage drug therapy independently (under consult agreement of course) as they currently do.

I am not sure if you are aware in your role, but many drug therapies both in the hospital and in the outpatient clinic are managed by the pharmacist and communicated to the physician electronically as they are being performed or after the fact during patient review. I am concerned that if this now requires prior notification and consent as described in section 4, there will be a significant decline in access as physicians and LIP's will have to take over much of the work that is being performed by pharmacists under these agreements. It is not feasible to expect the physician to review and provide consent prior to a pharmacist initiating changes.
A specific example of this would be an anti-coagulation clinic that 2 pharmacists manage under consult for 2 primary care and one cardiology office here. These pharmacists see 50-60 patients per day for these 3 offices and document all decisions in the medical record and adhere to our requirements for clinical decision making. To move this workload to the physician or even LIP's would lead to patient safety concerns as we would be unable to manage the additional patient volume. I am unsure how you can seriously consider this in the face of increasing physician burnout and access concerns in much of the state.

Sincerely,
Dr. Nathaniel Russell

(C) Quality assurance mechanisms. The following quality assurance mechanisms shall be implemented to verify information contained within the consult agreement, and ensure the managing pharmacist’s actions are authorized and meet the standards listed in sections (A) and (B) of this rule:
(1) Verification of ongoing physician-patient relationship. A physician-patient relationship can be established by detailing criteria set forth in section (A)(2) of this rule, within the consult agreement.
(2) Verification that physician diagnosis is within the physician’s scope of practice. Establishing that a diagnosis is within the physician’s scope of practice may be established by detailing the criteria set forth in section (A)(4) of this rule, within the consult agreement.
(3) Verification that pharmacist’s training and experience is related to the drug therapy. Establishing that a pharmacist’s requisite training and experience with a particular drug therapy is related to the diagnosis for which the drug therapy is prescribed, may be established by detailing the criteria set forth in

section (A)(6) of this rule, within the consult agreement.

(4) When the managing pharmacist changes the duration of treatment for the current drug therapy; adjusts a drug's strength, dose, dosage form, frequency of administration, route of administration, discontinues a drug, prescribes a new drug, or orders urine or blood tests, as authorized under section B)(1)(a), and (B)(1)(b) of this rule, the managing pharmacist must:

(a) Notify the primary physician prior to any action. The notification shall include a description of:

(i) The decision criteria considered by the managing pharmacist in deciding to conduct an authorized action; and

(ii) A description of the proposed authorized action the managing pharmacist intends to conduct.

(b) Obtain the consent of the primary physician to conduct the proposed authorized action.

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

OSU Heart and Vascular Center
452 W. 10th Avenue
Columbus OH 43210
Phone: (614) 293-1965
Fax: (614) 366-2175

February 6, 2019

To: Sallie Debolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

To Whom It May Concern:

As a practicing physician in the state of Ohio, I would like to thank you for your service to the State Medical Board of Ohio and for all you do to enhance the care of our fellow Ohioans. I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a physician that currently utilizes the services of pharmacists as independent practitioners through collaborative practice agreements, I am in favor of pharmacists continuing to provide patient care in this manner as a means to improve quality, safety, and efficiency in our health system. The utilization of consult agreements between physicians and pharmacists at The Ohio State University Wexner Medical Center has improved patient outcomes and helped control healthcare costs. I believe pharmacists are a vital part of the interdisciplinary team and are vital for successful provision of high quality clinical services and improving access to care. I am supportive of the continued incorporation of pharmacist services into my day to day practice. I have appreciated the updates by the Board of Pharmacy over the last few years. The rules proposed by the Medical Board are generally acceptable and in line with current pharmacy rules.

However, I feel several provisions are converse to current practice and limit the utility of consult agreements. Sections (A)(2) and (C)(4) of 4731-35-02, in current form, would increase provider burden and decrease efficiency of the current system, significantly impacting the business of healthcare. Furthermore, (C)(4) would reduce quality of care by discrediting pharmacists' clinical decision making capabilities already authorized under agreed collaborative practice agreements and accompanying scope of practice. We are asking this language regarding "at least one time per year" in (A)(2) and the entirety of (C)(4) be removed (this is covered in (A)(1) of 4731-35-01).

If you have any questions, please do not hesitate to contact me. Thank you for your consideration.

Sincerely,

Thomas J Ryan, MD
Director, Ohio State Heart and Vascular Center
Wexner Medical Center at the Ohio State University Medical Center
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Office: 614-293-1965
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THE OHIO STATE UNIVERSITY
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2/6/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
Sallie.Debolt@med.ohio.gov

Dear Ms. DeBolt:

I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a physician that utilizes the services of pharmacists through collaborative practice agreements to provide care to my patients, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.

I have worked with the clinical pharmacist at our office to better manage my patient's with diabetes and I have seen significant improvement in diabetic control across the board. This is in part possible because the pharmacists schedule allows more frequent visits with the patients. If they were unable to participate in medication management in the way they currently have been I do think that this would interfere with their ability to titrate medications closely and would worsen the patient outcomes.

Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:
Ryan
3AB3032EFC4B49A...

Ryan

MD

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

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February 8th, 2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

Dear Ms. DeBolt:

I would like to thank you as a practicing pharmacist in the state of Ohio for your service to the State Medical Board of Ohio and for all you do to enhance the care of our fellow Ohioans. I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a pharmacist that works closely with physicians through collaborative practice agreements to provide care to our patients, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have through my practice.

Within The Ohio State University Department of General Internal Medicine, I work with more than 90 medical residents and 40 attending physicians with the opportunity to impact the health of more than 50,000 patients. With a focus on population health and chronic disease management, I provide medication therapy management services across 7 clinics. For some of the physicians I work with, I co-manage patients and staff each recommended change to their therapy with the physician prior to implementing the change. For others, I operate under collaborative practice agreements to make the changes real-time, notifying the physician of the orders immediately after implementing them so that they have the opportunity to alter the plan if desired. For many physicians, I work with their patients in both capacities, at their discretion, based on the individual patient. Collaborative practice agreements allow physicians a choice in how they involve pharmacists in the care of their patients and the opportunity to more efficiently optimize medication therapy for the patients we serve. This dynamic of pharmacist co-management through collaborative practice has allowed for significant improvement in clinical outcomes including overall reduction in HgbA1c and blood pressures for our patients, while freeing up the physicians to see a larger number of their more complex patients.

Based on my personal experience through practice and my strong feeling that the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

Jennifer Sabatino, PharmD, BCACP
Clinical Pharmacist
OSU General Internal Medicine

THE OHIO STATE UNIVERSITY
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2/6/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
Sallie.Debolt@med.ohio.gov

Dear Ms. DeBolt:

I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a physician that utilizes the services of pharmacists through collaborative practice agreements to provide care to my patients, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.

Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:
Heather Saha
EF31ADE6B45047D...

Heather Saha

Assistant Professor

February 8, 2019

Paul Samenuk
Pharmacist
University of Toledo Medical Center
3000 Arlington Ave.
Toledo, OH 43614

Sallie Debolt, Esq.
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy

Dear Ms. Debolt:

I am writing in regards to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. Consult Agreements for Pharmacist Management of Patient's Drug Therapy is of interest to me due to my current collaborative practice with our medical staff as a Licensed, Board Certified, credentialed, and privileged pharmacist practicing at the University of Toledo Medical Center. Within our hospital, I work side by side with physicians on a daily basis to provide unique value to our patients and improve overall quality of care.

Currently, consult agreements allow physicians to work collaboratively with pharmacists to dose antibiotics, anticoagulants, discontinue duplicate medications, and renally adjust medications. In my practice, we have pharmacists who independently change doses, frequencies, routes, and order labs through consult agreements. Pharmacists improve the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Additionally, our pharmacists serve as drug information experts and educators for both our residents, providers and patients. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

The proposal includes unnecessary additions (4731-35-02 D-1) requiring the pharmacist to have a detailed description of a continuous quality improvement project including regular meetings with the physician. This should not be outlined by the rules, but rather be dependent on the practice allowing variation from site to site. I recommend this be removed from the proposal. In addition, I further request that section C-4 (a) and (b) be deleted from proposed rule 4731-35-02 that indicates prior to any action a pharmacist can perform, the pharmacist must notify the physician and obtain consent. This requirement can be delineated in the consult

agreement; it delays therapy and care to our patients by unnecessary communication via phone calls.

In summary, I hope that the outlined proposals be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,

Paul J. Samenuk, R.Ph., MBA, BCPS

From:	Schroeder, Michelle Nicole
To:	Debolt, Sallie
Subject:	Comments on changes proposed 4731-35-01 & 4731-35-02
Date:	Wednesday, February 6, 2019 9:28:38 AM
Attachments:	image001.png

Dear. Ms. DeBolt,

I would like to thank you as a practicing pharmacist in the state of Ohio for your service to the State Medical Board of Ohio and for all you do to enhance the care of our fellow Ohioans. I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a pharmacist, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.

I currently direct a diabetes education & self-management program based in our outpatient Endocrinology office at the University of Toledo. I have personally been able to more effectively provide high quality and valuable care to my patients with diabetes through consult agreements. My patients are able to reduce their blood sugars and A1c levels quicker because they have an additional access point to healthcare services through me. Additionally, the physicians that I work closely with have been able to provide better care to more patients by utilizing my medication expertise as an extension of the care they provide. These physicians comment often how appreciative they are of the perspective that pharmacists bring to the care of our mutual patients.

Based on my personal experience, through practice, and that I feel that the citizens of Ohio deserve the highest level of care from all members of their healthcare team, I would ask the State Medical Board of Ohio to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

Michelle N. Schroeder, PharmD, RPh, BCACP, CDE

Assistant Professor

Program Coordinator, Outpatient Diabetes Education

Department of Pharmacy Practice, HEB 137C

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TO: State Medical Board of Ohio

FROM: Sarah Boehmer Schwartz MD

RE: Response to Proposed Rules 4731-35-01 and 4731-35-02: Consult Agreements

Thank you for the opportunity to provide comments on the Medical Board's recently proposed rules regarding consult agreements between pharmacists and physicians. Consult agreements have been an invaluable resource for physicians to expand access and improve quality, especially since the revision of the law in 2016. In general, I appreciate the added clarity that the medical board has provided specific to physician participation in a consult agreement. However, some of the new provisions outlined in the proposed rules create a significant burden that would outweigh many of the benefits of a consult agreement, and would negatively impact patient care.

I currently have consult agreements with pharmacists for anticoagulation management and diabetes education/management. These consult agreements allow me to provide my patients with enhanced and expanded care. They also provide more flexibility to my patients because some of their follow-up can be with the pharmacist. The pharmacists make clinical decisions within the confines of our agreement and are guided by predetermined order sets, algorithms, and patient parameters.

Specifically, the requirements for notification and consent prior to action by a pharmacist, as well as the requirement for regular meetings to review a written consult report represent my greatest concerns. The current regulations allow physicians and pharmacists to reach mutually agreeable terms that ensure adequate collaboration, expertise, oversight, and quality assurance mechanisms exist within the consult agreement. Physicians already have the flexibility to engage in a consult agreement that addresses training, communication, and quality assurance mechanisms that are appropriate for the medication management that is being performed.

Requiring a physician's consent prior to each action adds significant time without providing any benefit to the patient. Consult agreements already require a "description of the procedures, decision criteria, and plan the managing pharmacist is to follow in acting under a consult agreement." Asking a physician to confirm that the decision criteria and plan are correct prior to every change is unnecessary and only adds burden to the pharmacist and physician. Adding complexity into a medication adjustment may also cause a patient to experience suboptimal care while consent is being obtained.

Similarly on the requirement for regular meetings, the law already requires "communication between a pharmacist and physician acting under a consult agreement shall take place at regular intervals specified by the primary physician acting under the agreement." Additional requirements for regular meetings and written consult reports only add complexity and administrative burden to an already safe collaborative

Ultimately, I believe that these proposed rules run counter to the efficiencies that the law revision was intended to provide in 2016, and I recommend that the State Medical Board of Ohio reconsider adding any new requirements or barriers to care into the rules. I appreciate your consideration and the opportunity to provide feedback on the proposed rules. If you have any questions or would like to further discuss our comments, please reach out at the contact information below.

Sarah Boehmer Schwartz MD

March 7, 2019

E. Demond Scott, MD, MPH
Chief Medical Officer
AxessPointe Community Health Centers
143 Gougler Ave, Kent, Ohio, 44240

State Medical Board of Ohio
30 E. Broad St., 3rd Floor
Columbus, Ohio 43215
(614) 466-3934
Sallie.Debolt@med.ohio.gov

Dear Ms. Debolt,

I'm writing you to explain my concerns regarding the proposed rule changes to 4731-35-02(C)(4)(a,b), which will be making changes to consult agreements with pharmacists.

A study published by the American Medical Association (AMA) found that the work pharmacists do on the care team allows for reductions in medication therapy problems and improved patient outcomes[1], and the AMA has supported adding a pharmacist to the team to improve outcomes.[2] I have seen firsthand the benefit of having a collaborative practice agreement. In collaboration, physicians and pharmacists can improve patient centered outcomes, reduce drug therapy problems, and bridge the gap in preventative medicine during a time where we are seeing a shortage of primary care providers. In 2013, Ohio's patient to primary care provider ratio was 1482:1 and the need for additional providers was expected to rise by 8% by 2030.[3] The benefits I have seen could be greatly reduced, if not eliminated if these proposed rules are approved.

One of the greatest benefits of physician-pharmacist consult agreements is the increased access to care. A patient who may have to wait weeks to get in to see a provider can now get in to see a pharmacist within the next week. The patient can then have their medication adjusted at the pharmacist visits at a faster rate. Along with this, closer follow-up is possible, and outcomes can be achieved at a faster rate. One of the groups I see benefit most from the consult agreement is individuals with diabetes. This population is at a high risk for amputation, kidney dysfunction, blindness and more if their diabetes remains uncontrolled. For this reason, it is crucial that the patient be seen so that medications can be adjusted to help them meet goals and minimize the risk of complications related to diabetes. While hyperglycemia is a huge concern, so is hypoglycemia. For this reason, diabetes medications, specifically insulin, must be adjusted slowly, precisely, and with close monitoring. A physician is commonly limited to only seeing their patients once a month or once every two months, due to scheduling

requirements. This limitation then only allows for insulin adjustments to happen every couple months, delaying the control of their disease. More aggressive adjustments without close monitoring would put the patient at risk of low blood sugar. With a collaborative practice agreement, the patient can see a pharmacist, having the pharmacist adjust every week or two, helping to achieve goals at a significantly quicker pace, along with allowing for close monitoring. Achieving these goals sooner isn't just a matter of hitting a goal number sooner, it is a matter of helping the patient keep their limbs, stay off dialysis, or maintain their eye site.

After establishing the pharmacists' ability to provide care, many physicians have been depending on the pharmacists to help in matters such as these to allow them to improve the patient outcomes and to free up their schedules for other patients, especially at an underserved practice setting like mine. If the proposed rules are approved, it will negate the value of the consult agreements with pharmacists, and the time that physicians were gaining to provide more care will be limited once again. In addition, having to wait for approval by the physician, will serve as another delay in therapy for patients, therefore delaying therapy benefits. This benefit was locally demonstrated and highlighted by the CDC in a publication featuring our collaborative practice model at AxessPointe and two other community health centers in Ohio.[4]

The progress that has been made over the past several years was all with patients' health and wellbeing in mind. Both pharmacists and physicians have the same goal, and that is to improve the health of our patients. I believe that the proposed rule changes to 4731-35-01 and 4731-35-02 will be a great disservice to patients. These changes will burden the physicians, limit access to care and delay therapy benefits.

If you have any questions or would like to reach me, feel free to contact me. Thank you for your time and consideration in this matter.

E. Demond Scott, MD, MPH

E. Demond Scott, MD, MPH
Chief Medical Officer
AxessPointe Community Health Centers

1. Kaboli PJ, Hoth AB, McClimon BJ, Schnipper JL. Clinical pharmacists and inpatient medical care: A systematic review. Arch Intern Med. 2006;166: 955-964.
2. American Medical Association. Add a pharmacist to the team to see better outcomes. https://www.ama-assn.org/practice-management/payment-models/add-pharmacist-team-see-better-outcomes. Accessed January 29, 2019.
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OhioHealth

TO: State Medical Board of Ohio

FROM: Dr. Mayank K. Shah

RE: Response to Proposed Rules 4731-35-01 and 4731-35-02: Consult Agreements

Thank you for the opportunity to provide comments on the Medical Board's recently proposed rules regarding consult agreements between pharmacists and physicians. Consult agreements have been an invaluable resource for physicians to expand access and improve quality, especially since the revision of the law in 2016. In general, I appreciate the added clarity that the medical board has provided specific to physician participation in a consult agreement. However, some of the new provisions outlined in the proposed rules create a significant burden that would outweigh many of the benefits of a consult agreement, and would negatively impact patient care.

Specifically, the requirements for notification and consent prior to action by a pharmacist, as well as the requirement for regular meetings to review a written consult report represent my greatest concerns. The current regulations allow physicians and pharmacists to reach mutually agreeable terms that ensure adequate collaboration, expertise, oversight, and quality assurance mechanisms exist within the consult agreement. Physicians already have the flexibility to engage in a consult agreement that addresses training, communication, and quality assurance mechanisms that are appropriate for the medication management that is being performed.

Requiring a physician's consent prior to each action adds significant time without providing any benefit to the patient. Consult agreements already require a "description of the procedures, decision criteria, and plan the managing pharmacist is to follow in acting under a consult agreement." Asking a physician to confirm that the decision criteria and plan are correct prior to every change is unnecessary and only adds burden to the pharmacist and physician. Adding complexity into a medication adjustment may also cause a patient to experience suboptimal care while consent is being obtained.

Similarly on the requirement for regular meetings, the law already requires "communication between a pharmacist and physician acting under a consult agreement shall take place at regular intervals specified by the primary physician acting under the agreement." Additional requirements for regular meetings and written consult reports only add complexity and administrative burden to an already safe collaborative

Ultimately, I believe that these proposed rules run counter to the efficiencies that the law revision was intended to provide in 2016, and I recommend that the State Medical Board of Ohio reconsider adding any new requirements or barriers to care into the rules. I appreciate your consideration and the opportunity to provide feedback on the proposed rules. If you have any questions or would like to further discuss our comments, please reach out at the contact information below.

Sincerely,

Mayank K. Shah, MD
1051 Harding Memorial Parkway #A
Marion, OH 43302

OhioHealth

TO: State Medical Board of Ohio

FROM: OhioHealth Marion General Hospital Department of Surgery

RE: Response to Proposed Rules 4731-35-01 and 4731-35-02: Consult Agreements

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Correspondence c/o:
Kimberly Haviland, 1000 McKinley Park Dr., Marion, OH, Kimberly.Haviland@ohiohealth.com

OhioHealth

RE: Response to Proposed Rules 4731-35-01 and 4731-35-02: Consult Agreements

Name/Credentials	Signature
Mrunal Shah M.D. Family Medicine CMO, MGH	[signature]

OhioHealth

TO: State Medical Board of Ohio

FROM: OhioHealth Marion General Hospital Department of Surgery

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OhioHealth

RE: Response to Proposed Rules 4731-35-01 and 4731-35-02: Consult Agreements

Name/Credentials	Signature
David Fitkin, M.D.	

OhioHealth

TO: State Medical Board of Ohio

FROM: OhioHealth Marion General Hospital Department of Surgery

RE: Response to Proposed Rules 4731-35-01 and 4731-35-02: Consult Agreements

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OhioHealth

RE: Response to Proposed Rules 4731-35-01 and 4731-35-02: Consult Agreements

Name/Credentials	Signature
Rebecca Crockett DO	

OhioHealth

TO: State Medical Board of Ohio

FROM: OhioHealth Marion General Hospital Department of Surgery

RE: Response to Proposed Rules 4731-35-01 and 4731-35-02: Consult Agreements

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OhioHealth

RE: Response to Proposed Rules 4731-35-01 and 4731-35-02: Consult Agreements

Name/Credentials	Signature
John McDonough MD	John McDonough MD

OhioHealth

TO: State Medical Board of Ohio

FROM: OhioHealth Marion General Hospital Department of Surgery

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evidence based?

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OhioHealth

RE: Response to Proposed Rules 4731-35-01 and 4731-35-02: Consult Agreements

Name/Credentials	Signature
JOSEPH C. BENEDETTO DO	

OhioHealth

TO: State Medical Board of Ohio

FROM: OhioHealth Marion General Hospital Department of Surgery

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OhioHealth

RE: Response to Proposed Rules 4731-35-01 and 4731-35-02: Consult Agreements

Name/Credentials	Signature
S. PRASAD RAJI	[signature]

From: Shanker, Kirti
To: Debolt, Sallie
Subject: Pharmacist
Date: Tuesday, January 29, 2019 1:05:53 PM

Hello,

Just wanted to give you a feedback as to how pharmacists work collaboratively with the providers and improve quality of care!
Our pharmacists at OSU work very effectively and very knowledgeable with several medication management of several chronic medical conditions and especially Diabetes. I applaud the way our pharmacists manage insulin treatment.
The pharmacists in our office work closely and help the providers with any medication management issues and they should be given the autonomy to give us recommendations for management of care.
If the pharmacists have to discuss every medication issue with the provider this would delay care due to patient volume and I believe this would impact negatively with the quality of care that is provided to patients.

Sincerely,

Dr. Kirti Shanker, MD
OSU family Medicine
1800 zollinger Road
Upper Arlington

February 8, 2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

RE: Proposed Rules 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy

Dear Ms. DeBolt:

Thank you for the opportunity to provide written comments to the State Medical Board of Ohio on proposed rules 4731-35-01 and 4731-35-02 related to physician-pharmacist consult agreements.

The National Community Pharmacists Association (NCPA) represents the interests of America's community pharmacists, including the owners of more than 22,000 independent community pharmacies across the United States and 532 independent community pharmacies in Ohio. Together, they represent an $76 billion health care marketplace and employ 250,000 people. Our members are small business owners who are among America's most accessible health care providers, and many of our Ohio members have consult agreements currently in place.

After reviewing the proposed rules, NCPA would like to provide the following comments for consideration by the State Medical Board of Ohio.

NCPA is concerned subsections 4731-35-01(A)(i) and 4731-35-02(C)(4) are in direct contradiction to the purpose of the legislation governing physician-pharmacist consult agreements. When O.R.C. §4729.39 was passed unanimously as HB 188 three years ago, the intent was to reduce several of the burdensome processes hindering collaboration between physicians and pharmacists that are currently enumerated in these subsections. We believe the inclusion of these subsections would negate the progress that has been made over the past three years in providing more efficient and effective patient-centered care through physician-pharmacist consult agreements, and we respectfully request the Board to remove them.

NCPA is also concerned subsections 4731-35-01(A)(b), 4731-35-02(A)(3)(b-d), 4731-35-02(B)(2)(b-c), and 4731-35-02(D)(1)(a-e) place an unnecessary administrative burden upon both the physician and the pharmacist who enter into a consult agreement. The proposed subsections treat consult agreements in a completely different manner than collaborations between other health care providers and seem to imply physicians and pharmacists cannot be trusted to appropriately manage patients within a collaborative relationship, even though they

100 Daingerfield Road
Alexandria, VA 22314-2888
(703) 683-8200 PHONE
(703) 683-3619 FAX

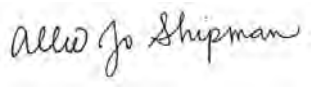
have been doing so successfully for the past three years since the enactment of O.R.C. §4729.39. We respectfully request the Board remove these subsections.

NCPA also respectfully brings to the Board's attention that subsections 4731-35-02(D)(2)(b-c) do not apply to every pharmacist or every physician-pharmacist consult agreement. We request the Board amend these subsections to apply only to pharmacists prescribing controlled substances pursuant to the consult agreement.

Finally, NCPA is concerned that certain subsections of the proposed rules previously mentioned fall outside of the scope of regulatory authority provided to the Board by O.R.C. §4729.39(C) and could be construed as regulatory overreach. We respectfully encourage the Board to ensure that any and all rules related to physician-pharmacist consult agreements are promulgated *in consultation with the state board of pharmacy* and are focused on the regulation of physician actions, while allowing the state board of pharmacy to promulgate rules under the section focused on the regulation of pharmacist actions.

NCPA appreciates the opportunity to share our comments and recommendations with you regarding proposed rules 4731-35-01 and 4731-35-02 related to physician-pharmacist consult agreements. If you have any questions or wish to discuss our comments further, please contact me at 703-600-1179 or alliejo.shipman@ncpanet.org.

Sincerely,



Allie Jo Shipman, PharmD
Associate Director, State Government Affairs

Sirine Shoukair
Clinical Pharmacist
University of Toledo
3000 Arlington Ave
Toledo OH 43614

February 7, 2019

Sallie Debolt, Esq., Senior Counsel

State Medical Board of Ohio

30 E. Broad Street, 3rd Floor

Columbus, OH 43215

Dear Ms Debolt,

Thank you for the opportunity to review the proposed draft Medical Board Rules 4731-35-01 Consult Agreements and 4731-35-02 Standards for Managing Drug Therapy. As a clinical pharmacist specialized in anticoagulation therapy and pharmacotherapy at The University of Toledo Medical Center we have partnered with our medical staff to optimize patient care through the utilization of consult law. Physicians collaborate with pharmacists as the medication experts within the interdisciplinary patient care team making their expertise imperative to assisting us with the care of our patients. This knowledge of evidence-based care can be managed within an agreed upon scope of the Consult Agreement through the combined rules of the Ohio Medical and Pharmacy Board.

Our request would be to delete C-4 a and b from proposed rule 4731-35-02 (C-4) that indicates prior to any action a pharmacist can perform; the pharmacist must notify the physician and obtain consent.

Our anticoagulation clinic oversee the management of more than 670 patients, and we interact with over a 100 patient per day to address anticoagulation management and dose adjustment. The Medical Staff processes of FPPE and OPPE review our pharmacists at the University of Toledo for quality assurance and their partnering physicians retrospectively reviews and acknowledges the activities of the pharmacist as a quality measure in compliance with current rules and regulations. The proposed language requiring advanced notification and consent would take the physician and pharmacist away from other patient care duties and decreasing the number of lifesaving and quality of care improving interventions our physicians and pharmacists can make for our patients.

Consult agreements allow physicians to work collaboratively with pharmacists to manage chronic diseases in the ambulatory setting. Physicians and pharmacists collaborate to manage patients in primary care and in anticoagulation. Our pharmacists provided over 6000 patient encounters in 2018 demonstrating improved outcomes such as compliance, fewer adverse reactions, and quicker achievement of therapeutic goals similar to the Impact Trial and other similar studies. Additionally, Pharmacists have been recognized by the U.S. Department of Health and Human Services (HHS) to improve the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

In summary: the proposed changes would discourage collaborative practice and obstruct our current quality-based workflow for both the medical and pharmacy teams. With the current consult agreements, the physicians and pharmacists work closely together to ensure the best patient care happens to patients. If

the proposed changes occur, there will be more unnecessary phone calls, longer time to patient care, and potential harm to patients. We are pleased the Medical Board has provided physicians additional guidance on managing consult agreements although we would ask the Medical Board to consider removing 4731-35-2 C-4 a and b from the proposed draft Medical Rules

Sincerely,

Sirine Shoukair, PharmD, CACP, BCPS

From: Amanda Singrey
To: Debolt, Sallie
Subject: Comments on consult agreements between physicians and pharmacists
Date: Monday, February 4, 2019 11:54:15 AM

Dear Ms. Debolt:

I am writing to comment on the Board's draft rules on 4731-35-01 and Consult agreements and 4731-35-02 Standards for managing drug therapy.

I am a clinical pharmacist practicing in the primary care setting. The physicians on my team refer their patients to me who are not at therapeutic goal for certain disease states (such as hypertension and diabetes) and allow me to collaborate with them through the current consult agreement rules to adjust their medication regimens and order necessary labs to get the patients to goal. This set-up allows me to have close follow-up with patients and assist in getting the patients' disease states to goal between their normal physician visits. In my experience, the physicians really value my ability to adjust medication therapy without needing their prior approval as it makes the process more efficient for them and allows patients to have immediate change in therapy when needed. If I had to obtain physician approval first, this would almost always delay change in therapy as I would need to hear back from the physician and then get in contact with the patient again. Similarly, if I had to have a physician approve a lab order, the patient would have left the building by the time the physician gets to my message and responds. I am also able to order medications and refills for the disease states I manage which again removes that burden from the physicians and saves them time to see more patients.

I am concerned with several of the proposed rule changes as I feel they will limit the ability of the pharmacist to assist physicians in an efficient way. I also fear it will harm patients by adding extra unnecessary steps delaying their therapy and increasing the chance of losing them to follow-up. **I kindly ask that you please consider removing section (C)(4) and section (D)(1) for these reasons.** The inclusion of (C)(4) seems to remove the collaborative nature of team-based care, and the ability of the pharmacist to manage disease states would be greatly restricted to essentially providing recommendations, which can typically be done without a consult agreement. Pharmacists are well-qualified to manage drug therapy and in my experience, physicians really value the pharmacist's clinical expertise on which medications to start/stop/adjust to get a patient to goal. Section (D)(1) would be a large amount of administrative work that seems unnecessary as the decision criteria the pharmacist uses to justify a medication change would be documented in their progress notes which can be made available to the physicians. I believe that having a separate consult report containing all this information would be repetitive and cumbersome, both for the pharmacist and the physician.

I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rule. Thank you for your time and thoughtful consideration.

Sincerely,
Amanda M. Singrey, PharmD, BCACP, CTTS, RPh

February 7, 2019

Mary Catherine Smith
Emergency Department Pharmacist
University of Toledo Medical Center
3000 Arlington Ave
Toledo, Ohio 43614

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Dear Ms. Debolt:

I am writing in regards to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. Consult Agreements for Pharmacist Management of Patient's Drug Therapy is of interest to me due to my current collaborative practice with our medical staff as a Licensed, credentialed, and privileged pharmacist practicing at the University of Toledo Medical Center. Within our hospital, I work side by side with physicians on a daily basis who provide unique value to our patients and improve overall quality of care.

Currently, consult agreements allow physicians to work collaboratively with pharmacists to dose antibiotics, anticoagulants, discontinue duplicate medications, and renally adjust medications. In my practice, we have pharmacists who independently change doses, frequencies, routes, and order labs through consult agreements. Pharmacists improve the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Additionally, our pharmacists serve as drug information experts and educators for both our residents, providers and patients. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

The proposal includes unnecessary additions (4731-35-02 D-1) requiring the pharmacist to have a detailed description of a continuous quality improvement project including regular meetings with the physician. This should not be outlined by the rules, but should be dependent on the practice allowing variation from site to site. I recommend this be removed from the proposal.

Under the consult agreements in place at the University of Toledo Medical Center the pharmacists and physicians are able to provide the very best care for the patient. The physicians truly appreciate the assistance we provide in regards to renal adjustments, kinetic dosing, and ordering labs. By requiring approval for every medication change, it will significantly burden physicians and delay patient care.

In summary, I hope that the proposal be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,

Mary Catherine Smith, PharmD

From: Smith, Russell W.
To: Debolt, Sallie
Subject: Proposed Rule 4731-35-01 and 02
Date: Thursday, February 7, 2019 2:50:34 PM

Dear Ms Debolt,

Thank you for the opportunity to review and provide comments to the proposed draft Medical Board Rules 4731-35-01 Consult Agreements and 4731-35-02 Standards for Managing Drug Therapy. As the Director of Pharmacy at The University of Toledo Medical Center we have partnered with our medical staff and Medical Executive Committee to optimize patient care through the utilization of consult law. Physicians partner with pharmacists as the medication experts within the interdisciplinary patient care team making their expertise imperative to assisting us with the care of our patients. Our request would be to delete C-4 a and b from proposed rule 4731-35-02 (C-4) that indicates prior to any action a pharmacist can perform, the pharmacist must notify the physician and obtain consent.

University of Toledo credentialed and privileged board certified pharmacists in 2018 partnered with our medical staff to perform about 36,000 actions (approx. 100 per day) under the current consult law. Pharmacists are reviewed by the Medical Staff processes of FPPE and OPPE for quality assurance and their partnering physicians retrospectively reviews and acknowledges the activities of the pharmacist as a quality measure in compliance with current rules and regulations. The current consult agreement in conjunction with our approved Medical Executive Committee policies has allowed us to currently have over 300 days since the last medication related harm event. The proposed language requiring advanced notification and consent would take the physician and pharmacist away from other patient care duties and decreasing the number of lifesaving and quality of care improving interventions our physicians and pharmacists can make for our patients.

Consult agreements allow physicians to work collaboratively with pharmacists to manage chronic diseases in the ambulatory setting. Physicians and pharmacists partner to manage patients in primary care and in anticoagulation. Our pharmacists provided over 6000 patient encounters in 2018 demonstrating improved outcomes such as compliance, fewer adverse reactions, and quicker achievement of therapeutic goals similar to the Impact Trial and other similar studies. Pharmacists have been recognized by the U.S. Department of Health and Human Services (HHS) in a December 2018 report as key components to improve the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

In summary: the proposed changes would discourage collaborative practice and obstruct our current quality-based workflow for both the medical and pharmacy teams. With the current consult agreements, the physicians and pharmacists work closely together to ensure the best patient care happens to patients. If the proposed changes occur, there will be more unnecessary phone calls, longer time to patient care, and potential harm to patients. We are pleased the Medical Board has provided physicians additional guidance on managing consult agreements although we would ask the Medical Board to consider removing 4731-35-2 C-4 a and b from the proposed draft Medical Rules.

Sincerely,

Russell Smith B.S. Pharm D, MBA, BCPS
Director of Pharmacy

Department of Pharmacy

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russell.smith@utoledo.edu

From: Dr. Wendell Spangler
To: Debolt, Sallie
Subject: Ohio State Medical Board potential rule changes
Date: Wednesday, February 6, 2019 5:10:45 PM

I would like to take this time to send you a message regarding proposed OSMB rule changes. My main concern would be our hospital runs a Coumadin Clinic and manages it (we have to fill out initial papers and sign yearly updates)--they manage my patients INR levels otherwise. The new requirement would require MD to review consult agreement details with patient and notify MD prior to any action being taken and no action without consent of physician. The doctor already gives INR parameters when starting Coumadin. The pharmacy follows evidence based guideline dosing protocols for the medications ordered as well. The patient would not likely be able to get instructions while they are in the Coumadin Clinic if physician consent has to be obtained every time and likely will lead to more errors--some patients are quite hard to get a hold of and the patient can be instructed what to do right at their Coumadin Clinic appointment. When a patient is inpatient, antibiotic doses would potentially be held up as well due to required approval of the provider (now talking about antibiotics on medical floor). I believe that most/all of my hospital providers/colleagues would agree this is not in the best interest of our patients. Thank you for taking the time to review my suggestions.

Truly,

Wendell Spangler MD (Paulding County Hospital, Paulding, Ohio)
My cell # is 419-399-7058 if would like to talk to me regarding this issue

Dear Ms. Sallie Debolt,

On behalf of the Greater Cincinnati Society of Health-System Pharmacists (GCSHP), I would like to formally submit comments on the proposed language for the new Medical Board of Ohio rules regulating consult agreements between physicians and pharmacists. GCSHP represents pharmacists in the Greater Cincinnati Area that work in Health-Systems, including hospital, outpatient clinic, and home-based care practices. GCSHP pharmacists practice in conjunction with our physician colleagues to provide optimal patient care. Our pharmacists provide medication counseling, drug dose optimization, and monitoring to help the medical team achieve common disease state goals.

Although GCSHP understands the need for guidance of pharmacist practice under a consult agreement, our organization feels the current language in the proposed rules significantly diminishes the scope and role of the pharmacist in managing a patient's medication therapy under the provision of a consult agreement. Additionally, due to the burdensome requirements placed on our physician colleagues, the current language may reduce the overall feasibility of pharmacy consults for inpatient practice. We are concerned that limiting the scope of pharmacy practice will effect patient safety by prohibiting pharmacist ability to modify and adjust medications based on patient specific factors such as organ function and co-morbidities.

As such, we would like to recommend the following changes:

4731-35-01 Consult Agreements

- Removal of Section A-1-i – requirement for physician approval prior to adjustment to the dose of a controlled substance.
    - Given the current challenges in Ohio with management of opioids and opioid addiction, limiting the ability for pharmacists to manage controlled substances will have the potential to perpetuate the problem of opioid overuse by preventing pharmacists from adjusting doses down or discontinuing opioids that are no longer needed for the patient.

4731-35-02 – Standards for Managing Drug Therapy

- Modification of section A-3 – The language around physician communication to the patient is excessive and discourages patients from allowing a pharmacist to participate in their care through a consult agreement. In addition, the requirement for notification of the patient's primary care physician may represent an unnecessary action for inpatient providers. The action of notifying a patient's PCP each time a pharmacist carries out a vancomycin, aminoglycoside, or inpatient warfarin consult seems unrealistic and unnecessary. These activities are unlikely to impact the patient's longterm management and primary care physicians would likely find these frequent notifications irrelevant and inconvenient. We recommend sub-bullets (b), (c), and (d) be removed from the rules.
- Removal of section A-6 – The requirement that the authorizing physician ensure the managing pharmacists' training and experience are adequate is an excessive burden on the physician. As pharmacists are extensively trained in pharmacology and pharmacotherapy through their

prerequisite education in order to become licensed, further scrutiny of this training and experience by the authorizing physician is excessive.

- Clarification of section A-7 – Further clarification of "prompt review".
- Modification of section B-1 – Placement of a consult agreement infers that the provider has already made the decision based on the pharmacist training and education to provide them with the scope to manage the requested therapy. Recommend acknowledgment that the decision to undergo a consult agreement independently indicates a pharmacist's ability to "adjust prescribed and agreed upon drug's strength, dose, dosage form, frequency of administration, discontinue a drug, or to prescribe new drugs; and order blood urine, and other tests related to drug therapy being managed."
- Modification of section B-2 - Recommend removing requirement for provider to establish decision-making criteria for pharmacists under a consult agreement. Recommend that agreement to undergo a consult agreement independently indicates that the provider is working collaboratively with a pharmacist to employ their training and expertise, including decision-making abilities, in the agreed upon drug management.
- Modification of section C-4-a – Recommend removal of requirement for pharmacist to notify primary physician prior to any action. This requirement is extremely onerous on both the physician and the managing pharmacist, and will discourage physicians from entering into consult agreements with pharmacists. This will negatively impact patients' access to the necessary care they could receive from a pharmacist to manage their medications under a consult agreement. In addition, this may result in undue delays in patient care; pharmacists are rendered unable to respond to aberrant lab values in a timely manner, which has the potential to cause significant harm.
- Modification of section D-1 – Recommend removal of the requirement for primary physician and managing pharmacist to hold regular meetings. This requirement is onerous on both the physician and the managing pharmacist, and will discourage physicians from entering into consult agreements with pharmacists.

Thank you for your consideration of our comments for incorporation into these rules. Please feel free to contact me with any questions or clarifications.

Sincerely,

The Greater Cincinnati Society of Health-System Pharmacists (GCSHP)

Contact: Beth Stacy
Email: beth.stacy@uchealth.com

February 8, 2019

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult Agreements and 4731-35-02 Standards for Managing Drug Therapy

Dear Ms. Debolt:

I am writing in regards to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. The suggested rule changes, specifically those that require pharmacists to notify the physician of any action prior to implementation (4731-35-02 C-4) would discourage collaborative practice and obstruct our current quality-based workflow. Pharmacists are the medication expert within the interdisciplinary patient care team making their expertise imperative to the care of patients. This expertise and evidence-based care can be managed independently within an agreed upon scope of practice. The removal of the autonomy afforded to pharmacists through consult agreements would lead to a tedious and inefficient process for chronic disease management and patient care for hospitalized patients. It would definitely have a negative impact on the pharmacist, provider and patient. Logistically, a busy provider may not always be available - making it difficult for both the pharmacist and patient's to reach them; thereby delaying care and conceivably causing harm in certain circumstances.

I recommend that the proposal requiring affirmation from a physician prior to dosing adjustment be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,

Shawn Stansbery D.O.
853 Scott Blvd
Bowling Green, OH 43402

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

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Division of General Internal Medicine
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614-293-4953 Phone
614-293-6890 Fax

2/5/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
Sallie.Debolt@med.ohio.gov

Dear Ms. DeBolt:

I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a physician that utilizes the services of pharmacists through collaborative practice agreements to provide care to my patients, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.

Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:
Shannon Stevenson
788BD91CE236406...

Shannon Stevenson

DO

From: Laura Stewart
To: Debolt, Sallie
Subject: comments on state medical board of Ohio consult agreements rules for pharmacist
Date: Friday, February 8, 2019 11:46:24 AM

Hi Sallie,
I am providing feedback as requested for the proposed rules establishing standards and procedure for a physician who is entering into a consult agreement for pharmacist management of a patient's drug therapy.

Not sure I understand the purpose of a consult agreement if any action pursuant to the drug being managed has to result in a communication with the primary physician? How does that action maintain good patient care. That requirement will only frustrate physicians with unnecessary phone calls and delays in patient care especially in ambulatory clinics (i.e. coumadin clinics) as per Proposed Law: 4731-35-02 (4)(a&b) pgs 2-3

Have these changes been vetted with physicians who have consult agreements with pharmacists?
From an institutional pharmacy practice perspective this proposed rule will definitely have a negative to hospitalists who rely on pharmacists to manage such drugs as warfarin, vancomycin, argatroban, TPN per current rules 4729.39.

Proposed Law: 4731-35-02 (4)(a&b) pgs 2-3
(4) When the managing pharmacist changes the duration of treatment for the current drug therapy; adjusts a drug's strength, dose, dosage form, frequency of administration, route of administration, discontinues a drug, prescribes a new drug, or orders urine or blood tests, as authorized under section B)(1)(a), and (B)(1)(b) of this rule, the managing pharmacist must:
(a) Notify the primary physician prior to any action. The notification shall include a description of:
(i) The decision criteria considered by the managing pharmacist in deciding to conduct an authorized action; and
(ii) A description of the proposed authorized action the managing pharmacist intends to conduct.
(b) Obtain the consent of the primary physician to conduct the proposed authorized action.

Providing access to patient's medical record may be difficult in this electronic world and the rules with HIPPA. How can a pharmacist have access to individual physician practice's EMR and does that open up issues from a EMR management perspective. How does the Medical board see this proposed law working from a medical information perspective?

Proposed Law: 4731-35-01 Letter "C" page 3
(C) Managing Drug Therapy.
(1) For the purpose of implementing the management of a patient's drug therapy by an authorized managing pharmacist acting pursuant to a consult agreement, the primary physician must:
(a) Provide the managing pharmacist with access to the patient's medical record;

How would this law impact the institutional practice as patients are prescribed antibiotic therapy by a prescriber and then via consult agreement pharmacist manage the therapy until physician discontinues the therapy? Also from an outpatient clinic perspective isn't this redundant as a patient has already agreed to come to the clinic has agreed to the medication therapy that will be managed by a pharmacist?

Proposed Law: 4731-35-02 (A)(3), pg 1
(3) The physician, prior to the effective date of the consult agreement, and prior to a pharmacist managing the patient's drug therapy, shall communicate the content of the proposed consult agreement to each patient whose drug therapy is managed under the agreement, in such a manner that the patient or the patient's representative understands scope and role of the managing pharmacist, which includes the following:
(a) That participation in the consult agreement is voluntary and that the patient may choose not to participate;
(b) That the agreement will not be utilized unless the patient or the patient's authorized representative consents to the consult agreement;

Those are my comments. I don't know if you remember me, though I had previously worked at Mount Carmel in the IT department and I had many conversations with you regarding prescriptive authority for PA's and interpretation of the rules.

I no longer work at Mount Carmel and I am practicing my first love of Pharmacy and working with clinicians again.

Hope all is well for you.

Laura Stewart MBA, RPh
Clinical Manager, Pharmaceutical Services
Genesis Healthcare System
2951 Maple Ave.
Zanesville, Ohio 43701

Office: 740-454-5258
Fax: 740-454-4059

Confidentiality Notice

Message Sent: 2019-02-08 11:46:20

February 7, 2019

Sallie Debolt, Esq.
Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
Sallie.Debolt@med.ohio.gov

To Ms. Debolt and the Medical Board,

We are writing with concern regarding the proposed rules for implementing 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy. We work closely with pharmacists in managing drug therapy and we are concerned that these rules would damage the effectiveness of the physician-pharmacist-patient relationship that the consult agreements are intended to establish. In particular, the requirement to notify the physician prior to any action taken and prohibition on taking any action without consent of the physician essentially nullifies the consult agreement. This returns the relationship to the prior state and would cause delays in providing and improving therapy for the patient. If the pharmacist cannot act in collaboration with the physician then there is no purpose for the agreement. What's more the section on reporting seems to have been written with the assumption that pharmacists would be practicing in a traditional community pharmacy, but this is often not the case. In many cases the pharmacists work elbow to elbow with the physicians with whom they have consult agreements and the pharmacists notes are part of the same electronic medical record as other provider's notes. Thus, the reporting requirements have been written from an overly narrow viewpoint.

In closing, we do not feel that the proposed rules honor the spirit of the law and instead essentially negate the law. We anticipate that this change would result in heavily impeded workflows, delayed patient care, increased stress upon physicians, and reduced interdisciplinary collaboration.
We strongly urge you to consider the negative impact that this proposed language would have on our patients as well as our practice. Thank you for your time and consideration.

Dennis Sullivan, M.D., M.A. (Bioethics) Surgeon	
Mark Pinkerton, M.D., M.S. Family Medicine	

From: John D Sutton
To: Debolt, Sallie
Subject: Collaborative Practice Agreements
Date: Friday, February 8, 2019 11:23:05 AM
Attachments: image001.png

We have been serving our underserved population under a collaborative practice agreement with pharmacists for the last year, and we have been able to demonstrate significant success in chronic disease management with this. The suggested changes will greatly limit the existing process and established care that has been demonstrably successful in our office, a federally qualified health center look-alike. These changes would increase barriers in access to care and seem unnecessary in my experience.

Sincerely

John Sutton MD
Medical Director
My Community Health Center
330-363-1134

Ubuntu-"My humanity is bound up in yours for we can only be human together". -Desmund Tutu

Department of Medicine
Chair: Lance D. Dworkin, M.D.
Admin.Vice-Chair: Basil E. Akpunonu, M.D.
Administrator: Beth Smotherman
Assistant to Chair: Maureen Gilmore

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Health Science Campus
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COLLEGE OF MEDICINE AND LIFE SCIENCES
THE UNIVERSITY OF TOLEDO

Division Chiefs
Cardiovascular Medicine: Mark W. Burket, M.D.
Community Internal Med: Allen Markowicz, M.D.
Dermatology: Lorie D. Gottwald, M.D.
Endocrinology: Juan C. Jaume, M.D.
Gastroenterology: Ali Nawras, M.D.
General Internal Medicine: Basil E. Akpunonu, M.D.
Hematology/Oncology: John Nemunaitis, M.D.
Infectious Diseases: Joan Duggan, M.D.
Nephrology: Deepak Malhotra, M.D., Ph.D.
Pulmonary/Critical Care: Jeffrey R. Hammersley, M.D.
Rheumatology: M. Bashar Kahaleh, M.D.

February 8, 2019

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy

Dear Ms. Debolt:

I am writing in regards to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. Consult Agreements for Pharmacist Management of Patient's Drug Therapy is of interest to me due to my current collaborative practice with a pharmacist as a PA practicing at South Toledo Internist, 3355 Arlington Avenue, Toledo, Ohio. Within my outpatient clinic, I work side by side with clinical pharmacists on a daily basis who provide unique value to our patients and improve overall quality of care.

Currently, consult agreements allow physicians to work collaboratively with pharmacists to manage chronic diseases. In my practice, we have pharmacists who independently manage diabetes, hypertension, and dyslipidemia through consult agreements. Pharmacists improve the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Additionally, our pharmacists serve as drug information experts and educators for both our residents, providers and patients. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

The proposal includes unnecessary additions (4731-35-02 D-1) requiring the pharmacist to have a detailed description of a continuous quality improvement project including regular meetings with the physician. This should not be outlined by the rules, but should be dependent on the practice allowing variation from site to site. I recommend this be removed from the proposal.

Our collaborative model has allowed us to work towards a path of achieving improvement in HbA1C control. Additionally, our pharmacists provide weekly/biweekly phone follow up with our diabetic patients allowing them to get to their blood sugar and A1C goals quickly

In summary, I hope that the proposal be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,

Brian Tasma

Brian Tasma, M.D.

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

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Columbus, OH 43221
614-293-4953 Phone
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February 7, 2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
Sallie.Debolt@med.ohio.gov

Dear Ms. DeBolt:

I am reaching out on behalf of the Division of General Internal Medicine and our faculty group practice, as we appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

All of our physicians utilize the services of pharmacists through collaborative practice agreements and we have serious concerns about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). We fear this language will limit the pharmacist's ability to provide efficient and effective patient care.

Enclosed are comment letters from **36** of our Division faculty members.

Ines Aranguren, MD	Assistant Professor
Seuli Brill, MD	Associate Professor
Jeanne Caligiuri, MD	Assistant Professor
Chris Chiu, MD	Assistant Professor
Shawn Corcoran, MD	Assistant Professor
Roopan Farris, MD	Assistant Professor
Matthew Flanigan, MD	Assistant Professor
Marty Fried, MD	Assistant Professor
Aaron Friedberg, MD	Assistant Professor
Susie Friedman, MD	Assistant Professor
Kevin Goist, MD	Assistant Professor
Deborah Gordish, MD	Assistant Professor
Jodi Grandominico, MD	Assistant Professor
Gail Grever, MD	Associate Professor
Tanya Gure, MD	Associate Professor
Christopher Hanks, MD	Associate Professor
Harrison Jackson, MD	Assistant Professor
Sarah Jonaus, MD	Assistant Professor
Rita Konfala, MD	Assistant Professor
Cynthia Kreger, MD	Professor
Michael Langan, MD	Associate Professor
Kristina Lehman, MD	Assistant Professor

Guibin Li, MD, PhD	Associate Professor
Shengyi Mao, MD	Assistant Professor
Erin McConnell, MD	Assistant Professor
Jared Moore, MD	Associate Professor
Robert Murden, MD	Professor
Kruti Patel, MD	Assistant Professor
Nathan Richards, MD	Assistant Professor
Patty Ryan, MD	Assistant Professor
Heather Saha, MD	Assistant Professor
Shannon Stevenson, DO, MA	Assistant Professor
Neeraj Tayal, MD	Associate Professor
Corina Ungureanu, MD	Assistant Professor
Geoffrey Vaughan, MD	Assistant Professor
Harrison Weed, MD, MS	Professor

We appreciate the State Medical Board of Ohio reviewing our comments on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy and urge you to reconsider the proposed changes.

Sincerely,

DocuSigned by:
Neeraj Hari Tayal
CDB6C44259844C9...

Neeraj H. Tayal, MD
Associate Professor, Clinical Medicine
Division Director, General Internal Medicine & Geriatrics

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2/5/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
Sallie.Debolt@med.ohio.gov

Dear Ms. DeBolt:

I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a physician that utilizes the services of pharmacists through collaborative practice agreements to provide care to my patients, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.

By developing collaborative practice agreements with our clinical pharmacists, I have seen a clear benefit to my formerly uncontrolled diabetic patients. From what I have experienced, it is not advanced technologies that makes this possible. It is the frequent outreach and medication adjustments made every 1-2 weeks that makes all the difference. We have developed high quality protocols that our pharmacists use every day and we are seeing dramatic improvements in the health of our population. We are doing the same for our smokers. In the near future, we hope to expand this to include hypertension and anticoagulation management. We can also leverage this to wean patients from controlled substances. The proposed language would negate all the benefits we are seeing from collaborative practice. I would implore you reconsider the language in the sections above.

Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:
Neeraj Hari Tayal
CDB6C44259844C9...

Neeraj Hari Tayal

Director - Division of General Internal Medicine and Geriatrics

From: Taylor MD, Diana L
To: Debolt, Sallie
Subject: Response to Proposed Rules 4731-35-01 and 4731-35-02: Consult Agreements
Date: Tuesday, February 5, 2019 2:46:30 PM

TO: State Medical Board of Ohio

FROM: Diana Taylor, M.D.

RE: Response to Proposed Rules 4731-35-01 and 4731-35-02: Consult Agreements

Thank you for the opportunity to provide comments on the Medical Board's recently proposed rules regarding consult agreements between pharmacists and physicians. Consult agreements have been an invaluable resource for physicians to expand access and improve quality, especially since the revision of the law in 2016. In general, I appreciate the added clarity that the medical board has provided specific to physician participation in a consult agreement. However, some of the new provisions outlined in the proposed rules create a significant burden that would outweigh many of the benefits of a consult agreement, and would negatively impact patient care.

Specifically, the requirements for notification and consent prior to action by a pharmacist, as well as the requirement for regular meetings to review a written consult report represent my greatest concerns. The current regulations allow physicians and pharmacists to reach mutually agreeable terms that ensure adequate collaboration, expertise, oversight, and quality assurance mechanisms exist within the consult agreement. Physicians already have the flexibility to engage in a consult agreement that addresses training, communication, and quality assurance mechanisms that are appropriate for the medication management that is being performed.

Requiring a physician's consent prior to each action adds significant time without providing any benefit to the patient. Consult agreements already require a "description of the procedures, decision criteria, and plan the managing pharmacist is to follow in acting under a consult agreement." Asking a physician to confirm that the decision criteria and plan are correct prior to every change is unnecessary and only adds burden to the pharmacist and physician. Adding complexity into a medication adjustment may also cause a patient to experience suboptimal care while consent is being obtained.

Similarly on the requirement for regular meetings, the law already requires "communication between a pharmacist and physician acting under a consult agreement shall take place at

regular intervals specified by the primary physician acting under the agreement." Additional requirements for regular meetings and written consult reports only add complexity and administrative burden to an already safe collaborative

Ultimately, I believe that these proposed rules run counter to the efficiencies that the law revision was intended to provide in 2016, and I recommend that the State Medical Board of Ohio reconsider adding any new requirements or barriers to care into the rules. I appreciate your consideration and the opportunity to provide feedback on the proposed rules. If you have any questions or would like to further discuss our comments, please reach out at the contact information below.

Diana Taylor, M.D.
Family Physician
Delaware, Ohio

ROCKING HORSE COMMUNITY HEALTH CENTER
rockinghorsecenter.org | 937-324-1111 | info@rockinghorsecenter.org

February 7, 2019

From:
Dr. Yamini Teegala, MD
Medical Director
Rocking Horse Community Health Center
651 N. Limestone St, Springfield, OH 45505

Dr. Andrew Straw, PharmD, BCADM
Clinical Pharmacist
Rocking Horse Community Health Center
651 N. Limestone St, Springfield, OH 45505

To: Sallie Debolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

Dear Ms. DeBolt:

On behalf of clinic providers, we are writing to express our concern with the proposed rules found in OAC 4731-35-01 and 4731-35-02. Rocking Horse Community Health Center (RHCHC) is proud of our physician-pharmacist collaboration and the advance care that we are capable of providing as a team. We strongly feel that these rules will not only compromise this collaboration, but also decrease the quality of care that we can provide. Overall, we feel that these proposed rules will not advance the practice of medicine or the practice of pharmacy in a positive direction.

RHCHC established a collaborative agreement with pharmacists for diabetes care in January 2017. This has allowed physicians to identify high-risk patients and connect them with pharmacists who can manage their therapy according to the collaborative agreement. Since 2017, collaboration with pharmacists has resulted in:

- Clinic-level improvement of diabetes related quality measures
- Patients referred with an A1C greater than 9.0% have an average A1C reduction of 2.1%
- 86.9% of all referred diabetes patients have achieved their blood pressure goal
- 551 office visits provided by pharmacists

This impact may not have been possible if the proposed rules had been place. We are most concerned with the language found in 4731-35-02 Section C (4) which states that a pharmacist must notify and receive consent of the physician prior to any action being taken. This requirement undermines the essential purpose of the collaborative agreement and will place a great deal of burden onto our physicians. If this rule were approved, we find there to be no

ROCKING HORSE COMMUNITY HEALTH CENTER
rockinghorsecenter.org | 937-324-1111 | info@rockinghorsecenter.org

expressed difference between practicing with a collaborative agreement to without one. We anticipate that this change would result in heavily impeded workflows, delayed patient care, increased stress upon physicians, and reduced interdisciplinary collaboration.

We strongly urge you to consider the negative impact that this proposed language would have on our patients as well as our practice. Thank you for your time and consideration.

Sincerely,

Dr. Yamini Teegala, MD
Medical Director

Dr. Andrew Straw, PharmD, BCADM
Clinical Pharmacist

Dr. Jo M Moughby, PharmD
Resident Clinical Pharmacist

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

Andrew M. Thomas, MD, MBA
Chief Clinical Officer
Senior Associate Vice President, Health Sciences
Associate Professor of Clinical Internal Medicine

130 Doan
410 West 10th Avenue
Columbus, Ohio 43210
andrew.thomas@osumc.edu

To: Sallie Debolt, Senior Counsel, State Medical Board of Ohio

On behalf of medical and pharmacy leadership at The Ohio State University Medical Center (OSUWMC), thank you for the opportunity to comment on proposed rules 4731-35-01 Consult Agreements and 4731-35-02 Standards for managing drug therapy. The rules proposed by the Medical Board are generally acceptable and in line with current pharmacy rules, with a few exceptions that are outlined below.

OSUWMC employs a patient-centered care approach utilizing the skillsets of many disciplines to create best outcomes for patients, including the role of the pharmacist in optimizing medication use for patients. The proposed rules as written would severely limit the ability for patients and physicians to benefit from the collaborative practice of pharmacists. The rules, as written, are from the standpoint of managing a single patient with a single physician and single pharmacist. From the health-system standpoint, practice doesn't occur in this manner. Instead, systems must be built which allow for consistency of care delivery from myriad providers and pharmacists for our patient populations. Furthermore, rules as constructed do not account for the typical practice of medicine and pharmacy in an institutional setting and these rules would significantly frustrate and unnecessarily burden physicians. As an example, OSUWMC has implemented the consult rules through the credentialing and privileging of pharmacists by the medical staff. The credentialing and privileging process is innate to health-system practice and provides for the appropriate safeguards and peer review and oversight.

We respectfully request that the State Medical Board of Ohio revise these rules to mirror the State of Ohio Board of Pharmacy rules on consult agreements (4729-1-6) and rules governing the practice of physician assistants (4730-2-06 and 4730-2-07). Specific recommendations for edits are provided below.

Proposed Rule 4731-35-01 – Consult Agreements

It is recommended to strike (A)(1)(b) and replace with language from OAC 4729:1-6-01(H) and 4729:1-06-01(I). This will provide the necessary guidelines around consent while also exempting inpatient management of patient care and will align with the State of Ohio Board of Pharmacy rules.

It is recommended to strike (A)(1)(i). Pharmacists are able to obtain DEA numbers and the intent of the law is to allow for consult agreements to be used for the management of many disease states, including those managed in part by prescribing of controlled substances including palliative medicine, epilepsy disorders and behavioral health diseases (e.g. attention-deficit/hyperactivity disorder), amongst others.

It is recommended to move the language in (A)(2) to create a new (D) and adjust requirements covered, which would state "Institutional and ambulatory outpatient facilities may implement a consult agreement and meet the requirements of (A)(1)(b) through (A)(1)(p) of this rule through institutional credentialing standards or policies.

Alternatively, Institutional and institutional ambulatory outpatient facilities could be carved out from of (A)(1)(b) through (C)(1)(d) if they follow the institution's credentialing and privileging process. The medical staff has oversight and is the governing body for granting an expanded scope of practice.

It is recommended to strike (A)(5)(b) through (A)(5)(d) as (A)(1)(a) already accounts for the pharmacists and physicians in the agreement and takes into account the consult agreement may be executed on behalf of physician or pharmacist practice groups or through institutional credentialing and privileging. It may be advisable to restructure (A)(5) to state, "Amendments to the consult agreement are required when there are changes to (A)(1)(c) through (A)(1)(f)."

It is recommended to add section (A)(8) stating the same language as 4729:1-6-02(A)(2), "Institutional or ambulatory outpatient facilities may implement a consult agreement and meet the requirements of paragraphs (A)(1)(c) through (A)(1)(f) and (A)(5) (if adopted as recommended in the preceding paragraph) of this rule through institutional credentialing standards or policies. Such standards or policies shall be referenced as part of the consult agreement and available to an agent of the board upon request.

It is recommended to edit (B) Recordkeeping to state, "The primary physician, physician practice group, or institution as defined in rule 4729-17-01 of the administrative code…" in order to allow for recordkeeping to be maintained by the institution as are all other medical records.

It is recommended to edit (C)(1) to add the following language, "…the primary physician, physician practice group, or institution as defined in rule 4729-17-01 shall:."

It is recommended to delete the first sentence of (C)(1)(ii), "An agent of the primary physician" as this is replicated in the following sentence. Sections (C)(1)(c) and (C)(1)(d) are redundant based on paragraph (A)(1)(c) through (A)(1)(f) and are recommended to be deleted.

Proposed Rule 4731-35-02 Standards for Managing Drug Therapy

It is recommended to align this rule more closely with 4729:1-6-03 and physician assistant rules 4730-2-06 and 4730-2-07 of the administrative code. This will allow for the collaborative practice of pharmacists and physicians to function in a more seamless, optimized manner.

It is recommended to modify the end of (A)(2) to the following. "The physician shall periodically assess the patient" removing the language requiring this assessment to occur at least one time per year. This will align the language with that found in the ORC 4729.39(A)(1) which reads, "Each physician has an ongoing physician-patient relationship with each patient whose drug therapy is being managed" while avoiding excessive visits, as general payor standards, including CMS, define frequency of every visits to maintain "established" status as every 3 years. This adjustment will avoid unnecessary burden on providers and negative impact on access to care. Frequency of physician assessments may be defined in the consult agreement.

It is recommended to delete (A)(3) and replace with language from OAC 4729:1-6-01(H) and 4729:1-06-01(I). This will provide the necessary guidelines around consent while also exempting inpatient management of patient care and will align with the State of Ohio Board of Pharmacy rules. Additionally, if 4730-35-01(A)(1)(b) is modified as above, this entire paragraph may not be necessary.

It is recommended to delete (A)(6) as this is redundant and covered in 4731-35-01(A)(1)(m). Additionally, pharmacists receive training in doctoral degree programs and take licensure exams. Physicians ought not to be burdened by additional requirements when these are already otherwise met.

It is recommended to either delete or align (A)(7) with rules for nurse practitioners and/or physician assistants. Communication is often documented in the medical record and discussed amongst care teams. It is recommended to allow for each physician practice or institution to determine what, if any requirements should exist around review of records.

It is recommended to delete or modify (B)(1) and (B)(2) and instead refer to the consult agreement requirements in 4731-35-01(A)(c-f). This provides enough context while allowing for the clinical practice of medication optimization to appropriately occur.

It is recommended to delete (C)(4) in its entirety and instead refer to 4731-35-01(A)(1)(g-h). It is impractical to require notification and consent of the primary physician before taking any action. If left unchanged, this language would render all consult agreements ineffectual. This clause is essentially reversing the intent of the consult agreement legislation.

It is recommended to modify (D)(1) to remove the requirement of regular meetings and make the guidance broad enough to apply to physician practices and institutions. Continuous Quality Improvement (CQI) programs are often managed via tracking populations of patients who receive interventions (e.g. pharmacist-managed patients) to appreciate outcomes. Also, privileging programs in institutions require peer-review or similar reviews which are then approved by the governing medical committee and may appropriately serve this purpose.

It is recommended to modify (D)(2)(a) to state, “A pharmacist has had their substance prescriber registration revoked, suspended, or denied by the state board of pharmacy:”

It is recommended to modify (D)(2)(c) to state, “If prescribing controlled substances, a pharmacist fails to obtain or maintain a valid DEA registration.”

Thank you for the opportunity to comment on the proposed consult agreement rules and consideration for inclusion of the recommendations listed above.

Respectfully,

Andrew Thomas, MD, MBA
Chief Clinical Officer
Senior Associate Vice President for Health Sciences
The Ohio State University Wexner Medical Center

TO: State Medical Board of Ohio

FROM: Julia Thomas, RPh, M.S.

RE: Response to Proposed Rules 4731-35-01 and 4731-35-02: Consult Agreements

Thank you for the opportunity to provide comments on the Medical Board's recently proposed rules regarding consult agreements between pharmacists and physicians. Consult agreements have been an invaluable resource for physicians to expand access and improve quality, especially since the revision of the law in 2016. In general, the clarity that the medical board has provided in the proposed rules regarding physician involvement in a consult agreement is beneficial. However, some of the new provisions outlined in the proposed rules would negate the positive benefits of a well-designed and executed consult agreement. The proposed changes will delay patient care and ultimately, negatively impact patient care.

In my current role as an ambulatory care pharmacist working with patients with diabetes, I work under a consult agreement to help manage insulin and other diabetic medications. The clinical and financial impact of uncontrolled diabetes is well-known and documented in the medical literature. Utilizing a consult agreement that enables an individual's drug therapy to be modified, escalated, or changed in a timely manner helps patients receive optimized therapy to treat their disease. Prior to using a consult agreement, patients would have a medication or dose change and then scheduled to come back in 3 months. This scenario potentially left the patient at suboptimal treatment for 3 months. Under the current model, therapy changes are made prior to the patient's next appointment to help them reach their clinical goals. For example, I worked with a patient whose hemoglobin A1c was 12.9 in May 2018. Through frequent patient-pharmacist interaction and insulin dose changes, her A1c decreased to 7.9 in December.

Two aspects of the proposed rule that concern me the most are requiring physician notification and consent prior to any action by a pharmacist and the requirement for regular meetings to review a written consult reports.

Requiring a physician's consent prior to each action executed under the consult agreement adds significant time without providing any benefit to the patient. Current regulations require that consult agreements be developed in a manner that addresses physician oversight, pharmacist training, communication, scope of medication management allowed, and quality assurance processes. The procedures, decision criteria, and plan the managing pharmacist is to follow when engaged with a patient under a consult agreement is defined. Asking a physician to confirm that the decision criteria and plan are correct prior to every change is unnecessary and only adds burden to the pharmacist and physician. Adding complexity into a medication adjustment may also cause a patient to experience suboptimal care while consent is being obtained.

Similarly on the requirement for regular meetings, the law already requires "communication between a pharmacist and physician acting under a consult agreement shall take place at regular intervals specified by the primary physician acting under the agreement." Each interaction that I have with a patient is documented and sent to the primary physician for notification and review. This includes notes in which all I did was leave a voicemail for a patient. Additional requirements for regular meetings and written consult reports only add complexity and administrative burden to an already safe collaboration.

Ultimately, I believe that these proposed rules run counter to the efficiencies that the law revision was intended to provide in 2016. Respectively, I request that the State Medical Board of Ohio reconsider adding any new requirements or barriers to care into the rules. I appreciate your consideration and the opportunity to provide feedback on the proposed rules. If you have any questions or would like to further discuss these comments, please reach out at the contact information below.

Respectively,

Julia A.M. Thomas, RPh, MS
OhioHealth Ambulatory Pharmacist

Julie.Thomas@ohiohealth.com
614-788-5558

OhioHealth

TO: State Medical Board of Ohio

FROM: Craig S. Thompson M.D.

RE: Response to Proposed Rules 4731-35-01 and 4731-35-02: Consult Agreements

Thank you for the opportunity to provide comments on the Medical Board's recently proposed rules regarding consult agreements between pharmacists and physicians. Consult agreements have been an invaluable resource for physicians to expand access and improve quality, especially since the revision of the law in 2016. In general, I appreciate the added clarity that the medical board has provided specific to physician participation in a consult agreement. However, some of the new provisions outlined in the proposed rules create a significant burden that would outweigh many of the benefits of a consult agreement, and would negatively impact patient care.

I have used our Coumadin clinic in our outpatient clinic for years and it has helped deliver timely and optimal care for patients on Coumadin. These changes would be detrimental to this process. Specifically, the requirements for notification and consent prior to action by a pharmacist, as well as the requirement for regular meetings to review a written consult report represent my greatest concerns. The current regulations allow physicians and pharmacists to reach mutually agreeable terms that ensure adequate collaboration, expertise, oversight, and quality assurance mechanisms exist within the consult agreement. Physicians already have the flexibility to engage in a consult agreement that addresses training, communication, and quality assurance mechanisms that are appropriate for the medication management that is being performed.

Requiring a physician's consent prior to each action adds significant time without providing any benefit to the patient. Consult agreements already require a "description of the procedures, decision criteria, and plan the managing pharmacist is to follow in acting under a consult agreement." Asking a physician to confirm that the decision criteria and plan are correct prior to every change is unnecessary and only adds burden to the pharmacist and physician. Adding complexity into a medication adjustment may also cause a patient to experience suboptimal care while consent is being obtained.

Similarly on the requirement for regular meetings, the law already requires "communication between a pharmacist and physician acting under a consult agreement shall take place at regular intervals specified by the primary physician acting under the agreement." Additional requirements for regular meetings and written consult reports only add complexity and administrative burden to an already safe collaborative

Ultimately, I believe that these proposed rules run counter to the efficiencies that the law revision was intended to provide in 2016, and I recommend that the State Medical Board of Ohio reconsider adding any new requirements or barriers to care into the rules. I appreciate your consideration and the opportunity to provide feedback on the proposed rules. If you have any questions or would like to further discuss our comments, please reach out at the contact information below. Sincerely, Craig S. Thompson, MD 1040 Delaware Ave Marion, Ohio 43302 740-383-7831 office

Craig S Thompson MD 2/4/19

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COLLEGE OF MEDICINE AND LIFE SCIENCES
THE UNIVERSITY OF TOLEDO

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Nephrology: Deepak Malhotra, M.D., Ph.D.
Pulmonary/Critical Care: Jeffrey R. Hammersley, M.D.
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February 8, 2019

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy

Dear Ms. Debolt:

I am writing in regards to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. Consult Agreements for Pharmacist Management of Patient's Drug Therapy is of interest to me due to my current collaborative practice with a pharmacist as a PA practicing at South Toledo Internist, 3355 Arlington Avenue, Toledo, Ohio. Within my outpatient clinic, I work side by side with clinical pharmacists on a daily basis who provide unique value to our patients and improve overall quality of care.

Currently, consult agreements allow physicians to work collaboratively with pharmacists to manage chronic diseases. In my practice, we have pharmacists who independently manage diabetes, hypertension, and dyslipidemia through consult agreements. Pharmacists improve the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Additionally, our pharmacists serve as drug information experts and educators for both our residents, providers and patients. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

The proposal includes unnecessary additions (4731-35-02 D-1) requiring the pharmacist to have a detailed description of a continuous quality improvement project including regular meetings with the physician. This should not be outlined by the rules, but should be dependent on the practice allowing variation from site to site. I recommend this be removed from the proposal.

Our collaborative model has allowed us to work towards a path of achieving improvement in HbA1C control.

In summary, I hope that the proposal be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,

PA-C

Ben Tobias, PA-C
University of Toledo Physicians Group

Dr. John Tumbush, D.O. ,F. A.A.F.P, RPh
Evans Middlefield Heath Center
15976 East High Street
Middlefield Ohio 44062
440-478-9215
John.Tumbush@UHhospitals.org
Feb 7th, 2018

Sallie Debolt, Esq.
Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

Dear Sallie Debolt, Esq.:

My name is John Tumbush and I am a primary care physician working with University Hospitals in Middlefield, Ohio. I am writing to express concerns about the proposed standards for a physician entering into a consult agreement for pharmacist directed medication therapy management. My practice, Evans Middlefield Health Center manages the care of over 5200 patients in small town in rural Northeast Ohio.

I began my career as a pharmacist for 3 years at Cleveland Metropolitan Hospital. Being trained as the medication expert was a tremendous advantage for me in medical school and even more so as a physician. I went back to medical school so I could have more direct contact with patients because pharmacists at the time were limited in their exposure. Pharmacists are underutilized for the level of training they receive and are a tremendous asset to the health care team. I was very optimistic with changes to consult/collaborative practice in 2015.

Those changes promote a progressive care model using a pharmacist to extend my practice and provide care to more patients. In rural northeast Ohio I cannot emphasize how important that is. Given the nature of the education/training, the pharmacist is able to manage medication therapy for my most challenging patients with multiple comorbidities and medications. I find that many patients are more willing to make changes and take cheaper or more appropriate medicines when a pharmacist is involved in their care. Pharmacists have 6-8 years of education that is focused just on medication. Many have 1-2 years residency training. This high level of education should allow them to make decisions without having a written or verbal OK on them. Nurse practioners have these privileges with significantly less training in medication therapy.

The provider status bill sponsored by Senator Dolan passed in 2018 was the final piece of the puzzle. It allows me to set up contracts with payors where the pharmacist can be recognized and integrated as part of interdisciplinary care.

The proposed rules from the State Medical Board are similar to the State Board of Pharmacy 2016 ruling, but the modifications nullify the pharmacist's ability to provide care independently. This was not the intent behind the rule.

I am specifically concerned that Section 4731-35-02.C.4.a-b prevents a pharmacist making any changes to drug therapy or monitoring without an extensive notification and consent process. This process puts undue burden on the consulting relationship and reduces its efficacy delivering timely appropriate care. I am also concerned that Section 4731-35-02.D.1 adds paperwork burden to a process that is flourishing throughout the state. These changes diminish the pharmacist role and essentially eliminate them in expanding access to care.

Thank you for your time and consideration in advance. I welcome any follow-up questions or concerns you have.

Sincerely

Dr. John Tumbush, D.O. ,F. A.A.F.P, RPh
Family Practice Middlefield Ohio
Cell Phone 440-478-9215

February 7, 2019

Chad Tuckerman, Pharm.D., BCPS
Internal Medicine Pharmacist, Opioid Coordinator
The University of Toledo Medical Center
3000 Arlington Avenue
Toledo, Ohio 43614
Chad.Tuckerman@utoledo.edu

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy

Dear Ms. Debolt:

I am writing in regards to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. Consult Agreements for Pharmacist Management of Patient's Drug Therapy is of interest to me due to my current collaborative practice with our medical staff as a Licensed, Board Certified, credentialed, and privileged pharmacist practicing at the University of Toledo Medical Center. Within our hospital, I work side by side with physicians on a daily basis who provide unique value to our patients and improve overall quality of care.

Currently, consult agreements allow physicians to work collaboratively with pharmacists to dose antibiotics, anticoagulants, discontinue duplicate medications, and renally adjust medications. In my practice, we have pharmacists who independently change doses, frequencies, routes, and order labs through consult agreements. Pharmacists improve the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Additionally, our pharmacists serve as drug information experts and educators for both our residents, providers and patients. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

The proposal includes unnecessary additions (4731-35-02 D-1) requiring the pharmacist to have a detailed description of a continuous quality improvement project including regular meetings with the physician. This should not be outlined by the rules, but should be dependent on the practice allowing variation from site to site. I recommend this be removed from the proposal.

In collaboration with my physicians and care team, we have made a huge impact on hospital-acquired infections, decrease length of stays, inappropriate dosing based on the patient's disease states and renal/liver function, and safe and effective therapeutic choices. We have educated patients in order to help decrease readmissions rates in areas of heart failure,

diabetes, and anticoagulation to name a few. There are numerous studies, even published in medical journals geared towards physicians, which show the impact having a pharmacist on the team provides in numerous areas. Such as antimicrobial stewardship, pain management, and taking ownership of medication reconciliation.

In summary, I hope that the proposal be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,

Chad Tuckerman, Pharm.D., BCPS
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2/5/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
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Sallie.Debolt@med.ohio.gov

Dear Ms. DeBolt:

I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a physician that utilizes the services of pharmacists through collaborative practice agreements to provide care to my patients, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.

Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:
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Ungureanu

MD

OhioHealth

TO: State Medical Board of Ohio

FROM: OhioHealth Corporation

RE: Response to Proposed Rules 4731-35-01 and 4731-35-02: Consult Agreements

Thank you for the opportunity to provide comments on the Medical Board's recently proposed rules regarding consult agreements between pharmacists and physicians. Consult agreements have been an invaluable resource for OhioHealth to expand access and improve quality, especially since the revision of the law in 2016. In general, we appreciate the added clarity that the medical board has provided specific to physician participation in a consult agreement. However, some of the new provisions outlined in the proposed rules create a significant burden that would outweigh many of the benefits of a consult agreement. Specific references to each section of the rule are below, but generally, if the rules were enacted as written, OhioHealth would be forced to dismantle many of our current consult agreements between pharmacists and physicians, interrupting care for thousands of patients. Furthermore, we believe that the existing rules and regulations for consult agreements create a safe, collaborative approach to patient care, and that new requirements do not add any additional benefit to patient care or safety.

The existing regulations provide a framework for physicians to leverage the skills of pharmacists using consult agreements that promote safety, collaboration, access, and quality. Currently, consult agreements must provide detailed descriptions of the scope of the pharmacist, appropriate training, decision making criteria, and communication requirements. Additionally, quality assurance and continuous quality improvement programs must be in place to ensure that the physician has supervision and comfort that the actions of the pharmacist under a consult agreement provide positive patient outcomes and remain within the scope defined in the agreement. Consult agreements being voluntary for the physician, patient, and pharmacist also ensures that pharmacists are performing medication management only in situations where there is a strong trust and collaboration. What has resulted is an excellent balance of rigor and oversight that grants physicians and pharmacists the capability to optimally manage their patients and their medication therapies.

OhioHealth has consult agreements in place that allow physicians to use pharmacists, as medication experts, to manage drug therapies, improving quality outcomes and freeing up physician time to better meet patient care needs. Currently, consult agreements are used in dedicated clinics to manage anticoagulant therapies and lipid treatment; in physician offices to manage diabetes and hypertension; and in hospitals to manage antibiotic dosing, nutrition therapy, anticoagulation, and anti-arrhythmia medications. Through our consult agreements, our pharmacists contribute to the care of thousands of our patients annually. Enactment of these proposed rules would threaten our anticoagulant clinics and would create significant barriers to patient care in our hospitals and physicians offices, resulting in reduced quality and access for

our patients. The proposed rules would also halt OhioHealth's plans to continue expanding consult agreements to create additional patient care services in physician offices, hospitals, and in transitions of care between our care sites. These future efforts and opportunities to further improve patient care would not be possible with the proposed rules.

OhioHealth advocates for the State Medical Board of Ohio to change the proposed rules to be congruent with current law and rules with regards to the actions of a pharmacist and the relationship between the pharmacist and physician under a consult agreement and to exclude the following specific points.

4731-35-01(A)(5)(b) The subtraction, or addition of an authorized pharmacist; or
4731-35-01(A)(5)(c) The subtraction or addition of an authorized physician; or

OhioHealth agrees in premise that a consult agreement should be amended any time a significant change has occurred to its content. However, the current wording in the proposed rules requires an amendment for each addition or removal of a pharmacist or physician. While this makes sense for agreements that individually list providers, OhioHealth frequently utilizes institutional credentialing or privileging, as described under OAC 4729:1-6-02(A)(1)(a)(iii) and proposed OAC 4731-35-01(A)(1)(a)(iii) to authorize physicians and pharmacists under the agreement. Requiring an amendment every time a pharmacist or physician is added or removed via this method would require weekly amendments, and would be unworkable. **OhioHealth recommends removing 4731-35-01(A)(5)(b) and 4731-35-01(A)(5)(c), or adding an exception for consult agreements that identify participants based on institutional credentialing or privileging.**

4731-35-02(B)(2) The primary physician must also establish:

(a) Decision criteria the managing pharmacist is to consider when acting pursuant to sections (B)(1)(a), and (B)(1)(b) of this section; and
(b) A plan the managing pharmacist is to follow prior to conducting an authorized action pursuant to sections (B)(1)(a), and (B)(1)(b) of this section; and
(c) A plan the managing pharmacist is to follow after having conducted an authorized action pursuant to sections (B)(1)(a), and (B)(1)(b) of this section.

This section may cause confusion, as ORC 4729.39(B)(3)(c) already requires "description of the procedures, decision criteria, and plan the managing pharmacist is to follow in acting under a consult agreement." Furthermore, the Board of Pharmacy and the rules further clarify under 4729:1-6-02(A)(1)(d) and 4731-35-01(A)(1)(d) that "Such a description should provide a reasonable set of parameters of the activities a managing pharmacist is allowed to perform under a consult agreement." OhioHealth believes that the existing regulations provide appropriate guidance on the contents of a consult agreement. The wording of this section may imply that additional detail is required over and above what is currently required. **OhioHealth recommends revising the language in this section to be congruent with the existing referenced regulations.**

OhioHealth

4731-35-02(C)(4) When the managing pharmacist changes the duration of treatment for the current drug therapy; adjusts a drug's strength, dose, dosage form, frequency of administration, route of administration, discontinues a drug, prescribes a new drug, or orders urine or blood tests, as authorized under section B)(1)(a), and (B)(1)(b) of this rule, the managing pharmacist must:

(a) Notify the primary physician prior to any action. The notification shall include a description of:

(i) The decision criteria considered by the managing pharmacist in deciding to conduct an authorized action; and

(ii) A description of the proposed authorized action the managing pharmacist intends to conduct.

(b) Obtain the consent of the primary physician to conduct the proposed authorized action.

The requirement for prior physician approval, and even notification, before any action under a consult agreement is an unnecessary significant barrier to patient care and removes any benefits gained from having a consult agreement in place. As described above, physicians engaged in consult agreements should have the flexibility to determine when the pharmacist must obtain a specific approval. Physicians are engaged in writing consult agreements that ensure the best possible outcomes for their patients, so there is no need for physicians to re-approve the actions of a pharmacist under a consult agreement each time a change is made. Furthermore, regular communication is already required with the physician under a consult agreement. Requiring that communication occur prior to an action only delays care to the patient and adds redundant approvals to a physician's workflow. **OhioHealth recommends that this section of the proposed rules be removed.**

4731-35-02(D)(1) Regular meetings. The primary physician and managing pharmacist must meet on a regular basis as established in the consult agreement, during which the managing pharmacist is to provide the primary physician with a written consult report, detailing:

(a) Changes or modifications made to patient's drug therapy and the decision criteria used by the managing pharmacist;

(b) Urine or blood tests authorized by the managing pharmacist, and the decision criteria used by the managing pharmacist;

(c) Evaluations made by the managing pharmacist;

(d) A summary of the managing pharmacist's annual follow-up consultation with patient;

(e) Other information that may be relevant to evaluating the effectiveness of the drug therapy regime.

This requirement for regular meetings is a significant and unreasonable administrative burden that is unnecessary, since regular communication is already a required component of the consult agreement. OhioHealth has hundreds of pharmacists and physicians engaged in consult agreements, covering thousands of patient lives throughout Ohio. Scheduling and holding meetings with each of them would be an impossible task, and would not provide any value over

OhioHealth

the already required regular communication. **OhioHealth recommends removing this section of the proposed rules.**

Ultimately, OhioHealth believes that the referenced proposed rules run counter to the improvements to consult agreements that the law revision was intended to provide in 2016, and we recommend that the State Medical Board of Ohio reconsider adding new requirements that might create barriers to care. We appreciate your consideration and the opportunity to provide feedback on the proposed rules. If you have any questions or would like to further discuss our comments, please reach out at the contact information below.

Bruce Vanderhoff, MD, MBA
Senior Vice President and Chief Medical Officer
OhioHealth
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Charles McCluskey, PharmD, MBA, BCPS
Vice President, Pharmacy Services
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THE OHIO STATE UNIVERSITY
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2/4/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
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Sallie.Debolt@med.ohio.gov

Dear Ms. DeBolt:

I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a physician that utilizes the services of pharmacists through collaborative practice agreements to provide care to my patients, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.

Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:
Vaughan
751AEEC65AAD428...

Vaughan

Assistant professor

Charles F. von Gunten, MD, PhD
Vice President Hospice and Palliative Medicine,
Kobacker House
800 McConnell Drive
Columbus, OH 43058

Adjunct Professor of Medicine
The Ohio State University School of Medicine

February 1, 2018

Sallie Debolt, Senior Counsel
State Medical Board of Ohio
30 East Broad Street, 3rd Floor
Columbus, OH 43215-6127
Sallie.Debolt@med.ohio.gov

RE: Controlled Substances: Prescribing for Subacute and Chronic Pain, Rule Numbers 4731-11-01, 4731-11-02, and 4731-11-14.

Dear Ms. Debolt:

Consultation agreements with pharmacists have been an invaluable resource for physicians to expand access and improve quality, especially since the revision of the law in 2016. In general, I appreciate the added clarity that the medical board has provided specific to physician participation in a consultation agreement with a pharmacist. However, some of the new provisions outlined in the proposed rules create a significant burden that would outweigh many of the benefits of a consult agreement, and would negatively impact patient care.

I have experience in this matter. When I led the development of palliative care at the University of California, San Diego hospitals from 2006-2012, I took advantage of the California law that is quite similar to that in Ohio. The collaborative agreements between physicians and our pharmacists permitted our team to better serve the patients in UCSD's cancer center, particularly those receiving high doses of opioids and/or difficult pain syndromes. There was particular success with the sickle cell population. The program received a national award from the American Cancer Society. Those pharmacists now lead the national association of specialist pharmacists working in palliative care.

In 2012, Dave Blom, CEO of OhioHealth, recruited me from California and charged me with building a program of hospice and palliative medicine that serves OhioHealth across its 12 hospitals and the 40 counties we serve. I insisted that our teams include dedicated clinical pharmacists with specialist skills in palliative medicine based on my experience in California. Our pharmacy department acknowledged that these pharmacists hold the specialist expertise in opioids and other medications for the treatment of pain and other symptoms. They are now a system resource. We are slated to add pharmacists in our regional hospitals now that our teams at Riverside Methodist Hospital, Grant Medical Center, and Kobacker House have demonstrated their value. We are pursuing their medical staff privileging as is envisioned under the 2016 revision of Ohio Law.

Therefore, I'm distressed by the requirements for notification and consent prior to action by a pharmacist, as well as the requirement for regular meetings to review a written consult report. The current regulations allow physicians and pharmacists to reach mutually agreeable terms that ensure adequate collaboration, expertise, oversight, and quality assurance mechanisms exist within the consult agreement. Physicians already have the flexibility to engage in a consult agreement that addresses training, communication, and quality assurance mechanisms that are appropriate for the medication management that is being performed.

Requiring a physician's consent prior to each action does nothing to improve the current situation. Consult agreements already require a "description of the procedures, decision criteria, and plan the managing pharmacist is to follow in acting under a consult agreement."

There are very few physicians with specialist expertise in palliative medicine. There is a national shortage. In Columbus alone, between the 3 major health systems, I'm aware of 21 open positions; 13 of them are at OhioHealth. Our local physician fellowship programs only produce 9 fellows per year. The ability to reach the 30% of hospitalized patients, and a similar number of patients with serious illness in the oncology, cardiovascular, and neuroscience outpatient areas and the 600 patients at home with hospice care will best be enabled if the medical board permits the pharmacists to independently prescribe opioids in a collaborative manner with our specialist physicians. Asking one of our maximally deployed physicians to confirm that the decision criteria and plan are correct prior to every change is unnecessarily burdensome and means we will need that many more specialist physicians to meet the patient need. The growing reluctance of every physician to prescribe opioids only makes this need more pressing.

Ultimately, I believe that these proposed rules run counter to the efficiencies that the 2016 revision to the law intended. Ohio law already requires "communication between a pharmacist and physician acting under a consult agreement shall take place at regular intervals specified by the primary physician acting under the agreement." Our teams meet daily to discuss patient care.

I strongly advocate the State Medical Board of Ohio reconsider adding any new requirements or barriers to the rules.

I would be happy to speak to members of the Board, particularly those who have no experience working collaboratively with specialist clinical pharmacists, should you think that advisable.

Sincerely,

Charles F. von Gunten, MD, PhD, FACP

TO: State Medical Board of Ohio

FROM: Sanjay Vora

RE: Response to Proposed Rules 4731-35-01 and 4731-35-02: Consult Agreements

Thank you for the opportunity to provide comments on the Medical Board's recently proposed rules regarding consult agreements between pharmacists and physicians. Consult agreements have been an invaluable resource for physicians to expand access and improve quality, especially since the revision of the law in 2016. In general, I appreciate the added clarity that the medical board has provided specific to physician participation in a consult agreement. However, some of the new provisions outlined in the proposed rules create a significant burden that would outweigh many of the benefits of a consult agreement, and would negatively impact patient care.

We have been using these arrangement for management of warfarin therapy and my comments and concerns are based specifically for management of Coumadin through our anticoagulation clinic managed by our Pharmacists.

Specifically, the requirements for notification and consent prior to action by a pharmacist, as well as the requirement for regular meetings to review a written consult report represent my greatest concerns. The current regulations allow physicians and pharmacists to reach mutually agreeable terms that ensure adequate collaboration, expertise, oversight, and quality assurance mechanisms exist within the consult agreement. Physicians already have the flexibility to engage in a consult agreement that addresses training, communication, and quality assurance mechanisms that are appropriate for the medication management that is being performed.

Requiring a physician's consent prior to each action adds significant time without providing any benefit to the patient. Consult agreements already require a "description of the procedures, decision criteria, and plan the managing pharmacist is to follow in acting under a consult agreement." Asking a physician to confirm that the decision criteria and plan are correct prior to every change is unnecessary and only adds burden to the pharmacist and physician. Adding complexity into a medication adjustment may also cause a patient to experience suboptimal care while consent is being obtained.

Similarly on the requirement for regular meetings, the law already requires "communication between a pharmacist and physician acting under a consult agreement shall take place at regular intervals specified by the primary physician acting under the agreement." Additional requirements for regular meetings and written consult reports only add complexity and administrative burden to an already safe collaborative

Ultimately, I believe that these proposed rules run counter to the efficiencies that the law revision was intended to provide in 2016, and I recommend that the State Medical Board of Ohio reconsider adding any new requirements or barriers to care into the rules. I appreciate your consideration and the opportunity to provide feedback on the proposed rules. If you have any questions or would like to further discuss our comments, please reach out at the contact information below.

Sanjay Vora, MD

February 8, 2019

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult Agreements and 4731-35-02 Standards for Managing Drug Therapy

Dear Ms. Debolt:

I am writing in regards to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. The suggested rule changes, specifically those that require pharmacists to notify the physician of any action prior to implementation (4731-35-02 C-4) would discourage collaborative practice and obstruct our current quality-based workflow. Pharmacists are the medication expert within the interdisciplinary patient care team making their expertise imperative to the care of patients. This expertise and evidence-based care can be managed independently within an agreed upon scope of practice. The removal of the autonomy afforded to pharmacists through consult agreements would lead to a tedious and inefficient process for chronic disease management and patient care for hospitalized patients. It would definitely have a negative impact on the pharmacist, provider and patient. Logistically, a busy provider may not always be available - making it difficult for both the pharmacist and patient's to reach them; thereby delaying care and conceivably causing harm in certain circumstances.

As a contractor within the hospital, it is imperative that patients receive timely care for the management of acute conditions as well. In particular, patients admitted for withdrawal management. Protocols supported by the American Society of Addiction Medicine are imperative to provide sufficient care. In collaboration with hospitals, interchange, dosing, and substitutions are currently timely and adequate to meet current needs and expected standards of medication management. I fear these changes will result in great harm to patients.

I recommend that the proposal requiring affirmation from a physician prior to dosing adjustment be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,
Matthew Walters, RN
Director of Clinical Services- SpecialCare Hospital Management
1551 Wall Street Ste. 210
St.Charles, MO 63303

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

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Division of General Internal Medicine
Martha Morehouse Pavilion
Suite 2335
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614-293-6890 Fax

2/6/2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215
Sallie.Debolt@med.ohio.gov

Dear Ms. DeBolt:

I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a physician that utilizes the services of pharmacists through collaborative practice agreements to provide care to my patients, I am concerned about language included in 4731-35-02 Standards for managing drug therapy in section (C)(4) and section (D)(1). I fear this language will limit the pharmacist's ability to provide efficient and effective patient care as I have witnessed through my practice.

As physician chair of pharmacy at The Ohio State University Medical Center I strongly oppose these new restrictions. They will impair our practice and threaten to make our processes less safe for patients.

Based on my personal experience through practice and because I feel the citizens of Ohio deserve the highest level of care from members of their healthcare team, I would ask you to remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 Standards for managing drug therapy.

Again, I sincerely appreciate the State Medical Board of Ohio providing me with the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

Sincerely,

DocuSigned by:
Harrison G. Weed, MD
BA5A46B9D567406...

Harrison G. Weed, MD

Professor of Internal Medicine

THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

Division of Hematology & Oncology
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Fax: (614) 293-6420

February 7, 2019

To: Sallie Debolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

To Whom It May Concern:

As a practicing physician in the state of Ohio, I would like to thank you for your service to the State Medical Board of Ohio and for all you do to enhance the care of our fellow Ohioans. I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

As a physician that currently utilizes the services of pharmacists as independent practitioners through collaborative practice agreements, I am in favor of pharmacists continuing to provide patient care in this manner as a means to improve quality, safety, and efficiency in our health system. The utilization of consult agreements between physicians and pharmacists at The Ohio State University Wexner Medical Center has improved patient outcomes and helped control healthcare costs. I believe pharmacists are a vital part of the interdisciplinary team and are vital for successful provision of high quality clinical services and improving access to care. I am supportive of the continued incorporation of pharmacist services into my day to day practice. I have appreciated the updates by the Board of Pharmacy over the last few years. The rules proposed by the Medical Board are generally acceptable and in line with current pharmacy rules.

However, I feel several provisions are converse to current practice and limit the utility of consult agreements. Sections (A)(2) and (C)(4) of 4731-35-02, in current form, would increase provider burden and decrease efficiency of the current system, significantly impacting the business of healthcare. Furthermore, (C)(4) would reduce quality of care by discrediting pharmacists' clinical decision making capabilities already authorized under agreed collaborative practice agreements and accompanying scope of practice. We are asking this language regarding "at least one time per year" in (A)(2) and the entirety of (C)(4) be removed (this is covered in (A)(1) of 4731-35-01).

If you have any questions, please do not hesitate to contact me. Thank you for your consideration.

Sincerely,

Tzu-Fei Wang, MD
Wexner Medical Center at the Ohio State University Medical Center
Division of Hematology & Oncology
460 W 10th Avenue
Columbus, OH 43210
Office: 614-293-9441
Fax: 614-293-6420

From: Wexler, Randy
To: Debolt, Sallie
Subject: Pharmacist Consults
Date: Tuesday, January 29, 2019 3:46:38 PM

Please provide the following comments to those reviewing/implementing this legislation.

To the State Medical Board,

I am writing to express my concerns with new language proposed with respect to collaborative arrangements between physicians and pharmacist's (4731-35-01 Consult agreements 4731-35-02 Standards for managing drug therapy). These proposed rules are not only burdensome, but are actually antithetical to where primary care has evolved with respect to patient-centered team-based primary care. This model of care is not only the preferred model of care not only within the primary care community, but the payer community as well. This preference is demonstrated by the growth of value based contracts, and primary care team based models of support such as Comprehensive Primary Care Plus from the Centers for Medicare and Medicaid Services, as well as the Ohio Department of Medicaid's Ohio CPC.

In particular I am concerned with the proposed new requirement that the pharmacist notify the physician prior to any action which includes changing or discontinuing a drug, ordering tests such as urine or blood and that the pharmacist include a detailed description of the proposed action, and obtain the consent of the primary care physician.

I have worked with a clinical pharmacist for the past 5 years. She manages the insulin on my diabetic patients, provides bridging recommendations for patients on anticoagulation who need invasive interventions, and smoking cessation education just to name a few. I receive a detailed report from her for review following each patient encounter. Any test or pharmaceutical that she orders is cosigned by me. The requirement of prior approval essentially constructs barriers to good patient care.

Primary care, especially in the current environment of value based healthcare is a team support. Pharmacist's are highly educated licensed professionals. In addition, during a routine clinical day, it is quite deleterious to care to implement the prior authorization review requirements as proposed as it not only negatively impacts the patient the pharmacist is managing, but the patient the clinician is caring for at the same time.

The offices of Ohio State University Family Medicine require all patients with a hemoglobin A1c greater than 9 to see the pharmacist for medication management and diabetes education. The clinical pharmacist with whom I work has taken patients with A1c's above 9, and brought their diabetes under control. Our pharmacist spends an hour with them at the first visit, and 30 minutes at subsequent visits. No clinician has that amount of time and this in depth visit along with the pharmacists expertise is what provides the benefit.

Given the variety of environment's in which pharmacists collaborate, and the reality that one size fits all policies have unintended consequences, I would respectfully request an exception for pharmacists who practice in a team-based environment, within a providers office, such that the provider is available in real-time during all hours for which the pharmacist is managing patients.

Randy Wexler MD MPH FAAFP
Clinical Vice Chair – Family Medicine
Associate Professor of Family Medicine
The Ohio State University Wexner Medical Center
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F – 614-293-7001

Cincinnati Children's
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Patty Manning-Courtney, MD
Vice President, Medical Operations, Ambulatory

Richard M. Ruddy, MD
Chief of Staff, Liberty Campus

Christine M. White MD, MAT
Associate Chief of Staff, Inpatient Service

February 8, 2019

To: Sallie Debolt, Senior Counsel, State Medical Board of Ohio

On behalf of medical and pharmacy leadership at Cincinnati Children's, thank you for the opportunity to comment on proposed rules 4731-35-01 Consult Agreements and 4731-35-02 Standards for managing drug therapy. These proposed rules would regulate the use of consult agreements between physicians and pharmacists. It is exciting to see the legislature in the State of Ohio recognize the collaborative practice opportunities that exist between physicians and pharmacists, who are experts in medication therapy management.

Cincinnati Children's Hospital Medical Center employs a patient-centered care approach utilizing the skillsets of many disciplines to create best outcomes for patients, including the role of the pharmacist in optimizing medication use for patients. The proposed rules as written would severely limit the ability for patients and physicians to benefit from the collaborative practice of pharmacists. The rules are written from the standpoint of managing a single patient with a single physician and single pharmacist. From a very large academic medical center, patient care cannot be managed in this manner. Instead, systems must be built which allow for consistency of care delivery from myriad providers and pharmacists for our patient populations. Furthermore, rules as constructed do not account for the typical practice of medicine and pharmacy in an institutional setting and these rules would significantly frustrate and unnecessarily burden physicians. Given changes to the consult agreement law, institutional practice now often utilizes credentialing and privileging processes to enable pharmacists to make medication changes and optimize patient medication regimens. As the rules are currently proposed, it would be too cumbersome to operationalize such a program in a complex, large institutional setting.

We respectfully request that the State Medical Board of Ohio revise these rules to mirror the State of Ohio Board of Pharmacy rules on consult agreements and rules governing the practice of physician assistants (4730-2-07 and 4730-2-07). Specific recommendations for edits are provided below.

Proposed Rule 4731-35-01 – Consult Agreements

It is recommended to strike (A)(1)(b) and replace with language from OAC 4729:1-6-01(H) and 4729:1-06-01(I). This will provide the necessary guidelines around consent while also exempting inpatient management of patient care and will align with the State of Ohio Board of Pharmacy rules.

Cincinnati Children's Hospital Medical Center
3333 Burnet Avenue
Cincinnati, OH 45229-3039

Phone: 513-636-4200
Fax: 513-636-0333

Cincinnati Children's
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Associate Chief of Staff, Inpatient Service

It is recommended to change the language in (A)(2) to state, "...requirements of paragraphs (A)(1)(b) through (A)(1)(f)..." This will align the language with the State of Ohio Board of Pharmacy. This is necessary since (A)(1)(b) has been added and does not exist in this place in the OAC 4729:1-6-02.

It is recommended to strike (A)(5)(b) through (A)(5)(d) as (A)(1)(a) already accounts for the pharmacists and physicians in the agreement and takes into account the consult agreement may be executed on behalf of physician or pharmacist practice groups or through institutional credentialing and privileging. It may be advisable to restructure (A)(5) to state, "Amendments to the consult agreement are required when there are changes to (A)(1)(c) through (A)(1)(f)."

It is recommended to add section (A)(8) stating the same language as 4729:1-6-02(A)(2), "Institutional or ambulatory outpatient facilities may implement a consult agreement and meet the requirements of paragraphs (A)(1)(c) through (A)(1)(f) and (A)(5) (if adopted as recommended in the preceding paragraph) of this rule through institutional credentialing standards or policies. Such standards or policies shall be referenced as part of the consult agreement and available to an agent of the board upon request.

It is recommended to edit (B) Recordkeeping to state, "The primary physician, physician practice group, or institution as defined in rule 4729-17-01 of the administrative code..." in order to allow for recordkeeping to be maintained by the institution as are all other medical records.

It is recommended to edit (C)(1) to add the following language, "...the primary physician, physician practice group, or institution as defined in rule 4729-17-01 must:." It is also recommended to delete the first sentence of (C)(1)(ii), "An agent of the primary physician" as this is replicated in the following sentence. Sections (C)(1)(c) and (C)(1)(d) are redundant based on paragraph (A)(1)(c) through (A)(1)(f) and are recommended to be deleted.

Proposed Rule 4731-35-02 Standards for Managing Drug Therapy

It is recommended to align this rule more closely with 4729:1-6-03 and physician assistant rules 4730-2-06 and 4730-2-07 of the administrative code. This will allow for the collaborative practice of pharmacists and physicians to function in a more seamless, optimized manner.

It is recommended to delete (A)(3) and replace with language from OAC 4729:1-6-01(H) and 4729:1-06-01(I). This will provide the necessary guidelines around consent while also exempting inpatient management of patient care and will align with the State of Ohio Board of Pharmacy rules. Alternatively, if 4730-35-01(A)(1)(b) is modified as above, this entire paragraph may not be necessary.

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Chief of Staff, Liberty Campus

Christine M. White MD, MAT
Associate Chief of Staff, Inpatient Service

It is recommended to delete (A)(6) as this is redundant and covered in 4731-35-01(A)(1)(m). Additionally, pharmacists receive training in doctoral degree programs and take licensure exams. Physicians ought not to be burdened by additional requirements when these are already otherwise met.

It is recommended to either delete or align (A)(7) with rules for nurse practitioners and/or physician assistants. Communication is often documented in the medical record and discussed amongst care teams. It is recommended to allow for each physician practice or institution to determine what, if any requirements should exist around review of records.

It is recommended to delete or modify (B)(1) and (B)(2) and instead refer to the consult agreement requirements in 4731-35-01(A)(c-f). This provides enough context while allowing for the clinical practice of medication optimization to appropriately occur.

It is recommended to delete (C)(4) in its entirety and instead refer to 4731-35-01(A)(1)(g-h). It is impractical to require notification and consent of the primary physician before taking any action and would significantly delay patient care. If left unchanged, this language would render all consult agreements ineffectual. This clause is essentially reversing the intent of the consult agreement legislation.

It is recommended to modify (D)(1) to remove the requirement of regular meetings and make the guidance broad enough to apply to physician practices and institutions. Continuous Quality Improvement (CQI) programs are often managed via tracking populations of patients who receive interventions (e.g. pharmacist-managed patients) to appreciate outcomes. Also, privileging programs in institutions require peer-review or similar reviews which are then approved by the governing medical committee and may appropriately serve this purpose.

It is recommended to modify (D)(2)(c) to state, "If prescribing controlled substances, a pharmacist fails to obtain or maintain a valid DEA registration."

Thank you for the opportunity to comment on the proposed consult agreement rules and consideration for inclusion of the recommendations listed above.

Respectfully,

Derek S. Wheeler, MD, MMM, MBA
Professor and Associate Chair, Clinical Affairs
Department of Pediatrics
University of Cincinnati College of Medicine

Chief of Staff
Cincinnati Children's Hospital Medical Center

Cincinnati Children's Hospital Medical Center
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Sarah E. Wheeler, PharmD
2865 Chamberlain Road
Fairlawn, OH 44333

February 4, 2019

Sallie DeBolt, Esq., Senior Counsel
State Medical Board of Ohio
30 E. Broad Street, 3rd Floor
Columbus, OH 43215

Dear Ms. DeBolt:

Thank you for the opportunity to comment on the State Medical Board of Ohio's proposed rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy.

I have been privileged to care for my fellow Ohioans as a member of their healthcare team and to work alongside physicians to provide our patients the highest quality care possible. I am concerned that language included in 4731-35-01 Consult agreements in section (A)(1)(i) and in 4731-35-02 Standards for managing drug therapy section (C)(4) and section (D)(1) will create barriers to quality patient care.

Consult agreements provide our patients access to drug therapy management by pharmacists and allow for patients to receive timely adjustments to their medication regimens to optimize health outcomes. The language in 4731-35-01 section (A)(1)(i) and 4731-35-02 section (C)(4) and section (D)(1) will likely result in delays in therapy and therapeutic goal attainment for patients managed under consult agreements and simultaneously detract from physicians' ability to provide care for more patients.

For the benefit of our patients, I urge the State Medical Board of Ohio to remove in entirety section (A)(1)(i) from 4731-35-01 Consult agreements and sections (C)(4) and (D)(1) from 4731-35-02 Standards for managing drug therapy. The citizens of Ohio deserve the highest quality medical care from their healthcare team, and our Medical Board and Pharmacy Board regulations should support this.

I sincerely appreciate the State Medical Board of Ohio providing the opportunity to comment on the proposed rules on 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy, and I look forward to continuing to work alongside physicians to provide care to our fellow Ohioans.

Sincerely,

Sarah E. Wheeler, PharmD

OhioHealth

TO: State Medical Board of Ohio

FROM: TeamHealth Emergency Department Physicians practicing at OhioHealth Marion General Hospital

RE: Response to Proposed Rules 4731-35-01 and 4731-35-02: Consult Agreements

Thank you for the opportunity to provide comments on the Medical Board's recently proposed rules regarding consult agreements between pharmacists and physicians. Consult agreements have been an invaluable resource for physicians to expand access and improve quality, especially since the revision of the law in 2016. In general, we appreciate the added clarity that the medical board has provided specific to physician participation in a consult agreement. However, some of the new provisions outlined in the proposed rules create a significant burden that would outweigh many of the benefits of a consult agreement, and would negatively impact patient care.

At Marion General Hospital, we have worked closely with our pharmacists to ensure medications, including those managed through consult agreements such as aminoglycosides, vancomycin, and warfarin, are appropriately managed as the patient transitions from the emergency department to inpatient. The emergency department physicians are also interested in exploring additional opportunities for consult agreements with pharmacists including one that would optimize antimicrobial stewardship.

Specifically, the requirements for notification and consent prior to action by a pharmacist, as well as the requirement for regular meetings to review a written consult report represent our greatest concerns. The current regulations allow physicians and pharmacists to reach mutually agreeable terms that ensure adequate collaboration, expertise, oversight, and quality assurance mechanisms exist within the consult agreement. Physicians already have the flexibility to engage in a consult agreement that addresses training, communication, and quality assurance mechanisms that are appropriate for the medication management that is being performed.

Requiring a physician's consent prior to each action adds significant time without providing any benefit to the patient. Consult agreements already require a "description of the procedures, decision criteria, and plan the managing pharmacist is to follow in acting under a consult agreement." Asking a physician to confirm that the decision criteria and plan are correct prior to every change is unnecessary and only adds burden to the pharmacist and physician. Adding complexity into a medication adjustment may also cause a patient to experience suboptimal care while consent is being obtained.

Similarly on the requirement for regular meetings, the law already requires "communication between a pharmacist and physician acting under a consult agreement shall take place at regular intervals specified by the primary physician acting under the agreement." Additional requirements for regular meetings and written consult reports only add complexity and administrative burden to an already safe collaborative process.

Ultimately, we believe that these proposed rules run counter to the efficiencies that the law revision was intended to provide in 2016, and we recommend that the State Medical Board of Ohio reconsider adding any new requirements or barriers to care into the rules. We appreciate your consideration and the opportunity to provide feedback on the proposed rules. If you have any questions or would like to further discuss our comments, please reach out at the contact information below.

OhioHealth

Correspondence c/o:
Diane Bailey, 1000 McKinley Park Dr., Marion, OH Diane.Bailey@ohiohealth.com

RE: Response to Proposed Rules 4731-35-01 and 4731-35-02: Consult Agreements

Name/Credentials	Signature
Matthew White, MD	
Karen Gaber-Patel, DO	
Brandon Forbes MD	
Melissa Mekesa, MD	
Charles Collier PA-C	PA-C
John Sh[illegible] MD	

From:	Williams, Leanne (willi2l3)
To:	Debolt, Sallie
Subject:	Comments for 4731-35-01 and 4731-35-02
Date:	Thursday, February 7, 2019 5:14:39 PM

Dear Sallie Debolt,

I am a third-year pharmacy student from the University of Cincinnati and I am writing in regards to the proposed changes to consult agreements between physicians and pharmacists.

The new rules 4731-35-01 and 4731-35-02 will essentially leave those with a Doctor of Pharmacy degree with zero autonomy when it comes to drug therapy. I would like to take a moment and highlight the differences in curriculum between that of a doctor of medicine and pharmacy.

I used my own university, Cincinnati, to show what a typical pharmacy and medical program curriculum look like. These lists are below: (**please note that these lists are not all inclusive but instead draw attention to the major focus of each program**)

Degree 1:
Drug Delivery I
Principles of Medicinal Chemistry
Pharmacy Calculations
Principles of Pharmacology and Pharmacotherapy
Therapeutics I
Clinical Pharmacokinetics
Evidence-based Pharmacotherapy I
Case Studies in Therapeutics I
Therapeutics of nonprescription drugs
Therapeutics II
Case Studies in Therapeutics II
Pharmacy Practice Skills Development I
Therapeutics III Therapeutics IV
Evidence Based Pharmacotherapy II

Degree 2:
Healthcare Emergency management
Clinical Skills 101 and 102
Fundamentals of Molecular Medicine
Fundamentals of Cellular Medicine
Musculoskeletal – Integumentary
Brain, Mind and Behavior
Blood and Cardiovascular system
Renal and Pulmonary Systems
Gastoinstestinal/Endocrine/Reproduction
Multi-systems
Health Care Emergency Management II
Principles in Interprofessional Collaborative Practice

Degree 1 is a Doctor of Pharmacy curriculum with 14 total courses dedicated specifically to medications. Degree 2 is a Doctor of Medicine curriculum with zero courses dedicated specifically to medications. When looking at the course objectives for the college of medicine, it is listed that each course covering a body system should:

Describe STANDARD therapeutic approaches to treat common diseases affecting each of these organ systems.
Explain the BASIC science underlying the therapeutic benefits and adverse side effects of pharmacologic agents.

The differences in these curriculums help emphasize the differences in roles between pharmacist and physician.

As a pharmacy student, I want to make sure that the Ohio Medical Board knows how much respect and gratitude that I have for our physicians in Ohio. I am not trained as physicians are to diagnose, to heal or to perform procedures. I am, however, extensively trained in medications. Pharmacists and Physicians are not in a turf war, rather we are handling two entirely separate and important roles; one in which the physician provides diagnoses and the pharmacist provides drug therapy. One of us is an expert in the effect of disease on the body, and one of us is an expert in the effect of drugs on the body. And our patients in Ohio only get the most expert level of care when each of our experts is practicing at the top of their licenses.

For these reasons, I hope you will NOT support the proposed rule changes to 4731-35-01 and 4731-35-02. I believe we can do better to ensure the best medical care is delivered to Ohioans, and we should.

Regards,

Leanne Williams

Doctor of Pharmacy Candidate 2020
James L Winkle College of Pharmacy
University of Cincinnati

From: Wunsch, Kaitlin (wunschke)
To: Debolt, Sallie
Subject: Comments on Collaborative Practice Agreement Draft Rules
Date: Friday, February 8, 2019 12:44:30 PM

Dear Ms. DeBolt:

I would like to thank you for your service to the State Medical Board and for all you do for the care of our state's citizens. I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 consult agreements and 4731-35-02 standards for managing drug therapy. I, as a student of The University of Cincinnati James L. Winkle College of Pharmacy, represent my individual opinion on the draft rules.

As a student-pharmacist, I am concerned about language included in 4731-35-02 standards for managing drug therapy in section (C)(4) and section (D)(1). Our curriculum is largely based on our ability to provide quality, individualized patient care as it pertains to the management of patient's disease states and medications. We spend several years learning the same guidelines and treatment options that physicians learn with additional training in pharmacology and pharmacotherapy. We practice the application of this knowledge through a variety of experiences on rotations, at work, and through volunteer opportunities in our community.

As proposed, this language would limit pharmacists' ability to assist patients with their medication management, and thus inhibit our ability as students to learn valuable skills we will use to improve patient health in our role as healthcare professionals. Through current collaborative practice opportunities, the students at The University of Cincinnati have already been learning how to collaborate with physicians though experiential rotations and have witnessed first-hand how beneficial a pharmacist is to the patient care process and healthcare team. To enhance patient outcomes, the continued collaboration between pharmacists and physicians through collaborative practice is necessary, not the further fragmentation of patient care that would likely take place with the way the rules are being proposed to be re-written.

With everything we have learned about the opportunities to improve health outcomes in our state and the vigor of our developed Pharm.D. curriculum, I believe the citizens of Ohio deserve access to the highest level of care from all members of their healthcare team. I ask the State Medical Board of Ohio remove in entirety section (C)(4) and section (D)(1) from 4731-35-02 standards for managing drug therapy.
Again, I sincerely appreciate the State Medical Board of Ohio providing us with the opportunity to comment on the board's draft rules on 4731-35-01 consult agreements and 4731-35-02 standards for managing drug therapy.

Regards,

Kaitlin Wunsch, Doctor of Pharmacy Student at The University of Cincinnati James L. Winkle College of Pharmacy

From:	Xu, Katie
To:	Debolt, Sallie
Subject:	Phamacy Student- Comment on 4731-35-01 Consults agreements and 4731-35-02 Standards for managing drug therapy
Date:	Tuesday, February 5, 2019 1:25:45 PM

Dear Ms. DeBolt,

Thank you for your service to the State Medical Board of Ohio and all that you do to ensure proper care for Ohioans. I appreciate the opportunity to comment on the board's draft rules on 4731-35-01 Consults agreements and 4731-35-02 Standards for managing drug therapy.

Following reviewing these drafts, I am concerned about the language utilized in section (C)-4 and (D)-1 because it will limit the pharmacist's ability to effectively manage patient's care. I am a pharmacy student at the Ohio State University who has worked as a pharmacy intern at the James Anticoagulation clinic for the past two years. Through my internship, I have the privilege to see the advances of the ambulatory care practice of pharmacy and the autonomy that my pharmacists have at the clinic. The patients that we have seen in the clinic have been impressed at the clinical knowledge of our pharmacists and the management of their care. The hematologists and cardiologists that we work with as well at the anticoagulation clinic appreciate having pharmacists to help manage their patients on a more frequent basis and alleviate some of their workloads.

Pharmacist-run clinics have been shown to increase adherence for patients and to reduce adverse effects and hospitalizations. Ohioans deserve this advanced level of care where pharmacists and physicians can work alongside each other with autonomy and collaboration to both provide their expertise rather than in a hierarchy system that healthcare does not support as a whole.

Thank you again for the opportunity to comment on these drafts,

Katie Xu
Community Outreach Chair, SNPhA
Advocacy Chair, Rho Chi Upsilon Chapter
Doctor of Pharmacy Candidate Class of 2020, The Ohio State University
xu.947@osu.edu, 614-446-1692

From: Janet Zeedyk
To: Debolt, Sallie
Subject: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy
Date: Friday, February 8, 2019 5:23:26 PM

February 8, 2019

Sallie Debolt
Senior Counsel
State Medical Board of Ohio
30 E. Broad St.
Columbus, OH 43215

Subject: 4731-35-01 Consult agreements and 4731-35-02 Standards for managing drug therapy

Dear Ms. Debolt:

I am writing in regards to the proposed rule changes to the Consult Agreements and Standards for Managing Drug Therapy. Consult Agreements for Pharmacist Management of Patient's Drug Therapy is of interest to me due to my current collaborative practice with a pharmacist as a PA, practicing at Paulding County Hospital. Within my outpatient clinic and when I cover inpatient, I work side by side with clinical pharmacists on a daily basis who provide unique value to our patients and improve overall quality of care.

Currently, consult agreements allow physicians to work collaboratively with pharmacists to manage chronic diseases. In my practice, we have pharmacists who independently manage diabetes, hypertension, and dyslipidemia through consult agreements. Pharmacists improve the continuity of care, level of care and overall quality of the patients' health and healthcare experience. Additionally, our pharmacists serve as drug information experts and educators for both our residents, providers and patients. Pharmacy expertise is a vital part of the patient care team and outcomes-based healthcare.

The proposed rule changes, specifically those that require pharmacists to notify the physician of any action prior to implementation (4731-35-02 C-4) would discourage collaborative practice and obstruct our current quality-based workflow. Pharmacists are the medication expert within the interdisciplinary patient care team making their expertise imperative to the care of patients. This expertise and evidence-based care can be managed independently within an agreed upon scope of practice. The removal of the autonomy afforded to pharmacists through consult agreements would lead to a tedious and inefficient process for chronic disease management that would negatively impact the pharmacist, provider and patient. Logistically, a busy provider may not always be in clinic making it difficult for both the

pharmacist and patient's to reach them. In this case the pharmacist is the best resource to manage chronic diseases and ensure timely care is provided. I recommend that this requirement be removed from the proposal.

Coumadin clinic helps me to regulate patient's coumadin. They take care of many visits that I would have to do, and improve the care that the patients get. When I place a patient on an antibiotic that interacts with their coumadin, they will take care of monitoring and adjusting the dose as needed. It really saves a significant amount of time and it is easily within their scope of training and practice. They also help to figure out dosing of drugs when patient has poor kidney function, and yet requires a strong antibiotic. It saves me time calculating dosing and improves patient safety. I know that they are going to monitor that dose each time the patient gets new labs done to make sure they are still on the correct dose.

In summary, I hope that the proposal be removed and that changes to current rules and regulations do not hinder the positive effects of current consult agreements as outlined by the Ohio State Board of Pharmacy (OAC 4729:1-6-02 Consult agreements).

Sincerely,

Janet Zeedyk PA-C
PO Box 1047
608 Erie Street
Antwerp OH 45813

Ohio State Medical Board of Ohio

30 E. Broad St., 3rd Floor
Columbus, Ohio 43215
Phone: (614) 466-3934
Web: www.med.ohio.gov

MEMORANDUM

TO: Amol Soin, M.D., Chair, Policy Committee
Members, Policy Committee

FROM: Kimberly C. Anderson, Chief Legal Counsel

RE: Subacute and Chronic Pain Rules

DATE: March 7, 2019

The rule regarding prescribing for subacute and chronic pain, Rule 4731-11-14, Ohio Administrative Code, became effective on December 23, 2018. In the past few weeks, Board staff has become aware that the rule is having some negative impact for patients diagnosed with non-terminal cancer and patients diagnosed with terminal conditions.

The comments regarding the patients diagnosed with non-terminal cancer are summarized by a letter we received from the Ohio Hospital Association, which is attached. In summary, these patients may have severe pain requiring dosages which exceed 120MED and they are unable to quickly obtain appointments with board certified pain management specialists or board certified hospice and palliative care specialists. In order to address this issue, I have revised the rule to exempt board certified hematologists and board certified oncologists from that portion of the rule. The definitions are included in the attached revised Rule 4731-11-01, Ohio Administrative Code.

Board staff has also received comments from physicians indicating that the definition of terminal condition is causing delays for those patients. Patients diagnosed with a terminal condition are exempted from the rule, but the definition of terminal condition comes from Section 2133.01 of the Revised Code, which requires a second opinion. I have changed the definition of terminal condition to eliminate the need for a second opinion.

In order to reduce delay in making these changes, I recommend filing the revised rules directly with the Common Sense Initiative rather than requiring an initial circulation to interested parties. The Medical Board became aware of these issues through feedback from interested parties.

Action Requested: Request the full Board to approve filing the rules, as amended, with the Common Sense Initiative.

From: Sean McGlone
To: Debolt, Sallie; Anderson, Kimberly
Subject: Chronic Pain Rule -- hospital concern
Date: Wednesday, February 13, 2019 3:34:25 PM
Attachments: image001.png

Hi Sallie and Kim. I hope you are doing well. I wanted to make you aware of a concern we are hearing from hospitals regarding the recently-implemented chronic pain rules. This is not a concern we heard about prior to the rule being finalized, but appears to have become a concern as members have worked to implement the new rules.

The specific provision at issue is the requirement that a physician may not prescribe a dosage in excess of 120 MED unless the physician is board certified in pain medicine or hospice/palliative care or has received a written recommendation to exceed 120 MED from a physician who is board certified as such. OAC 4731-11-14(E).

According to some hematology/oncology physicians, this requirement is delaying appropriate pain treatment for cancer patients who are above this MED limit, because of the delay in obtaining (and in some cases inability to obtain) a written recommendation from a physician who is board certified in pain medicine or hospice/palliative care (because of a shortage of such doctors in some communities, and long wait times to see them). Though the rules do not apply to terminal cancer patients, there are many cancer patients who are not terminal whose pain during treatment is very intense and whose routine treatment could exceed 120 MED. In fact, some terminal patients would be expected to experience less pain than nonterminal patients because the terminal patients are not undergoing (sometimes) painful treatments.

We understand these rules just recently became effective, but we wanted to share with you some feedback we are hearing from the hospital community to inform you and the Board of the experience "on the ground" in implementing the rules. As we continue to hear concerns from members on these rules and others we will share them with you, so that if there is an opportunity to refine the rules in the future because of additional implementation concerns, that feedback can be taken into account.

I would be happy to discuss this further.

Thanks for your consideration of this concern.

Sean

Sean McGlone | Senior Vice President and General Counsel
Sean.McGlone@ohiohospitals.org

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4731-11-01 Definitions.

As used in Chapter 4731-11 of the Administrative Code:

(A) "Controlled substance" means a drug, compound, mixture, preparation, or substance included in schedule I, II, III, IV, or V pursuant to the provisions of Chapter 3719. of the Revised Code.

(B) "Controlled substance stimulant" means any drug, compound, mixture, preparation, or substance which is classified as a stimulant in controlled substance schedule II, III, or IV listed in section 3719.41 of the Revised Code, or which is classified as a stimulant in controlled substances schedule II, III, or IV pursuant to section 3719.43 or3719.44 of the Revised Code.

(C) "Cross-coverage" means an agreement between an Ohio-licensed physician and another Ohio licensed physician or healthcare provider acting within the scope of their professional license under which the physician provides medical services for an active patient, as that term is defined in paragraph (D) of rule this rule, of the other physician or healthcare provider who is temporarily unavailable to conduct the evaluation of the patient.

(1) This type of agreement includes on-call coverage for after hours and weekends.

(2) The medical evaluation required by paragraph (C) of rule 4731-11-09 of the Administrative Code may be a limited evaluation conducted through interaction with the patient.

(D) For purposes of paragraph (D) of rule 4731-11-09 of the Administrative Code, "active patient" as that term is used in paragraph (C) of this rule, means that within the previous twenty-four months the physician or other healthcare provider acting within the scope of their professional license conducted at least one in-person medical evaluation of the patient or an evaluation of the patient through the practice of telemedicine as that term is defined in 21 C.F.R. 1300.04, in effect as of the effective date of this rule.

(E) "Utilize a controlled substance or controlled substance stimulant" means to prescribe, administer, dispense, supply, sell or give a controlled substance or controlled substance stimulant.

(F) "Recognized contraindication" means any contraindication to the use of a drug which is listed in the United States food and drug administration (hereinafter, "F.D.A.") approved labeling for the drug, or which the board determines to be accepted as a contraindication.

(G) "The board" means the state medical board of Ohio.

(H) "BMI" means body mass index, calculated as a person's weight in kilograms divided by height in meters squared.

(I) "Physician" means an individual holding a certificate under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery and practicing within his or her scope of practice as defined by section 4731.51 of the Revised Code.

(J) "Board certified addictionologist or addiction psychiatrist" means a medical doctor or doctor of osteopathic medicine and surgery who holds one of the following certifications:

(1) Subspecialty board certification in addiction psychiatry from the american board of psychiatry and neurology;

(2) Board certification in addiction medicine from the american board of addiction medicine;

(3) Certification from the American society of addiction medicine;

(4) Subspecialty certification in addiction medicine from the American board of preventive medicine; or

(5) Board certification with additional qualification in addiction medicine from the American osteopathic association.

(K) "Office based opioid treatment", or "OBOT", means treatment of opioid addiction utilizing a schedule III, IV or V controlled substance narcotic.

(L) "Acute pain" means pain that normally fades with healing, is related to tissue damage, significantly alters a patient's typical function and is expected to be time limited and not more than six weeks in duration.

(M) "Minor" has the same meaning as in section 3719.061 of the Revised Code.

(N) "Morphine equivalent daily dose (MED)" means a conversion of various opioid analgesics to a morphine equivalent dose by the use of accepted conversion tables provided by the state of Ohio board of pharmacy at: https://www.ohiopmp.gov/ (effective 2017).

(O) "Extended-release or long-acting opioid analgesic" means an opioid analgesic that:

(1) Has United States food and drug administration approved labeling indicating that it is an extended-release or controlled release formulation;

(2) Is administered via a transdermal route; or

(3) Contains methadone.

(P) "Opioid analgesic" has the same meaning as in section 3719.01 of the Revised Code and means a controlled substance that has analgesic pharmacologic activity at the opioid receptors of the central nervous system, including but not limited to the following drugs and their varying salt forms or chemical congeners: buprenorphine, butorphanol, codeine (including acetaminophen and other combination products), dihydrocodeine, fentanyl, hydrocodone (including acetaminophen combination products), hydromorphone, meperidine, methadone, morphine sulfate, oxycodone (including acetaminophen, aspirin, and other combination products), oxymorphone, tapentadol, and tramadol.

(Q) "Hospice care program" has the same meaning as in section 3712.01 of the Revised Code.

(R) "Palliative care" has the same meaning as in section 3712.01 of the Revised Code.

(S) "Terminal condition" means an irreversible, incurable, and untreatable condition caused by disease, illness, or injury from which, to a reasonable degree of medical certainty as determined in accordance with reasonable medical standards by a physician who has examined the patient, both of the following apply:

(1) There can be no recovery.

(2) Death is likely to occur within a relatively short time if life-sustaining treatment is not administered.

has the same meaning as in section 2133.01 of the Revised Code.

(T) "Medication therapy management" has the same meaning as in rule 4729:5-12-01 of the Administrative Code.

(U) "Subacute pain" means pain that has persisted after reasonable medical efforts have been made to relieve it and continues either episodically or continuously for more than six weeks but less than twelve weeks following initial onset of pain. It may be the result of underlying medical disease or condition, injury, medical or surgical treatment, inflammation, or unknown cause.

(V) Chronic pain" means pain that has persisted after reasonable medical efforts have been made to relieve it and continues either episodically or continuously for twelve or more weeks following initial onset of pain. It may be the result of an underlying medical disease or condition, injury, medical treatment, inflammation, or unknown cause. "Chronic pain" does not include pain associated with a terminal condition or with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition.

(W) "Board certification in hospice and palliative care" means either of the following:

(1) Subspecialty certification in hospice and palliative medicine granted by a certification board that is a member of the American board of medical specialties.

(2) Certification of added qualification in hospice and palliative medicine by the American osteopathic association bureau of medical specialties.

(X) "Board certified hematologist" means a medical doctor or doctor of osteopathic medicine and surgery who holds one of the following certifications:

(1) Subspecialty board certification in hematology from the American board of internal medicine;

(2) Subspecialty board certification in pediatric hematology-oncology from the American board of pediatrics;

(3) Board certification with additional qualification in hematology from the American osteopathic association.

(Y) "Board certified oncologist" means a medical doctor or doctor of osteopathic medicine and surgery who holds one of the following certifications:

(1) Subspecialty board certification in medical oncology from the American board of internal medicine;

(2) Subspecialty board certification in gynecologic oncology from the American board of obstetrics and gynecology;

(3) Subspecialty board certification in pediatric hematology-oncology from the American board of pediatrics;

(4) Subspecialty board certification in complex general surgical oncology from the American Board of Surgery;

(5) Board certification with additional qualification in oncology from the American osteopathic association;

(6) Board certification with additional qualification in gynecological oncology from the American osteopathic association.

Replaces: 4731-21-01

Effective: 12/23/2018
Five Year Review (FYR) Dates: 1/31/2020
Promulgated Under: 119.03
Statutory Authority: 4731.052, 4731.05 , 4730.39, 3719.062
Rule Amplifies: 3719.062 , 4731.74, 4731.052, 4730.39

Prior Effective Dates: 4731-11-01: 11/17/1986, 10/31/1998, 09/01/2000, 01/31/2015, 03/23/2017, 08/31/2017, 12/07/2017
4731-21-01: 11/11/1998, 11/30/2008, 8/31/2007

4731-11-14 Prescribing for subacute and chronic pain.

(A) Prior to treating, or continuing to treat subacute or chronic pain with an opioid analgesic, the physician shall first consider and document non-medication and non-opioid treatment options.

(1) If opioid analgesic medications are required as determined by a history and physical examination, the physician shall prescribe for the minimum quantity and potency needed to treat the expected duration of pain and improve the patient's ability to function.

(2) The physician shall comply with the requirements of rule 4731-11-02 of the Administrative Code.

(B) Before prescribing an opioid analgesic for subacute or chronic pain, the physician shall complete or update and document in the patient record assessment activities to assure the appropriateness and safety of the medication including:

(1) History and physical examination including review of previous treatment and response to treatment, patient's adherence to medication and non-medication treatment, and screening for substance misuse or substance use disorder;

(2) Laboratory or diagnostic testing or documented review of any available relevant laboratory or diagnostic test results. If evidence of substance misuse or substance use disorder exists, diagnostic testing shall include urine drug screening;

(3) Review the results of an OARRS check in compliance with rule 4731-11-11 of the Administrative Code;

(4) A functional pain assessment which includes the patient's ability to engage in work or other purposeful activities, the pain intensity and its interference with activities of daily living, quality of family life and social activities, and the physical activity of the patient;

(5) A treatment plan based upon the clinical information obtained, to include all of the following components:

(a) Diagnosis;

(b) Objective goals for treatment;

(c) Rationale for the medication choice and dosage; and

(d) Planned duration of treatment and steps for further assessment and follow-up.

(6) Discussion with the patient or guardian regarding:

(a) Benefits and risks of the medication, including potential for addiction and risk of overdose; and

(b) The patient's responsibility to safely store and appropriately dispose of the medication.

(7) The physician shall offer a prescription for naloxone to the patient receiving an opioid analgesic prescription under any of the following circumstances:

(a) The patient has a history of prior opioid overdose;

(b) The dosage prescribed exceeds a daily average of eighty MED or at lower doses if the patient is co-prescribed a benzodiazepine, sedative hypnotic drug, carisprodal, tramadol, or gabapentin; or

(c) The patient has a concurrent substance use disorder.

(C) Prior to increasing the opioid dosage to a daily average of fifty MED or greater the physician shall complete and document the following in the patient's medical record:

(1) The physician shall review and update the assessment completed in paragraph (B) of this rule, if needed. The physician may rely on an appropriate assessment completed within a reasonable time if the physician is satisfied that he or she may rely on that information for purposes of meeting the further requirements of this chapter of the Administrative Code;

(2) The physician shall update or formulate a new treatment plan, if needed;

(3) The physician shall obtain from the patient or the patient's guardian written informed consent which includes discussion of all of the following:

(a) Benefits and risks of the medication, including potential for addiction and risk of overdose.

(b) The patient's responsibility to safely store and appropriately dispose of the medication.

(4) Except when the patient was prescribed an average daily dosage that exceeded fifty MED before the effective date of this rule, the physician shall document consideration of the following:

(a) Consultation with a specialist in the area of the body affected by the pain;

(b) Consultation with a pain management specialist;

(c) Obtaining a medication therapy management review by a pharmacist; and

(d) Consultation with a specialist in addiction medicine or addiction psychiatry, if aberrant behaviors indicating medication misuse or substance use disorder are noted.

(5) The physician shall consider offering a prescription for naloxone to mitigate risk of overdose.

(D) Prior to increasing the opioid dosage to a daily average of eighty MED or greater, the physician shall complete all of the following:

(1) Enter into a written pain treatment agreement with the patient that outlines the physician's and patient's responsibilities during treatment and requires the patient or patient guardian's agreement to all of the following provisions:

(a) Permission for drug screening and release to speak with other practitioners concerning the patient's condition or treatment;

(b) Cooperation with pill counts or other checks designed to assure compliance with the treatment plan and to minimize the risk of misuse or diversion;

(c) The understanding that the patient shall only receive opioid medications from the physician treating the chronic pain unless there is written agreement among all of the prescribers of opioids outlining the responsibilities and boundaries of prescribing for the patient; and

(d) The understanding that the dosage may be tapered if not effective or if the patient does not abide by the treatment agreement.

(2) Offer a prescription for naloxone to the patient as described in paragraph (B) of this rule.

(3) Except when the patient was prescribed an average daily dosage that exceeded eighty MED before the effective date of this rule, obtain at least one of the following based upon the patient's clinical presentation:

(a) Consultation with a specialist in the area of the body affected by the pain;

(b) Consultation with a pain management specialist;

(c) Obtain a medication therapy management review; or

(d) Consultation with a specialist in addiction medicine or addiction psychiatry if aberrant behavior indicating medication misuse or substance use disorder may be present.

(E) The physician shall not prescribe a dosage that exceeds an average of one hundred twenty MED per day. This prohibition shall not apply in the following circumstances:

(1) The physician holds board certification in pain medicine, ~~or~~ board certification in hospice and palliative care, board certification in hematology, or board certification in oncology;

(2) The physician has received a written recommendation for a dosage exceeding an average of one hundred twenty MED per day from a board certified pain medicine physician or board certified hospice and palliative care physician who based the recommendation on a face-to-face visit and examination of the patient. The prescribing physician shall maintain the written recommendation in the patient's record; or

(3) The patient was receiving an average daily dose of one hundred twenty MED or more prior to the effective date of this rule. The physician shall follow the steps in paragraph (E)(2) of this rule prior to escalating the patient's dose.

(F) During the course of treatment with an opioid analgesic at doses below the average of fifty MED per day, the physician shall provide periodic follow-up assessment and documentation of the patient's

functional status, the patient's progress toward treatment objectives, indicators of possible addiction, drug abuse or drug diversion and the notation of any adverse drug effects.

(G) During the course of treatment with an opioid analgesic at doses at or above the average of fifty MED per day, the physician shall complete and document in the patient record the following no less than every three months:

(1) Review of the course of treatment and the patient's response and adherence to treatment.

(2) The assessment shall include a review of any complications or exacerbation of the underlying condition causing the pain through appropriate interval history, physical examination, any appropriate diagnostic tests, and specific treatments to address the findings.

(3) The assessment of the patient's adherence to treatment including any prescribed non-pharmacological and non-opioid treatment modalities;

(4) Rationale for continuing opioid treatment and nature of continued benefit, if present.

(5) The results of an OARRS check in compliance with rule 4731-11-11 of the Administrative Code.

(6) Screening for medication misuse or substance use disorder. Urine drug screen should be obtained based on clinical assessment of the physician with frequency based upon presence or absence of aberrant behaviors or other indications of addiction or drug abuse.

(7) Evaluation of other forms of treatment and the tapering of opioid medication if continued benefit cannot be established.

(H) This rule does not apply to the physician who prescribes an opioid in any of the following situations:

(1) The medication is for a patient in hospice care.

(2) The patient has terminal cancer or another terminal condition, as that term is defined in section 4731-11-01 ~~2133.01~~ of the Administrative ~~Revised~~ Code.

(I) This rule does not apply to inpatient prescriptions as defined in Chapter 4729. of the Revised Code.

Replaces: 4731-21-02, 4731-21-06

Effective: 12/23/2018
Five Year Review (FYR) Dates: 12/23/2023
Promulgated Under: 119.03
Statutory Authority: 4731.052, 4731.05 , 4730.39, 4730.07, 3719.062
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Prior Effective Dates: 11/11/1998, 11/30/2008, 8/31/2017