

## NATIONAL ASSOCIATION OF CHAIN DRUG STORES

October 5, 2023

The Honorable Jason Smith Chairman, House Committee on Ways and Means U.S. House of Representatives 1139 Longworth House Office Building Washington, DC 20515

## Submitted via WMAccessRFI@mail.house.gov

**Re:** Request for Information: Improving Access to Health Care in Rural and Underserved Areas – Untapped Access Solutions as Close as Local Pharmacies

Chairman Smith,

The National Association of Chain Drugs Stores (NACDS) appreciates the opportunity to respond to the Request for Information (RFI) issued by the House Committee on Ways and Means to identify and explore bold solutions needed to reshape our nation's healthcare system and bring new access to care in rural and underserved areas. NACDS applauds the Committee's work to address today's barriers to healthcare access, especially since our healthcare system has the highest spending with the worst health outcomes, as compared to other high-income countries.<sup>1</sup> To achieve different results, the nation needs new solutions. In particular, community pharmacies continue to offer undeniable capacity to meaningfully address healthcare access gaps, yet this capacity remains vastly untapped and threatened by the practices of Pharmacy Benefit Managers (PBMs). Defending and optimally leveraging the clinical expertise, trust, and accessibility of community pharmacies to provide low-acuity, chronic, and preventive care services can help alleviate healthcare capacity strains, including physician shortages, long wait times, and excessive travel distances.

Consider that nearly 90% of Americans live within 5 miles of a community pharmacy<sup>2</sup> and 86% of adults report that pharmacies are easy to access.<sup>3</sup> Pharmacies are open extended hours – including nights and weekends – when other healthcare providers are unavailable. High-risk Medicaid patients visit their pharmacy 35 times per year compared to 4 visits per year with primary care physicians.<sup>4</sup> Similarly, Medicare beneficiaries also visit pharmacies significantly more often than primary care providers - 13 visits per year compared to 7 visits per year. That difference is even more pronounced in rural communities - 14 visits compared to 5 visits yearly.<sup>5</sup> There are also 15% more pharmacy locations compared to physician practices in low-income communities.<sup>6</sup> This infrastructure allows for scalable healthcare access solutions across diverse communities.

Community pharmacies stand ready as the nation's most accessible healthcare resource to help transform access to care, including across rural and underserved areas. To leverage pharmacies in improving our nation's health for future generations, **NACDS urges the Committee to:** 

1. Support "Real PBM Reform" in Medicare and Medicaid with the passage of measures like S. 2052, the Protect Patient Access to Pharmacies Act and H.R. 1613, the Drug Price Transparency in Medicaid Act and support broader reforms to halt the manipulative practices of PBMs that continue to increase healthcare costs for

<sup>&</sup>lt;sup>1</sup> The Commonwealth Fund. U.S. Health Care from a Global Perspective, 2022: Accelerating Spending, Worsening Outcomes. January 2023, available at: https://www.commonwealthfund.org/publications/issue-briefs/2023/jan/us-health-care-global-perspective-2022

<sup>&</sup>lt;sup>2</sup> https://www.japha.org/article/S1544-3191(22)00233-3/fulltext

<sup>&</sup>lt;sup>3</sup> https://accessagenda.nacds.org/dashboard/

<sup>&</sup>lt;sup>4</sup> <u>https://www.pharmacytimes.com/view/pharmacists-as-influencers-of-patient-adherence-</u>

<sup>&</sup>lt;sup>5</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7364370/

<sup>&</sup>lt;sup>6</sup> https://www.japha.org/article/\$1544-3191(22)00094-2/fulltext

patients and threaten the viability of community pharmacies to continue serving their communities, including in rural areas.

- 2. Support successful passage of the Equitable Community Access to Pharmacist Services Act (H.R. 1770/S. 2477) to foster convenient Medicare beneficiary access to pharmacist services for common health threats, like influenza and COVID-19, building on the effectiveness and equitable reach of pharmacy-based care during the pandemic that averted more than 1 million deaths, prevented more than 8 million hospitalizations, and saved \$450 billion in health care costs.<sup>7</sup>
- 3. Leverage community pharmacies in innovative healthcare models by requiring the CMS Innovation Center to include pharmacies in the design and implementation of value-based care models to explore new opportunities to advance healthcare outcomes and promote healthcare savings.

# DISCUSSION

# I. Sustainable Provider and Facility Financing

The Committee is requesting improvements needed to align Medicare payment systems and structure to support access to care, including in rural and underserved areas. While pharmacies offer unparalleled access to care, manipulative practices by Pharmacy Benefit Managers (PBMs) continue to threaten the viability of community pharmacies, undermining resolution to the exact problem the Committee's RFI outlines - gaps in healthcare access. Unfortunately, America's pharmacies have been struggling with reimbursement challenges for over a decade as a result of the competition-eroding practices of PBMs that impact timely patient access, pharmacy sustainability, and pharmacy's innovative vision to empower patients' total health and wellness. As illustrated by MedPAC, Medicare Part D's direct and indirect remuneration (DIR) fees, or fees that PBMs claw back from pharmacies weeks or months after they pay pharmacy claims, skyrocketed from \$8.7 billion (11%) in 2010 to \$62.7 billion (29%) in 2021, which is in part due to the expanded market leverage of PBM-insurers and a non-transparent pharmaceutical supply chain.

The top three PBMs manage about 80% of prescription drug volume.<sup>8</sup> Five of the top six PBMs are owned by large national health insurers. This business environment makes it very difficult for pharmacies to negotiate fair business practices and transparency because the PBMs and health insurers have more commercial market power and leverage in the relationship due to their size and scale. This creates a one-way street with negative consequences for patients, pharmacies, employers, taxpayers, and communities – seemingly for all but the PBMs and payers.

Retail pharmacies are in crisis, facing unsustainable financial pressures as they are increasingly reimbursed by payers below the cost of buying and dispensing prescription drugs. Dire financial pressures have forced an alarming number of pharmacies to take drastic steps, such as possibly paring back hours of operation and delaying innovative care services that otherwise could improve health outcomes. PBMs' retroactive fees and claw backs often occur weeks or months after a transaction closes, when the PBM arbitrarily decides to recoup a portion of the pharmacy's reimbursement. These fees and claw backs have made the economic viability of community pharmacies increasingly difficult, due to the unpredictability of reimbursement and the increased damage to bottom lines.

It is important to examine pre-COVID pharmacy closures. According to IQVIA, between December 2017 and December 2020, almost 2,200 pharmacies closed nationwide.<sup>9</sup> Some of the PBMs' abuse of pharmacies was abated during the pandemic, and the nation's reliance on pharmacies over the past three years further mitigated pharmacy closures. However, the ominous situation for pharmacies is worse than ever before.

The epidemic of pharmacy closures is reducing access to vital healthcare services, especially in rural areas where options are already limited. Communities across the nation depend on neighborhood pharmacies among all healthcare destinations. A recent study published in the Journal of the American Medical Association also found that pharmacy

<sup>&</sup>lt;sup>7</sup> https://pubmed.ncbi.nlm.nih.gov/36202712/

<sup>&</sup>lt;sup>8</sup>https://www.xcenda.com/insights/skyrocketing-growth-pbm-formulary-exclusions-concerns-patient-access

<sup>&</sup>lt;sup>9</sup> IQVIA Data, 2020. Closures disproportionately impacted rural areas.

closures led to a significant drop in medication adherence for older adults taking cardiovascular medications, which has obvious implications for patient health and healthcare costs. Preserving patient access to robust pharmacy provider services and networks like health screenings, disease state management, vaccinations (e.g., flu, COVID-19), patient counseling, medication adherence, and testing— all in addition to essential medication access — can help improve health outcomes and generate overall healthcare savings for Americans.

We look forward to continuing to work with the Committee and other Members of Congress to stop the manipulation by PBMs both domestically and internationally that increases patients' medication costs, limits patients' choice of pharmacies, restricts access to medicines that are right for them, and jeopardizes the pharmacies and pharmacy teams on whom patients rely. In particular, NACDS urges the Committee to support "Real PBM Reform" in Medicare and Medicaid with the passage of measures like S. 2052, the Protect Patient Access to Pharmacies Act, and H.R. 1613, the Drug Price Transparency in Medicaid Act along with other reforms that align with NACDS' Principles of PBM reform to halt the manipulative practices of Pharmacy Benefit Managers that continue to exacerbate healthcare costs for patients and threaten neighborhood pharmacies and the patients they serve, including in rural and urban areas. *See Appendix 1 - NACDS' Principles of PBM Reform to increase transparency and ensure comprehensive reform of harmful PBM tactics and practices.* 

## II. Health Care Workforce

To supplement the capacity of the healthcare workforce and meaningfully improve access to care, NACDS urges the Committee to support **successful passage of the** *Equitable Community Access to Pharmacist Services Act* (H.R. 1770/S. 2477). Today, pharmacists are among the only healthcare professionals omitted from Medicare statute as Part B providers. Therefore, their accessibility and clinical expertise have been largely untapped in promoting better care quality and access for Medicare beneficiaries. This bill would help to extend improvements in care access that were deployed to tackle the COVID-19 pandemic by leveraging community pharmacies to extend access to lifesaving vaccines, tests, and antivirals. By conservative estimates, pharmacy interventions during the COVID-19 pandemic averted more than 1 million deaths, prevented more than 8 million hospitalizations, and saved \$450 billion in health care costs.<sup>10</sup> Congress can build upon this success to achieve a healthier future for all, with a healthcare system that prioritizes access and equity, by supporting the successful passage of H.R. 1770.

Throughout the COVID-19 pandemic, pharmacies were a trusted, equitable provider of vaccinations, tests, and antivirals, providing more than 307 million COVID-19 vaccines to date, in addition to more than 42 million tests, and dispensing more than 8 million antiviral courses.<sup>11</sup> Compared to medical centers, pharmacies provided more than 90% of COVID-19 vaccinations, excluding temporary and government public health sites.<sup>12</sup> During 2022-2023, more than two-thirds of adult COVID-19 vaccinations were administered at pharmacies.<sup>13</sup> With respect to testing, pharmacies provided 87% of the free tests administered through the Improving Community Access to Testing (ICATT) program.<sup>14</sup> Similarly, in considering pharmacies' impact on antiviral access, HHS reported that 87.5% (35,000 of the 40,000) antiviral dispensing sites are pharmacies.<sup>15</sup>

Not only did pharmacies provide unparalleled access to COVID-19 vaccines, tests, and antivirals, pharmacies surpassed expectations when it came to serving vulnerable and underserved communities. For example, 43% of people vaccinated through the Federal Retail Pharmacy Program were from racial and ethnic minority groups, exceeding CDC's goal of 40% — the approximate percent of the U.S. population comprised of racial and ethnic groups other than non-Hispanic White.<sup>16</sup> Pharmacies also supported concerted efforts to foster testing and antiviral access in vulnerable communities,

countermeasuresagainst-covid19.html

<sup>&</sup>lt;sup>10</sup> <u>https://pubmed.ncbi.nlm.nih.gov/36202712/</u>

<sup>&</sup>lt;sup>11</sup> https://www.liebertpub.com/doi/10.1089/hs.2023.0085

<sup>&</sup>lt;sup>12</sup> https://www.iqvia.com/insights/the-iqvia-institute/reports/trends-in-global-adult-vaccination

<sup>&</sup>lt;sup>13</sup> <u>https://www.liebertpub.com/doi/10.1089/hs.2023.0085</u>

<sup>&</sup>lt;sup>14</sup> Miller MF, Shi M, Motsinger-Reif A, Weinberg CR, Miller JD, Nichols E. Community-based testing sites for SARSCoV-2 — United States, March 2020–November 2021.MMWR Morb Mortal Wkly. 2021;70(49):1706-1711.

<sup>&</sup>lt;sup>15</sup> US Department of Health and Human Services. <u>https://www.hhs.gov/about/news/2023/04/14/factsheet-hhs-announces-amend-declaration-prep-act-medical-</u>

<sup>&</sup>lt;sup>16</sup> <u>https://www.gao.gov/assets/720/718907.pdf</u>

helping to ensure access points across diverse populations, especially in those communities without other healthcare providers within reach.

Pharmacies unequivocally demonstrated their ability to meaningfully expand critical access to care across vulnerable communities during the COVID-19 pandemic, and the American people took notice. According to a poll conducted by Morning Consult and commissioned by NACDS in December of 2022, 64% of adults agree that learning the lessons of the pandemic means keeping in place policies that make it easier for patients to access services from pharmacists and other pharmacy team members.<sup>17</sup>

The *Equitable Community Access to Pharmacist Services Act* (H.R. 1770/S. 2477) leverages the proven impact of community pharmacies to foster convenient Medicare beneficiary access to pharmacist services for common health threats, like influenza and COVID-19, building on the effectiveness and equitable reach of pharmacy-based care during the pandemic. Supporting Medicare beneficiaries with the option to seek low-acuity care for common illnesses from their local pharmacies helps enhance access and equity, in a manner that meaningfully supplements existing care capacity in a tangible way. We urge the Committee to leverage community pharmacies moving forward to help achieve your goals to improve access to care, including in rural and underserved areas. We applaud the Committee's consideration of increasing reports of physician shortages, longer wait times, people traveling longer distances to seek care or foregoing care altogether. It is clear that the American people deserve more accessible options to improve their health, including access to the clinical care and expertise of their local pharmacist that proved irreplaceable over the last three years. **The Committee can help make more accessible care a long-term reality across diverse communications by supporting the successful passage of the** *Equitable Community Access to Pharmacist Services Act* **(H.R. 1770/S. 2477).** 

## II. Innovative Models and Technology

In alignment with the Committee's request for policies to advance innovative care models and technology, especially those that improve access to care in rural and underserved areas, NACDS urges the Committee to require inclusion of pharmacists and pharmacies in the CMS Innovation Center's ongoing work to develop, implement, and test value-based care models. Despite strong evidence indicating that pharmacist-provided care improves health outcomes and reduces downstream costs, pharmacists and pharmacies have yet to be directly engaged as care providers in existing CMS Innovation Center's value-based care models. More detail on the tremendous value of including pharmacies in CMS' work to advance value-based care can be found in a 2021 report available <u>here</u>.

The report highlights a myriad of evidence supporting the clinical effectiveness of pharmacists to move the needle on healthcare quality, outcomes, and value. For example, a CMS Innovation Center-funded, pharmacy-led chronic care management initiative was designed to serve an underserved population through collaboration with University of Southern California and AltaMed. This initiative aimed to optimize patient health and reduce avoidable hospitalizations and emergency visits for high-risk patients by integrating pharmacists into safety net clinics. This collaborative program resulted in reduced rates of uncontrolled blood sugar by nearly a quarter (23%), improvements in 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). Through this project, pharmacists identified 67,169 medication-related problems in 5,775 patients, which resulted in a 33% reduction in readmissions per patient per year.<sup>18</sup> *For more examples, see Appendix 2 – Evidence of Value - Pharmacist-Provided Care (Examples)*.

Additionally, pharmacists as medication experts are positioned to help reverse increased spending attributable to suboptimal medication use and promote better health outcomes. For example, it was estimated that up to \$21.9 billion could be saved within the US healthcare system by optimizing medication use.<sup>19</sup> Also, it has been estimated that lack of

<sup>17</sup> https://accessagenda.nacds.org/dashboard/

<sup>&</sup>lt;sup>18</sup> Chen SW. Comprehensive Medication Management (CMM) for Hypertension Patients: Driving Value and Sustainability. University of Southern California. <u>http://betheresandiego.org/storage/files/cmm-for-htn-usc-steven-chen-condensed-slide-deck.pdf</u>; Chen SW. Integration of Pharmacy Teams into Primary Care. The Center for Excellence in Primary Care and the Center for Care Innovations. May 2015. <u>https://www.careinnovations.org/wp-</u> content/uploads/2017/10/USC.CEPC\_.pharm\_webinar\_FinalV.pdf

<sup>&</sup>lt;sup>19</sup> 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

medication adherence causes 125,000 deaths, at least 10% of hospitalizations, and hundreds of billions of preventable healthcare spending.<sup>20</sup> Healthcare spending on non-optimal medication therapy is estimated at \$528.4 billion per year<sup>21</sup> and medication non-adherence is estimated to cost the system \$290 billion per year.<sup>22</sup> Importantly for Medicare beneficiaries, it was recently estimated that medication nonadherence for diabetes, heart failure, hyperlipidemia, and hypertension resulted in billions of Medicare fee-for-service expenditures, millions in hospital days, and thousands of emergency department visits that could have been avoided. If the 25% of beneficiaries with hypertension who were nonadherent became adherent, Medicare could save \$13.7 billion annually, with over 100,000 emergency department visits and 7 million inpatient hospital days that could be averted.<sup>23</sup> Pharmacists can help curb these wasteful spending trends and improve health more broadly.

Looking across quality measures used in CMS programs, pharmacists are well positioned to help address a wide variety of quality measures by optimizing medication use, improving uptake of preventive care, like screenings and vaccinations, and supporting improvements in chronic disease control. *For more information, see Appendix 3 - Quality Metrics in CMS Programs Suited for Pharmacist Influence (Examples).* Research continues to support pharmacists' ability to meaningfully impact these priority clinical areas, yet pharmacies and pharmacists have not had the opportunity to directly engage in the CMS Innovation Center's models.

Congress should act on this opportunity to improve outcomes, advance access, and reduce preventable healthcare spending by leveraging community pharmacies in innovative healthcare models, including by requiring the CMS Innovation Center to include pharmacists and pharmacies in the design and implementation of their value-based care models. Doing so would not only strengthen development of innovative care models, but would also support needed advancements in access, in addition to healthcare technology and data interoperability.<sup>24</sup>

## CONCLUSION

In summary, community pharmacies stand ready to deploy their accessibility and clinical expertise to advance healthcare access, improve health outcomes, foster equity, and prevent unnecessary spending. We urge the Committee to help unleash the untapped potential of pharmacies – the nation's most accessible healthcare setting. NACDS applauds the Committee's work to address today's barriers to healthcare access in pursuit of better health for the nation today and for future generations.

For questions or further discussion, please contact NACDS' Sara Roszak, Senior Vice President, Health and Wellness Strategy and Policy, at <a href="mailto:sroszak@nacds.org">sroszak@nacds.org</a> or 703-837-4251.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM President and Chief Executive Officer National Association of Chain Drug Stores

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<sup>&</sup>lt;sup>20</sup> 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. <u>https://annals.org/aim/fullarticle/1357338/interventions-improve-adherence-self-administered-medications-chronic-diseases-unitedstates</u>

<sup>&</sup>lt;sup>21</sup> 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

<sup>&</sup>lt;sup>22</sup> 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.

<sup>&</sup>lt;sup>23</sup> Lloyd, Jennifer T., Maresh, Sha, Powers, Christopher, Shrank, WH, Alley, Dawn E; "How Much Does Medication Nonadherence Cost the Medicare Fee-for-Service Program?"; Medical Care; January 2019.

<sup>&</sup>lt;sup>24</sup> https://leavittpartners.com/wp-content/uploads/2023/04/Pharmacy-Data-Interoperability-04.03.23.pdf

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS' member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 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 members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit NACDS.org.

# Appendix 1: NACDS' Principles for PBM Reform STOP PHARMACEUTICAL BENEFIT MANIPULATION

### I. Help to Preserve Patient Access to Pharmacies by Addressing PBMs' Retroactive Pharmacy Fees

**Retroactive DIR Fees/Claw backs** – **Retroactive DIR Fees/Claw backs** – Pharmacy access can be undermined when health plans and their middlemen, PBMs, arbitrarily "claw back" fees retroactively from pharmacies weeks or months after a claim has been adjudicated/processed. This manipulation of pharmacy reimbursement may diminish access to care (e.g., pharmacies being forced to close their doors or pare back hours and healthcare services) when PBMs are unpredictable and not transparent, and when payment falls below a pharmacy's costs to acquire and dispense prescription drugs. Policymakers should prohibit payers or PBMs from retroactively reducing and/or denying a processed pharmacy drug claim payment, and obligate them to offer predictable and transparent pharmacy reimbursement to better protect pharmacies as viable and reliable access points for care.

#### II. Provide Fair and Adequate Payment for Pharmacy Patient Care Services

**Reasonable Reimbursement & Rate Floor** – Pharmacy access remains at risk when PBMs reimburse pharmacies below the cost to acquire and dispense prescription drugs. Pharmacy reimbursement that falls below the costs to acquire and dispense prescription drugs threatens future sustainability for pharmacies to provide valuable medication and pharmacy care services to communities. To help maintain robust public access to pharmacies, policymakers should adopt a reimbursement rate floor that requires PBMs to use comprehensive reimbursement models that are no less than the true cost to purchase and dispense prescription drugs.

**Standardized Performance Measures** – A crucial part of comprehensive DIR fee reform is advancing pharmacy quality that improves outcomes for beneficiaries and drives value in care – which are essential to controlling costs in the healthcare system. Arbitrary performance measures developed by PBMs assess the performance of the pharmacy without pharmacies' input, and they create a moving target for pharmacies to show value and improve health outcomes. Measures vary across the various plans and dictate DIR fees (or claw backs at the state level) imposed on pharmacies, as well as help create substantial system dysfunction and unnecessary spending in the Part D program. Policymakers should standardize PBMs' performance measures for pharmacies to help set achievable goals for pharmacies before signing a contract, and to promote harmonization in the healthcare system and improvements in health outcomes.

### III. Protect Patient Choice of Pharmacies

**Specialty** – Some PBMs require patients with rare and/or complex diseases to obtain medications deemed "specialty drugs" from designated "specialty pharmacies" or mail-order pharmacies. This impedes patients' access to their convenient local pharmacies where specialty drugs are filled as well. Prescription drugs should not be classified as "specialty drugs" based solely on the cost of the drug or other criteria used to limit patient access and choice—instead, definitions should focus on clinical aspects such as requiring intensive clinical monitoring. Policymakers should establish appropriate standards for defining and categorizing specialty drugs to ensure comprehensive and pragmatic patient care and access. Policymakers should prohibit PBMs from steering patients to only specialty pharmacies, including those owned by the PBMs, for their prescription needs.

**Mail Order** – Medication access and care can be weakened when PBMs manipulate the system by requiring patients to use mail-order pharmacies only. Some plans impose penalties such as higher copays or other financial disincentives for choosing a retail pharmacy instead of a mail-order pharmacy which is often owned by the PBM. Policymakers should support patient choice and access by enacting laws to prohibit PBMs from requiring or steering patients to use mail-order pharmacies.

**Any Willing Pharmacy** - Due to PBMs' network and contract barriers, pharmacies willing and ready to serve patients may be ineligible to provide important pharmacy services, and patients may experience unnecessary delays and interruptions in patient care. Patients should have the choice and flexibility to utilize the pharmacy that best meets their healthcare needs. Policymakers should require PBMs and plans to include any pharmacies in their networks if the pharmacy is willing to accept the terms and conditions established by the PBM. This will help to maximize patient outcomes and cost savings.

## IV. Enforce Laws to Stop PBM Manipulation and Protect Pharmacies and Patients

**Audits** – PBMs routinely conduct audits to monitor a pharmacy's performance and reverse or claw back pharmacy payments when there are alleged issues with a particular pharmacy claim. PBM audits interrupt the pharmacy workflow, can extend wait times, and detract attention from the quality of care patients receive. Policymakers should support fair pharmacy audit practices to ensure timely patient care delivery at community pharmacies and bring efficiency, transparency, and standardization to the PBM audit process.

**Oversight Authority** – There are growing concerns that pro-patient, pro-pharmacy public policy successes might be undercut if PBMs fail to comply with new laws and regulations – and/or if states fail to fully enforce them. Such failure could significantly impact pharmacy reimbursement and overall patient access. Policymakers should establish and enforce laws already on the books to regulate harmful PBM reimbursement practices that may harm patients and the healthcare system as we know it, especially at the pharmacy counter, and empower state regulators to do the same to enforce PBM transparency and fair and adequate pharmacy reimbursement.

# Appendix 2: Evidence of Value - Pharmacist-Provided Care (Examples) Review of Research Demonstrating Impact of Pharmacy Care on Outcomes, Quality, Costs

Research shows that pharmacy-based clinical care services can improve health outcomes, quality of care and reduce downstream costs. Below are excerpts from NACDS' report, <u>Accelerating the Center for Medicare and Medicaid Innovation's Mission –</u> <u>Integrating Community Pharmacy Care into Value-Based Programs Amid COVID-19 Pandemic Recovery & Beyond</u>, as well as other recent research that analyzes the impact of pharmacy services.

**Background.** Pharmacy care interventions range from medication adherence interventions to vital preventive care, chronic disease management, and medication optimization services. These services include immunizations, point-of-care testing (e.g., COVID-19, cholesterol, blood pressure, HIV, Hepatitis C and Hemoglobin A1c), patient education, risk assessment, screenings (e.g., for social determinants of health, depression, and substance use disorders), and acute care and treatment for "minor" or self-limiting ailments (e.g., urinary tract infections, influenza, strep throat).

## Pharmacies Increase Access to Preventive Care, Screenings

A growing body of research demonstrates the positive impacts of preventive services, including vaccine administration, point-of-care testing and screenings for early detection, and management and treatment of chronic diseases delivered in a pharmacy setting on health, access, and spending.

- Improving Adult Vaccination Rates. An examination of the role of pharmacists in administering immunizations concluded their involvement was correlated with higher rates of immunizations, compared to administration of vaccines by traditional providers.<sup>25</sup> Recent data on influenza immunizations underscore the growing role of pharmacies. In 2018, the CDC reported that 32.2 percent of flu shots were administered at a pharmacy.<sup>26</sup> Further, influenza vaccinations administered in pharmacies were 52 percent higher during the 2020-21 flu season compared to 2019-2020, and pharmacies provided over 14 million more flu shots than other providers.<sup>27</sup>
- Decreasing Barriers to Access. Pharmacies provide crucial access to vaccines during off-clinic hours when physician offices are unavailable. One study found that of more than 6 million vaccinations administered by pharmacists over 12 months, 30.5 percent were administered during non-traditional office hours.<sup>28</sup> The literature also demonstrates that allowing

<sup>&</sup>lt;sup>25</sup> Isenor, J., Edwards, N., Alia, T. (2016). "Impact of pharmacists as immunizers on vaccination rates: A systematic review and meta-analysis." *Vaccine*. 34(47) 5708–5723.

<sup>&</sup>lt;sup>26</sup> CDC, "Early-Season Flu Vaccination Coverage–United States, November 2018," accessed October 1, 2021.

<sup>&</sup>lt;sup>27</sup> CDC, "Influenza Vaccinations Administered to Adults in Pharmacies and Physician Medical Offices, United States," accessed October 1, 2021.

<sup>&</sup>lt;sup>28</sup> Goad, J., Taitel, M., Fensterheim, L. et al. (2013). "Vaccinations Administered During Off-Clinic Hours at a National Community Pharmacy: Implications for Increasing Patient Access and Convenience." *Annals of Family Medicine*. 11(5), 429-436.

pharmacists to provide immunizations and practice at the top of their license has improved vaccination coverage,<sup>29</sup> and pharmacies have been shown to be a cost-effective healthcare setting for providing immunizations.<sup>30</sup>

- Reducing Medical Costs. A 2014 analysis of the direct medical costs of administering vaccines in different settings found that the direct medical cost per adult vaccination was 11 to 26 percent lower in pharmacies compared to physician offices and other medical settings.<sup>31</sup>
- Improving Outcomes and Overall Savings Related to Influenza. A 2018 study that modeled the clinical and economic impacts of using pharmacies to administer influenza vaccinations estimated that including pharmacies in addition to traditional locations for vaccination (e.g., clinics, physician offices, urgent care centers) could prevent up to 16.5 million symptomatic influenza cases and 145,278 deaths at an estimated cost savings of \$4.1 to \$11.5 billion.<sup>32</sup>
- Supporting Early Diagnosis with Screenings. A review of 16 studies in which over 100,000 patients were screened for diabetes and cardiovascular disease risk factors at community pharmacies determined that pharmacy-based screenings successfully led to identifying a significant portion of patients at risk of or suffering from type 2 diabetes or cardiovascular disease.<sup>33</sup> Pharmacy-based programs to screen for behavioral health challenges, such as substance use disorders, anxiety, and depression are also associated with increased early detection and coordinated linkage to treatment<sup>34</sup> in addition to promising outcomes when pharmacies screen for social determinants of health.<sup>35</sup> A study of an social determinants of health screening tool implemented in community pharmacies that was administered to 9,800 patients over 6 weeks found that patients who completed the screener saw an average decrease in medical spending of \$1,500.<sup>36</sup>
- Expanding Point-of-Care Testing Access in Underserved Populations. Studies have shown community pharmacies can expand testing for HIV to underserved communities and areas with high rates of poverty.<sup>37</sup> Other successful examples include pharmacy-based screening for hepatitis C, influenza, and strep throat.<sup>38</sup> Increasing access to community pharmacy care for immunizations and preventive care broadly can both improve care for beneficiaries and decrease avoidable costs both central goals of VBPs and APMs.

#### Leveraging Pharmacies to Improve Chronic Disease Management

An estimated 60 percent of the U.S. adult population has one chronic condition and 40 percent have two or more.<sup>39</sup> Pharmacists can provide a range of activities to support chronic disease management including monitoring chronic disease clinical markers, medication optimization or adherence interventions, and disease specific counseling. Increasing access to pharmacy care can improve the management of chronic conditions – a key goal of many value-based programs.

- Improving Outcomes with Chronic Care Management. A review by the Department of Veterans Affairs of over 60 research studies found that patients receiving chronic care management from a pharmacist had a higher likelihood of meeting blood pressure, cholesterol and blood glucose goals, compared to those receiving usual care.<sup>4041</sup> A retrospective study that assessed clinical outcomes in patients with diabetes, with and without management by a pharmacist, found that the pharmacy intervention group had greater improvements in the individual areas of A1c, blood pressure, and statin goal attainment that were statistically significant. In this study, 40 percent of patients in the pharmacist intervention group achieved all three clinical goals after the intervention, compared with only 12 percent of patients in the usual care group.<sup>42</sup>
- Increasing Adherence and Health. A review of 22 studies analyzing community pharmacist-led interventions showed that these services increase patients' medication adherence and contribute to improved blood pressure control, cholesterol management, and chronic obstructive pulmonary disease and asthma control. Most of the effective interventions examined

<sup>36</sup> Pharmacy Quality Alliance, PQA Social Determinants of Health Resource Guide, January 2022.

<sup>&</sup>lt;sup>29</sup> Drozd EM, Miller L, et al. (2017). "Impact of Pharmacist Immunization Authority on Seasonal Influenza Immunization Rates across States." Clinical Therapeutics. doi: 10.1016/j.clinthera.2017.07.004

<sup>30</sup> Burson, R., Buttenheim, A., Armstrong, A. et al. (2016). "Community Pharmacies as Sites of Adult Vaccination: A systematic review." Human Vaccines & Immunotherapeutics. 12:12, 3146-3159.

<sup>&</sup>lt;sup>31</sup> Winegarden W. (2018). Promoting Access and Lowering Costs in Health Care: The Case of Empowering Pharmacists to Increase Adult Vaccination Rates. The Pacific Research Institute

<sup>&</sup>lt;sup>32</sup> Bartsch SM et al. (2018). Epidemiologic and economic impact of pharmacies as vaccination locations during an influenza epidemic. Vaccine.

<sup>&</sup>lt;sup>33</sup> Willis A, Rivers P, Gray LJ, Davies M, Khunti K. (2014). "The Effectiveness of Screening for Diabetes and Cardiovascular Disease Risk Factors in a Community Pharmacy Setting." PLoS ONE. 9(4): e91157. doi: 10.1371/journal.pone.0091157.

<sup>&</sup>lt;sup>34</sup> O'Reilly, C et al. (2015). "A feasibility study of community pharmacists performing depression screening services." Research in Social and Administrative Pharmacy. 11(3), 364-381.

<sup>&</sup>lt;sup>35</sup> Hippensteele, Alana, "Pharmacists' Role in Tackling Social Determinants of Health," *Pharmacy Times*, May 18, 2020.

<sup>&</sup>lt;sup>37</sup> Weidle, P, Lecher, S, Botts, L, et al. (2014). "HIV testing in community pharmacies and retail clinics: A model to expand access to screening for HIV infection." Journal of the American Pharmacist Association. 54(5), 486-492. Collins, B et al.. "The "No Wrong Door" Approach to HIV Testing: Results From a Statewide Retail Pharmacy-Based HIV Testing Program in Virginia, 2014-2016." Public Health Rep. 2018 Nov-Dec; 133(2 Suppl): 34S-42S.

<sup>&</sup>lt;sup>38</sup> Isho N, et al. (2017). "Pharmacist-initiated hepatitis C virus screening in a community pharmacy to increase awareness and link to care at the medical center." Journal of the American Pharmacists Association. <sup>39</sup> CDC, "Chronic Diseases in America," accessed May 23, 2019.

<sup>&</sup>lt;sup>40</sup> Carmichael, J. et al. (2016). "Healthcare metrics: Where do pharmacists add value?" Am J Health-Syst Pharm. 73: 1537-47.

<sup>&</sup>lt;sup>41</sup> Greer N, Bolduc J, Geurkink E et al. (2016). "Pharmacist-led chronic disease management: a systematic review of effectiveness and harms compared with usual care." Ann Intern Med.

<sup>&</sup>lt;sup>42</sup> Prudencio J, Cutler T, Roberts S, Marin S, Wilson M. (2018). "The Effect of Clinical Pharmacist-Led Comprehensive Medication Management on Chronic Disease State Goal Attainment in a Patient-Centered Medical Home." JMCP. 24(5):423-429.

across the studies were multifaceted and included patient education and counseling often related to medications, medical conditions, or demonstration of effective technique (for example, inhaler technique). Other elements included simplification of treatment regimens, communication between patients and health care professionals, follow-up, and monitoring. The findings demonstrate that pharmacist-led interventions may positively impact patients' satisfaction and knowledge.43

## Medication Optimization Associated with Improved Patient Outcomes and Lower Costs

One of the most cited ways that community pharmacists have demonstrated positive impacts on patient care, outcomes and costs is through the provision of medication optimization services – defined as "patient-centered activities that improve health outcomes by addressing medication appropriateness, effectiveness, safety, adherence, and access."44

- Medication Synchronization for Chronic Diseases. A study evaluating pharmacy-based medication synchronization programs for Medicaid fee-for-service beneficiaries with conditions such as hypertension, hyperlipidemia and diabetes found improvements in adherence to cardiovascular medications, improved cardiovascular clinical outcomes and significantly lower rates of hospitalization and emergency department visits, compared to a control group.<sup>45</sup> Further, a Government Accountability Office (GAO) review of available data on the impact of synchronization found most studies showed positive impacts of medication synchronization on patients.<sup>46</sup>
- Medication Adherence for Diabetes and Cardiovascular Disease Treatments. An evaluation of the Pennsylvania Project a . pharmacy-based medication adherence program across 107 pharmacies with 283 participating pharmacists – found a statistically significant improvement in adherence across five classes of medications examined. In this program, pharmacists screened patients for nonadherence and wellbeing using validated tools, and based on screening results, pharmacists provided brief interventions. The study estimated that the program resulted in \$241 of annual savings per patient for improved adherence to oral diabetes medications and \$341 for improved adherence to statin medications.<sup>47</sup> A review 29 studies on pharmacy-based interventions that aimed to improve medication adherence for cardiovascular disease found that, in general, interventions were cost effective for cardiovascular disease prevention and for cardiovascular disease management, savings from averted care exceeded the cost of the interventions.<sup>48</sup>
- Adherence and Reduced Medical Costs. A 2015 study estimated individuals with better adherence to angiotensin converting enzyme (ACE) inhibitors and angiotensin-receptor blockers (ARBs) had \$4,920 to \$6,389 in reduced adherencerelated medical costs per person and 14 to 26 percent lower adherence-related drug costs.<sup>49</sup> A recent analysis of a comprehensive mediation review (CMR) program offered by Community Health Group to Medicare Advantage enrollees with 3 or more selected chronic diseases and at least 8 Part D medications found that members receiving CMR had a 16.7% lower average total cost of care after 2 years in the program compared to members who did not.<sup>50</sup>
- Medicare Advantage and Part D Adherence Efforts. CMS' 2018 National Impact Assessment Report determined that Medicare Advantage (MA) plans and prescription drug plans (PDPs) that focused on improving adherence for select medications to treat cholesterol, hypertension and diabetes saw an estimated \$4.2 to \$26.9 billion in avoided costs between 2011 and 2015.<sup>51</sup>
- Medication Optimization and Improved Adherence. A study that used Medicare FFS claims data to estimate the prevalence of medication non-adherence among beneficiaries with diabetes, heart failure, hypertension and hyperlipidemia projected that Medicare could save \$13.7 billion annually if the 25 percent of non-adherent beneficiaries with hypertension became adherent.52

# Appendix 3: Quality Metrics in CMS Programs Suited for Pharmacist Influence

Quality Metrics in CMS Programs Suited for Pharmacist Influence		
Measure Topic	Measure Examples	CMS Programs

<sup>&</sup>lt;sup>43</sup> Milosavljevic A, Aspden T, Harrison J. (2018). "Community pharmacist-led interventions and their impact on patients' medication adherence and other health outcomes: a systematic review." International Journal of Pharmacy Practice. 26(5).

<sup>&</sup>lt;sup>44</sup> American Pharmacists Association, "Medication Optimization Services within the Patient Care Process Proposed Statements," accessed September 24, 2019.

<sup>&</sup>lt;sup>45</sup> Krumme A. Glynn, R., Schneeweiss, S. et al. (2018). "Medication Synchronization Programs Improve Adherence to Cardiovascular Medications and Health Care Use." Health Affairs. 37(1)125-133.

<sup>&</sup>lt;sup>46</sup> Government Accountability Office. (2019). Limited Information Exists on the Effects of Synchronizing Medication Refills.

<sup>&</sup>lt;sup>47</sup> Pringle JL, et al. (2014). "The Pennsylvania Project: Pharmacist Intervention Improved Medication Adherence and Reduced Health Care Costs." Health Affairs. 48 Jacob, Verughese, et al. Pharmacist Interventions for Medication Adherence: Community Guide Economic Reviews for Cardiovascular Disease, The Community Preventive Services Task Force (CPSTF), American Journal of Preventive Medicine. 2022;62(3):e202-e222

<sup>&</sup>lt;sup>49</sup> Stuart, BC, Dai, M, Xu, J, Loh, FH, Dougherty, SJ. (2015). "Does Good Medication Adherence Really Save Payers Money?" Medical Care. 53(6):517-523. <sup>50</sup> Case Study Part 2. A multi-year analysis of the value of a Comprehensive Medication Review program. OutcomesMTM. Accessed July 14, 2022.

<sup>&</sup>lt;sup>51</sup> CMS. (2018). National Impact Assessment of the Centers for Medicare & Medicaid Services (CMS) Quality Measures Report.

<sup>&</sup>lt;sup>52</sup> Lloyd, J. T., Maresh, S., Powers, C. A., Shrank, W. H., & Alley, D. E. (2019). How Much Does Medication Nonadherence Cost the Medicare Fee-for-Service

Chronic Disease Outcor	nes	
Chronic Disease Assessment and Management	Blood pressure control A1c control Depression remission Osteoarthritis function assessment	Universal Foundation Measures Merit-Based Incentive Payment System (MIPS) Program Qualified Health Plan (QHP) Quality Rating System (QRS) Medicaid Medicare Shared Savings Program Million Hearts Medicare Part C Star Rating
Patient Experience	CAHPS: Health Promotion and Education CAHPS: Health Status/Functional Status CAHPS: Getting Timely Care, Appointments and Information	Universal Foundation Measures Medicare Shared Savings Program
Medication Adherence	and Optimization	
Medication Adherence, Persistence or Optimization	High risk medications in the elderly Adherence to optimal medications for diabetes, cholesterol, blood pressure, COPD, asthma, schizophrenia, heart failure Concurrent use of benzodiazepines and opioids Improvement in management of oral medication Statin therapy in cardiovascular disease Statin therapy in diabetes	Universal Foundation Measures Medicaid, Merit-Based Incentive Payment System (MIPS) Program Medicaid Qualified Health Plan (QHP) Quality Rating System (QRS) Home Health Quality Reporting Home Health Value Based Purchasing Medicare Part D Star Rating Medicare Shared Savings Program Million Hearts
Transitions of Care		·
Reducing Preventable Readmissions	All Cause Readmissions	Universal Foundation Measures Hospital Compare Merit-Based Incentive Payment System (MIPS) Program Medicare Part C Star Rating Medicaid Qualified Health Plan (QHP) Quality Rating System (QRS) Hospital Readmission Reduction Program
Medication Review/ Reconciliation	Medication Reconciliation Post-Discharge	Medicare Part C Star Rating Merit-Based Incentive Payment System (MIPS) Program Physician Compare
Preventive Care and Sci	reening	
Immunization Assessment and Delivery	t Adult Immunization Status Childhood Immunization Status Immunizations for Adolescents Pneumo Vaccination Status for Older Adults Preventive Care and Screening: Influenza Immunization Zoster (Shingles) Vaccination	Universal Foundation Measures Medicare Part C Star Rating Merit-Based Incentive Payment System (MIPS) Program Qualified Health Plan (QHP) Quality Rating System (QRS) Medicaid Home Health Value Based Purchasing Hospital Inpatient Quality Reporting Inpatient Psychiatric Facility Quality Reporting
Antibiotic Stewardship	Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)	Merit-Based Incentive Payment System (MIPS) Program Qualified Health Plan (QHP) Quality Rating System (QRS)
Screenings and Interventions	BMI, weight, and nutrition assessment Suicide risk assessment Screening & intervention for alcohol/ tobacco DEXA scans Functional status and cognitive assessments Spirometry HIV screening Falls risk assessment/screening Blood pressure and/or diabetes screening Screening for social drivers of health	Universal Foundation Measures Medicare Part C Star Rating Medicaid Merit-Based Incentive Payment System (MIPS) Program Medicare Shared Savings Program Hospital Compare Inpatient Psychiatric Facility Quality Reporting End-Stage Renal Disease Quality Incentive Program