

Submitted via E-Mail

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Ohio Department of Medicaid Office of Contracts and Procurement Managed Care Procurement RFI PO Box 182709 Columbus, OH 43218-2709

ATTN: RFP/RLB Unit

RE: Ohio Department of Medicaid Request for Information- Ohio Medicaid Managed Care Program

On behalf of the 1,600 chain pharmacies operating in the state of Ohio, the National Association of Chain Drug Stores is submitting comments to the Ohio Department of Medicaid's (ODM) Medicaid Managed Care Request for Information.

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS' over 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 157,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability.

NACDS believes that creating a framework for the Ohio Managed Care Program provides an opportunity to protect both patients and providers as the use of managed care in the Medicaid program increases. We are providing these comments in hopes of partnering with ODM in the development of this framework to help create standards that will serve to maintain the strong link between Medicaid patients and community pharmacies and the valuable services that these pharmacies provide.

Specifically, in our comments, NACDS discusses:

- A. Adequate Pharmacy Reimbursement in the Ohio Managed Care Program
- B. Network Adequacy and Access Standards
- C. Recommendations for Cost Savings Approaches Under Ohio Medicaid Pharmacy Program
- D. Leverage Pharmacy Care to Improve Access and Quality of Care for Ohio Medicaid Population
- E. Improve Transparency, Efficiency, and Accountability of Pharmacy Benefit Managers
- F. Standardized Provider Oversight and Quality Measures for Managed Care Plans

A. Adequate Pharmacy Reimbursement in the Ohio Managed Care Program

Community pharmacies acknowledge ODM's efforts to reform and restore transparency and accountability to the Ohio Managed Care Plans. It is also notable that beginning in January 2019, ODM has adopted requirements for all pharmacy benefit managers (PBM)s to use a pass-through model that would require the managed care plans to report the exact amount the PBM pays pharmacists for prescriptions, including the product cost and dispensing fee. Additionally, we understand that the adoption of the pass-through model was targeted to ending unfair spread pricing practices where state funds that were paid to plans for

prescription drugs were not being reflected in the actual reimbursements that participating pharmacies were receiving. However, despite these intentions and efforts, these changes have not fully translated into fair and accurate reimbursement levels for pharmacies. In fact, the current situation is ominous, requiring further action.

Although spread pricing has been prohibited and pass-through models are required in the Ohio Managed Care program, pharmacy reimbursement rates are still at levels that are insufficient to cover the full price of acquiring and dispensing prescription drugs in the Medicaid program. In fact, reimbursement levels under some of the current managed care plans are even lower with covered drugs being reimbursed below acquisition cost and absent a professional dispensing fee. Even with the adoption of pass-through models and the removal of spread pricing, lack of further attention and adjustments to pharmacy reimbursement rates will result in an extreme financial loss to pharmacies and potentially hamper access to beneficiary care. It is extremely important that ODM not stop at requiring pass-through models and prohibiting spread pricing. Rather, ODM must further these remedial efforts by immediately making the necessary adjustments to ensure that pharmacies receive adequate reimbursement that is truly reflective of the cost to acquire and dispense prescription drugs in the Medicaid program. Below we offer suggestions that would assist with these efforts to ensuring fair and accurate reimbursement rates for pharmacies.

• The Setting of a Medicaid Rate Floor for Pharmacy: As a part of the efforts to increase accountability in Ohio's Medicaid Pharmacy Program, beginning July 1, 2020, ODM is proposing to adopt an appeals process for pharmacies that will ensure that the cost of pharmacies doing business is met. Like the initiative to prohibit spread pricing and require the use of a pass-through model, this is also a notable effort to ensuring that reimbursement rates adequate to accommodate the cost to acquire and dispense prescription drugs within the Medicaid program; however, this initiative is void of a standard for payment. While an appeals process provides a mechanism for pharmacies to contest low reimbursement, it does not set a standard or a framework that the plans should follow for establishing reimbursement. Community pharmacies strongly believe that in addition to and before an appeals process can be established and adopted, the state should establish a reimbursement rate standard or adopt a minimum reimbursement rate that pharmacies should receive that will at least cover the true cost of purchasing and dispensing prescription drugs. Additionally, this standard for payment should be adopted well before July 1, 2020, to provide immediate relief to participating pharmacies that are currently bearing the finical burden of extremely insufficient reimbursement rates.

Like many other states, Ohio has a fairly large managed care population. However, unlike other states, Ohio has not created a reimbursement rate floor for participating providers which would guarantee that providers are not paid below the current Medicaid fee-for-service (FFS) rates. By establishing a sufficient standard of payment and reimbursement rate floor, these same payment reassurances and protections can be extended to pharmacy providers when prescription drugs are carved into the managed care program. Establishing the same reimbursement rate floor for pharmacies will increase transparency as well as create a level playing field for all providers, thereby allowing for some financial stability and predictability of reimbursement in these private contracts.

In addition to adopting the FFS rate as a rate floor for the drug product, it is also imperative that managed care plans are required to address pharmacy reimbursement comprehensively and adopt cost-based professional dispensing fees. A fair and accurate dispensing fee takes into account a wide variety of factors such as payroll and personnel expenses, inventory services and warehouse expenses, insurance, building, computer, and rental of equipment. Similar to the considerations for establishing a professional dispensing fee for the FFS program, Ohio Medicaid should also consider adequate dispensing fees that incorporate a built-in inflationary component per annum of Consumer Price Index for its dispensing fee its managed care program. By incorporating a built-in inflationary component of

the dispensing fee, pharmacy providers will receive reimbursement that is much more reflective of the cost to provide healthcare services in the marketplace. Furthermore, dispensing fees should be based on an annual comprehensive cost of dispensing surveys, like the Ohio Medicaid Survey of the Average Cost of Dispensing a Medicaid Prescription to accurately represent the cost of dispensing a Medicaid Prescriptions.

When considering the adoption of a reimbursement rate floor, ODM and managed care plans should take into consideration the fact that the FFS reimbursement rates are based on either a state or national pharmacy survey of the actual invoice cost of prescription drugs as required by the 2016 Covered Outpatient Drugs Final Rule. In 47 states, the cost is determined by the actual prices paid by pharmacy providers to acquire drug products marketed or sold by specific manufacturers. Thus, if states and managed care plans were to use the FFS rate as a reimbursement ceiling, as opposed to a floor, it would result in pharmacy providers being reimbursed below the actual cost of acquiring the drug products. Accordingly, pharmacies would face increasing financial burdens, which could potentially lead to access issues for Medicaid beneficiaries. By adopting the National Average Drug Acquisition Cost (NADAC) as approved in the current state plan as the rate floor in its managed care plan, ODM would not only be ensuring that reimbursement rates are accurate and relevant, but they would also allow pharmacies to be paid at rates that are reflective of the true cost to dispense prescription drugs to Medicaid beneficiaries.

The adoption of the FFS rate as a rate floor for managed care plans would not only ensure adequate reimbursement rates, but it would also be aligned with other proposed federal regulations and legislate initiatives. Specifically, in the November 2018 Medicaid Program; Medicaid and Children's Health Insurance Plan (CHIP) Managed Care Proposed Rule¹, CMS recognized that some states are experimenting with payment models that use cost-based reimbursement models. To encourage states to develop these payment models and to eliminate the need for states to modify their payment models as only minimum or maximum fees schedules, the Proposed Rule gives states the authority to require managed care plans to adopt cost-based rates for network providers that furnish a particular service under the contract. Lastly, because these rates have already been approved as a part of the state plan, the Proposed Rule removes requirements for prior approval for payment arrangements that are based on the state plan approved rates, thus making it easier for such rates to be applied to managed care plans.

Similarly, on September 25, the U.S. Senate Committee on Finance released the text of the Prescription Drug Pricing Reduction Act (PDPRA) of 2019 (S. 543) to reform drug pricing, which also includes provisions that would require payments to be made in the same manner as the cost-based reimbursement requirements in Federal regulation as set forth for FFS programs. Specifically, the provision would require plans to not only use a pass-through model, but it also requires plans to reimburse pharmacies at rates that are limited to the ingredient cost and a dispensing fee, which can be no less than the rates that the state is paying under the state plan or waiver for the FFS population. While this language has not been passed by Congress, it is a clear indication that efforts are targeted to ensuring that managed care pharmacy reimbursement rates are fair and adequate to cover the true costs to acquire and dispense prescription drugs to Medicaid beneficiaries. As such, ODM should also adopt similar requirements to ensure that pharmacies are reimbursed accordingly for prescription drugs dispensed to state managed care beneficiaries.

As ODM works to create a framework for managed care plans, we strongly urge you to ensure that payment rates are at levels that help to preserve patient access once transitioned to managed care.

¹ <u>83 Federal Register 57264; CMS 2408-P</u>

The adoption of the FFS reimbursement rate as a rate floor in managed care plans would ensure that pharmacy providers receive fair and adequate reimbursement rates that truly reflect costs. Currently, Kansas, Louisiana, and North Carolina, are using their current FFS rates for pharmacy reimbursement in their managed care programs. Additionally, Michigan, New York, and Virginia, are all actively considering proposals to also establish a reimbursement rate floor by using their approved fee for service rates in their managed care programs. As these other states have recognized the importance of maligning fair and accurate reimbursement rates in their managed care programs, we implore ODM to do the same to ensure continued patient access to needed prescription drugs and services.

- <u>Single PBMs Should be Carved-out of National Pharmacy Contracts:</u> As the state considers the above reimbursement suggestions, it is imperative that any contracts for the single PBM are free of requirements that would result in negative downstream impacts on pharmacy providers and the payments they receive. Another option that achieves greater pricing transparency is requiring a carve out, from national pharmacy contracts, of pass-through rates for health plans specific to Ohio. If Ohio maintains the current pass-through model with no state-specific carve-out from national pharmacy contracts, the state may be subsidizing spread models in other states and plans, while not obtaining actual costs. In national pharmacy contracts, Ohio would have limited to no knowledge if it is subsidized or being subsidized by other states under the current model. Carving out reimbursement rates ensures that Ohio is remunerating the true and actual economics for the state. Therefore, we urge ODM to require PBMs to carve the Medicaid managed care plans for Ohio out of the national pharmacy provider agreements.
- Plans Should Meet the 85% Medical Loss Ratio (MLR) Requirements: In the May 2016 Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability Final Rule², CMS adopted rules that required managed care plans to calculate and report their MLR experience for each contract year and was to apply to rate periods for contracts starting on or after July 1, 2017. The rule stated that actuarially sound rates were to be set to achieve an MLR of at least 85% and should apply to rate periods for contracts starting on or after July 1, 2019. Additionally, states are given the flexibility to set a standard higher than 85% and/or impose a remittance requirement. Based on the extremely low rates that pharmacy providers are receiving, we are concerned that ODM is not enforcing this minimum.

Because of the excessively insufficient reimbursement rates that pharmacies are receiving despite recent efforts to remove spread pricing practices, we question if ODM is requiring Medicaid managed care plans in Ohio to maintain Medical Loss Ratios at or above 85%? Our concern is based on the August 16, 2018, report by the state auditor³ stating that the Medicaid "Department's contract with its Plans indicates that the minimum medical loss ratio shall not fall below 85 percent". As such, we seek clarification on exactly how medical loss ratios calculated for Medicaid managed care plans in Ohio and further question what cost elements are considered pharmacy care costs as opposed to overhead and other non-care costs?

Per the May 15, 2019 CMS Informational Bulletin⁴, CMS has provided guidance on calculating and reporting the MLR. Specifically, the guidance says that states are responsible for ensuring that managed care plans are complying with the MLR requirements and thus should routinely audit reported data and MLR calculations to ensure that revenues, expenditures, and other amounts are

² 81 Federal Register 27497; CMS 2390-F

³ https://ohioauditor.gov/auditsearch/Reports/2018/Medicaid Pharmacy Services 2018 Franklin.pdf

⁴ https://www.medicaid.gov/federal-policy-guidance/downloads/cib051519.pdf

appropriately identified and classified within each managed care plan's MLR. This will allow states to distinguish which amounts were actually paid for benefits, or activities that improve health care quality, and which amounts were actually paid for administrative services, taxes, or other activities. That said, we strongly urge ODM to audit the reported data and MLR calculations to ensure that plans did, in fact, discontinue all spread pricing practices that may be hidden due to misrepresented ratios. Additionally, we strongly urge ODM fully utilize the CMS guidance on calculating and reporting the MLR to avoid further decreasing the already low pharmacy reimbursement rates.

Additionally, because pharmacies are still being reimbursed below cost, in conjunction with the audits of the reported data and MLR calculations, we strongly urge ODM to commission a follow-up study to determine if the move to pass-through rates on January 1, 2019, provided any savings to the state and if so seek opportunities to reallocate such savings to provide cost-based dispensing fees to pharmacies. In doing such a study the state should focus on the following topics:

- Spread amounts as calculated prior to 2019 and broken down by PBM;
- Spend trend year over year is broken down by utilization and per prescription trend;
- Comparison to spend trends of key players in consultants' databases; and
- Spread amounts are broken down between adjudicated and reconciled rates (if possible)

B. Network Adequacy, Access Standards, and Patient Freedom of Choice

One of the major barriers for individuals to access health care services and pharmacy benefits is the adoption and implementation of restricted provider networks that increase patient difficulty in access to prescription drugs and other healthcare services. Restrictive provider networks and the lack of access standards, increases the likelihood that patients will face access barriers and may not be able to get their prescriptions when they need them, thus increasing non-adherence and associated health complications and costs. Medication non-adherence—that is, patients not taking their medications as prescribed by their healthcare provider—contributes to \$100-290 billion in unnecessary healthcare expenditures every year as a result of increased hospitalizations and other avoidable, expensive medical services.⁵⁻⁷

A systematic literature review of 79 studies conducted in 2018 revealed the adjusted total cost of non-adherence across multiple disease groups ranged from \$949 to \$52,341.8 A 2017 white paper found that the direct medical costs and consequences related to not taking medication as prescribed is estimated to be 7 to 13 percent of national health spending annually – approximately \$250 billion to \$460 billion in 2017, translated to a potential cost to taxpayers of \$6 trillion over 10 years.9 And a 2016 cost-benefit analysis concluded that between one and two thirds of medicine-related hospitalizations are caused by poor adherence. Improving adherence could result in annual per-person savings ranging from \$1,000 to \$7,000,

⁵ Rosenbaum L, Shrank WH; "Taking Our Medicine - Improving Adherence in the Accountability Era;" New England Journal of Medicine; Aug. 22, 2013

⁶ Network for Excellence in Health Innovation; "Bend the Curve: A Health Care Leader's Guide to High Value Health Care;" 2011. https://www.nehi.net/writable/publication_files/file/health_care_leaders_guide_final.pdf

⁷ The NCPIE Coalition; "Enhancing Prescription Medicine Adherence: A National Action Plan;" 2007. http://www.bemedwise.org/docs/enhancingprescriptionmedicineadherence.pdf

⁸ Cutler RL, et al; "Economic Impact of Medication Non-Adherence by Disease Groups: A Systematic Review;" *BMJ Open* 2018; 8:e016982. doi:10.1136/bmjopen-2017-016982 https://bmjopen.bmj.com/content/bmjopen/8/1/e016982.full.pdf

⁹ "A Treatable Problem: Addressing Medication Nonadherence by Reforming Government Barriers to Care Coordination;" *Prescriptions for a Healthy America*; October 2017.

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depending on the disease state.¹⁰ Multiple, credible sources have drawn the same conclusion: medication non-adherence is a costly, preventable problem that dramatically affects total cost of care.

ODM should be mindful of the importance of ensuring that there is network adequacy and provider capacity to administer the services that Medicaid beneficiaries need. Ensuring patient access through a transparent process will create the necessary checks and balances to ensure adequate provider payment rates within the Medicaid program that would further ensure patient access to needed providers.

Restrictive provider networks are not appropriate for Medicaid recipients. Medicaid beneficiaries are less mobile than the general population as they rely more heavily on public transportation and have fewer options for traveling to providers that are not conveniently located. Restricting provider networks results in restricted patient ability to access their healthcare providers and unnecessary disruptions in needed care. As a result, there is the potential for increased overall healthcare expenditures due to the use of more costly healthcare services among Medicaid patients. Therefore, in order to ensure continuity of care and minimize healthcare costs, Ohio Medicaid managed care plans should be required to maintain open provider networks that would allow patients continued access to providers they have come to know and trust.

In order to ensure that patients have access to the pharmacy of their choice, we strongly urge ODM to require managed care plans to follow the same pharmacy access standards as required for the Medicaid FFS program by allowing any pharmacies willing to accept a plan's standard terms and conditions the opportunity to participate in a managed care plan network. By adopting the same FFS standards, Medicaid patients would have access to a sufficient number of locations from which to get their medications.

Community pharmacies supports network adequacy standards that promote access based on enrollees' needs, availability of care and providers, and utilization of services. If ODM moves in the direction to establishing defined network standards, community pharmacies believe that establishing a transparent process with defined access standards will provide the necessary oversight and will help to ensure that patients have adequate access to needed healthcare services. Additionally, ODM should prohibit managed care plans from requiring pharmacies to participate in other networks as a condition to participate in a Medicaid network as well as prohibit plans/PBMs from excluding pharmacies from other networks if they do not participate in a Medicaid managed care network.

To remove the difficulty of patients accessing prescription drugs and other valuable services that pharmacies provide, patients should have the freedom to select a pharmacy within a network that best fits their personal health needs and provides the most accessible care. At minimum, in the case of retail pharmacy, any network standards should follow those that have been established by the Medicare Part D program, which has clear requirements for its beneficiaries' access to prescription drugs and pharmacy services. Specifically, the standards require that 90 percent of beneficiaries in urban areas have access to a pharmacy within 2 miles, 90 percent of beneficiaries in suburban areas have access to a pharmacy within 5 miles, and 70 percent of beneficiaries in rural areas have access to a pharmacy within 15 miles. We believe these standards work well in ensuring beneficiary access and encourage their adoption in the Ohio Medicaid Managed Care Program.

<u>Eliminating Conflicts of Interest:</u> As a part of the initiatives to increase accountability and transparency in the Ohio Medicaid pharmacy program, ODM is adopting initiatives that will eliminate potential conflicts of interest, reduce costs, and expand access beginning January 1, 2020. As such ODM has established standards

¹⁰ Patterson JA, et al; "Cost-Benefit of Appointment-based Medication Synchronization in Community Pharmacies;" *American Journal of Managed Care*; 2016. https://www.ajmc.com/journals/issue/2016/2016-vol22-n9/cost-benefit-of-appointment-based-medication-synchronization-in-community-pharmacies

regarding patient access to specialty drugs. Below are some additional suggestions for ODM to consider as they work towards implementing these standards.

Mandatory Mail Order Limits Patient Access to Community Pharmacies: In addition to network adequacy imposing a barrier on patient access to needed prescription drugs, there are also barriers that are placed on patients by policies that require patients to use mail order services for their prescription drug needs. To further ensure patient choice to all healthcare providers, we urge Ohio Medicaid to adopt provisions that would also prohibit managed care plans from imposing financial incentives that would steer patients to use mail order pharmacy services. As previously stated, patient choice should not be restricted once patients are enrolled in a managed care program. It is apparent from the continuous growth in state Medicaid expenditures that Medicaid patients tend to be sicker and require more heath care, especially prescription drugs. Medicaid patients would continue to benefit from coordinated prescription management by their local pharmacist, which would be in jeopardy if plans can pursue mandatory mail order services.

Section 1902(a)(23) of the Social Security Act allows beneficiaries to obtain services from any qualified Medicaid provider that agrees to provide such services. While there are waiver options for managed care plans in that regard, we believe patients that are enrolled in managed care plans should be allowed the same protections of using the provider of their choice. NACDS and its members also believe that allowing patients the freedom of choice to use the community pharmacies they have come to know, and trust is a positive step towards improving patient adherence to their medication regimens. Development of rules that prohibit mandatory mail order will serve as an important tool to help ensure that patients take their medications as prescribed as well as improve health outcomes and reduce overall healthcare cost by decreasing the use of more costly medical interventions such as emergency room visits and hospitalizations.

• Properly Defined Specialty Drugs is Essential to Patient Access to Medications Used to Treat Complex Chronic Conditions: As several studies have shown, specialty drugs are and will continue to be a rapidly growing share of total drug expenditures for public and private health plans. Due to these rising costs, management of specialty products has become one of the most challenging issues facing health care payers. As a result, there has been an increased interest in developing and implementing programs to control costs while at the same time ensuring patients access to these drugs. However, the increased need to control costs has caused managed care plans to inaccurately define and classify specialty drugs in ways that could potentially cause unnecessary limited or restricted access to these life-sustaining drugs.

Patient access to specialty drugs used to treat complex chronic conditions is just as important as access to traditional prescription drugs. Another barrier to patient access to prescription drugs is the use of aggressive specialty drug programs that often mandate that their enrollees obtain specialty or high cost drugs through a mail order program. We believe that Ohio Medicaid should develop requirements that would prohibit managed care plans from limiting specialty medications through closed, exclusive networks. Patients should have access to their specialty medications through retail pharmacies with specific specialty clinical management services that meet patients' needs in their own neighborhoods. Such access can be critical to maintaining the health of vulnerable patients with chronic illnesses.

• <u>Defining and Categorizing Specialty Drugs:</u> The definition of specialty drugs and the agents that are included in this category is evolving and varies widely across health plans. As a method for defining and categorizing specialty drugs, most states and managed care plans have been developing definitions that place drugs on the specialty drugs list when the total monthly cost of that drug

exceeds a specified amount. Community pharmacies have concerns with proposed definitions of specialty drugs that are based on cost, and believe that the definition for specialty drugs should be primarily focused on the clinical aspects of these drugs (i.e. route of administration, storage requirements, handling of the product, and the need for medical staff supervision), which would allow for more accurate classification and placement on a specialty drug list.

Access to retail community pharmacies is vitally important for patients with complex, chronic, and progressive medical conditions. These patients often have an increased need for follow-up and often the community pharmacist is the most readily accessible provider for them. While there are many available options to control prescription drug spending, it is imperative to maintain continuous patient access to these medications by allowing patients to use the provider of their choice for their prescription drug needs.

Because the cost of specialty drugs is a growing concern, it is not a suitable tool to use for classification purposes. When using cost as a determining factor for classifying specialty drugs, there is a great risk that some drugs will be inaccurately classified as specialty, while others that are truly specialty drugs will be inaccurately excluded. When looking at the number of specialty drugs commonly used to treat complex, chronic, and progressive medical conditions, several of these drugs would not be included on the specialty drug lists, as they would not meet the established cost thresholds.

We believe that Ohio managed care plans should properly define specialty drugs and should develop standards on how managed care plans determine which drugs are included on specialty drugs lists. The definition of specialty drugs should be created in a way to avoid inappropriate categorization of drugs. With this in mind, we are suggesting that Ohio Medicaid consider the following model definition of specialty drug for use by managed care plans:

Specialty Drugs: Model Definition-

(A) DEFINITION OF SPECIALTY DRUG - A prescription drug shall be designated as a specialty drug when it cannot be routinely dispensed at a majority of retail community pharmacies and it meets a majority of the following criteria: (i) requires special handling or storage; (ii) requires complex and extended patient education or counseling; (iii) requires intensive monitoring; (iv) requires clinical oversight; or (v) requires product support services; and the drug is used to treat chronic and complex, or rare medical conditions:

- 1. that can be progressive; or
- 2. that can be debilitating or fatal if left untreated or undertreated.

(B) UPDATING THE SPECIALTY DRUG LISTS - The Department shall provide notification of any changes to all applicable specialty drug lists and shall make such lists available on a state operated website and upon request to participating pharmacies. The Department shall also provide a process for participating pharmacies to comment on, contest, or appeal the specialty drug list.

Appropriately Defining Specialty Pharmacy: In addition to retail community pharmacies, specialty
pharmacies also serve to provide patients access and ensure adherence to prescribed regimens to
treat complex chronic conditions. In addition to adequately defining specialty drugs, there is also a
need to properly define specialty pharmacy. We believe the definition of specialty pharmacy should
describe pharmacies that have the capabilities of providing specialty drugs to the relevant patient

populations. Moreover, the definition of specialty drugs should apply only to those products that require a specialty pharmacy's infrastructure, expertise, and level of service. To assist with the development of a definition that adequately defines specialty pharmacy, we are suggesting the following model definition that should be used in coordination with the definition of specialty drug:

A specialty pharmacy is a state licensed pharmacy that dispenses specialty prescriptions for people with serious health conditions requiring complex therapies. These include conditions such as, but not limited to, cancer, hepatitis C, rheumatoid arthritis, HIV/AIDS, multiple sclerosis, cystic fibrosis, organ transplantation, human growth hormone deficiencies, and hemophilia and other bleeding disorders. In addition to being state licensed and regulated, specialty pharmacies should facilitate education and coordination with prescribers and payors and have clinical review and drug utilization protocols in place, provide patient care services and a comprehensive patient management program, have a support program for patients facing reimbursement challenges, and be accredited by an independent third party.

• Importance of Community Pharmacies and Stakeholder Review and Comment When Defining Specialty Drugs: Community pharmacies are the face of neighborhood healthcare and are integral to providing patients with convenient, cost-effective, innovative, and healthcare outcome directed patient care service. As such, community pharmacies believe that there should be standards for how specialty drugs are defined and for determining which drugs are included on specialty drug lists. As the number of beneficiaries using specialty drugs increases, it will be increasingly important that patients have continuous access to community pharmacists to ensure patients are correctly taking their medications. Therefore, we must protect the patient's right to choose the pharmacy provider that best suits their health care needs.

Understanding how specialty drugs are dispensed is an important component of determining the regulatory framework for specialty drugs. Recognizing the integral role of community pharmacies for dispensing specialty drugs, the pharmacy industry is committed to supporting an approach to the regulation of specialty drug benefits that provides patients with prescription drug services that optimize the patient's healthcare outcomes and provides patients with the convenient readily accessible community pharmacies for specialty prescription drugs as well as their other prescription drugs. The well-being of our patients is the top priority for our pharmacies.

As Ohio Medicaid considers the above definitions, we also suggest that the state adopt a process to allow for stakeholder review and comment on the specialty drug definition and lists prior to the adoption for use. A public review and comment period would allow stakeholders the ability to provide valuable input, which can serve as a critical step to ensuring and maintaining patient access to specialty drugs and to ensuring that drugs are adequately and appropriately placed on specialty drug lists.

C. Recommendations for Cost Savings Approaches Under Ohio Medicaid Pharmacy Program:

Community pharmacies realize that over the past several years states throughout the country have wrestled with the rising cost of prescription drugs in their Medicaid programs. Recognizing these severe financial pressures, community pharmacies are committed to partnering with state Medicaid programs to implement initiatives that control prescription drug spending, maintain beneficiary access to prescription drugs and pharmacy services, and taking positive steps towards improving patient adherence to their medication regimens, while ensuring that all providers receive fair and adequate reimbursement.

Growth in Medicaid spending for the pharmacy benefit is driven primarily by the cost of prescription drugs. While ODM is working to establish accountability and transparency in its pharmacy program, there is still an

opportunity to implement additional initiatives that will further help curtail the constant rise in prescription drug costs. Below are some examples of additional ways to effectively control costs associated with the prescription drug spend.

<u>Seek CMS Approval to Implement Mandatory Co-payments:</u> Ohio Medicaid should implement mandatory copays for prescriptions dispensed to Medicaid beneficiaries to generate additional savings. Like many other states Ohio has co-payments and other cost sharing measures in place for prescriptions dispensed to certain Medicaid beneficiaries. The Deficit Reduction Act (DRA) of 2005 (P.L.109-171) gave states the authority to both increase cost sharing amounts and make the payment of cost sharing mandatory for certain Medicaid beneficiaries.

It is important to keep in mind the impact of uncollected co-payments on pharmacies. Seeking CMS approval to implement mandatory co-payments will shift liability from the state to the patient to cover the cost of prescription drugs. The Medicaid pharmacy reimbursement structure in every state assumes that the co-payment has been collected, and the pharmacy's reimbursement is reduced by that amount. These systems are in place even though Medicaid providers have historically been able to collect only 50 percent of all co-payments assessed. Many community pharmacies, especially those located in low-income urban and remote rural areas where many Medicaid beneficiaries live, incur significant losses each year because they are unable to collect co-payments.

In addition to losses suffered by community pharmacies, it is important to note that when payment of cost sharing is optional for Medicaid beneficiaries, they lose their effectiveness in controlling utilization and influencing cost effective choices. A Medicaid beneficiary facing a higher co-payment for the use of an expensive brand-name drug, will be more likely to declare an inability to afford the higher co-payment, rather than opt for a lower-cost generic drug with a much lower co-payment. Cost sharing can encourage the use of equally effective, lower cost therapies, such as generic drugs. Without mandating the payment of co-payments, states are limiting their own ability to increase generic utilization and manage prescription drug costs.

• State Option to Provide Health Homes for Medicaid Enrollees with Chronic Conditions: The Patient Protection and Affordable Care Act (P.L.111-148) includes a series of grants and pilot programs aimed at improving health care quality and controlling costs with coordinated care models. Section 2703, State Option to Provide Health Homes for Enrollees with Chronic Conditions, provides states the option to create a health home for Medicaid beneficiaries with chronic conditions. Services provided to patients enrolled in the health home would include a comprehensive set of medical services such as care coordination and comprehensive care management.

As a part of the provisions under Section 2703, the Secretary of Health and Human Services started awarding planning grants to those states who are interested in developing a health home as a part of their Medicaid program. In addition to planning grants, those states that are approved for implementation of the health home will receive 90% federal medical assistance percentage (FMAP) for health home services provided during the first two years that the State Medicaid Plan amendment is in effect. As of August 2019, there are 21 states and the District of Columbia with a total of 36 approved Medicaid Health Homes. ¹²

¹¹ Provisions of the DRA were codified as a part of the Medicaid, Children's Health Insurance Programs, and Exchanges: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes for Medicaid and Exchange Eligibility Appeals, and Other Provisions Related to Eligibility and Enrollment for Exchanges, Medicaid and CHIP, and Medicaid Premiums and Cost Sharing Rule.

¹² https://www.medicaid.gov/state-resource-center/medicaid-state-technical-assistance/health-home-information-resource-center/downloads/hhmap.pdf.

As an avenue to increasing medication adherence, coordinated care models can improve patient care by promoting safe and effective medication use. Community pharmacists are uniquely qualified and positioned to reduce the problem of poor medication adherence. As a trusted member of the healthcare team, community pharmacists collaborate with others to positively address patient outcomes and mitigate rising healthcare costs. ¹³ Healthcare spending on non-optimal medication therapy (estimated at \$528.4 billion per year)¹⁴ and medication nonadherence (estimated at \$100-290 billion per year and attributed to 10% of hospitalizations)¹⁵ could be significantly decreased with the development of more purposeful policies and programs that fully leverage patient touch points in the community setting that fully utilize the skillset of community pharmacists. With the adoption of a medical home and through coordinated efforts with other healthcare providers, Ohio Medicaid can improve health outcomes and reduce the use of more costly medical interventions such as hospitalizations and emergency room visits which will result in greater savings to the state.

• Prescription Drug Cost Avoidance: Problems states face in ensuring that Medicaid is the payer of last resort fall into two categories: problems verifying whether beneficiaries have private health coverage and problems collecting payments or "pay-and-chase" when such coverage exists. Based on Medical Expenditure Panel Survey data from calendar year 2016, an average of 8% of respondents who reported having Medicaid coverage also reported having private health coverage at the same time. In addition, the average amount of costs recovered through pay and chase programs is 17%, which does not include the cost to administer the program. By implementing a cost avoidance program which utilizes access to real-time eligibility information, the costs of administering a pay-and-chase program is mitigated and the cash flow remains with state Medicaid agencies.

By accessing real-time patient eligibility from payer sources, Ohio Medicaid will be able to identify other pharmacy coverage that a patient may have and avoid Medicaid claims representing millions of dollars, an immediate savings for states and managed care programs. The prospective cost avoidance savings identified would be in addition to states' current pay-and-chase programmatic efforts. Over time, prescription cost avoidance will mitigate the need for existing retrospective pay and chase models used for pharmacy services.

D. Leverage Pharmacy Care to Improve Access and Quality of Care for Ohio Medicaid Population:

Access to care is a critical factor, strongly influencing patient outcomes and especially important in underserved communities and vulnerable populations. Physician shortages and unnecessary restrictions on other care providers, such as pharmacists, prevent patients from receiving the most accessible and timely care. Approximately 65 million people live in regions without adequate primary care and experts estimate a shortage of providers: up to 122,000 physicians by 2032 within the United States. ¹⁶ Better leverage of the skills and expertise of all healthcare professionals practicing within the community would support physicians in bridging gaps in care and reduce undue strain across the whole healthcare continuum resulting in better care for individuals enrolled in managed care plans.

¹³ Accreditation Council for Pharmacy Education (ACPE); "Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree;" Accessed July 2018. https://www.acpe-accredit.org/pdf/Standards2016FINAL.pdf.

¹⁴ Watanabe JH, McInnis T, Hirsch JD; "Cost of Prescription- Drug Related Morbidity and Mortality;" *Annals of Pharmacotherapy*; March 26, 2018. http://journals.sagepub.com/doi/10.1177/1060028018765159

¹⁵ Rosenbaum L, Shrank WH; "Taking Our Medicine - Improving Adherence in the Accountability Era;" *New England Journal of Medicine*; August 22, 2013. Shrank WH, Polinski JM; "The Present and the Future of Cost-Related Non-Adherence in Medicare Part D;" J Gen Intern Med 30(8):1045–6. Pretorius RW, et al. "Reducing the Risk of Adverse Drug Events in Older Adults;" *American Family Physician*; March 1, 2013. https://www.aafp.org/afp/2013/0301/p331.html .

¹⁶ State and Federal Efforts to Enhance Access to Basic Health Care. The Commonwealth Fund. https://www.commonwealthfund.org/publications/newsletter- a rticle/state-and-federal-efforts-enhance-access-basic-health-care Association of American Medical Colleges. New Findings Confirm Predictions on Physician Shortage. April 2019. https://www.aamc.org/newsinsights/press- releases/new-findings-confirm-predictions-physician-shortage

Pharmacists' Ability to Improve Care: Evidence strongly supports pharmacists' ability to provide clinical care, especially related to promoting healthy behaviors including medication adherence, smoking cessation, immunizations, dietary changes, and more. Pharmacists are also well-positioned to encourage follow-up compliance with primary care providers and specialists given frequent touchpoints with patients. In fact, research suggests high-risk Medicaid patients visit pharmacies up to 10 times more frequently than they visit other care settings. ¹⁷

Compelling and longstanding evidence demonstrates that pharmacist-provided care is a fundamental component to the vitality and sustainability of providing high-quality and accessible healthcare to Americans. ^{18,19,20,21} In fact, national and federal agencies, such as the Centers for Disease Control and Prevention and the U.S. Surgeon General, have encouraged and recognized the value of pharmacists in efforts to collaboratively improve quality and healthcare outcomes. ²² Additionally, federal programs like the Public Health Service, the Indian Health Service, and the Veterans Health Administration have proven that greater inclusion of pharmacists in direct patient care leads to less administrative burden on other healthcare providers, improved cost efficiency, more cohesive healthcare teams, and most importantly, improved patient outcomes. ²³

Community pharmacists, as the most accessible and frequently visited member of the healthcare team, ²⁴ complement the care provided by others by facilitating convenient access to affordable and high-quality preventive, chronic, and acute care. The role of community pharmacists has evolved rapidly over the last two decades to include immunizations, screenings, health and wellness, treatment for minor illnesses, medication optimization and adherence, chronic care management, and more. And importantly, it was recently estimated that up to \$21.9 billion could be saved within the US healthcare system by optimizing medication use. ²⁵ Further, it has been estimated that lack of medication adherence causes 125,000 deaths, at least 10% of hospitalizations, and hundreds of billions of preventable healthcare spending. ²⁶ Community pharmacists in neighborhoods across Ohio stand ready to address such issues, especially for the Medicaid populations they serve. However, the current payment system only incentivizes the volume of prescriptions pharmacies dispense, without regard for the clinical services pharmacists are well qualified to provide with demonstrated benefit to optimize patient care and improve outcomes. A subset of examples of pharmacist-provided care

¹⁷ Hemberg N, Huggins D, et al.; "Innovative Community Pharmacy Practice Models in North Carolina"; North Carolina Medical Journal; June 2017. http://www.ncmedicaljournal.com/content/78/3/198.full

¹⁸ Dalton K, Byrne S.; "Role of the pharmacist in reducing healthcare costs: current insights."; Integr Pharm Res Pract.; 2017;6:37–46. Published 2017 Jan 25. doi:10.2147/IPRP.S108047. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5774321/

¹⁹ Newman TV, Hernandez I, et al.; "Optimizing the Role of Community Pharmacists in Managing the Health of Populations: Barriers, Facilitators, and Policy Recommendations."; *J Manag Care Spec Pharm.*; 2019 Sep;25(9):995-1000. doi: 10.18553/jmcp.2019.25.9.995. https://www.ncbi.nlm.nih.gov/pubmed/31456493

²⁰ Armistead LT, Ferreri SP' "Improving Value Through Community Pharmacy Partnerships."; *Population Health Management*; 2018. https://www.liebertpub.com/doi/abs/10.1089/pop.2018.0040?journalCode=pop

²¹ Milosavlijevic A, et al; "Community pharmacist-led interventions and their impact on patients' medication adherence and other health outcomes: a systematic review."; International Journal of Pharmacy Practice; June 2018. https://onlinelibrary.wiley.com/doi/full/10.1111/ijpp.12462

²² Giberson S, Yoder S, Lee MP; "Improving Patient and Health System Outcomes through Advanced Pharmacy Practice. A Report to the U.S. Surgeon General."; Office of the Chief Pharmacist, U.S. Public Health Service; Dec 2011.

https://www.accp.com/docs/positions/misc/improving patient and health system outcomes.pdf Surgeon General supports USPHS report on pharmacists as providers. APhA. January 2012. https://www.pharmacist.com/CEOBlog/surgeon-general-supports-usphs-eport-pharmacists-providers?is sso called=1

²³ Giberson S, Yoder S, Lee MP; "Improving Patient and Health System Outcomes through Advanced Pharmacy Practice. A Report to the U.S. Surgeon General."; Office of the Chief Pharmacist. U.S. Public Health Service; Dec 2011. https://www.accp.com/docs/positions/misc/improving_patient_and_health_system_outcomes.pdf

²⁴ Hemberg N, Huggins D, et al.; "Innovative Community Pharmacy Practice Models in North Carolina."; North Carolina Medical Journal; June 2017. http://www.ncmedicaljournal.com/content/78/3/198.full

²⁵ Shrank WH, Rogstad TL, Parekh N.; "Waste in the US Health Care System: Estimated Costs and Potential for Savings."; *JAMA*; Published online October 07, 2019322(15):1501–1509. doi:10.1001/jama.2019.13978

²⁶ Viswanathan M, Golin CE, et al.; "Interventions to Improve Adherence to Self-Administered Medications for Chronic Diseases in the United States: A Systematic Review."; Ann Intern Med.; 2012. https://annals.org/aim/fullarticle/1357338/interventions-improve-adherence-self-administered-medications-chronic-diseases-united-states

services and corresponding benefits is included:

- Value of Pharmacist-provided Smokina Cessation Interventions. Given the high prevalence of smoking in Ohio (> 20% of adults²⁷), the addition of a pharmacist-led smoking cessation program to the managed care plan offerings should be strongly considered. Pharmacist-led smoking cessation programs are cost-effective: one study demonstrated incremental discounted costeffectiveness was \$720-1418/life-year saved.²⁸ Another study conducted in New Mexico assessed tobacco quit rates among smokers who participated in a 6-month community pharmacy-based program. Patients were scheduled for an initial visit with a pharmacist and then seen for follow-up visits at 1 month, 3 months, and 6 months from the initial visit. Average quit rates were 25% at the end of 6 months, comparable to similar programs headed by other providers.²⁹ As of 2019, 12 states have statutes or regulations in place authorizing pharmacists to prescribe the tobacco cessation aids without a Collaborative Practice Agreement or local standing order. 30 Pharmacists are well qualified to provide smoking cessation interventions broadly across communities as an important preventive care intervention, which offers substantial potential to improve patient health outcomes and quality of life. NACDS urges ODM to support and sustain communitypharmacist led clinical care, including smoking cessation interventions, by including such services within clinical offerings for patients.
- Value of Pharmacist-provided Lifestyle and Wellness Interventions. Pharmacists have the ability to make significant impacts on obesity and other health and wellness risk factors through increased access to quality patient-centered wellness care. In Ohio, 34% of adults are considered to be obese, a risk factor for some of the leading causes of death. 31 Community pharmacists are well-positioned to provide weight and lifestyle management services along with medication management to further improve patient outcomes. 32 In one study, community pharmacist-provided wellness coaching resulted in improved clinical outcomes, including significantly reduced total cholesterol, LDL, diastolic blood pressure, and fasting blood glucose. 33 And in another example, pharmacist-led wellness visits were provided to employees in a community pharmacy. Employees benefited from appointments that included wellness education, goal setting, and monitoring through physical assessments and point of care testing. Through the provision of these services, pharmacists decreased employees' blood pressure and glucose; thus, leading to improved health outcomes. 34 NACDS urges ODM to support and sustain community pharmacist-led clinical care, including lifestyle and wellness interventions, by including such services within clinical offerings for patients.
- <u>Value of Pharmacist-provided Chronic Care</u>. Nationally, utilization of prescription medications
 continues to increase in parallel to the rising prevalence of chronic conditions. At the point of
 dispensing, pharmacists are well positioned to deliver chronic care management services. Ohio
 pharmacists can not only identify drug therapy problems that threaten medication safety and

²⁷ https://www.americashealthrankings.org/explore/annual/measure/Smoking/state/OH

²⁸ https://onlinelibrary.wiley.com/doi/abs/10.1592/phco.22.17.1623.34118

²⁹ Khan N, Anderson JR, et al.; "Smoking Cessation and Its Predictors: Results from a Community-Based Pharmacy Tobacco Cessation Program in New Mexico."; *The Annals of Pharmacotherapy*; September 2012. https://naspa.us/wp-content/uploads/2018/10/Khan.-Smoking-Cessation-New-Mexico.pdf

³⁰ NASPA; "Pharmacist Prescribing: Tobacco Cessation Aids"; August 2019. https://naspa.us/resource/tobacco-cessation/

³¹ https://www.americashealthrankings.org/explore/annual/measure/Smoking/state/OH

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5741031/pdf/iprp-4-079.pdf

³³ https://www.ncbi.nlm.nih.gov/pubmed/23636151

³⁴ https://www.ncbi.nlm.nih.gov/pubmed/31269732

efficacy, but also suggest or make necessary modifications to resolve such problems appropriately using their clinical judgment. Evidence supports pharmacists' ability to identify and resolve drug therapy problems, improving patient health outcomes and reducing downstream harms and costs. 35,36,37

Specifically, a retrospective chart review conducted in a geriatric practice evaluated the impact of pharmacist identification of drug therapy problems and the corresponding action to resolve such issues. In the one-year review, 3,100 drug therapy problems were identified during 3,309 patient encounters. The most common issue was dose too low, followed by dose too high. The most common interventions were laboratory monitoring and dose changes, with an estimated financial savings of up to \$270,591. 38

Other examples of pharmacy-led chronic care management programs include a \$12 million CMMI grant to the University of Southern California and AltaMed, aimed to optimize patient health and reduce avoidable hospitalizations and emergency visits by integrating pharmacists into safety-net clinics in Southern California. This collaborative program resulted in reduced rates of uncontrolled blood sugar by nearly a quarter (23%), improvements in elevated LDL with 14% more patients controlled, and improvements in blood pressure with 9% more patients controlled at 6 months in the intervention group (collaborative care model with pharmacists as leads) versus the control group (primary care physicians only). The program resulted in a 33% reduction in readmissions per patient per year primarily attributed to medications estimated at 6 months. Through this project, pharmacists identified 67,169 medication-related problem in 5,775 patients. The top actions made by pharmacists to resolve these problems included: 14,981 dose change/drug interval, 5,554 medications added, 4,230 tests ordered, 3,847 medications discontinued, and 2,665 medication substituted. NACDS urges ODM to support and sustain community-pharmacist led clinical care, including chronic care and medication optimization, by including such services within clinical offerings for patients.

Value of Pharmacist-provided Medication Assisted Treatment Services for Opioid Use Disorder. As
the state considers improvements for providing well-coordinated and holistic healthcare to
Medicaid beneficiaries – particularly as it relates to the provision of medication assisted treatment
(MAT) services for opioid use disorder (OUD) – we strongly urge ODM to utilize community
pharmacists among the various providers of MAT services in the Medicaid program.

Pharmacists have a critical role to play in providing individuals struggling with OUD with convenient options for receiving MAT services. As the face of neighborhood healthcare, pharmacists are trusted healthcare professionals who regularly interact with patients to provide expert advice on proper medication use and deliver a growing number of important healthcare

³⁵ MacDonald D, Chang H, et al.; "Drug Therapy Problem Identification and Resolution by Clinical Pharmacists in a Family Medicine Residency Clinic."; 2018. https://pubs.lib.umn.edu/index.php/innovations/article/view/971

³⁶ Westberg SM, Derr SK, et al.; "Drug Therapy Problems Identified by Pharmacists Through Comprehensive Medication Management Following Hospital Discharge."; Journal of Pharmacy Technology; June 2017. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5998417/

³⁷ Newman TV, Hernandez I, et al.; "Optimizing the Role of Community Pharmacists in Managing the Health of Populations: Barriers, Facilitators, and Policy Recommendations."; *J Manag Care Spec Pharm*; 2019 Sep;25(9):995-1000. doi: 10.18553/jmcp.2019.25.9.995. https://www.ncbi.nlm.nih.gov/pubmed/31456493

³⁸ Campbell AM, Corbo JM, et al.; "Pharmacist-Led Drug Therapy Problem Management in an Interprofessional Geriatric Care Continuum: A subset of the PIVOTS Group."; American Health and Drug Benefits; December 2018. http://www.ahdbonline.com/issues/2018/december-2018-vol-11-no-9/2678-pharmacist-led-drug-therapy-problem-management-in-an-interprofessional-geriatric-care-continuum-a-subset-of-the-pivots-group

services to the public. Pharmacists' extensive education and training makes them uniquely suited to provide care to patients with OUD.

Community pharmacists are already involved in numerous activities to help patients with OUD. These activities include educating patients on safe opioid use, the importance of proper and safe storage and disposal of opioid products, alternatives to opioids, and dangers of mixing opioids with other medications like benzodiazepines, providing increased access to naloxone as well as naloxone administration, needle exchange programs, and engagement in opioid awareness, management, and prevention programs. While these services cover a wide range of areas, there are still many more services that pharmacists can (and in some states do) provide to further the advancement of OUD treatment and MAT in state Medicaid programs.

Pringle, Aruru, and Cochran³⁹ noted that by allowing community pharmacists to be more involved in direct patient care, community pharmacists can help to eliminate gaps and barriers in treatment and increase access to naloxone and other MAT drugs as well as play a critical role in implementing strategies to help reduce population OUD risk. For example, pharmacists can contribute to reducing OUD population prevalence by using Screening, Brief Intervention, and Referral to Treatment (SBIRT) which has been developed, tested, and implemented in numerous healthcare settings to identify persons who are misusing alcohol and other drugs. Through a screening process, pharmacists identify those at risk of OUD and provide brief counseling and motivational interviewing, as well as linkage to care. Allowing community pharmacists to be more involved in direct patient care helps increase provider capacity while also eliminating gaps and barriers in treatment and increasing access to naloxone and other MAT services.

Pharmacy-based SBIRT services are already being rolled out in Pennsylvania and Virginia. Recently, the Ohio Department of Mental Health and Addiction Services was awarded a five-year, \$10 million cooperative agreement from the federal Substance Abuse and Mental Health Services Administration for a statewide SBIRT program. ⁴⁰ Designed to reduce morbidity and mortality of substance abuse through early intervention and the integration of medical and behavioral health approaches, the program goal is for any time an Ohioan interacts with a medical, behavioral, or mental health professional, they will be appropriately screened and receive the necessary intervention. Notably, the Ohio Medicaid program covers SBIRT services provided by Advance Practice Nurses, Physicians, Physician Assistants, and in clinics (e.g. Federally Qualified Health Centers [FQHCs] and Rural Health Clinics [RHC]). However, Ohio Medicaid beneficiaries are not able to obtain these services from their local community pharmacies.

In contrast to this limitation, the Medicaid program in Virginia does reimburse and support pharmacists providing SBIRT services. To improve access to early identification, linkage to care, and MAT services, we urge ODM to follow the lead of Virginia and ensure

³⁹ Pringle JL, Aruru M, Cochran J, "Role of pharmacists in the Opioid Use Disorder (OUD) crisis, Research in Social & Administrative Pharmacy" (2018), doi: https://doi.org/10.1016/j.sapharm.2018.11.005.

⁴⁰ https://mha.ohio.gov/Health-Professionals/Training-and-Workforce-Development/SBIRT

that SBIRT services are available to Medicaid beneficiaries in the state where provided in community pharmacies.

Medication Assisted Treatment Services. There are several other notable state programs that are actively leveraging community pharmacies and pharmacists to improve access to OUD treatment medications. In Rhode Island, a MAT program is funded by a \$1.6 million NIDA grant. Under this initiative, the Rhode Island Hospital is conducting a pilot program involving six pharmacies working with 125 patients to manage their MAT. In the pilot, patients receive their initial MAT prescription from a physician at CODAC, a large addiction-treatment program with seven locations in Rhode Island. After the physician determines a patient is stable on their medication, a pharmacist working under a collaborative practice agreement takes over the patient's care. Visiting the pharmacy once or twice a week, patients meet in a private room with their pharmacist. The pharmacist places a swab under the patient's tongue for several minutes, which will be sent to a lab for analysis to reveal whether that patient has taken the full dose of their prescribed medication or used any illicit substances. With that information, pharmacists counsel patients about recovery goals, struggles, and successes. They also employ motivational interviewing, a counseling technique that helps patients overcome ambivalence and make behavioral changes. Most patients enrolled in the pilot are expected to take buprenorphine, but patients also have the option of Vivitrol, a once-a-month injection of naltrexone which blocks the effects of opioids. (Methadone is not available as it can only be obtained at federally regulated clinics.)

Currently, Rhode Island is the only state to adopt a pharmacy-based addiction treatment project of this scope. However, there are other similar and notable pilot programs in Kentucky and Maryland. The Kentucky project allows pharmacists to manage patients with OUD on Vivitrol and the Maryland program offers buprenorphine through a single pharmacy connected to the Health Department. Some states have initiated Medicaid program changes to utilize community pharmacies and pharmacists to play a critical role in providing treatment services to patients with OUDs.

Recently, Colorado and Texas have pursued program changes that enhance OUD treatment options for patients at the pharmacy level. In Colorado, legislation was enacted in 2018 that permits pharmacists acting under a collaborative practice agreement to administer injectable MAT for OUDs and receive an enhanced dispensing fee for the administration under the Colorado medical assistance program. Similarly, in Texas, the state submitted a State Plan Amendment in recent months that will expand the pharmacy benefit to reimburse pharmacists for administering Vivitrol to beneficiaries covered under Medicaid fee-for-service and Medicaid managed care. We strongly urge ODM to utilize pharmacists to provide similar services to Medicaid beneficiaries in Ohio, enhancing opportunities for accessible care given the ongoing crisis.

<u>Value-based Care Delivery.</u> As Value-Based Payment Models (VBPMs) in healthcare continue to
evolve, NACDS strongly encourages Ohio Medicaid to consider the benefits of coordinated care
programs and VBPMs. Successful health outcomes for value-based models and other coordinated
care programs will be dependent on ensuring multiple provider types across the care continuum

are able to provide disease state management, medication management, and preventive services to beneficiaries. ⁴¹ Considering the growing evidence that pharmacists are uniquely positioned to improve medication management and clinical care across the care continuum and provide a range of health services in the community and as part of care teams, NACDS strongly recommends that the ODM develop and implement models of care that leverage the unique position and expertise of pharmacists as underpinned by research demonstrating the proven ability for pharmacists to improve care.

Improved care coordination and chronic care management are the cornerstones of VBPMs, and medication management is central to both objectives. While VBPMs have previously primarily focused on physicians and hospitals, they are now expanding to include more providers. The goal of VBPMs is to align performance and health outcomes with compensation by assessing performance using quality and health metrics, and to provide tools and programs to improve patient health outcomes. Value-based payment model reform has the potential to improve outcomes, enhance care coordination, and create more system efficiencies.

The contribution of community pharmacy in helping achieve the goals of VBPMs is extremely promising, especially as these care models realign incentives for pharmacies to not only dispense medications, but to optimize therapy and improve health. While value-based payment models in community pharmacy are still in their early stages, there is significant potential to improve access and quality and reduce costs. NACDS urges ODM to consider development of VBPMs and incentive programs for community pharmacy as a part of the strategy to improve access and quality of care for Medicaid beneficiaries in Ohio. Below we offer examples of value-based models in community pharmacy.

 Wellmark Blue Cross Blue Shield Value Based Pharmacy Program- (Payor: Medicare, Medicaid, and Commercial)

<u>Background:</u> In July 2016, Wellmark identified high performing independent and chain pharmacies in Iowa and South Dakota to participate in a new value-based model, focused on better serving patients with asthma, diabetes, hyperlipidemia, and depression. Goals of this program include ensuring that the patient is on the right drug and is adherent, and in the longer-term, to reduce emergency department visits, hospital readmissions, and total cost of care.

<u>Program Details:</u> For inclusion in the network, participating pharmacies must offer multiple clinical services (e.g. year-round immunization program, comprehensive medication reviews, health screenings, and medication synchronization appointments). Participating pharmacies are also required to formally document services delivered and actively communicate information to patients' providers, provide adequate space for private or semi-private consultations, develop a service plan based on community-specific needs, establish formal immunization protocol and/or collaborative practice agreement(s), and ongoing pharmacist training.

⁴¹ Choudhry NK, Fischer MA, Smith BF, et al; "Five Features of Value-Based Insurance Design Plans Were Associated with Higher Rates of Medication Adherence"; *Health Affairs*; March 2014. https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2013.0060; Roebuck MC; "Medical Cost Offsets from Prescription Drug Utilization Among Medicare Beneficiaries"; *J Manag Care Spec Pharm.*' 2014;20(10):994-995. doi:10.18553/jmcp.2014.20.10.99.

Eligible members for the program include those with ≥1 chronic medication or diagnosed with a chronic condition. Example metrics to evaluate pharmacy performance vary by disease state and include:

- Diabetes blood sugar control and blood pressure control
- Depression readmissions
- Cardiovascular risk cholesterol goals, is patient on correct statin intensity?
- Asthma assess how often patient is utilizing rescue inhaler

<u>Payment Structure:</u> Wellmark's VBPP network is structured outside of the Pharmacy Benefit Manager (PBM) relationship. VBPP payment structure is per member per month (PMPM) with bonuses. Bonus from shared savings is received based on Wellmark's evaluation of costs.

Preliminary Results: As of July 2018, researchers are collecting and analyzing VBPP data to determine the impacts of this program. However, the Continuous Medication Monitoring (CoMM) pharmacy pilot, which informed the creation of the ongoing Wellmark VBPP model, had significant results. Specifically, the CoMM pilot was designed to assess the effects of continuous medication monitoring (CoMM) on total costs of care, proportion of days covered (PDC) rates and the use of high-risk medications by elderly patients. The pilot results demonstrated lower total costs of care and meaningfully better medication adherence. Per member per month (PMPM) costs were approximately \$300 lower for patients who received medications only from the pharmacy offering the CoMM program as compared to patients receiving medications from other pharmacies. This pilot validated that paying pharmacists to proactively address the safety, effectiveness, and adherence of medications at the time of dispensing can support optimization of medication therapy and decrease costs. 42

 Wisconsin Pharmacy Quality Collaborative (WPQC)⁴³- (Payors: Medicaid, Medicare Part D, Medicare, Commercial, and SeniorCare)

<u>Background:</u> Established in 2008, the WPQC is an initiative of the Pharmacy Society of Wisconsin (PSW), which connects community pharmacists with patients, physicians, and health plans to improve the quality and reduce the cost of medication use across Wisconsin. In 2012 the PSW received a \$4.1 million Health Care Innovation Award from the Centers for Medicare & Medicaid Services (CMS) to expand the WPQC statewide. Currently, over 500 pharmacists are actively certified through WPQC. Current health plan partners include the Wisconsin Medicaid and SeniorCare programs and the United Way of Dane County, representing approximately 20% of the state population, or over 1 million Wisconsin lives.

<u>Program Details:</u> WPQC is a network of pharmacies with pharmacists who provide medication therapy management (MTM) services, such as comprehensive medication reviews (CMRs) to complex, high-risk patients. This model leverages pharmacists to reduce medication complexity and errors, improve adherence, and empower patients to safely manage their medication

43 http://www.pswi.org/wpqc http://www.pswi.org/WPQC/About-WPQC/About-WPQC

https://www.dhs.wisconsin.gov/publications/p01558.pdf

http://www.pswi.org/WPQC/WPQC-Payers/Benefits-to-Payers

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⁴² Pilot: While some of the pharmacy services promoted and measured are different between the current Wellmark Blue Cross Blue Shield VBPP and the CoMM pilot, in the CoMM, pharmacists assessed each of the medications being dispensed, identified, and resolved any medication-related problems, and then documented their actions. Examples of drug therapy problems include doses too high or low, duplicate therapy, omissions in drug therapy, etc. Doucette, William R, et al.; "Pharmacy performance while providing continuous medication monitoring."; *Journal of the American Pharmacists Association*; Volume 57, Issue 6, 692-697. https://www.japha.org/article/S1544-3191(17)30788-4/fulltext

regimens. WPQC and its health plan partners facilitate the provision of MTM services for patients taking multiple medications to treat chronic conditions, those at risk of falls and adverse drug events (ADEs), and those recently discharged from the hospital. The UWDC CMR program supports community and senior center case managers to identify older adults at risk of falls and ADEs and intervene by scheduling WPQC- provided CMRs and offering home falls safety assessments. Services can also be provided at the pharmacy or the patient's residence. Similarly, a partnership in Milwaukee between WPQC pharmacies and UniteMKE trains community health workers in medication adherence screening. The community health workers then make CMR referrals to WPQC pharmacies.

Eligible patients must meet at least one of the following criteria to receive WPQC CMR services: take four or more prescription medications to treat/prevent two or more chronic conditions, diagnosis of diabetes, have multiple prescribers, or low health literacy. Patients also qualify for a CMR in the 14 days following discharge from a hospital or long-term care facility to prevent a readmission to the hospital. Additionally, a referral from a prescriber automatically qualifies any patient covered by a participating health plan for WPQC services.

<u>Preliminary Results</u>: In 2016, the Wisconsin Department of Health Services Division of Health Care Access and Accountability completed an evaluation of the project work. The evaluation showed that patients who received a CMR at some point prior to hospitalization exhibited a decrease of \$524 in inpatient costs per hospitalized patient in comparison with a control group that had not received a CMR. This finding suggests that CMRs provided through WPQC may have been impacting health care utilization between 2012-15. Results from the pilot phase of WPQC (2008-2010), which included Unity Health Insurance and Group Health Cooperative of South-Central Wisconsin showed:

- 10:1 Return on Investment (ROI) for services which directly impacted medication cost;
- ROI was maintained at 2.5:1 when combining services which directly impacted medication cost and comprehensive medication reviews; and
- Facilitating the use of health plan formularies to ensure the least expensive equivalent medication, pharmacists can save payers and patients 3-4 times the cost of medications.

<u>Payment Structure:</u> Compensation for the CMR service is provided by participating health plans on an FFS basis and includes one initial visit and three follow-up visits with the pharmacist annually at no cost to the patient.

• Community Care of North Carolina – Enhanced Pharmacy Services Network⁴⁴ - (Payor: Medicare and Medicaid Innovation Grant)

<u>Background:</u> In 2014, Community Care of North Carolina (CCNC) was awarded a 3-year grant from the CMS Center for Medicare & Medicaid Innovation (CMMI) to test payment reform in community pharmacies for Medicaid, Medicare, and dually eligible Medicare-Medicaid and NC

⁴⁴ https://www.communitycarenc.org/

Health Choice beneficiaries by using a collaborative care model where community pharmacy is part of the medical home team.

<u>Program Details:</u> Participating pharmacies are given access to CCNC information that allows pharmacists to review prescription claims data, adherence data, and population management tools. Pharmacies are allowed to participate in the CPESN-NC framework if they deliver enhanced services, document interventions, and meet minimum established criteria. CPESN-NC pharmacies must provide a proactive waste management program that prevents medication waste by verifying patient need prior to each fill, patient counseling and adherence coaching, and assistance with medication reconciliation especially after hospital discharge.

<u>Preliminary Results</u>: Outcomes from this grant have not been published yet. Based upon preliminary results, high-risk Medicaid patients supported by CPESN pharmacies are:

- 45% less likely to have an inpatient hospitalization admission,
- 35% less likely to have a preventable hospital admission or readmission,
- 15% less likely to experience an emergency department visit,
- 25% more likely to engage their primary care provider (PCP), and
- 20% more adherent to their medications.

Primary goals of this grant were to improve quality and reduce costs while enhancing the ability of the primary care provider (PCP) to improve care outcomes for patients with chronic diseases.

<u>Payment Structure</u>: The payment structure is per member per month (PMPM) based on the patient risk or complexity and pharmacy performance score. Pharmacy performance score is based upon the following metrics: risk-adjusted total cost of care, risk-adjusted inpatient hospitalizations, risk-adjusted emergency department visits, adherence to antihypertensive medications, adherence to statins, adherences to DM medications, and patients' adherence to multiple chronic medications. Payment is based on current Medicare Chronic Care Management codes.

Patients must have high preventable risks. For example, a patient with high preventable risk is a 55-year-old with diabetes and high cholesterol who has a history of two previous ER visits and is nonadherent to their cholesterol medication. A pharmacist can help this patient become more adherent to the cholesterol medication and reduce the likelihood of a \$3,000 or significantly higher ER visit.

• Inland Empire Health Plan (IEHP) Pharmacy P4P Program⁴⁵- (Payors: Medi-Cal and Medicare)

<u>Background:</u> In 2013, IEHP, a Medi-Cal and Medicare health plan that provides managed care for more than 1.2 million California residents, developed the IEHP Pharmacy Pay-For-Performance (P4P) Program – one of the first programs of its kind – designed to improve pharmacy services through IEHP's 450 community pharmacy providers. The focus of the program aimed to validate the roles of community pharmacies in promoting healthcare quality and define a pharmacy payment model for outcome-based services while improving members'

⁴⁵ https://ww3.iehp.org/en/providers/pharmaceutical-services/pharmacy-p4p-program

health, reducing costs, and increasing the plan's star rating. IEHP has a Pharmacy Quality Star Ratings system created to help IEHP members locate high-quality pharmacies based on data collected. The searchable system displays the rating of each participating pharmacy. The ratings range from 1 to 5 stars, with 5 stars being the best.

Program Details: The initiative began with a focus on pharmacist review of member's Proportion of Days Covered (PDC), which is a measure of medication adherence. Pharmacists worked to achieve members' adherence goal of PDC ≥ 80%. In a later phase, the Pharmacy Home Program began, which provided reimbursement for pharmacies that reached PDC member adherence goals and included medication therapy management (MTM) services to provide care for diabetes, high blood pressure, high cholesterol, and/or asthma. The most recent phase of the program, Safe Rx Network, commenced with a focus on medication safety, and requires pharmacists to review all relevant drug utilization review (DURs) alerts, and determine the most appropriate interventions. DUR alerts and appropriate intervention can mitigate the risk of adverse or medication-related events. There are four DUR alert categories in the program: drug-drug interactions, high dose exceeding maximum recommended dose, therapeutic and ingredient duplication, and high-risk medications for the elderly. To evaluate the program, IEHP measures DUR interventions, percentage (%) of total processed claims with safety DUR alerts, and percentage (%) of overall inappropriate claims avoided. IEHP is preparing to expand their quality-focused initiatives with a Point-of-Care (POC) MTM Pharmacy Program with expected launch date in 2019.

<u>Preliminary Results:</u> Prior to current phase of the DUR program, pharmacists were able to significantly increase medication adherence rates. Likewise, based on current DUR program data collection and calculations, overridden DUR alerts are trending down from baseline. Therefore, pharmacists are intervening on DUR alerts more often: this process helps to optimize medication therapy and ensure that only safe and effective medications reach patients.

<u>Payment Structure:</u> Pharmacies are paid a certain amount of dollars per prescription claim that is processed with an overridden DUR alert providing that a payable PSC code is included. The P4P payment per claim will be determined based on final paid prescription volume. Furthermore, there is a bonus payment associated with not filling a prescription after receiving a DUR notification or alert. A pharmacy will receive bonus payment if the percentage of paid prescription volume associated with overridden DUR alerts of the total paid prescription is lower than IEHP threshold. Pharmacies can also earn payment for participating in a Text Message Incentive Program. Monetary support will be allocated to encourage pharmacies to implement a text message system to provide notification to IEHP members. For pharmacies to meet the requirement for opt-in, IEHP members much opt-in >50%. Pharmacies may also earn payment based on member satisfaction survey results.

NACDS Recommendations for Ohio Medicaid Program Refinements: For the greatest impact on access and quality of care for beneficiaries, NACDS highly recommends that the Ohio Medicaid program look across the continuum of care for all opportunities to innovate. For example, by supporting and developing models of care that bolster community pharmacists' ability to deliver on meaningful clinical initiatives as demonstrated by a myriad of evidence, as highlighted above. Ignoring the evidence of pharmacist-provided clinical care denies beneficiaries access to necessary transformation in healthcare delivery, and while pharmacists in Ohio have recently been recognized at the state level as healthcare providers, the Medicaid program has not yet modernized to fold in pharmacists. Specifically, to best leverage community pharmacists to improve care, ODM should formally recognize pharmacists as clinical care providers and adapt billing systems for pharmacies to

submit claims for clinical care delivered to Medicaid beneficiaries. To accelerate innovation and advance care, ODM should also include pharmacies and pharmacists in existing and future value-based payment models.

E. Improve Transparency, Efficiency, And Accountability of Pharmacy Benefit Managers

Other ways that the state can improve the transparency, efficiency, and accountability of pharmacy benefit managers is by establishing clear program Integrity and Auditing standards. NACDS supports efforts to control fraud, waste, and abuse within the Medicaid program. However, we believe that there should be a balance between the need to ensure integrity in the Medicaid program and the need to afford due process and equal protection to providers.

Pharmacy providers have always been subject to intense auditing by states. Accordingly, we believe that Ohio Medicaid should require managed care plans to adopt additional safeguards for pharmacy providers. As such, we urge Ohio Medicaid to require managed care plans to adopt procedures to provide such due process protections. Below are some suggestions that we believe Ohio Medicaid should consider when establishing fair procedures, practices, and standards in Medicaid audits.

- Oversight of Auditing Activities: As with any auditing process, there are likely to be issues and provider concerns that need to be addressed. To ensure that there is proper oversight of auditing activities, managed care plans should be required to have a designated Medicaid auditing project officer. The primary function of the project officer would be to closely monitor auditors to identify issues within the auditing process and resolve those issues in a timely manner. In addition, the project manager should serve as a point of contact to providers and be readily accessible to work with providers to address any concerns that the provider cannot resolve directly with the auditor.
- <u>Look Back Period</u>: In line with requiring a designated Medicaid auditing project officer, Ohio Medicaid should also develop guidance on the auditing look back period, which should not exceed more than eighteen months from the date that the claim being audited was adjudicated. Allowing the review of claims that are older than eighteen months increases the administrative burden on pharmacies to research claims that may or may not be kept in house. Thus, an undetermined or lengthy look back period subjects providers to research claims that are possibly too old for the provider to work with the state or plan to obtain proper payment if those particular claims were in fact adjudicated incorrectly.
- Third-Party Liability: Beneficiaries may have more than one form of coverage for prescription drugs and can switch between Medicaid managed care plans. In cases where retroactive other coverage is identified or cases where beneficiaries switch managed care plans, most plans require the pharmacy provider to identify the other coverage and resubmit claims to the primary insurance carrier. This is a disjointed, inefficient, and costly process in which most cases a retrospective third-party liability is identified, and pharmacies are required to reverse and rebill claims that have been paid in error. This not only adds to the administrative burden of reversing such claims, but it also improperly shifts the financial risk from the plan to participating pharmacies if payment is not received for those prescriptions that have already been dispensed and used by the beneficiary.

Because coverage differs from plan-to-plan there is an increased possibility that the prescriber and/or drug may not be covered, prescribed quantity and/or days' supply may not be covered, patients may have a higher copayment or be subject to new deductible requirements, or the claim may be too old to receive payment through an electronic process, thus requiring paper claims or other processes to receive payment. Furthermore, if a claim was originally adjudicated and accepted online and it is determined that retroactive disenrollment has occurred, pharmacies will not have an opportunity to file with any other insurance because commercial insurance generally will not accept dated claims. We believe that as managed care plans attempt to recoup payments, plans should be limited to no more

than eighteen months look back period to ensure that pharmacies are resubmitting claims within the new plans billing window and can receive payment for the drugs that have been dispensed.

NACDS believes that there is a need to have the correct payer cover the impacted claims and that this process must be done in line with the current federal requirements. As stated under section 45 CFR 162.1901, the Medicaid pharmacy subrogation transaction is the transmission of a claim from a Medicaid agency to a payer for the purpose of seeking reimbursement from the responsible health plan for a pharmacy claim the state has paid on behalf of a Medicaid recipient. This provision allows Medicaid agencies to use the subrogation standard to pursue reimbursement from other payers, not providers. We believe this provision is also applicable to managed care plans providing coverage to Medicaid beneficiaries seeking reimbursement from other plans. In addition, we believe that this provision provides managed care plans the appropriate mechanism to seek payment of these claims directly from the new plan provider without inadvertently causing undue and onerous administrative and financial burdens on pharmacies who have acted appropriately in the prescription filling and adjudication processes.

- <u>Record Requests:</u> Failure to limit the number of record requests from providers can cause significant
 administrative burdens and inhibit a provider's ability to respond to audit requests in a timely manner.
 Providers are subject to numerous audits. To allow pharmacies to respond timely to record requests,
 audits should be limited to the number of records that can be requested from a provider. In addition,
 auditors should be required to accept medical records electronically and to reimburse providers for
 reasonable shipping and copying costs or other administrative costs associated with providing nonelectronic records.
- <u>Prohibition of Extrapolation</u>: Managed care plans should be prohibited from using any audit program that bases its finding on extrapolation. Extrapolation audits have been shown to be unreliable and inequitable. They result in unfair, erroneous, and overbroad reaches to the recoupment of funds that, in most instances, should not be subject to recoupment. When used in an audit, estimated overpayment amounts are based on the unproven assumption that the problems found in the sample occur at a similar frequency for all prescriptions filled by that provider during a specified period. Accordingly, recoupment amounts are also assessed on the unproven assumption that the estimated overpayments hold true for all prescriptions filled during the review period. As a result, pharmacies are being asked to repay amounts that are much larger than the payments questioned in the sample.

NACDS believes that all audits should be based on reasonable and fair examination of claims. Therefore, we strongly encourage Ohio Medicaid to develop standards and guidelines for managed care audits that will ensure that all Medicaid audits are conducted using generally accepted auditing standards and in accordance with state and federal law.

F. Standardized Provider Oversight and Quality Measures for Managed Care Plans

One way the state could improve transparency, efficiency, and accountability of managed care plans is with the adoption and implementation of a standardized pharmacy performance metrics that will be used across all managed care plans in Ohio. The adoption and implementation of standardized pharmacy metrics would reduce the total cost of care by aligning incentives for pharmacies and plans to further improve medication adherence and other clinically important measures. For example, medication adherence is one of the most cited areas where community pharmacies can play a role in improving health outcomes and reducing costs. Community pharmacists routinely collaborate with other healthcare providers, health systems, and caregivers to positively address patient outcomes and mitigate rising healthcare costs.

The adoption and implementation of standardized pharmacy quality measures for use across all managed care plans would not only improve health outcomes of enrolled beneficiaries, but it would also align with current efforts by the Centers for Medicare & Medicaid Services (CMS) to developing and implementing a meaningful Quality Rating System (QRS) for Medicaid Managed Care plans with the overarching goal of providing transparent, actionable ratings to the public based on healthcare quality and outcomes, consumer experience, and cost. In the May 2016 Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability Final Rule (81 Federal Register 27497; CMS 2390-F), CMS finalized proposals to establish a Medicaid managed care quality rating system in each state that would report performance information on all health plans and align with existing rating systems like those of Medicare Advantage and the Marketplace. CMS believes a quality rating system based on a common set of performance measures would provide enrollees with information about quality of care similar to that, which is available to privately insured individuals, increase transparency in Medicaid, and CHIP managed care, and allows comparison of plans that operate in multiple jurisdictions.

To further these initiatives, in the November 2018 Medicaid Program; Medicaid and Children's Health Insurance Plan (CHIP) Managed Care Proposed Rule (83 Federal Register 57264; CMS 2408-P) (November 2018 Proposed Rule), for the first time CMS proposed to establish a standardized set of mandatory quality measures to be implemented across states. Specifically, in the November 2018 Proposed Rule CMS proposed to identify a uniform set of quality measures that will be mandatory for inclusion in the state's QRS; implement Cross-Program QRS Alignment where CMS proposed to align the Medicaid and CHIP QRS, where appropriate, with other CMS managed care programs, including the Medicare Advantage Star Rating System and the Medicare-Medicaid Plan (MMP) Financial Alignment Initiative, as well as with the QRS for qualified health plan. NACDS supports the development of a standardized set of mandatory quality measures to be implemented across states and managed care plans. Establishing a standardized set of mandatory measures would allow Ohio Medicaid the ability to ensure that states are administering their managed care programs as a comprehensive system, which in turn, facilitates ease of administrative burden on plans and providers.

Additionally, to develop better outcomes measures that accurately reflect quality, safety, and value without burdening innovation, NACDS supports efforts that encourage measure harmonization and synchronization. In the current marketplace, there are numerous duplicative measures that overlap resulting in isolated quality initiatives that focus on different settings or different patient populations. Because these measures are to apply across the same target populations, a lack of measure harmonization and synchronization will create misunderstanding about how such measures and measure results are to be interpreted and used, unnecessarily increasing the data collection burden, inhibiting the ability to compare measure results to determine if there is a valuable outcome, and hindering the ability to adequately identify areas of needed improvement. The development of a standardized set of measures along with better harmonization of measures will not delay or create barriers for the development or utilization of measures, but instead, would eliminate duplication and overlap as well as eliminate inadvertent variances among related measures that could ultimately affect the outcomes that these metrics are intended to measure.

NACDS and its members are strongly committed to ensuring that patients have to access to high quality healthcare services. We recognize the importance of developing and implementing a meaningful measure for Medicaid managed Care plans with the overarching goal of providing transparent, actionable ratings to the public based on healthcare quality and outcomes, consumer experience, and cost. A standard set of metrics would apply consistent performance metrics to pharmacy adherence programs, ensuring that a pharmacy can implement medication adherence programs across plans that consistently improve medication adherence and reduce overall Medicaid costs. Ohio Medicaid should require managed care plans to adopt a set of standard quality metrics for medication adherence and other pharmacy programs to align quality standards that reflect evidence-based strategies to best improve beneficiary health, reduce overall Medicaid costs, and drive better medication optimization and health outcomes.

One-way Ohio Medicaid can incorporate important indicators of system/managed care plan performance is by ensuring the adoption and incorporation of proven medication-related metrics. Medications are the primary intervention to treat chronic diseases, and medications are involved in 80% of all treatment regimens. Substantial evidence links improved adherence to reduced hospitalizations, delayed progression of disease, improved treatment outcomes for chronic disease, and cost savings. When patients adhere to their prescription regimens and properly fill their medications, they avoid more costly future medical interventions, thereby decreasing overall Medicaid spending.

Medication-related measures are particularly important to Medicaid beneficiaries, given the challenges they face financially. Consequently, we urge Ohio Medicaid to ensure the incorporation of strong medication-related measures for Managed Medicaid plans. Such measures would help to ensure the best quality care for Medicaid beneficiaries while also helping to ensure that managed care programs are operating more efficiently. Below are suggestions of measures that could be considered and applied across all managed care plans, and a full listing of potential quality measures for consideration are included in Appendix A.

- Medication Adherence for Diabetes Medications
- Medication Adherence for Cholesterol Medications
- Medication Adherence for Hypertension Medications
- High Risk Medication Use in Elderly Patients
- Appropriate Treatment of Hypertension in Persons with Diabetes

Both the Medicare Star Ratings Program and Quality Rating System for the Marketplaces include medication adherence measures. Similar incorporation of these measures by managed care plans participating in the Ohio Managed Care Program would promote alignment of quality goals across CMS programs, and should thus be a top priority for the Medicaid program.

<u>Conclusion:</u> NACDS thanks you for the opportunity to share our views. Community pharmacies are committed to serving Medicaid patients and providing them with quality care and services. NACDS and its members support efforts to develop a Managed Care Program that will ensure patient access to all healthcare service and we look forward to working with ODM on these very important issues.

Sincerely,

Steven C. Anderson, IOM, CAE

President and Chief Executive Officer

⁴⁶ Agency for Healthcare Research and Quality. Medication Adherence: Comparative Effectiveness. Evidence Report / Technology Assessment. Number 208; Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease; *New England Healthcare Institute*; August 2009.

APPENDIX A.

MIPS Performance - Quality Measures*	Part C/ D Stars	NQF#	MIPS Quality	ACO#	HEDIS	CPC+
Medication Reconciliation Post-Discharge	C20	0097	46	12	Yes	_
Documentation of Current Medications	-	0419	130		No	_
30-Day All Cause Readmission After Discharge	C21	1789	HCPR6	8	Yes	156
		1703				150
Adherence for Diabetes Medications	D11	-	-	- 22/27	No	422
Poor Diabetes Control (A1c >9%)	-	0059	1 110	22/27	Yes	122
ACE/ARB in Coronary Artery Disease and	-	0066	118	33	Yes	-
Diabetes LDL Management in Diabetes			2	23	Yes	
Adherence for Hypertension (ACE/ARB)	D12				No	
Persistence of Beta Blocker Treatment After an	-	0070	7/8	31	Yes	
Functional Status Assessments for Congestive	_	Q377	377		No	
Heart Failure		Q377	377		NO	
ACE/ARB in Heart Failure	-	0081	5	-	No	-
Antiplatelet Therapy in Coronary Disease	-	0067	6	-	No	_
Controlling High Blood Pressure	C16	0018	373	28	Yes	165
Improvement in Blood Pressure	-	Q373	373	-	No	-
Screening for High Blood Pressure	_	Q317	317	21	No	_
Anti-platelet Therapy in Ischemic Vascular		0068	204	30	No	164
Disease		0000	201	30	110	101
Statin Therapy for the Prevention and	-	Q438	438	42	Yes	347
Treatment of Cardiovascular Disease						
Adherence for Cholesterol (Statins)	D13	-	-	_	No	_
Influenza Immunization	C03	0041	110	14	Yes	147
Pneumococcal Vaccination Status for Older	-	0043	111	15	Yes	127
Adults						
Immunizations for Adolescents	-	1407	240	-	Yes	-
Penicillin Allergy: Appropriate Removal or Confirmation	-	-	AAAAI18	-	No	-
Tobacco Use: Screening and Cessation	-	0028	226	17	Yes	138
Unhealthy Alcohol Use: Screening & Brief Counseling	-	2152	431	-	Yes	-
Tobacco Use and Help with Quitting Among	-	Q402	402	-	No	-
Initiation & Engagement of Substance Abuse or	_	-	305	-	Yes	139
Dependence Treatment			- 55		. 55	100
Evaluation or Interview for Risk of Opioid	_	Q414	414	-	No	_
Misuse		~ · · · ·	141		113	
Use of Opioids from Multiple Providers	_	_	_	_	Yes	_
Use of Opioids at High Dosage	_		_	_	Yes	_
Weight Assessment and Counseling for	_	0024	239	_	Yes	_
Nutrition and Physical Activity – Child		0021	233			
Falls: Risk Assessment	-	0101	154	13	Yes	-
Falls: Screening for Future Fall Risk	C18	0101	318	13	Yes	139
Use of High-Risk Meds in the Elderly	-	0022	238	-	Yes	-
Potentially Harmful Drug-Disease Interactions	-	-	-	-	Yes	-
in the Elderly					-	
Depression Utilization of the PHQ-9 Tool	-	0712	371	18	Yes	160
Maternal Depression Screening	_	Q372	372	-	No	_

Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment	-	1365	382	-	No	-
Adult Major Depressive Disorder (MDD): Suicide	-	0104	107	-	No	-
Antidepressant Medication Management	-	0105	9	-	Yes	-
Adherence to Antipsychotic Medications For	-	1879	383	-	Yes	-
Optimal Asthma Control	-	Q398	398	-	No	-
Medication Management for People with Asthma	-	1799	311	-	Yes	122
Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation	-	0091	51	-	Yes	-
Chronic Obstructive Pulmonary Disease (COPD): Long Acting Beta Agonist Therapy	-	0102	52	-	No	-
Annual Hepatitis C Virus (HCV) Screening for Active Injection Drug Users	-	Q387	387	-	No	-
One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk	-	3059	400	-	No	-
Tuberculosis (TB) Prevention for Patients on a	-	Q337	337	-	No	-

^{*}Last updated 2018