

January 17, 2020

The Honorable Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.

Washington, D.C. 20201

Submitted electronically via: PatientsOverPaperwork@cms.hhs.gov

Re: Request for Feedback on Scope of Practice on Executive Order 13890

Dear Administrator Verma:

The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to respond to the Centers for Medicare and Medicaid Services' (CMS') request for additional recommendations and reforms to inform implementation of the Executive Order (EO) #13890 on Protecting and Improving Medicare for Our Nation's Seniors.¹

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 members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit nacds.org.

Executive Summary

The transformation of health care in the United States must extend to all facets of the care continuum. NACDS strongly supports this shift; yet, the transformation must include community pharmacy to secure more value, drive innovation and patient outcomes, and accomplish cost-effectiveness. We further support the goal of strengthening the Medicare program by improving Medicare beneficiaries' access to community-based care, which clearly includes pharmacies as healthcare destinations. In order for the Administration to meet its laudable goals on choice, competition, access, and quality outlined in EO #13890, and the goals and objectives of the November 2018 "Reforming America's Healthcare System Through Choice and Competition Report," we proffer that CMS should: (1) modernize Medicare policies to remove needless and unwarranted barriers with respect to the coverage and payment of pharmacy care services. And (2) take the following proactive initiatives for the benefits of Medicare beneficiaries and taxpayers. Our recommendations are as follows:

- **Recognize Pharmacists as Providers and Suppliers Across Medicare Program and in Value-Based Payment Programs**
- **Require Real-Time Benefit Tool Integration with Pharmacy Systems & Authorize Pharmacists to Act on Opportunities to Initiate Cost-Effective Alternatives**
- **Establish Pharmacy Care Incentive Programs & Standardized Quality Metrics**
- **Allow Pharmacist-Initiated Electronic Prior Authorization**
- **Support Coverage and Payment for Pharmacy-based Telehealth Services**
- **Implement, Expand, and Clarify General Supervision Rules for "Incident-to" Billing**
- **Allow Pharmacists to Help Treat Patients with Opioid Use Disorder**

¹ Executive Order on Protecting and Improving Medicare for Our Nation's Seniors. October 2019. <https://www.whitehouse.gov/presidential-actions/executive-order-protecting-improving-medicare-nations-seniors/>

I. Inclusion of Pharmacy as Providers and Suppliers of Healthcare Services Advancing Choice, Competition, Access, and Quality in Medicare. The creation of a supplier of healthcare services across the Medicare program through the Calendar Year (CY) 2021 proposed and final Medicare Physician Fee Schedule rulemaking, consistent with the treatment of pharmacies in the Medicare Diabetes Prevention Program (MDPP).²

As the healthcare industry transitions toward the delivery of value-based care, modifications to the current landscape to advance competition and patient choice are urgently warranted. 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, especially in the context of an aging population with increasing prevalence of chronic disease and use of medications.^{3,4,5,6} Despite the fact that primary and preventive care services have generally been provided by primary care physicians, nurse practitioners, and physician assistants, the role of community pharmacists has blossomed in the last 10 years to encompass immunizations, screenings, health and wellness care, treatment for minor illnesses, medication optimization, adherence and chronic care management programs among many others. Other pharmacy programs have been designed and implemented to provide patients convenient access to affordable, quality preventive and acute care, including screening/brief intervention and treatment for drug misuse and abuse of opioids, HIV prevention like PrEP (Pre-Exposure Prophylaxis) and PEP (Post-Exposure Prophylaxis), and minor ailment treatment subject to protocols. Pharmacy-based services are especially important to improve access to care for seniors and medically underserved populations as the time available to primary care physicians continue to be stretched thin. Additional information on the unique expertise, training and contributions of various providers, including pharmacists, bring to patient care may be found in Appendix #1. Community pharmacies provide clinical healthcare services in most neighborhoods across the country, sometimes as the only healthcare provider within walking or driving distance in rural and medically underserved areas, offering solutions to address unmet needs related to healthcare quality, health inequality and social determinants of health.

“We all want to build a healthcare system that puts the patient at the center, provides them with piece of mind, and treats them like a person, not a number. Nobody knows how to do that better than America’s community pharmacists...”⁷

~ Alex Azar, HHS Secretary

As cited by CMS, more and more states⁸ and private payers now leverage pharmacists to improve care for patients. Most notably, pharmacy care transformation has already happened in certain federal agencies and programs, such as the Veterans Affairs, Public Health Service, Department of Defense, certain states and Canada, where programs leverage the full practice of pharmacy to successfully achieve better health and budgetary goals.⁹ In these programs, pharmacists run patient care clinics and perform other significant clinical care services, such as ordering, changing or discontinuing medications and ordering necessary lab tests. According to a study conducted by the Johns Hopkins Center for Health Security, “for more than 40 years, pharmacists in the US federal government system such as the Department of Veterans Affairs and the Indian Health Service (IHS), have collaboratively managed disease through medication and other clinical

² Medicare Diabetes Prevention Program (MDPP) Expanded Model. Centers for Medicare & Medicaid Services. <https://innovation.cms.gov/initiatives/medicare-diabetes-prevention-program/>

³ 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/>

⁴ 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>

⁵ 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>

⁶ Milosavljevic 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>

⁷ Remarks to the National Community Pharmacists Association. Department of Health and Human Services. April 2019.

<https://www.hhs.gov/about/leadership/secretary/speeches/2019-speeches/remarks-to-the-national-community-pharmacists-association.html>

⁸ CMCS. State Flexibility to Facilitate Timely Access to Drug Therapy by Expanding the Scope of Pharmacy Practice using Collaborative Practice Agreements, Standing Orders or Other Predetermined Protocols. January 2017. <https://www.medicare.gov/federal-policy-guidance/downloads/cib011717.pdf>

⁹ Department of Veterans Affairs. Pharmacists at VA. <https://www.vacareers.va.gov/Careers/Pharmacists/>

Church RM. The Expanded Role Of Pharmacists In The Public Health Service: An Overview Of A Pharmacy Practice Model. Hosp Formul. Sep 1989. <https://www.ncbi.nlm.nih.gov/pubmed/10294667>

pharmacy services.”^{10,11} By 1974, more than 90 percent of IHS sites had one or more pharmacist-run disease management programs in place. In doing so, these federal programs along with the federal prison system and other military programs embraced reform efforts to eliminate unnecessary, confining, and unwarranted restrictions on scope of practice for pharmacists, and to utilize pharmacists in a manner that is consistent with the full extent of their education, training and abilities to drive better health outcomes.¹² These reform initiatives have fostered development and execution of innovative patient care models within federal agencies and programs, reducing the costs of care services and expanding access to more affordable care in medically underserved areas to name a few. Unfortunately, these practice models have yet to be broadly implemented across all federal programs, like the Medicare Program, due to various restrictive, unwarranted and unnecessary barriers and policies.¹³

The Centers for Disease Control and Prevention (CDC)¹⁴ and the U.S. Surgeon General¹⁵ continue to urge stakeholders in the health care system to recognize the value of pharmacists in efforts to collaboratively improve quality and healthcare outcomes through services such as transitions of care, chronic disease management, and more.¹⁶ Specifically, the CDC released several guidance documents that support the integration of pharmacists into chronic care programs, including hypertension control. Most importantly, the National Community Preventive Services Task Force,¹⁷ governed by the CDC, recently recommended pharmacy-based adherence interventions for cardiovascular disease prevention based on a comprehensive literature review of 48 studies.^{18,19} The greater inclusion of pharmacists in direct patient care within these federal programs has led to less administrative burden on other healthcare providers, improved cost efficiency, more cohesive healthcare teams, and most importantly, improved patient outcomes.²⁰ Yet, CMS can and must take action for the benefit of Medicare beneficiaries and taxpayers by ensuring payment parity for community pharmacists, resulting in more competition and consumer choice.

The lack of pharmacist recognition as a provider and/or supplier of clinical care within the Medicare program undermines the sustainability of pharmacy care. Medicare and other programs have recognized the value of all other healthcare professionals across the care continuum by defining them as providers, eligible clinicians, suppliers of care and providing corresponding reimbursement for services rendered – except for pharmacists. In other words, unlike nurse practitioners, physician assistants, clinical nurse specialists, physical therapists, clinical psychologists, speech-language pathologists, audiologists, and nutrition professionals to name a few, pharmacists (many of whom are Doctors of Pharmacy) have been totally restricted in their ability to sustain clinical patient care services in value-based or

¹⁰ Shearer MP, Geleta A, et al. Serving the Greater Good: Public Health & Community Pharmacy Partnerships. Center for Health Security. Johns Hopkins Bloomberg School of Public Health. 2017. http://www.centerforhealthsecurity.org/our-work/pubs_archive/pubs-pdfs/2017/public-health-and-community-pharmacy-partnerships-report.pdf

¹¹ Morrison CM, Glover D, et al. Partnering with Pharmacists in the Prevention and Control of Chronic Diseases. A Program Guide for Public Health. Centers for Disease Control. 2012. https://www.cdc.gov/dhdsdp/programs/spha/docs/pharmacist_guide.pdf

¹² 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

¹³ Shearer MP, Geleta A, et al. Serving the Greater Good: Public Health & Community Pharmacy Partnerships. Center for Health Security. Johns Hopkins Bloomberg School of Public Health. 2017. http://www.centerforhealthsecurity.org/our-work/pubs_archive/pubs-pdfs/2017/public-health-and-community-pharmacy-partnerships-report.pdf

¹⁴ A Program Guide for Public Health: Partnering with Pharmacists in the Prevention and Control of Chronic Diseases. CDC. August 2012.

https://www.cdc.gov/dhdsdp/programs/spha/docs/pharmacist_guide.pdf

¹⁵ 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-report-pharmacists-providers?is_sso_called=1

¹⁶ A Program Guide for Public Health: Partnering with Pharmacists in the Prevention and Control of Chronic Diseases. CDC. August 2012.

https://www.cdc.gov/dhdsdp/programs/spha/docs/pharmacist_guide.pdf

¹⁷ 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-report-pharmacists-providers?is_sso_called=1

¹⁸ The Community Guide. About The Community Preventive Services Task Force. <https://www.thecommunityguide.org/task-force/about-community-preventive-services-task-force>

¹⁹ CDC. Using the Pharmacists' Patient Care Process to Manage High Blood Pressure: A Resource Guide for Pharmacists. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services; 2016.

<https://www.cdc.gov/dhdsdp/pubs/docs/pharmacist-resource-guide.pdf><https://www.cdc.gov/dhdsdp/pubs/docs/CPA-Team-Based-Care.pdf>

²⁰ Guide to Community Preventive Services. Cardiovascular Disease: Tailored Pharmacy-based Interventions to Improve Medication Adherence.

<https://www.thecommunityguide.org/findings/cardiovascular-disease-tailored-pharmacy-based-interventions-improve-medication-adherence>

²⁰ 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.

alternative payment models. Yet, this arbitrary program exclusion of pharmacists is contrary to the robust evidence that pharmacists improve quality of care, health outcomes, patient experience, and reduce downstream healthcare costs.²¹ Moreover, with medications being the primary medical intervention for most conditions, and pharmacists being the most educated and trained on medication optimization, CMS must address this illogical discrepancy. Specifically, CMS must lift rigid and unwarranted restrictions on pharmacists' ability to care for our nation's seniors while also advancing sustainable payment models that support pharmacists as providers and suppliers of healthcare. As explained in more detail below, these actions will yield more access and better care for our nation's seniors while yielding tremendous value to the Medicare program and taxpayers.

As aptly noted by Administrator Verma, "Pharmacists are on the front lines of patient care and have keen insight to the issues that patients face." This statement is undoubtedly very true. Yet, existing unwarranted barriers and limitations pose obstacles for patients accessing high-quality clinical care in accessible, convenient healthcare destinations, like community pharmacies. Despite a broad array of evidence supporting community pharmacists' ability to improve health outcomes and reduce downstream costs,²² payment to community pharmacies is limited for services other than dispensing medications, especially in Medicare where pharmacists are not recognized as Part B providers; nor suppliers of healthcare. These misaligned incentives serve as a barrier to broad and comprehensive pharmacist-provided clinical and preventive care, serves as a detriment to the optimal efficiency of our health system to care for our nation's seniors. By ensuring pharmacies are recognized as providers and suppliers of healthcare across the Medicare program, beneficiaries can feel confident seeking care from community pharmacists without fear that services will not be covered, as is the case today. The comprehensive accessibility of pharmacists, paired with coverage of pharmacy care services within Medicare through provider and supplier status of healthcare, has unparalleled potential to effectively and efficiently help the Medicare program meet outlined objectives on choice, competition, access, and quality.

Additionally, inclusion of pharmacies as suppliers of healthcare and providers of care within the Medicare program would go a long way to empower patients "to select the right care, at the right time, in the right place, from the right provider," arguably at a higher capacity than ever before given the wide range of clinical care and the vast accessibility of community pharmacies. This concept goes to the heart of HHS' policies of putting patients first and advancing accessibility to high quality care. In addition to the ability for pharmacies to increase patient choice, access, convenience, competition, and the care setting that best meets their needs, pharmacies are exceptionally capable of expanding the reach, and accelerating the success of CMS' value and quality-based care programs and initiatives, thereby encouraging competition and a diversity of sites for patients to access care. Eliminating discrimination against coverage of care services provided by pharmacies and ensuring healthcare coverage and payment parity can result in the delivery of enhanced value across the entire care continuum through more patient touches and care coordination, driving value for the entire Medicare program and meaningfully enhancing competition, choice, and access.

²¹ 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.

Government Accountability Office. (July 2019). [Limited Information Exists on the Effects of Synchronizing Medication Refills.](#)

Pringle JL, et al. (2013). The Pennsylvania Project: Pharmacist Intervention Improved Medication Adherence and Reduced Health Care Costs. *Health Affairs*, 33(8), 1444-1452.

Vegter S, et al; "Improving Adherence to Lipid-Lowering Therapy in a Community Pharmacy Intervention Program: A Cost-Effectiveness Analysis;" *Journal of Managed Care & Specialty Pharmacy*; July 2014. <https://www.jmcp.org/doi/10.18553/jmcp.2014.20.7.722>

Spence MM, et al; "Evaluation of an Outpatient Pharmacy Clinical Services Program on Adherence and Clinical Outcomes Among Patients with Diabetes and/or Coronary Artery Disease;" *Journal of Managed Care & Specialty Pharmacy*; October 2014. <https://www.jmcp.org/doi/10.18553/jmcp.2014.20.10.1036>

²² 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/2016/2016vol22-n9/cost-benefit-of-appointment-based-medication-synchronization-in-community-pharmacies>

Rosenbaum L, Shrank WH; "Taking Our Medicine - Improving Adherence in the Accountability Era;" *New England Journal of Medicine*; Aug. 22, 2013
Pringle JL, et al.; "The Pennsylvania Project: Pharmacist Intervention Improved Medication Adherence and Reduced Health Care Costs;" *Health Affairs*; August 2014. <https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2013.1398>

Brennan TA, et al; "An Integrated Pharmacy-Based Program Improved Medication Prescription and Adherence Rates in Diabetes Patients;" *Health Affairs*; January 2012. https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2011.0931?url_ver=Z39.88-2003&rft_id=ori%3Arid%3Acrsref.org&rft_dat=cr_pub%3Dpubmed

Cranor CW, Bunting BA, et al; "The Asheville Project: Long- Term Clinical and Economic Outcomes of a Community Pharmacy Diabetes Care Program;" *Journal of the American Pharmacists Association*; 2003. <https://www.sciencedirect.com/science/article/pii/S1086580215300073?via%3Dihub>

NACDS urges CMS to take immediate action to eliminate the federal barriers of coverage options recognizing pharmacies as:

1. A supplier of healthcare services across the Medicare program through the Calendar Year (CY) 2021 proposed and final Medicare Physician Fee Schedule rulemaking, consistent with the treatment of pharmacies in the Medicare Diabetes Prevention Program (MDPP),²³ and
2. Granting pharmacists provider status through CMMI's extensive waiver authority for existing and future value-based payment models. (See Appendix #2)

This recognition would be tremendously beneficial to create reimbursement means that provide sustainable beneficiary access to accessible clinical care provided in benefactor's local healthcare destination – their community pharmacy. Seniors would have the choice to seek clinical care in accessible, convenient community pharmacies, thereby championing the Administration's goals on choice, competition, access, and quality.²⁴

II. CMS Could Meaningfully Reduce Waste and Avoidable Costs by Including Community Pharmacies as Suppliers of Health Care Services across Medicare Part B and Medicare Advantage.

In an effort to protect taxpayers and improve Medicare for our nation's seniors, opportunities to combat waste observed within the Medicare program still exist. Specifically, the United States is a top healthcare spender compared to similar countries, with approximately a third of that spending categorized as waste.²⁵ Healthcare spending on non-optimal medication therapy is estimated at \$528.4 billion per year²⁶ and medication non-adherence costs the system \$290 billion per year.²⁷ Further, experts note that up to \$21.9 billion could be saved by optimizing medication use. Also, the lack of medication adherence causes approximately 125,000 deaths, at least 10% of hospitalizations, and hundreds of billions of preventable healthcare spending.²⁸ For Medicare beneficiaries in the Part D program, 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 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.²⁹ Moreover, one in three Americans 65 or older has multiple chronic conditions, and one study estimated that in 2009 and 2010, 25% of Americans ages 65 to 69 took at least *five* prescription drugs to treat chronic conditions and this rose to 46% for those ages 70 to 79.³⁰

In addition to suboptimal medication use, approximately 60% of Americans live with at least one chronic disease, such as heart disease, diabetes or chronic lung disease.³¹ Chronic diseases are the leading causes of death and disability in America, and also a primary driver of healthcare costs; and, 90% of the nation's \$3.5 trillion in annual health care expenditures are for people with chronic and mental health conditions.³² Specific to Medicare FFS beneficiaries in 2017,

²³ <https://innovation.cms.gov/initiatives/medicare-diabetes-prevention-program/>

²⁴ Reforming America's Healthcare System Through Choice and Competition. Department of Health and Human Services. Dec 2018.

<https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf>

²⁵ Shrank WH, Rogstad TL, Parekh N. Waste in the US Health Care System: Estimated Costs and Potential for Savings. *JAMA*. 2019.

<https://jamanetwork.com/journals/jama/article-abstract/2752664>

²⁶ 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>

²⁷ 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.

²⁸ 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>

²⁹ 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. <https://www.ncbi.nlm.nih.gov/pubmed/30676355>

³⁰ Charlesworth, Christina, et al, "Polypharmacy Among Adults Aged 65 Years and Older in the United States: 1988–2010," *J Gerontol A Biol Sci Med Sci*. 2015 Aug; 70(8): 989–995.

³¹ About Chronic Diseases. National Center for Chronic Disease Prevention and Health Promotion. <https://www.cdc.gov/chronicdisease/about/index.htm>

³² Health and Economic Costs of Chronic Diseases. National Center for Chronic Disease Prevention and Health Promotion.

<https://www.cdc.gov/chronicdisease/about/costs/index.htm#ref1>

57% had high blood pressure, 41% had high cholesterol, 33% had arthritis, and 27% had diabetes.³³ In fact, 17% of Medicare FFS beneficiaries in 2017 had 6 or more chronic conditions, 21% had 4-5 chronic conditions, and 29% had 2-3 chronic conditions. In addition, a Johns Hopkins study reported that approximately 50% of patients with chronic illness do not take their medications as prescribed leading to morbidity, mortality, and costs of approximately \$100 billion per year.³⁴

Likewise, the literature is replete with evidence that pharmacists achieve patient outcomes and value through medication optimization programs and initiatives. With respect to preventive care in our nation, only 45.4% of adults received an influenza vaccine for the 2016-17 season, pneumococcal vaccine coverage among adults at increased risk was only 24.5%, and herpes zoster coverage was only 34.9% among adults age 60 and up.³⁵ Low vaccine uptake can result in disabilities and death, as well as financial burdens from increased medical visits, increased hospitalizations, and lost income. Experts estimate that unvaccinated individuals and resulting health effects lead to approximately \$7.1 billion in healthcare costs annually.³⁶ Also, only 8% of Americans ages 35 and older reported having received all of the appropriate, high-priority clinical preventive services recommended for them, and nearly 5% reported having received none of them.³⁷ Specific to Medicare, 68% of adults 65 and older received an influenza vaccine during the 2018-2019 flu season, compared to the 90% target set by Healthy People 2020.³⁸ Deemed the most accessible and frequently visited member of the healthcare team,³⁹ pharmacists are well-positioned to fill this and others gaps of care. Literature strongly supports pharmacies as vaccine destinations and extending full pharmacist authority to provide immunizations has cost-effectively improved vaccination coverage.⁴⁰ Specifically, a study published by Harvard Medical School reported the mean cost of vaccination at a variety of healthcare settings. As noted, the mean cost of vaccines at community pharmacies was significantly lower than scheduled physician visits and mass vaccination clinics. The reported costs are shown in the following chart:⁴¹

Vaccination Cost Per Setting: Data from Harvard Medical School

Healthcare Setting	Mean Vaccination Cost
Pharmacy	\$11.57
Mass vaccination clinic	\$17.04
Doctor's office	\$28.67

Thus, in assessing care delivery for patients, a one size model does not fit all, requiring innovation in healthcare delivery models⁴² and better use of pharmacists as medication experts. Community pharmacists are well educated, trained and qualified to provide a variety of convenient, clinical care services with proven benefit to improve medication use, chronic care, and preventive care, especially to benefit patient outcomes and reduce avoidable costs. Pharmacists are especially poised to provide immunizations, preventive screenings, health and wellness care, treatment for minor illnesses,

³³ Chronic Conditions Among Medicare Beneficiaries. Centers for Medicare & Medicaid Services. 2017. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Chartbook_Charts

³⁴ Shearer MP, Geleta A, et al. Serving the Greater Good: Public Health & Community Pharmacy Partnerships. Center for Health Security. Johns Hopkins Bloomberg School of Public Health. 2017.

³⁵ Vaccination Coverage Among Adults in the United States. National Health Interview Survey. Centers for Disease Control and Prevention. 2017. <https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/NHIS-2017.html>

³⁶ Ozawa S, Portnoy A, Getaneh H, Clark S, Knoll M, Bishai D, Yang HK, Patwardhan PD. Modeling The Economic Burden Of Adult Vaccine-Preventable Diseases In The United States. Health Aff. 2016 Nov 1;35(11):2124-2132. <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2016.0462>

³⁷ Borsky A, Zhan C, Miller T, Ngo-Metzger Q, Bierman AS, Meyers D. Few Americans Receive All High-Priority, Appropriate Clinical Preventive Services. Health Affairs. 2018;37(6):925-928. doi:10.1377/hlthaff.2017.1248

³⁸ <https://www.cdc.gov/flu/fluvaxview/coverage-1819estimates.htm#results>

³⁹ Manolakis PG, Skelton JB. Pharmacists' Contributions to Primary Care in the United States Collaborating to Address Unmet Patient Care Needs: The Emerging Role for Pharmacists to Address the Shortage of Primary Care Provider. Am J Pharm Educ. Dec 2010. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3058447/>

⁴⁰ Drozd EM, Miller L, et al. Impact of Pharmacist Immunization Authority on Seasonal Influenza Immunization Rates across States. Aug 2017. Clinical Therapeutics. doi: 10.1016/j.clinthera.2017.07.004. <https://www.ncbi.nlm.nih.gov/pubmed/28781217>

⁴¹ Prosser LA, O'Brien MA, et al. Non-traditional settings for influenza vaccination of adults: costs and cost effectiveness. Pharmacoeconomics. Feb 2008. <https://link.springer.com/article/10.2165%2F00019053-200826020-00006>

⁴² Retchin S, Dow A. Right-Sizing the Nation's Workforce for the Affordable Care Act. November 5, 2014. Academic Medicine.

<http://acmedmicmedicineblog.org/right-sizing-the-nations-workforce-for-the-affordable-care-act/> (noting that workforce needs new approaches to providing care, citing that more than half of covered Medicaid patients still sought vaccinations, screenings, health counseling and other care in emergency rooms).

medication optimization/adherence, and chronic care management programs, among many other clinical care services⁴³ and a myriad of evidence supports the ability of pharmacists to improve healthcare quality and value, providing critical and accessible healthcare delivery in neighborhoods across the country, while saving downstream healthcare dollars.⁴⁴ Additionally, because pharmacies are well integrated into the communities they serve, pharmacists deliver these essential clinical interventions to advance quality of care, with an understanding of the regional, social, and economic challenges uniquely faced by that population. Further, pharmacies are capable of delivering other clinically important interventions to save Medicare money, such as engaging in care coordination and transitions of care efforts.

One recent traditional medication example involves the Pennsylvania Project, a large-scale community pharmacy demonstration study. This Project evaluated the impact of medication adherence on five chronic medication classes. The study involved 283 pharmacists who screened 29,042 patients for poor adherence risk and provided brief interventions to patients with increased risks. The intervention group experienced statistically significant improvements in adherence across all medication classes. Further, the intervention demonstrated a significant reduction in per patient annual healthcare spending for patients taking statins (\$241) and oral diabetes medications (\$341). Based on these findings, the study concluded that such pharmacy adherence programs would reduce costs for a plan with 10,000 members by \$1.4 million each year and could also be expected to increase the plan's star rating.⁴⁵

Another example is the Virginia team-based care program. This program aimed at reaching rural, underserved patients, which included a collaboration between A&B Pharmacy and Emporia Medical Associates, yielding significant patient outcomes. Through this program, pharmacists provided chronic care management (CCM) services for Emporia Medical Associates' Medicare patients. Pharmacists supported patients by providing medication reconciliation/ synchronization services, educating on how to self-monitor blood glucose and blood pressure, and answering questions about chronic disease management during monthly CCM appointments. Pharmacists also worked collaboratively with the physician to develop an appropriate care plan. The program resulted in an 8% increase in medication reconciliation, an 11% increase in use of tobacco cessation services, and a 6% increase in the number of patients receiving chronic care management through the provision of pharmacist-led services. All participating patients also reported improvements in health outcomes related to healthy eating and exercise.⁴⁶

Another example of the clinical value of pharmacy care services is the CMMI-funded, pharmacy-led chronic care management initiative 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. Further, 100% of program physicians either

43 The Pharmacy's New Role in Providing Healthcare Services;" PM3260 Magazine. January 23, 2014. <https://www.pm360online.com/the-pharmacys-new-role-in-providing-healthcare-services/>. Larkin PJ; "A Pharmacy Forum: Becoming A Health and Wellness Destination;" Winsight Grocery Business; April 2016. <https://www.winsightgrocerybusiness.com/pharmacy-forum-becoming-health-wellness-destination> Barrett, J; "Pharmacists Play Key Role in the Future of Health Care;" Pharmacy Times; June 2017. <https://www.pharmacytimes.com/conferences/ashp-summer-2017/what-role-do-pharmacists-have-in-the-future-of-health-care>

44 (See Appendix #3) Total mean direct medical costs decreased by \$1,200 to \$1,872 per patient per year compared with baseline. Cranor CW, Bunting BA, et al; "The Asheville Project: Long-Term Clinical and Economic Outcomes of a Community Pharmacy Diabetes Care Program;" Journal of the American Pharmacists Association; 2003. <https://www.sciencedirect.com/science/article/pii/S1086580215300073?via%3Dihub>. Milosavljevic 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; 2018. <https://onlinelibrary.wiley.com/doi/full/10.1111/ijpp.12462>. Lee JK, et al; "Effect of a Pharmacy Care Program on Medication Adherence and Persistence, Blood Pressure, and Low-Density Lipoprotein Cholesterol: A Randomized Controlled Trial;" Journal of the American Medical Association; 2006;296(21):2563-2571. <https://jamanetwork.com/journals/jama/fullarticle/204402>. Fikri-Benbrahim N, et al; "Impact of a community pharmacists' hypertension-care service on medication adherence;" Social and Administrative Pharmacy; 2013. <https://www.ncbi.nlm.nih.gov/pubmed/23391845> 47. Brennan TA, et al; "An Integrated Pharmacy-Based Program Improved Medication Prescription and Adherence Rates in Diabetes Patients;" Health Affairs; January 2012.

45 Pringle JL, et al., "The Pennsylvania Project: Pharmacist Intervention Improved Medication Adherence and Reduced Health Care Costs," Health Affairs (Aug. 2014), available at <https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2013.1398>

46 A Team-based Care Approach to Reach Rural, Underserved Virginia Patients. WWCDPC. 2018.

<https://chronicdisease.host/WWCDPC/admin/dompdf/SuccessStories.php?id=712>

Health Quality Innovators. A Partnership in Chronic Care Management. <http://qin.hqi.solutions/wp-content/uploads/2018/05/CCM-poster-with-3-video-QR-link.pdf>

“strongly agreed” or “agreed” that having pharmacists in their clinics improves their patients’ care.^{47, 48} A subset of other relevant examples outlining the clinical and economic value of pharmacist-provided care is included in Appendix #3.

As illustrated, the literature is full of examples that point to the strong, yet untapped potential of pharmacists to meaningfully innovate and improve our health system, especially reducing downstream healthcare spending. Such examples prove that pharmacy care services are scalable and can benefit broader populations across America if pharmacists had the opportunity to sustain these services as suppliers of healthcare in the Medicare program. In sum, community pharmacists are poised to mitigate unnecessary healthcare utilization and waste in Medicare especially through improved medication use and enhanced chronic and preventive care. This potential can be realized in communities across the country by eliminating the discriminatory and restrictive federal barriers which deny coverage and payment for clinical services provided by the nation’s medication experts – pharmacists.

III. Value Proposition of Advancing Pharmacy Care Across Medicare Program and Specific Recommendations.

Despite increasing demand, the rising shortage of primary care physicians observed throughout the nation increases strain and reduces capacity of the entire healthcare continuum to provide better care for seniors. Millions of Americans already lack adequate access to healthcare due to primary care physician shortages in their communities, despite many of these patients having health insurance coverage. Approximately 65 million people live in regions without adequate primary care⁴⁹ and experts estimate a shortage of providers: up to 122,000 physicians by 2032 within the United States.⁵⁰ Better utilization of the skills and expertise of all healthcare professionals, including pharmacists, would support physicians in bridging gaps in care and reduce undue strain across the whole healthcare continuum, resulting in better care.

Resources should be better deployed, and incentives are better aligned when the value and expertise of all healthcare professionals and team members across the care continuum are leveraged to their highest potential. In fact, pharmacists are uniquely qualified to provide patient care services through synergistic efforts that complement other provider services in a variety of ways, for example, through medication therapy optimization and promotion of medication adherence.^{51,52} Therefore, removing unwarranted regulatory burdens on pharmacists and fostering their ability to provide care for Medicare beneficiaries as suppliers of healthcare services, in line with their clinical expertise and training, sequentially reduces burden on other care providers across the entire continuum.

Pharmacists are well positioned to fill workforce shortages as the number of pharmacists in the United States continues to grow, with an excess of around 50,000 pharmacists expected in 2030.⁵³ Patients already visit their community pharmacies more than other healthcare providers,⁵⁴ and multiple studies have shown that when patients visit pharmacists for chronic disease management, vaccinations, or minor ailments care, they often do so outside of normal

⁴⁷ Chen SW, Hochman M, Olayiwola JN, Rubin A. Integration of Pharmacy Teams into Primary Care. The Center for Excellence in Primary Care and the Center for Care Innovations May 2015. https://www.careinnovations.org/wp-content/uploads/2017/10/USC.CEPC_pharm_webinar_FinalV.pdf

⁴⁸ Chen SW. Comprehensive Medication Management (CMM) for Hypertension Patients: Driving Value and Sustainability. University of Southern California. <http://betheresandiego.org/storage/files/cmm-for-htn-usc-steven-chen-condensed-slide-deck.pdf>;

⁴⁹ State and Federal Efforts to Enhance Access to Basic Health Care. The Commonwealth Fund. <https://www.commonwealthfund.org/publications/newsletter-article/state-and-federal-efforts-enhance-access-basic-health-care>

⁵⁰ 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>

⁵¹ 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. December 2011. https://www.accp.com/docs/positions/misc/improving_patient_and_health_system_outcomes.pdf

⁵² Manolakis PG, Skelton JB. Pharmacists' contributions to primary care in the United States collaborating to address unmet patient care needs: the emerging role for pharmacists to address the shortage of primary care providers. Am J Pharm Educ. 2010;74(10):S7. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3058447/>

⁵³ HRSA. National Center for Health Workforce Analysis. Allied Health Workforce Projections, 2016-2030: Pharmacists. 2016. <https://bhw.hrsa.gov/sites/default/files/bhw/nchwa/projections/pharmacists-2016-2030.pdf>

⁵⁴ 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>

clinic hours, and many of these patients do not have a primary care provider.^{55,56,57} This positions pharmacists well to complement and fortify the care delivered by other non-physician providers like nurse practitioners, physician assistants, and others, to help reduce unmet care needs and advance the Administration's mission on choice, competition, access, and quality of care.

Removing regulatory burdens on all providers will allow our healthcare system to function more efficiently. When all providers are working at the top of their licenses, each can contribute their unique expertise, affording others to spend more meaningful time with patients. In a model where each provider's unique talent and expertise is maximally deployed, the entire system can function at optimal efficiency and primary care providers, nurse practitioners, and physician assistants, for example, can spend more quality time with the patients who truly need their unique expertise. And pharmacists can spend more time providing the services they are uniquely qualified to deliver such as medication management and optimization, preventive care and chronic care interventions.^{58,59} Thus, care collaboration across the healthcare continuum provides patients with higher quality, safer, and more comprehensive care.⁶⁰

Pharmacists offer unique expertise and skills, fortifying the work of others across the health system. While limited head-to-head studies exist comparing different healthcare team members providing the same interventions, research indicates pharmacists add value compared to other providers, especially for medication-related interventions, chronic care, and preventive care. For example, a 2010 systematic review of pharmacist interventions concluded that such programs improve therapeutic and safety outcomes, and the results of various meta-analyses conducted for hemoglobin A1c, cholesterol levels, and blood pressure demonstrate the significant benefits of pharmacist care—favoring pharmacists' direct patient care impact over comparative services.⁶¹ Specifically, evidence suggests pharmacists can prescribe to the same standards as other providers of care, including the ability to better adhere to dosing guidelines when prescribing by protocol.⁶²

Additionally, research demonstrates that primary care physicians are more efficient when they delegate preventive care and chronic care management to other care-team members, like pharmacists.⁶³ This is especially important when considering workload and time constraints of primary care physicians. General practitioners have about 2 minutes per clinic visit to properly implement preventive care, leading to a care deficit of more than 5 hours per day for preventive care.⁶⁴ To buttress this point, approximately 1,773 hours of a physician's annual time, or 7.4 hours each working day would be needed to fully satisfy the United States Preventive Services Task Force (USPSTF) recommendations for these preventive services.⁶⁵

⁵⁵ Klepser ME, Adams AJ, Klepser DG. Antimicrobial Stewardship in Outpatient Settings: Leveraging Innovative Physician-Pharmacist Collaborations to Reduce Antibiotic Resistance. *Health Security*. 2015;13(3):166-173. doi:10.1089/hs.2014.0083

⁵⁶ Klepser ME, Klepser DG, Dering-Anderson AM, Morse JA, Smith JK, Klepser SA. Effectiveness of a pharmacist-physician collaborative program to manage influenza-like illness. *Journal of the American Pharmacists Association*. 2016;56(1):14-21. doi:10.1016/j.japh.2015.11.008

⁵⁷ Goad JA, Taitel MS, Fensterheim LE, Cannon AE. Vaccinations administered during off-clinic hours at a national community pharmacy: implications for increasing patient access and convenience. *Ann Fam Med*. 2013 Sep-Oct;11(5):429-36. doi: 10.1370/afm.1542. <https://www.ncbi.nlm.nih.gov/pubmed/24019274>

⁵⁸ 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. December 2011. https://www.accp.com/docs/positions/misc/improving_patient_and_health_system_outcomes.pdf

⁵⁹ Manolakis PG, Skelton JB. Pharmacists' contributions to primary care in the United States collaborating to address unmet patient care needs: the emerging role for pharmacists to address the shortage of primary care providers. *Am J Pharm Educ*. 2010;74(10):S7. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3058447/>

⁶⁰ Isasi F. The Expanding Role of Pharmacists in Transformed Health Care System. National Governors Association. 2015. <https://jcnp.net/wp-content/uploads/2015/09/NGA-TheExpandingRoleOfPharmacists.pdf>

⁶¹ Chisholm-Burns AM, et al. US Pharmacists' Effect as Team Members on Patient Care: Systematic Review and Meta-Analyses. *Medical Care*: October 2010 - Volume 48 - Issue 10 - p 923-933

https://journals.lww.com/lww-medicalcare/Fulltext/2010/10000/US_Pharmacists_Effect_as_Team_Members_on_Patient.10.aspx

⁶² Poh EW, McArthur A, et al. Effects of pharmacist prescribing on patient outcomes in the hospital setting. JBI Database of Systematic Reviews and Implementation Reports. September 2018. https://journals.lww.com/jbisrj/Abstract/2018/09000/Effects_of_pharmacist_prescribing_on_patient.9.aspx

⁶³ Altschuler J, Margolius D, Bodenheimer T, Grumbach K. Estimating a reasonable patient panel size for primary care physicians with team-based task delegation. *Ann Fam Med*. 2012 Sep-Oct;10(5):396-400. doi:10.1370/afm.1400. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3438206/>

⁶⁴ Caverly TJ et al. Much to do with nothing: microsimulation study on time management in primary care. 2018. *BMJ*. 2018;363. <https://www.bmj.com/content/363/bmj.k4983>

⁶⁵ Yarnall, Kimberly S H et al. "Primary care: is there enough time for prevention?" *American journal of public health* vol. 93,4 (2003): 635-41. doi:10.2105/ajph.93.4.635 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1447803/>

Research also indicates that medication reconciliation performed by pharmacists versus physicians was more comprehensive and was followed by lower odds of adverse drug events from admission prescribing errors.⁶⁶ Another relevant example includes a program designed to leverage the clinical expertise of pharmacists for Medicare and Medicaid beneficiaries, which led to improved medication adherence among patients in the pharmacist intervention group by 46% compared to the control group, who received usual care from their doctors and nurses.⁶⁷ Research also suggests that pharmacists are comparable to physicians in providing Annual Medicare Wellness Visits, and pharmacists offer an additional access point for valuable services for Medicare beneficiaries.⁶⁸ Additional information on the unique expertise, training and contributions various providers bring to patient care may be found in Appendix #1.

States offer far greater opportunity for pharmacists to improve care than what is leveraged by Medicare. And this is true despite the fact that substantial state pharmacy scope of practice reform is critical at the state level. Pharmacist provision of patient care services has resulted in the improvement of patient health outcomes and enhanced public and population health. Several states across the country have recently accelerated the pace of change to adopt broader authority for pharmacists to advance clinical patient care.⁶⁹ In fact, nearly all states now allow pharmacists to select, initiate, monitor, continue, discontinue, modify and/or administer drug therapy.⁷⁰ The form of this authority runs from autonomous prescriptive authority where a specific diagnosis is not needed (Idaho) to autonomous prescribing authority under predetermined, medical protocols (such as Kentucky and New Mexico); to statewide protocols (e.g. Colorado and California) to collaborative practice agreements.

Additionally, various states throughout the country provide pharmacists the authority to deliver services and initiate medications related to hormonal contraception, tobacco cessation products, minor ailment care, statin therapy for patients with diabetes, and HIV prevention services. Currently, 49 states permit pharmacists the ability to practice collaboratively via some form of authority with other healthcare providers to perform assessments, monitor therapy, and manage diseases and medications.⁷¹ Approximately 43 states also permit pharmacist prescribing via collaborative practice agreements. For detailed information on pharmacists' state scope of practice, refer to Appendix #4.

Given the advanced-level clinical training/expertise of pharmacists and their untapped potential, state scope of practice for pharmacists is still restrictive. Pharmacists are considered the most restricted health profession compared to nursing and medicine.⁷² To further compound these needless restrictions, Medicare underutilizes pharmacy care *even below* what is allowed at the state level. NACDS urges CMS to leverage the role of community pharmacies to provide care to seniors commensurate with the opportunities for pharmacist care in the states. We recommend implementation of the following recommendations across Medicare, including in Medicare Advantage and Fee for Service, to ensure broad sweeping, innovative gains for seniors.

Given that care coordination is paramount to advance healthcare, pharmacists enhance and complement the work of patients' primary care providers and other professionals to ensure care coordination and linkage to care.⁷³ Pharmacists are capable and well-positioned to assist patients with low-complexity conditions, allowing physicians to redirect their focus and time in providing dedicated and quality care on more serious and acute cases.

⁶⁶ Mergenhagen, KA, et al. Pharmacist- Versus Physician-Initiated Admission Medication Reconciliation: Impact on Adverse Drug Events. American Journal of Geriatric Pharmacotherapy. Vol 10, Issue 4. August 2012. <https://www.sciencedirect.com/science/article/abs/pii/S1543594612000888?via%3Dihub>

⁶⁷ Ameer H, Jain SH. How Pharmacists Can Help Ensure That Patients Take Their Medicines. Harvard Business Review. Jan 2019. <https://hbr.org/2019/01/how-pharmacists-can-help-ensure-that-patients-take-their-medicines>

⁶⁸ Sewell, Mary Jean. Et. al. Comparison of Pharmacist and Physician Managed Annual Medicare Wellness Services. J Manag Care Spec Pharm. 2016;22(12):1412-16, available at: <https://www.jmcp.org/doi/pdf/10.18553/jmcp.2016.22.12.1412>

⁶⁹ Adams AJ, Weaver KK. The Continuum of Pharmacist Prescriptive Authority. Annals of Pharmacotherapy. June 2016. Volume: 50 issue: 9, page(s): 778-784. <https://journals.sagepub.com/doi/abs/10.1177/1060028016653608>

⁷⁰ CDC "State Law Fact Sheet: Select Features of State Pharmacist Collaborative Practice Laws" updated Dec. 2012. http://www.cdc.gov/dhds/pubs/docs/Pharmacist_State_Law.PDF

⁷¹ Centers for Disease Control and Prevention. Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services; 2017. <https://www.cdc.gov/dhds/pubs/docs/CPA-Team-Based-Care.pdf>

⁷² Adams AJ. Transitioning pharmacy to "standard of care" regulation: Analyzing how pharmacy regulates relative to medicine and nursing. Res Social Adm Pharm. 2019 Oct;15(10):1230-1235. <https://www.sciencedirect.com/science/article/abs/pii/S155174111830562X?via%3Dihub>

⁷³ Adams AJ, Weaver KK. The Continuum of Pharmacist Prescriptive Authority. Annals of Pharmacotherapy. June 2016. Volume: 50 issue: 9, page(s): 778-784. <https://journals.sagepub.com/doi/abs/10.1177/1060028016653608>

In review of CMS' existing value-based healthcare models and programs, there is a clear focus on improved medication use, better management of chronic disease, and broader implementation of preventive care. As described, pharmacists are especially qualified and poised to address these key facets of value and quality-based care, making them a valuable, but thus far, seriously underutilized asset to CMS. The important positioning of pharmacists embedded into communities lends well to moving the needle on HHS' goals and objectives to advance healthcare quality, and the wide range of accessible clinical care services offered by pharmacies drive the value transformation of healthcare, supporting the "triple aim" to improve outcomes, patient experience, and reduce costs. Moreover, pharmacy-based initiatives and care services are directly aligned and synergistic with the goals of CMS' existing value-based healthcare programs, such as the Merit-based Incentive Payment System (MIPs), the Medicare Shared Savings Program for ACOs, the Part C and D Star measures, in addition to quality-based programs at the state level for Medicaid.

NACDS Recommendations: Recognize Pharmacists as Providers and Suppliers Across Medicare Program and in Value-Based Payment Programs. Pharmacists, as medication experts, are also well suited to impact many quality metrics existing and emerging in federal value-based payment models. In fact, pharmacists may in some cases be best positioned to influence certain metrics given their expertise on medications, accessibility within communities, and ongoing face-to-face clinical touchpoints with patients. For example, within the CMS' MIPS and alternative payment models (APMs), community pharmacists are well equipped to directly influence especially the following:

- "Quality MIPS" measures, which account for 50% of the MIPS Composite Score, and 25% of these are related to medications.
- "Improvement Activities" measures account for 15% of the total score, and 25% of these are related to medications.
- "Advancing Care Information" measures account for 25% of the MIPS composite score and 20% of these are related to medications.⁷⁴
- Two measures specifically mention pharmacists, including metrics around medication reconciliation after discharge in the quality category, and population management of medications in the clinical improvement category.⁷⁵

Similarly, many APM quality metrics are dependent upon improvements affected by optimized medication use. These include metrics such as blood pressure control, comprehensive diabetes care, preventive care, tobacco use, and more. Furthermore, many ACOs' top priority quality metrics can be impacted by medication optimization.⁷⁶ And, using the Agency for Healthcare Research and Quality (AHRQ) National Guidelines Clearinghouse, it has been estimated that there are 79 clinical quality metrics that pharmacists have or should have primary responsibility as the health professionals most closely involved in service delivery and many relate to medication management, adherence, and medication safety.⁷⁷ Further, using CMS' measure inventory⁷⁸ of finalized and implemented measures, NACDS provides examples of metrics that pharmacists are particularly well suited to influence across a variety of programs in Appendix #5. NACDS advocates for achievable, transparent, consistent, pharmacy-level measures aimed to improve health outcomes across Medicare's value and quality programs.

Yet, despite the fact that pharmacists are well suited to drive patient outcomes and these metrics, CMS failed to include pharmacists within the MIP Extension Final Rule. Specifically, in the 2016 Medicare Part B Final Rule for Merit-Based Incentive Payment System (MIPS) excludes Doctor of Pharmacy and pharmacists from being an "eligible clinician." However, all other parties listed below are deemed eligible clinicians.

⁷⁴ "Payment Methods in Outpatient Team-based Clinical Pharmacy Practice, Part 2: MACRA for Pharmacists."; American College of Clinical Pharmacy; October 2017.
⁷⁵ "A Whirlwind Tour of Value-Based Payment Models- with Pharmacists as your guide;" Pharmacy Today; June 2018. [https://www.pharmacytoday.org/article/S1042-0991\(18\)30783-7/fulltext](https://www.pharmacytoday.org/article/S1042-0991(18)30783-7/fulltext)

⁷⁶ CMS; "Consensus Core Set: ACO and PCMH/Primary Care Measures." <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/ACO-and-PCMH-Primary-Care-Measures.pdf>

⁷⁷ Carmichael J, Gurbinder J, Nguyen PA; "Healthcare Metrics: Where do Pharmacists Add Value?" *Am J Health-Syst Pharm*; 2016; 73:1537-47.
<https://www.ncbi.nlm.nih.gov/pubmed/27521240>

⁷⁸ Measures Inventory Tool. Centers for Medicare & Medicaid Services. https://cmit.cms.gov/CMIT_public/ListMeasures

MIPS Eligible Clinicians: 2016 Medicare Part B Final Rule

MIPS Program Eligible Clinicians	
• Doctor of medicine • Doctor of osteopathy • Doctor of dental surgery • Doctor of podiatric medicine • Doctor of dental medicine • Doctor of podiatric medicine • Chiropractors • Occupational therapists • Registered dietitians	• Registered nutrition professionals • Nurse practitioners • Physician assistants • Clinical nurse specialists • Physical therapists • Clinical psychologists • Qualified speech-language pathologists • Qualified audiologists • Certified registered nurse anesthetists

➤ WHAT'S MISSING – Doctor of Pharmacy & registered pharmacists.

Restricting the choice of Medicare beneficiaries' this way is nonsensical and without merit. Especially when you consider the high touches of community pharmacy. For instance, 75% of all adults reported having visited a pharmacy in the past year and a study of high-risk Medicaid beneficiaries found that they visited pharmacies 35 times per year, compared to seeing their primary care doctors 4 times per year, and specialists 9 times per year.⁷⁹ The accessibility of pharmacies, coupled with consumers reporting high trust⁸⁰ in the clinical expertise of pharmacists, creates vast opportunity for pharmacies to elevate not only quality of care, but also program integrity especially in Medicare, Medicaid, value-based and alternative payment models.

Pharmacists are increasingly part of team-based care delivery models with payers where they have an important role in improving the quality and safety of care, offering patients more comprehensive care, and reducing medical errors.^{81,82} Each community pharmacy touchpoint with beneficiaries offers an opportunity to not only provide recommended and evidence-based care but to also act as "checks" in the healthcare system to ensure that beneficiaries participating in VBP arrangements are getting the evidence-based, quality care they need. Successful outcomes for a value-based models and other coordinated care programs will be dependent on making sure that all providers across the care continuum are included. Yet, to date, pharmacy care has been needlessly excluded.

NACDS urges HHS to modernize the Medicare program and value-based models to improve quality, value, competition and patient choice by recognizing registered pharmacists as providers, clinicians and/or suppliers of health care services within VBP programs and CMMI demonstration models.

Across its many quality programs, including but not limited to MIPS and APMs, CMS should revise its regulatory language to allow pharmacies and pharmacists to participate. One way to achieve this would be to add pharmacy care suppliers to the list of eligible participants of these numerous value-based programs.

Restricting Pharmacists' Contributions to Care Unjustly Deprives Seniors from Necessary Improvements in Transformational Care Delivery. Antiquated barriers that restrict pharmacists' ability to meaningfully care for patients, especially Medicare beneficiaries, predate the vast expansion of coordinated care transformation, interprofessional care and the execution of value-based delivery models.

⁷⁹ Moose J, Branham A. (2014). Pharmacists as Influencers of Patient Adherence. *Pharmacy Times*. <https://www.pharmacytimes.com/publications/directions-in-pharmacy/2014/august2014/pharmacists-as-influencers-of-patient-adherence->

⁸⁰ An NACDS survey found that 76% of voters reported that a pharmacist is very or somewhat important when deciding to buy a medication for the first time.

⁸¹ Dalton K, Byrne S. (2017). Role of the pharmacist in reducing healthcare costs: current insights. *Integr Pharm Res Pract*. 2017; 6:37–46. doi:10.2147/IPRP.S108047. <https://www.ncbi.nlm.nih.gov/pubmed/29354549>

⁸² De Oliveira Jr, G. S., Castro-Alves, L. J., Kendall, M. C., & McCarthy, R. J. (2017). Effectiveness of Pharmacist Intervention to Reduce Medication Errors and Health-Care Resources Utilization After Transitions of Care: A Meta-analysis of Randomized Controlled Trials. *Journal of Patient Safety*. <https://doi.org/10.1097/PTS.0000000000000283>

Accordingly, as CMS continues to advance quality and value-based care initiatives, the inclusion of pharmacy care services across the Medicare program will empower patients “to select the right care, at the right time, in the right place, from the right provider.” We stand with CMS to create and support a robust, efficient and effective healthcare environment that advances patient choice and competition, through leverage of all qualified healthcare providers, to improve accessibility, quality, and affordability of care.

To create sustainable reimbursement pathways for integration of pharmacy care services to improve health, choice, competition, access, and quality of care, NACDS recommends the following two related items:

NACDS Recommendation 1A: Grant Supplier of Healthcare Services Status to Pharmacies Across Medicare

Despite a broad array of evidence supporting community pharmacists’ ability to improve health outcomes and reduce downstream costs⁸⁰ as described above, payment to community pharmacies is limited or restricted for services other than dispensing medications, especially in Medicare where pharmacists are not recognized as Part B providers. In fact, pharmacists are one of the only healthcare professionals with doctorate-level education and multiple years of clinical training, that lack a provider designation in federal law. In Medicare laws and regulations, services provided by clinical nurse specialists, physical therapists, clinical psychologists, speech-language pathologists, audiologists, and nutrition professionals, for example, are covered, but services provided by pharmacists are omitted. This unfortunate omission eliminates the possibility of developing sustainable care models for seniors to receive clinical care like medication optimization, chronic disease management, and preventive interventions, at pharmacies. As such, for broad impact on population health for seniors:

- **CMS should expand direct payment to pharmacies as suppliers of health care services across Medicare through the Calendar Year (CY) 2021 proposed and final Medicare Physician Fee Schedule rulemaking, consistent with the treatment of pharmacies in the Medicare Diabetes Prevention Program (MDPP) and mass immunizer status for vaccinations.⁸³**

This recognition would be tremendously beneficial for creating reimbursement pathways that provide sustainable beneficiary access to the clinical care provided by pharmacies and pharmacists. Further, seniors would be able to truly choose a healthcare setting that best meets their needs, including the ability to seek care in accessible, cost-effective, convenient community pharmacy locations. Including pharmacies as suppliers of healthcare champions the Administration’s goals on choice, competition, access, and quality.

NACDS Recommendation 1B: Inclusion of Pharmacists as Part B Providers and/or Eligible Clinicians in Value-Based Payment Models

On October 7, 2019, the *Journal of the American Medical Association* published a study by Humana and the University of Pittsburgh School of Medicine that estimated \$265 billion is wasted each year on healthcare in the United States – in other words, \$1 in every \$4 spent.⁸⁰ An accompanying op-ed written by the CEO of Humana argued that one solution to the problem is through adoption of a value-based care model that reduces costs and improves value. He wrote, “This integrated approach — which includes behavioral health, **pharmacy**, social determinants of health, home health and primary care — becomes the common framework in which caregivers and health plans can meet.”⁸¹ As described, pharmacies and pharmacists are ideally positioned to expand value-based care for seniors and move the needle on HHS’ objectives on quality. As such:

- **CMS should include pharmacies as suppliers of health care services and/or eligible clinicians as recommended above (Recommendation 1) AND use the authority granted under Section 1115A of the Patient Protection and Affordable Care Act (ACA) to test the impact of allowing pharmacists to be paid as Part B providers through CMMI’s extensive waiver authority.**

⁸³Medicare Diabetes Prevention Program (MDPP) Expanded Model. Centers for Medicare & Medicaid Services. <https://innovation.cms.gov/initiatives/medicare-diabetes-prevention-program/>

This would give those providers currently paid by Medicare the flexibility to leverage and integrate the full continuum of community-based services such as pharmacy care into new VBPMs and APMs.

NACDS Recommendation 2: Require Real-Time Benefit Tool Integration with Pharmacy Systems & Authorize Pharmacists to Act on Opportunities to Initiate Cost-Effective Alternatives

NACDS strongly supports CMS' integrating a patient-specific real-time benefit tool (RTBT) into the Part D benefit to drive lower prescription drug spending and minimize beneficiary out-of-pocket costs. Beneficiaries often arrive at the pharmacy counter with little or no insight as to what a medication will cost them, which can lead to overuse of unnecessarily expensive medications and the underuse of essential medications. As previously noted, medication adherence has a profound impact on health outcomes and total cost of care. Thus, we strongly agree with CMS that "reducing medication cost also yields benefits in patients' medication adherence" and that "increasing patient cost-share for a medication [is] associated with a significant decrease in medication adherence."⁸⁴

The integration of a RTBT into the Medicare Part D benefit, which provides decision support elements described in the proposed rule (i.e., clinically appropriate formulary alternatives and utilization management requirements such as step therapy, quantity limits, and prior authorization requirements) will give providers and beneficiaries the information needed to make better informed choices on their healthcare treatment.

Accordingly, we strongly urge RTBT at Pharmacy, and ensure that RTBT tools:

1. Preserve patient's right to pharmacy selection at the outset;
2. Ensure accurate and complete patient's out-of-pocket costs at formulary and pharmacy levels;
3. Avoid unintended economic costs to taxpayers and beneficiaries associated with steering patients to therapeutic alternatives that are subject to "spread pricing" due to excessive list prices and rebates;
4. No commercial messaging within RTBT transmissions to preclude undue steering by manufacturers and others; and
5. Ensure information integrity, fairness and accuracy among others.

NACDS recommends:

- **CMS should require that RTBTs are capable of integration within pharmacy systems.**
- **To prevent unnecessary delays for patients in therapy modifications based on the use of RTBTs, CMS should authorize pharmacists to substitute FDA-approved therapeutic equivalent generics and FDA designated cost-effective, therapeutic alternatives, similar to state generic substitution laws for pharmacists.**

NACDS Recommendation 3: Establish Pharmacy Care Incentive Programs & Standardized Quality Metrics

NACDS strongly urges CMS to establish *Medicare: Pharmacy Quality Incentive Programs* to promote the health of beneficiaries. At a minimum, CMS must set forth a standard set of well-defined performance measures beginning in the 2020 plan year and a corresponding assessment process to promote better health of Medicare beneficiaries and reduce needless and excessive administrative burdens on community pharmacies.⁸⁵

NACDS supports CMS' recent efforts to align the Medicare program with several of the Administration's policies and direction on healthcare quality, value, transparency, integrity, accountability and care coordination, including the recently announced Part D Payment Modernization Model.⁸⁶ We further applaud the Administration's efforts to implement such policies and transition toward value-based models in Medicare, promoting an accountable and competitive marketplace, while realigning incentives to yield improved health outcomes and total cost of care savings for Medicare.

⁸⁴ 83 Fed. Reg. at 62165.

⁸⁵ 83 Fed. Reg. at 62179.

⁸⁶ Part D Payment Modernization Model. Centers for Medicare and Medicare Services. 2019. <https://innovation.cms.gov/initiatives/part-d-payment-modernization-model/>

To further advance the Administration's policies, CMS' should develop standardized pharmacy performance metrics, as the first step in establishing a pharmacy quality incentive program. Such an initiative would represent an important, innovative strategy synergistic with the efforts described in Payment Modernization Model to enhance the Medicare Program by: (a) re-aligning incentives toward better quality and health; (b) lowering total cost of care spending; (c) supporting care coordination and transparency across settings; and (d) reducing the excessive and needless administrative burdens presently placed on community pharmacies.

Such a reform initiative is also consistent with and can help further the Administration's policies^{87,88,89,90} including:

1. Promote the transition towards value and health outcomes while minimizing the burden of reporting;
2. Hold healthcare providers accountable for a set of population-health metrics while fostering collaboration across the healthcare continuum;
3. Establish measures that are meaningful to providers and patients that help them assess quality and value, with the goal of improving both; and
4. Create federal policies based on "the needs those on the front-line serving patients, seeking to improve quality and health outcomes of beneficiaries they serve."⁹¹

While CMS has made significant strides implementing these policies in other parts of the Medicare Program, full reform is necessary. Specifically, the Medicare program should include pharmacy care incentives and standardized quality metric reforms.

Fragmentation of medical and pharmacy benefits can prevent optimal health outcomes for Medicare beneficiaries. Absent appropriate program quality measures and corresponding incentives aimed at driving better health outcomes and reducing total costs of care, substantial system disfunction and unnecessary spending will continue to occur. Failure to implement a pharmacy quality incentive program could unintentionally magnify the existing conflict between drug cost containment and the goal of improving health outcomes. Without a pharmacy quality incentive program, standalone Part D plans lack proper financial incentives to offer pharmacy quality and performance programs. We therefore strongly urge CMS to facilitate movement toward greater value by creating a pharmacy quality incentive program to ensure quality and value are essential pillars of the Part D program.⁹²

Pharmacy quality incentive programs would also strongly encourage plans and pharmacies to collaborate and better engage beneficiaries enrolled in accessible, convenient care settings. Likewise, Medicare beneficiaries would have the opportunity to be more engaged with their trusted pharmacists to improve their health and wellbeing. Establishing Medicare pharmacy quality incentive programs that reward quality, value and improved health outcomes will motivate participating entities to reduce total cost of care expenditures and ensure judicious stewardship of federal healthcare dollars.

⁸⁷ "Meaningful Measures Framework;" Centers for Medicare and Medicaid Services. <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html>

⁸⁸ The administration should ensure that delivery system reform models, which aim to hold providers accountable to a set of population-health metrics and total spending, foster collaboration across the systems... The administration should seek to develop measures that are meaningful to providers and patients, and help them assess quality and value, "Reforming America's Healthcare System through Choice & Competition Report (page 112);" U.S. Department of Health and Human Services, U.S. Department of the Treasury, U.S. Department of Labor; 2018. <https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf>.

⁸⁹ CMS Quality Strategy;" Centers for Medicare and Medicaid Services; 2018. <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Legacy-Quality-Strategy.html>

⁹⁰ "Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs;" Executive Orders - Budget & Spending; 2017. <https://www.whitehouse.gov/presidential-actions/presidential-executive-order-reducing-regulation-controlling-regulatory-costs/>

⁹¹ Administrator Verma emphasized the agency's aim to listen and be responsive to healthcare stakeholders by having federal policies be guided by the needs of those on the front-line serving patients. "CMS Administrator Verma Announces New Meaningful Measures Initiative and Addresses Regulatory Reform; Promotes Innovation at LAN Summit;" Centers for Medicare and Medicaid Services – Press Release; 2017. <https://www.cms.gov/newsroom/press-releases/cms-administrator-verma-announces-new-meaningful-measures-initiative-and-addresses-regulatory-reform>

⁹² The proposed action is consistent with CMS' Value Based Transformation (VBT) vision to advance value-based payment and care. This policy focuses on patients as consumers, providers as accountable patient navigators, payment for outcomes, and prevention of disease. See "Physician-Focused Payment Model Technical Advisory Committee Value Considerations for Model Development and Testing Fact Sheet," (2018), available at <https://innovation.cms.gov/Files/fact-sheet/ptac-value-fs.pdf>.

At the first step in establishing quality incentive programs, CMS must establish a standard set of metrics that measure pharmacy performance and quality. Establishing a set of performance measures would begin to realign incentives to encourage implementation of evidence-based interventions that promote clinically meaningful outcomes for beneficiaries while also incentivizing robust pharmacy care quality. Specifically, through the implementation of a standard set of metrics, community pharmacy could undertake an even more substantial role to improve medication optimization, facilitate care coordination, reduce medical errors, advance population health, and empower and motivate beneficiaries to achieve better health outcomes. A set of standard metrics can be developed in 2020.

Research and experience demonstrates that community pharmacies should be recognized as alternative care sites.^{93,94,95} In fact, community pharmacies have evolved into patient-centered healthcare destinations offering a wide range of accessible and affordable clinical care services including chronic care management and disease state monitoring, smoking cessation programs, transitions of care coordination, minor ailment care, immunization screening and administration, chronic and acute disease screening, mental health services, medication management, health and wellness programs, lifestyle counseling, and more. Additionally, pharmacy care interventions have been shown to substantially mitigate downstream healthcare costs^{96,97,98,99,100} and the value of community pharmacy can be leveraged through cross-sector collaboration and partnerships^{101,102} with other entities to further improve patient outcomes.^{103,104,105} This is especially relevant to Medicare beneficiaries in the current landscape of an aging population, increased chronic disease, and projected physician shortage, reinforcing the need for improved care coordination and innovative care delivery models.^{106,107} Such action would positively impact the health of Medicare beneficiaries, and preserve the value and integrity of Medicare, while ensuring a transparent and rigorous quality and cost performance model. The following outlines the specific benefits that CMS and Medicare beneficiaries would realize under a pharmacy quality incentive program.

Advance Quality, Value, and Improved Health Outcomes. Just as CMS has taken the lead on developing a standard quality program for physicians (MIPS/APMs, etc.), similar efforts would greatly benefit the Medicare program and help advance the movement towards value and a system focused on health outcomes. Proposed pharmacy quality incentive programs would represent innovation aimed at yielding better quality, outcomes, savings and improvement activities

⁹³ “The Pharmacy’s New Role in Providing Healthcare Services,” PM3260 Magazine. January 23, 2014. <https://www.pm360online.com/the-pharmacys-new-role-in-providing-healthcare-services/>

⁹⁴ Larkin PJ; “A Pharmacy Forum: Becoming A Health and Wellness Destination,” Winsight Grocery Business; April 2016.

<https://www.winsightgrocerybusiness.com/pharmacy-forum-becoming-health-wellness-destination>

⁹⁵ Barrett, J; “Pharmacists Play Key Role in the Future of Health Care,” Pharmacy Times; June 2017. <https://www.pharmacytimes.com/conferences/ashp-summer-2017/what-role-do-pharmacists-have-in-the-future-of-health-care>

⁹⁶ Total mean direct medical costs decreased by \$1, 200 to \$1, 872 per patient per year compared with baseline. Cranor CW, Bunting BA, et al; “The Asheville Project: Long- Term Clinical and Economic Outcomes of a Community Pharmacy Diabetes Care Program,” Journal of the American Pharmacists Association; 2003.

<https://www.sciencedirect.com/science/article/pii/S1086580215300073?via%3Dihub>

⁹⁷ Milosavljevic 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; 2018. <https://onlinelibrary.wiley.com/doi/full/10.1111/ijpp.12462>

⁹⁸ Lee JK, et al; “Effect of a Pharmacy Care Program on Medication Adherence and Persistence, Blood Pressure, and Low-Density Lipoprotein Cholesterol: A Randomized Controlled Trial,” Journal of the American Medical Association; 2006;296(21):2563-2571. <https://jamanetwork.com/journals/jama/fullarticle/204402>

⁹⁹ Fikri-Benbrahim N, et al; “Impact of a community pharmacists’ hypertension-care service on medication adherence,” Social and Administrative Pharmacy; 2013. <https://www.ncbi.nlm.nih.gov/pubmed/23391845>

¹⁰⁰ Brennan TA, et al; “An Integrated Pharmacy-Based Program Improved Medication Prescription and Adherence Rates in Diabetes Patients,” Health Affairs; January 2012. https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2011.0931?url_ver=Z39.88-2003&rft_id=ori%3Arid%3Acrossref.org&rft_dat=cr_pub%3Dpubmed

¹⁰¹ Increased collaboration between ACOs and plans may facilitate better and more affordable drug treatment options for beneficiaries by encouraging the use of generic prescription medications, where clinically appropriate, or reducing medical errors through better coordination between health care providers and plans. 83 Fed. Reg. at 68030.

¹⁰² ACOs that employ or contract with pharmacists are better at managing medication costs while delivering value. MacDonald JV; “ACO Hospitals Increasingly Seek Help from Pharmacists. Drug Topics,” December 2018; Volume 162, Issue 12. http://www.drugtopics.com/aco/aco-hospitals-increasingly-seek-help-pharmacists?elq_cid=5857498&elq_mid=4939&rememberme=1

¹⁰³ Van Boven JFM, et al; “Medication monitoring and optimization: a targeted pharmacist program for effective and cost-effective improvement of chronic therapy adherence,” Journal of Managed Care & Specialty Pharmacy; August 2014. <https://www.jmcp.org/doi/10.18553/jmcp.2014.20.8.786>

¹⁰⁴ Vegter S, et al; “Improving Adherence to Lipid-Lowering Therapy in a Community Pharmacy Intervention Program: A Cost-Effectiveness Analysis,” Journal of Managed Care & Specialty Pharmacy; July 2014. <https://www.jmcp.org/doi/10.18553/jmcp.2014.20.7.722>

¹⁰⁵ Spence MM, et al; “Evaluation of an Outpatient Pharmacy Clinical Services Program on Adherence and Clinical Outcomes Among Patients with Diabetes and/or Coronary Artery Disease,” Journal of Managed Care & Specialty Pharmacy; October 2014. <https://www.jmcp.org/doi/10.18553/jmcp.2014.20.10.1036>

¹⁰⁶ Dexter PR, et al; “Preparing for an Aging Population and Improving Chronic Disease Management,” AMIA Annual Symposium Proceedings; 2010. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3041380/>

¹⁰⁷ Gritters J; “The Cost of Long Wait Times,” Athena Health: Insight; 2017. [https://www.athenahealth.com/insight/cost-long-wait-times](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3041380/)

through the advancement of pharmacy care and care coordination.^{108,109} Such programs would standardize roles and performance measures to foster better care, while addressing profound business uncertainty by aligning program incentives. Incentive payments would support higher quality and health outcomes. Additionally, the construct of such programs should also ensure that high performing pharmacies are not disadvantaged by unintentionally driving beneficiaries from high performing to lower performing pharmacies. Pharmacy quality incentive programs are an integral component of reform because it would provide the right program incentives to advance quality and value of pharmacy care for beneficiaries. Without pharmacy quality incentive programs, plans lack incentives to offer the best possible pharmacy care to beneficiaries by those who touch beneficiaries the most.

NACDS is firmly committed to pharmacy quality incentive programs that includes upside and downside risk. Our expectation is that performance programs would include a significant glide path from a one-sided reward model to incremental upside and downside risk models in later years. Such an approach would be consistent with incentives built into the CMS' MIPS and APMs programs for physicians. Providing financial arrangements in the early years to reward community pharmacies directly for their performance would foster significant financial investment in exceptional pharmacy care quality and care coordination programs. Program metrics should be developed by CMS, in consultation with stakeholders, and these metrics should be tailored to pharmacy type, drug dispensed, and disease states being managed; directed toward value; and measure only those medications dispensed by the pharmacy.

NACDS is committed to advancing quality programs that improve outcomes for beneficiaries, reduces administrative burden for community pharmacies, and drives value in care. CMS could work with stakeholders and quality experts to establish the requisite program construct that includes a methodology to advance pharmacy-level performance, data collection and reporting, among other things. It also would include developing a set of metrics; attribution rules for determining which patients belong to which pharmacy (visit-based; assignment-based, et al.); methods for collecting composite scores, and methods for calculating achievable benchmarks and comparator groups.

In addition to defining "pharmacy incentive payments," CMS also would need to set forth standardized pharmacy quality measures and performance standards that serve as the basis for incentive payments. Such measures should be based on pharmacy-specific, proven and achievable criteria, and would take into account the drugs dispensed, and the disease state being managed. Furthermore, a definition for specialty pharmacy must also be established in regulation to ensure measures are appropriate for pharmacies that dispense specialty medications and provide related services to patients taking specialty medications. This effort would further demonstrate the quality services provided by pharmacists and could dovetail into other federal quality programs such as provider status and MIPS.

The biggest advantage of constructing pharmacy quality incentive programs would be the realignment of program incentives to advance health outcomes for Medicare beneficiaries through better frontline medication optimization care. Medication optimization services delivered by community pharmacies are central to the care of beneficiaries. Face-to-face interactions with beneficiaries at the point-of-dispensing medications to counsel and educate on adherence is critical to achieving national-scale improvements in health outcomes and lowered costs.^{110,111} In the age of convenience – with 24-hour and drive-through pharmacies – pharmacists understand the need for timely and effective prescription and healthcare information.

¹⁰⁸ Mechanic RE, et al; "Medical Group Responses to Global Payment: Early Lessons From the Alternative Quality Contract in Massachusetts;" Health Affairs; 2011. <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2011.0264>

¹⁰⁹ Larson BK, et al; "Insights from Transformations Under Way at Four Brookings-Dartmouth Accountable Care Organization Pilot Sites;" Health Affairs; 2012. <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2011.1219>

¹¹⁰ Patients who participated in brief face-to-face counseling sessions with a community pharmacist at the beginning of statin therapy demonstrated greater medication adherence and persistency than a comparison group who did not receive face-to-face counseling. The intervention group had statistically greater Medication Possession Ratio (MPR) than the control group every month measured. Taitel M, Jiang J, Rudkin K, Ewing S, Duncan I; "The impact of pharmacist face-to-face counseling to improve medication adherence among patients initiating statin therapy;" Patient Prefer Adherence; 2012;6:323-9. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3340117/>

¹¹¹ A systematic review was conducted using 51 studies determining the optimal modes of delivery for interventions to improve adherence to cardiovascular medications. Among person-dependent interventions (nonautomated phone calls, in-person interventions), phone calls showed low success rates (38%). In-person pharmacist interventions were effective when held in a pharmacy (83% successful) but were less effective in clinics (38%). Cutrona SL, Choudhry NK, et al; "Modes of Delivery for Interventions to Improve Cardiovascular Medication Adherence;" AJMC; December 2010. https://www.ajmc.com/journals/issue/2010/2010-12-vol16-n12/ajmc_10dec_cutrona929to942?p=1

The national payment mechanism for pharmacies is limited to the dispensing of a medication product, without regard to clinical services that optimize patient care. Pharmacists routinely counsel patients on new medications as part of the dispensing process, but innovative, new payment models are needed to support pharmacists as they delve deeper into preventive services, chronic care management, medication optimization, and other valuable services. Today, limited opportunities exist for pharmacies to be compensated for such clinical services in federal programs, which imposes a major barrier on pharmacy participation in innovative federal value-based models. Not only would recognition of pharmacists as healthcare providers improve access to care, but it would also lead to reduced healthcare costs. The implementation of pharmacy quality incentive programs would help support the value and sustainability of pharmacy in healthcare, with accountability for helping plans drive true value through the improvement of health outcomes and reduction of downstream costs. Therefore, we urge the agency to delineate a clear path forward by adopting a set path towards implementing such pharmacy quality incentive programs.

We welcome the opportunity to work with CMS to develop and execute pharmacy quality incentive programs that best serve beneficiaries, improve healthcare quality and total cost of care while at the same time reducing the excessive administrative burden on community pharmacies. Such an initiative will further demonstrate CMS' dedication to lead on quality,¹¹² and will be consistent with removing government burdens that impede value-based transformation and quality, aligning with ideas in Executive Order (EO) 13771, Reducing Regulation and Controlling Regulatory Costs,¹¹³ and CMS' Patients over Paperwork Initiative.¹¹⁴

- NACDS strongly urges CMS to establish *Medicare: Pharmacy Quality Incentive Programs* as part of transforming America's healthcare system to promote the health of beneficiaries.
- At a minimum, CMS must set forth a standard set of well-defined performance measures beginning in the 2021 plan year and a corresponding assessment process to promote better health of Medicare beneficiaries and reduce needless and excessive administrative burdens on community pharmacies.

NACDS Recommendation 4: Allow Pharmacist-Initiated Electronic Prior Authorization

In many instances, patients learn *at the pharmacy counter* that their provider prescribed a medication that is subject to a prior authorization (PA) by Medicare. The pharmacy must then contact the prescriber's office to notify of the PA requirement and then the prescriber or their staff can initiate the prior authorization. This process often leads to unnecessary delays in patients receiving the medication they need, as well as unnecessary burden and inefficiencies endured by both the pharmacy and the provider.

As NCPDP SCRIPT includes pharmacist-initiated prior authorizations, CMS should recognize pharmacists as eligible individuals who may request an initial determination for Part D enrollees. NCPDP SCRIPT Standard, Implementation Guide Version 2017071, approved July 28, 2017, supports pharmacists initiating and requesting ePAs, due to the requirements for prescriber, provider, and pharmacy information to be included on an initial determination request. Section 40.6 (Who May Request an Initial Determination) of that same guidance defines who may make a Part D standard or expedited initial determination request, which unintentionally excludes pharmacists due to certain terminology, such as the "enrollee's prescribing physician or other prescriber," or the "Staff of said prescriber's office acting on said prescriber's behalf (e.g., request is on said prescriber's letterhead or comes from the prescriber office fax machine)."

¹¹² "CMS Quality Strategy," *Centers for Medicare and Medicaid Services*; 2018. <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Legacy-Quality-Strategy.html>

¹¹³ "Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs," *Executive Orders - Budget & Spending*; 2017. <https://www.whitehouse.gov/presidential-actions/presidential-executive-order-reducing-regulation-controlling-regulatory-costs/>

¹¹⁴ "Patients Over Paperwork," *Centers for Medicare and Medicaid Services*; 2018. <https://www.cms.gov/Outreach-and-Education/Outreach/Partnerships/PatientsOverPaperwork.html>

To update e-prescribing standards and reduce undue administrative burden on patients, pharmacies, and prescribers, we strongly urge CMS to modify its proposed rule to allow pharmacists to submit prior authorization requests:

- **CMS should expand section 40.6 to include the pharmacist under the “Medicare Program; Secure Electronic Prior Authorization for Medicare Part D,” a proposed rule that would adopt the National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard for electronic Prior Authorization (“ePA”) Transactions.**¹¹⁵

NACDS Recommendation 5: Support Coverage and Payment for Pharmacy-based Telehealth Services

Telehealth services have been proven as a cost effective, quality way to deliver accessible healthcare to patients. These services hold the potential to benefit patients by expanding access to care while also improving efficiencies and reducing healthcare waste. However, telehealth is underutilized and increasing access to these services through myriad healthcare destinations, such as community pharmacies, could help improve uptake.¹¹⁶ CMS’ support of pharmacy-based telehealth services to be used as part of a beneficiary’s care team would improve access, choice, competition, and quality of care. Given their accessibility and integration into communities across the country, pharmacies and retail health clinics should be supported by CMS to provide telehealth care and services. Clinical pharmacy care services should be supported by CMS via telehealth options whereby pharmacists can provide clinical care remotely *and* in instances where pharmacies wish to offer telehealth services from other providers of care, like primary care physicians or specialists, to patients visiting their pharmacies. Pharmacies and retail health clinics are exploring opportunities to advance telehealth for patients, and increasingly expanding accessibility to patients by offering telehealth services.¹¹⁷ To better leverage community pharmacies to improve access to telehealth for beneficiaries, NACDS recommends:

- **CMS should authorize coverage and payment for pharmacy-based telehealth services as part of the beneficiary’s care team through the CY 2021 proposed and final Medicare Physician Fee Schedule rulemaking.**
- **CMS should allow pharmacists to bill Medicare “incident-to” through the CY 2021 proposed and final Medicare Physician Fee Schedule rulemaking by leveraging telemedicine to meet supervision requirements, which could greatly improve the feasibility and scalability of such initiatives to improve access to care.**

NACDS Recommendation 6: Implement a General Supervision for “Incident-to” Services

Pharmacists can currently bill incident-to for certain evaluation and management services such as chronic care management, transitional care management, tobacco cessation counseling, and Medicare Annual Wellness Visits under the direct supervision of a physician. However, the requirement for direct supervision requires participating pharmacists to be physically onsite with the collaborating provider, which is a barrier to the delivery of integrated care for beneficiaries across providers and settings. Allowing pharmacists to provide pharmacy-based services incident-to **under general supervision** instead would support the meaningful delivery of medication optimization, chronic disease management, and preventive care and screenings to Medicare beneficiaries in accessible, convenient pharmacy locations as part of larger care teams.

This action by CMS is especially important to remove unnecessary strain on medical practices where few physicians or providers have the time to reach most of their Medicare Part B–eligible patients for these services. Pharmacies and pharmacists in the community are well qualified and positioned to reach beneficiaries as they are visiting pharmacies already. By implementing a general supervision requirement, pharmacies can fill gaps in care, improve health for Medicare beneficiaries, and enhance efficiencies in our system. Beneficiaries are likely to benefit from pharmacy-based incident-to services, given that many of these services - while valuable - have low uptake today.

¹¹⁵ CMS. Medicare Program; Secure Electronic Prior Authorization for Medicare Part D. Proposed Rule. 84 FR 2845. June 2019.

<https://www.federalregister.gov/documents/2019/06/19/2019-13028/medicare-program-secure-electronic-prior-authorization-for-medicare-part-d>

¹¹⁶ Barnett ML, Ray KN, Souza J, Mehrotra A. Trends in Telemedicine Use in a Large Commercially Insured Population, 2005-2017. JAMA. 2018;320(20):2147–2149. <https://jamanetwork.com/journals/jama/fullarticle/2716547>

¹¹⁷ Livingston S. Storefront clinics expanded telehealth gaining ground. Modern Healthcare. February 2017.

<https://www.modernhealthcare.com/article/20170218/TRANSFORMATION02/170219900/storefront-clinics-expanded-telehealth-gaining-ground>

- To improve beneficiary access to care, CMS should explicitly allow pharmacists to provide services “incident-to” under general supervision by physicians or other practitioners for relevant evaluation and management services, including chronic care management, transitional care management, tobacco cessation, and Annual Wellness Visits billed incident-to through the CY 2021 proposed and final Medicare Physician Fee Schedule rulemaking.
- Specifically, CMS should add a provision at 42 CFR 410.32(b)(3) providing pharmacists with clear authorization to provide broad pharmacy care services under general supervision.

NACDS Recommendation 7: Expand “Incident-to” Billing for Initial Preventive Physical Exam/Welcome to Medicare Visit

7a. The Initial Preventive Physical Exam (IPPE), also known as the Welcome to Medicare Visit, is an opportunity for providers to assess a new beneficiary’s health status, identify needed preventive and clinical services, and create a care plan to meet their health needs. However, pharmacists are not currently able to provide services as part of a beneficiary’s care team during this important service. Allowing pharmacists to collaborate with a beneficiary’s care team for provision of the Welcome to Medicare Visit could support the delivery of medication optimization, immunization and other recommended clinical preventive services, and chronic disease management as demonstrated by the value pharmacists add in these key areas.

- **CMS should expand “incident-to” coverage and billing for pharmacists under general supervision for the IPPE/Welcome to Medicare Visit through the CY 2021 proposed and final Medicare Physician Fee Schedule rulemaking consistent with pharmacists’ state scope of practice laws which foster their ability to provide such care including preventive interventions and chronic care management.**

7b. NACDS also recommends to Clarify Physicians and Other Qualified Practitioners Can Bill “incident-to” Services Provided to Medicare Beneficiaries by Pharmacists at Levels Higher than Evaluation and Management (E/M) Code 99211

There are competing interpretations of whether pharmacists can bill for services using 99212-15. In 2014, the American Academy of Family Physicians (AAFP) petitioned CMS for clarification on whether a physician may bill for services provided by a pharmacist as “incident to” services.¹¹⁸ CMS responded stating that, “if all the requirements of the “incident to” statute and regulations are met, a physician may bill for services provided by a pharmacist as “incident to” services.”¹¹⁹ Subsequent communication from CMS later in 2014 confirmed this interpretation of “incident to” billing provisions.

However, the matter is further confused in states that consider pharmacists providers. In Washington, for example, pharmacists are recognized as providers by those commercial health plans under the state’s purview and they bill under the full range of CPT codes (99211-99215).¹²⁰ Nevertheless, at the national level, they may encounter barriers to physicians billing the same codes for the same services under incident-to arrangements. Despite the aforementioned CMS statements on this issue, pharmacists continue to have difficulties associated with “incident to” billing of E/M services. We urge CMS to look at Washington state in clarifying billing for E/M levels.

Given the complexities mentioned, while the services delivered by highly-trained pharmacists meet the requirements for physicians to bill at higher levels (E/M codes 99212-215), physicians are often discouraged from billing for pharmacists’ services at a level above E/M code 99211 due to concerns of a CMS audit, and billing departments and legal counsels are also reluctant. Absent CMS clarification, this issue is unlikely to change. This

¹¹⁸ American Academy of Family Physicians letter to Centers for Medicare & Medicaid Services, (Jan 2014), available at:

<https://www.aacfp.com/docs/positions/misc/AAFP%20MTM%20Letter%20to%20CMS%5E2.pdf>

¹¹⁹ Centers for Medicare & Medicaid Services response to American Academy of Family Physicians, (March 2014), available at:

<https://www.aacfp.com/docs/positions/misc/CMS%20Response%20to%20AAFP%20MTM%20Billing%20Letter.pdf>

¹²⁰ Roshan, Jeff. Credentialing and Privileging 101: Essential Steps to Bill for Patient Care Services. Slide 61. Presentation at APhA2018. March 28, 2018, available at: http://apha2018.pharmacist.com/sites/default/files/slides/Cred_and_Priv_101_3-18-18_104AB_HO.pdf

continued uncertainty is a true detriment to efficient, team-based care. Given pharmacists' ability to reduce unnecessary spending in Medicare, namely the \$528 billion spent annually on medication-related issues,¹²¹ it is critical that CMS clarify and support pharmacists to collaborate with physicians to better care for our nation's seniors via higher level incident-to services.

Further, the FY 2020 final PFS rule included deference to the AMA's Current Procedural Terminology ("CPT") definitions, which does not expressly state/ confirm that pharmacists are "other qualified health care professionals," as used for coding purposes. AMA's definition states: A "physician or other qualified health care professional" is an individual who is qualified by education, training, licensure/regulation (when applicable), and facility privileging (when applicable) who performs a professional service within his/her scope of practice and independently reports that professional service. These professionals are distinct from "clinical staff." A clinical staff member is a person who works under the supervision of a physician or other qualified health care professional and who is allowed by law, regulation, and facility policy to perform or assist in the performance of a specified professional service, but who does not individually report that professional service.¹²² Other policies may also affect who may report specific services. To address these unnecessary complexities, NACDS urges:

- **CMS reiterate and clarify that "incident to" services provided by a pharmacist can be billed E/M codes 92212-15.** We recommend that the clarification be discussed in the preamble to the regulation CMS prepares pursuant to the EO. CMS could also further communicate this in other public vehicles (e.g., MLN Matters) or in a prominent location on the CMS website. Clarifying this issue will help reduce the burden on healthcare practitioners who are willing, but currently unable to utilize pharmacists for more complex patient care needs.
- **To improve choice and access for beneficiaries, and increase uptake of underutilized care services, we recommend that as stated above, general supervision requirements are implemented for pharmacy-based incident-to care, even when higher E/M levels are billed.**

NACDS Recommendation 8: Allow Pharmacists to Help Patients with Opioid Use Disorder

Especially at the point of dispensing, pharmacies and pharmacists are uniquely positioned to offer Screening Brief Intervention and Referral to Treatment (SBIRT) services to at-risk patients. A recent article by Pringle, Aruru, and Cochran¹²³ 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 medication assisted therapy (MAT) drugs as well as play a critical role in implementing strategies to help reduce population opioid use disorder (OUD) risk. For example, pharmacists can contribute to reducing OUD prevalence by using SBIRT to identify persons who are misusing alcohol and other drugs. Through a screening process that is permissible through their existing scope of practice, pharmacists identify those at risk of OUD and provide brief counseling and motivational interviewing, as well as linkage to care. This would increase provider capacity while also eliminating gaps and barriers in treatment and increasing access to naloxone and other MAT drugs. Currently, pharmacy-based SBIRT services are being rolled out in Pennsylvania, Virginia, and Ohio. In Virginia, pharmacist-provided SBIRT services are reimbursed by Medicaid. While the expansion of pharmacist-provided SBIRT under Medicaid in Virginia is a positive step, further expansion of coverage is needed for this service to become sustainable. Further, we urge Medicare to consider the benefit to patients and communities affected by the opioid crisis if pharmacists could sustainably provide these care services. Recommendation 10 discusses MAT services in greater depth. However, pharmacists been tremendously underutilized by CMS in tackling the opioid crisis to date. In fact, pharmacists have more medication-related training than any other clinician and

¹²¹ Watanabe, J.H., McInnis, T. & Hirsch, J.D. (2018). Cost of Prescription Drug-Related Morbidity and Mortality, *Annals of Pharmacotherapy*, available at: <https://doi.org/10.1177/1060028018765159>

¹²² AMA. Instructions for Use of the CPT Codebook. November 2019. <https://bioportal.bioontology.org/ontologies/CPT?p=classes&conceptid=1022195>

¹²³ 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>.

pharmacist involvement in opioid use disorders helps improve access and outcomes, while reducing the risk of relapse.^{124,125}

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 program¹²⁶ involving six pharmacies working with 125 patients to manage their MAT. In the pilot, patients receive their initial MAT prescription from a physician. 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.)

MAT: DATA Waivers. According to the Drug Enforcement Agency ("DEA"), pharmacists are mid-level practitioners like PAs and NPs, and states¹²⁷ may allow pharmacists to prescribe Schedule II-V controlled substances under a Collaborative Practice Agreement.¹²⁸ Consequently, under certain states' scope of practice laws, pharmacists are eligible to prescribe Schedule III controlled substances but are unable to prescribe certain Schedule III medications, such as buprenorphine, because federal laws and regulations do not allow their eligibility for a DATA waiver. When pharmacists partner with physicians and other healthcare professionals to provide MAT, they streamline and improve care. Pharmacists' responsibilities for MAT and substance use disorder ("SUD") treatment can include treatment plan development, patient communication, care coordination, adherence monitoring and improvement activities, among others. A DATA-waived pharmacist working under a CPA in a state that permits prescribing of controlled substances would also be able to initiate buprenorphine and make dosage adjustments, which would greatly increase access to MAT and address treatment gaps.

We support efforts by HHS to better utilize all qualified health professionals to address this critical public health issue, and strongly believe allowing pharmacists to be data-waived providers for buprenorphine is also consistent with intent of the Administration's deregulatory efforts due to the hindrance that federal, as opposed to state, regulations have on pharmacists' ability to improve care by preventing them from increasing patient access to needed treatment in each state.

Given the devastating impacts of the opioid crisis:

- **HHS Secretary should use the authority granted in the Comprehensive Addiction and Recovery Act ("CARA") (P.L. 114-198) to revise the "qualifying other practitioner" requirements to allow for pharmacists to be able to provide medication-assisted treatment ("MAT") services, in addition to physicians, nurse practitioners, physician assistants, and others. The law states "[t]he Secretary may, by regulation, revise the requirements for being a qualifying other practitioner under this clause."¹²⁹**

¹²⁴ DiPaula, B.A. & Menachery, E. (Mar/Apr 2015). Physician-pharmacist collaborative care model for buprenorphine-maintained opioid-dependent patients, *Journal of the American Pharmacists Association*, 55(2), 187-192, available at: <https://www.ncbi.nlm.nih.gov/pubmed/25749264>

¹²⁵ Raisch, W. (2002). Opioid Dependence Treatment, Including Buprenorphine/Naloxone, *Pharmacology & Pharmacy*, 36(2), 312-321.

¹²⁶ Freyer F. In Rhode Island, Some Get Addiction Care at the Pharmacy. *Boston Globe*. March 2019. <https://www.bostonglobe.com/metro/2019/03/12/getting-addiction-care-pharmacy/m1mcceVILRXX1W9X3WdeOP/story.html>

¹²⁷ States that allow pharmacists to prescribe controlled substances when working under a collaborative practice agreement: California, Massachusetts (hospital only), Montana, New Mexico, North Carolina, Ohio, and Washington.

¹²⁸ See Drug Enforcement Agency, Mid-Level Practitioners Authorization by State. https://www.deadiversion.usdoj.gov/drugreg/practitioners/mlp_by_state.pdf

¹²⁹ P.L. 114-198, available at: <https://www.congress.gov/114/plaws/publ198/PLAW-114publ198.pdf>. Sec. 303.

Conclusion

To comprehensively advance healthcare value for the American people, *all entities* across the continuum of care must be maximized, leveraged, and fully utilized to their highest degree and potential to drive care coordination and patient outcomes, alleviating undue strain across all providers. NACDS urges CMS to consider opportunities to take advantage of the unique education, training, expertise, and value of *all healthcare providers, especially community pharmacists*, to meaningfully drive HHS' mission on quality, outcomes, and value. Innovative strategies that elevate and align the entire care continuum to synergistically advance quality and value are imperative to broad and meaningful care victories for seniors. The time is now to leverage community pharmacies across the nation as providers and suppliers of healthcare to further HHS objectives on access, choice, competition, and quality of care.

We look forward to corresponding action from CMS that promotes innovation in healthcare delivery to improve the health and wellness of our nation by recognizing the tremendous impact of pharmacy care. Thank you for your consideration of our comments and we look forward to working together to better protect and care for our nation's seniors.

Sincerely,

A handwritten signature in black ink, appearing to read "Steven C. Anderson". The signature is fluid and cursive, with a long horizontal stroke at the end.

Steven C. Anderson, IOM, CAE
President & Chief Executive Officer

Appendix #1: All Professions Across the Continuum of Care Have Unique Expertise to Improve Care for Seniors						
Profession	Estimated Number Practicing	Role: Defined by Professional Association	Degree Level	Degree Program Pre-Requisites	Professional Program Length	Experiential/ Clinical Hours Requirements
Pharmacist ¹³⁰	319,000	APhA: Pharmacists are healthcare professionals who help people achieve the best results from their medications. The pharmacist is the most knowledgeable healthcare professional when it comes to medicines and their use.	Doctoral	Bachelor's degree or required pre-professional courses if participating in a 5 or 6 year accelerated program	4 years	1740 hours (approximately 44 weeks)
Physician Assistant ¹³¹	131,000	AAPA: PAs are medical professionals who diagnose illness, develop and manage treatment plans, prescribe medications, and often serve as a patient's principal healthcare provider.	Master's	Bachelor's degree and completion of courses in basic and behavioral sciences Average of 3,000 hours+ of direct patient contact experience	3 years (27 continuous months)	2000 hours (approximately 1 year)
Nurse Practitioner ¹³²	270,000	AANP: NPs assess patients, order and interpret diagnostic tests, make diagnoses and initiate and manage treatment plans—including prescribing medications.	Master's or Doctoral	Active Registered Nurse license 1 – 2 years of clinical experience	2 – 3 years	500 hours minimum
Physical Therapist ¹³³	209,000	APTA: PTs are movement experts who optimize quality of life through prescribed exercise, hands-on care, and patient education.	Doctoral	Bachelor's degree or, if participating in a 3+3 curricular format, 3 years of specific pre-professional courses must be taken before the student can advance into a 3-year professional program	3 years	1200 hours (30 weeks) minimum

¹³⁰ Guidance for the Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree. Accreditation Council for Pharmacy Education. <https://www.acpe-accredit.org/pdf/GuidanceforStandards2016FINAL.pdf>

¹³¹ American Academy of Physicians Assistants. <https://www.aapa.org/>

¹³² American Association of Nurse Practitioners. <https://www.aanp.org/>

¹³³ American Physical Therapy Association. <https://www.apta.org/>

Occupational Therapist ¹³⁴	115,000	AOTA: OTs help people across the lifespan participate in the things they want and need to do through the therapeutic use of everyday activities (occupations).	Master's or Doctoral	Doctoral Program: -Bachelor's degree or higher prior to admission	2 – 3 years	Master's Program: -960 hours (24 weeks) minimum Doctoral Program: -960 hours (24 weeks) + an additional 640 hours (16 weeks)
Clinical Psychologists ¹³⁵	Not specified	APA: Clinical psychology is the psychological specialty that provides continuing and comprehensive mental and behavioral health care for individuals and families; consultation to agencies and communities; training, education and supervision; and research-based practice.	Doctoral	Bachelor's or Master's	4 – 7 years	1-year internship (hours not specified)
Clinical Social Worker ^{136,137}	Not specified	NASW: Clinical social work is the professional application of social work theory and methods to the diagnosis, treatment, and prevention of psychosocial dysfunction, disability, or impairment, including emotional, mental, and behavioral disorders.	Master's	Bachelor's	2 years	900 hours minimum
Speech-Language Pathologist ¹³⁸	175,000	ASHA: Speech-language pathologists (SLPs) work to prevent, assess, diagnose, and treat speech, language, social communication, cognitive-communication, and swallowing disorders in children and adults.	Master's or Doctoral	Bachelor's degree	2 – 4 years	400 hours minimum
Audiologist ¹³⁹	13,300	ASHA: Audiologists provide patient-centered care in the prevention,	Doctoral	Bachelor's degree	4 years	1820 hours minimum

¹³⁴ American Occupational Therapy Association. <https://www.aota.org/>

¹³⁵ Clinical Psychology. American Psychological Association. <https://www.apa.org/ed/graduate/specialize/clinical>

¹³⁶ NASW Standards for Clinical Social Work in Social Work Practice. National Association of Social Workers. <https://www.socialworkers.org/LinkClick.aspx?fileticket=Y0g4qdefLBE%3d&portalid=0>

¹³⁷ Educational Policy and Accreditation Standards. Council on Social Work Education (CSWE). <https://www.cswe.org/getattachment/Accreditation/Standards-and-Policies/2015-EPAS/2015EPASandGlossary.pdf.aspx>

¹³⁸ Scope of Practice in Speech-Language Pathology. American Speech-Language-Hearing Association. <https://www.asha.org/uploadedFiles/SP2016-00343.pdf>

¹³⁹ About Audiology. American Speech-Language-Hearing Association. <https://www.asha.org/Students/Audiology/>

		identification, diagnosis, and evidence-based intervention and treatment of hearing, balance, and other related disorders for people of all ages.				(approximately 46 weeks)
Chiropractors ¹⁴⁰	50,300	WFC: A health profession concerned with the diagnosis, treatment and prevention of mechanical disorders of the musculoskeletal system, and the effects of these disorders on the function of the nervous system and general health. There is an emphasis on manual treatments including spinal adjustment and other joint and soft-tissue manipulation.	Doctoral	Bachelor's degree or at least 3 years of undergraduate study	4 – 5 years	Clinical hours not specified 4,200 hours of combined classroom, laboratory, and clinical experience
Registered Dietician and Nutrition Professionals ^{141, 142}	80,000	AND: Registered dietitian nutritionists are the food and nutrition experts who can translate the science of nutrition into practical solutions for healthy living. RDNs use their nutrition expertise to help individuals make unique, positive lifestyle changes. ANA: Certified Nutrition Specialists practice science-based personalized nutrition therapy to power people to health. They are spearheading the transformation from population-based to personalized nutrition, and from disease care to authentic health care.	N/A	Bachelor's – RDN Master's or Doctoral – CNS	6 – 12 months	1200 hours – RDN 1000 hours – CNS

¹⁴⁰ World Federation of Chiropractic. https://www.wfc.org/website/index.php?option=com_content&view=article&id=90&Itemid=110

¹⁴¹ Academy of Nutrition and Dietetics. <https://www.eatrightpro.org/>

¹⁴² American Nutrition Association. <https://theana.org/certify/CNScandidate>

Appendix #2: CMS Authority

CMS has authority under the Medicare statute and regulations, as well as its broad demonstration power, to develop a standard set of pharmacy performance metrics as the first step in establishing a pharmacy quality incentive program. This authority aligns with ongoing CMS efforts to ensure high quality care for Medicare beneficiaries and protect the Medicare Trust Fund.

i. CMS has Authority Under Medicare Parts C and D

CMS's authority to administer the Medicare program includes oversight of plan access, quality, and beneficiary protections. Relevant statutory text provides CMS with the authority to use performance programs and measures to ensure compliance, noting: "performance measures established by the Secretary pursuant to subparagraph A(ii) shall include at least measures for" cost, quality programs, customer service and benefit administration, and claims adjudication. 42 U.S.C. § 1395w-111(g)(5)(b) (emphasis added). This language provides CMS authority to establish additional metrics beyond those specifically listed in the statute.

Even more specific authority related to pharmacy measures is provided in the statutory and regulatory requirements for Medication Therapy Management Programs (MTMPs) and quality assurance programs. See 42 U.S.C. § 1395w-104; 42 C.F.R. § 423.125(d). Specifically, when adopting MTMP regulations, CMS contemplated creating specific pharmacy measures along with minimum MTMP requirements to ensure programs are operating effectively for Medicare beneficiaries. CMS noted that, while it did not identify specific MTMP or pharmacy measures in its 2005 final Part D rule, it could do so in future rulemaking:

[W]e intend to work with industry and other stakeholders to develop a comprehensive strategy for evaluating plan performance that collectively considers multiple standards and services affecting the cost and quality of drug therapy. As industry practices evolve, including the expected expansion of electronic prescribing, we believe meaningful performance measures can be identified that will validate best practices and provide benchmarks that will spur further program and system improvements. Accordingly, we will work with industry to identify new standards for quality and performance that could eventually become plan requirements.

70 Fed. Reg. 4194, 4277 (Jan. 28, 2005) (emphasis added). CMS clearly understands that it has the authority to develop a comprehensive strategy for evaluating plan performance. Although CMS did not finalize other pharmacy standards in 2005, the agency noted that it has authority to create a platform as well as pharmacy measures in the future:

[W]e intend to utilize the Medicare Prescription Drug Benefit as a platform for driving the quality improvement of prescription drug therapy. We require plans to report details on their respective MTMPs, and we intend to collaborate further with industry to develop measures that can be used to evaluate programs and establish appropriate standards.

Id. at 4280 (emphasis added). Given the experience garnered from many years of administering the program, CMS now has such knowledge to reform Medicare to establish a pharmacy quality incentive program built on standardized quality measures.

CMS has additional authority to establish standardized pharmacy measures under its Star Rating system for Medicare Advantage and Part D plans. CMS originally established a Star system as part of its broad statutory requirements to disseminate information to beneficiaries to help them make informed plan choices. 42 U.S.C. §§ 1395w-21(d) & 22(e); 42 U.S.C. §1395w-101(d). Congress then expanded this system to include bonus payments and other benefits for high performing Medicare Advantage plans. Under the Star Rating system, CMS selects measures and data "based on its relevance and importance such that the ratings can meet the needs of beneficiaries using them to inform plan choice." 83 Fed. Reg. 16,440, 16,520 (Apr. 16, 2018). Consequently,

measures can be broadly established to help educate consumers about issues related to their Part D benefit, including pharmacy quality.

In particular, CMS has adopted Star Rating measures that are already directly tied to pharmacy performance. Measures related to medication adherence, diabetes treatment, and appropriate use of high-risk medications all rely on pharmacy data or pharmacy interventions, and these measures can account for a significant portion of a health plan's current Star Rating.¹⁴³ CMS has also clarified that it has the authority to adopt new Star Measures, amend existing measures, or entirely remove measures through its rulemaking process. Furthermore, CMS has noted that it can make technical or more minor changes through its Annual Call Letter.¹⁴⁴ Overall, CMS can use its Star Rating system to adopt standardized pharmacy quality measures or refine existing measures. Such actions would be fully consistent with existing CMS actions and the agency's overall approach to ensuring quality in prescription drug and Medicare Advantage plans.

PCMA acknowledges that CMS has authority to regulate Medicare pharmacy performance measures. PCMA, on behalf of its member PBMs, is challenging a North Dakota law that "requires PBMs to utilize benchmarks set by an unbiased, nationally-recognized entity when evaluating pharmacy performance, and it regulates the fees PBMs may levy on pharmacies due to their deficient performance." *PCMA v. Tufte*, 326 F. Supp. 3d 873, 893 (D.N.D. 2018). PCMA argued that this state law was preempted by 42 U.S.C. § 1395w-104(c), which as discussed above empowers CMS to establish pharmacy quality and performance measures used in the Medicare program. PCMA agrees that CMS has "'reserved for itself the role of partnering with private industry to identify the optimum performance measures'" for pharmacies in the Medicare program. 326 F. Supp. 3d at 892, quoting PCMA. In fact, PCMA notes that "CMS already regulates the area of pharmacy performance" in Medicare.¹⁴⁵ Although neither NACDS nor the court agreed with PCMA that the North Dakota quality measures law is preempted,¹⁴⁶ we do agree with PCMA that CMS has authority to adopt Medicare pharmacy performance standards. CMS can and should exercise that authority, by adopting standardized measures that properly assess and improve quality and performance.

ii. CMS has CMMI Demonstration Authority

CMS also has broad demonstration authority to develop a pharmacy quality program. As background, CMS already operates numerous quality reporting programs for various healthcare stakeholders (*e.g.*, hospitals, physicians, nursing homes, home health centers), and has noted that such value-based reforms align with the agency's overall quality strategy to improve outcomes and reduce costs.¹⁴⁷ While many of these programs are now codified in statute, the agency has often used its demonstration authority to first test value-based arrangements before they are fully enacted into law (*e.g.*, the hospital quality incentive demonstration, the physician group practice demonstration, health information technology related programs, and most recently the Part D Payment Modernization Model among others).

Section 402 of the Social Security Act authorizes the Secretary to develop and engage in demonstration projects "to determine whether, and if so which, changes in methods of payment or reimbursement for health care and services under health programs established by the Social Security Act ... would have the effect of increasing the efficiency and economy of health services under such programs through the creation of additional incentives to these ends without adversely affecting the quality of such services." 42 U.S.C. § 1395b-1(a)(1)(A). Importantly, this authority is not specific or limited to a type of provider, supplier, or other stakeholders, but instead has generally been interpreted expansively. CMS has also used this authority in the context of prescription drugs in its Medicare

¹⁴³ CMS. Medicare Star Ratings. <https://www.medicare.gov/find-a-plan/staticpages/rating/planrating-help.aspx?AspxAutoDetectCookieSupport=1> As an example, the Star measure entitled "Members Who Had a Pharmacist (or Other Health Professional) Help them Understand and Manage Their Medications."

¹⁴⁴ See *e.g.*, CMS. Letter to Medicare Advantage Organizations, Prescription Drug Plans Sponsors and Other Interested Parties Re: Request for Comments: Enhancements to the Star Ratings for 2017 and Beyond (Nov. 12, 2015), available at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2017-Star-Ratings-Request-for-Comments.pdf>

¹⁴⁵ Memorandum In Support Of PCMA's Motion For Summary Judgment in *PCMA v. Tufte*, p. 32 (Jan 19, 2018).

¹⁴⁶ The court granted summary judgment against PCMA on the preemption issue. 326 F. Supp. 3d at 894.

¹⁴⁷ CMS Value-Based Programs at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Value-Based-Programs.html>

Advantage Quality Bonus Payment Demonstration, which CMS initiated before implementing the MA Star Rating program.¹⁴⁸ Under Section 402, CMS could reasonably conduct a similar demonstration that focuses on pharmacy quality measures to determine if such a program would “increase the efficiency and economy” of services provided to Medicare beneficiaries. Such a program could address concerns CMS has already identified with DIR, as noted in its January fact sheet that outlines implications for beneficiary cost-sharing, Medicare subsidy payments, and plan liability.¹⁴⁹

Since 2010, CMS has largely moved its demonstration programs under the Center for Medicare and Medicaid Innovation, which has extensive authority to conduct different types of payment and incentive programs. Congress created the Innovation Center to “test innovative payment and service delivery models to reduce program expenditures ... while preserving or enhancing the quality of care furnished to individuals” in Medicare and Medicaid. 42 U.S.C. § 1315a(a)(1).

Importantly, this authority is actually broader than Section 402, since it allows programs to avoid budget neutrality requirements and successful models can be expanded via rulemaking rather than legislative action. While the Innovation Center has mainly focused on fee-for-service Medicare, it recently published a Request for Information (RFI) seeking a new direction for its programs. The RFI included a focus on Prescription Drug Models, stating that “CMS wants to test new models for prescription drug payment, in both Medicare Parts B and D and State Medicaid programs that incentivize better health outcomes for beneficiaries at lower costs and align payments with value...[m]odels that contemplate novel arrangements between plans, manufacturers, and stakeholders across the supply chain, including, but not limited to innovative value based purchasing arrangements, and models that would increase drug pricing competition while protecting beneficiaries’ access to drugs are of particular interest.”¹⁵⁰ The RFI request specifically contemplates a potential Innovation Center model focused on pharmacy quality metrics.

¹⁴⁸ See 75 Fed. Reg. 71,190, 71,220 (Nov. 22, 2010); *see also* CMS, Fact Sheet; Proposed Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Demonstration on Quality Bonus Payments, Nov. 10, 2010.

¹⁴⁹ See CMS, Fact Sheet, Medicare Part D – Direct and Indirect Remuneration (DIR) (January 19, 2017), <https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir>

¹⁵⁰ CMS. Request for Information: Innovation Center New Direction, available at <https://innovation.cms.gov/Files/x/newdirection-rfi.pdf>

Appendix #3: The Proven Clinical & Economic Value of Community Pharmacy Care	
Clinical Value/Result of Pharmacist Intervention	Source
Chronic Disease Outcomes	
Pharmacist-provided medication therapy management for medically underserved patients in FQHCs resulted in A1c goal achievement in 52.84% of patients and hypertension control was reported in 65.21%. Pharmacists identified and resolved more than 1400 medication-related problems and addressed multiple adverse drug event issues.	Rodis JL, et al. Improving Chronic Disease Outcomes Through Medication Therapy Management in Federally Qualified Health Centers. Journal of Primary Care & Community Health. 2017. https://www.ncbi.nlm.nih.gov/pubmed/28381095
Among black male barbershop patrons with uncontrolled hypertension, health promotion by barbers resulted in larger blood-pressure reduction when coupled with medication management in barbershops by pharmacists. The mean reductions in systolic and diastolic blood pressure were 21.6 and 14.9 mmHg greater, respectively, in participants assigned to the pharmacist-led intervention than in those assigned to the active control. In the intervention group, the rate of cohort retention was 95%, there were few adverse events, and self-rated health and patient engagement increased.	Victor RG, et al. A Cluster-Randomized Trial of Blood-Pressure Reduction in Black Barbershops. The New England Journal of Medicine. April 2018. https://www.nejm.org/doi/full/10.1056/NEJMoa1717250
Patients' A1c measurements as part of the pharmacist program were significantly reduced. Researchers observed a 16% decrease in all-diagnosis costs. Another study, by the same author, found that more than 50% of patients showed a decrease in A1c at each follow-up visit, and more than 50% saw improvement in lipid levels at each measurement. Additionally, total direct mean costs decreased by \$1,200 to \$1,872 per patient per year compared with baseline.	Cranor CW, Christensen DB. The Asheville Project: Short-term outcomes of a community pharmacy diabetes care program. Apr 2003. https://www.sciencedirect.com/science/article/pii/S108658021530005X?via%3Dihub Cranor CW, Bunting BA, et al; "The Asheville Project: Long- Term Clinical and Economic Outcomes of a Community Pharmacy Diabetes Care Program;" Journal of the American Pharmacists Association; 2003. https://www.sciencedirect.com/science/article/pii/S1086580215300073?via%3Dihub
Patients in the pharmacy program had a lower risk for discontinuing therapy and in a cohort of 1,000 patients, the intervention resulted in a reduction of 7 nonfatal strokes, 2 fatal strokes, 16 nonfatal heart attacks, 7 fatal heart attacks, and 16 revascularizations over patients' lifetimes. The intervention also produced considerable net cost savings.	Vegter S, et al.; "Improving Adherence to Lipid-Lowering Therapy in a Community Pharmacy Intervention Program: A Cost-Effectiveness Analysis;" Journal of Managed Care & Specialty Pharmacy; Available at https://www.jmcp.org/doi/10.18553/jmcp.2014.20.7.722 ; Last Accessed June 13, 2018.
The results for 6-month systolic BP reading showed significantly decreased rates for the pharmacist group versus the control group (-11.8mmHg vs - 6.2mmHg) and slightly smaller, but observable changes of diastolic BP in the intervention group versus the control group (-8.4 vs -6.2mmHg). Percentage of patients achieving good refill adherence was larger for the intervention group compared to the control group (59.7% vs 36.1%).	Shireman TI, et al.; "Cost-effectiveness of Wisconsin TEAM model for improving adherence and hypertension control in black patients;" <i>Journal of the American Pharmacists Association</i> ; March 2016. https://www.ncbi.nlm.nih.gov/pubmed/27184784
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	Greer N, Bolduc J, Geurkink E et al. (April 26 2016). Pharmacist-led chronic disease management: a systematic review of effectiveness and harms compared with usual care . Ann Intern Med. Epub ahead of print.
The pharmacy intervention group had statistically significantly higher improvements in the individual areas of A1c, blood pressure, and statin goal attainment. In this study, 40% of patients in the pharmacist intervention group achieved all 3 clinical goals after intervention , compared with only 12% of patients in the usual care group.	Prudencio J, Cutler T, Roberts S, Marin S, Wilson M. The Effect of Clinical Pharmacist-Led Comprehensive Medication Management on Chronic Disease State Goal Attainment in a Patient-Centered Medical Home . JMCP. 2018;24(5):423-429.

adherence to antihypertensive drug therapy in the pharmacist group was three times higher than the control group.	https://www.ncbi.nlm.nih.gov/pubmed/23391845 . Last Accessed June 13, 2018.
A study assessing pharmacy-based medication synchronization programs for Medicaid FFS beneficiaries with certain conditions (e.g., hypertension, hyperlipidemia and diabetes) found improved adherence to cardiovascular medications, cardiovascular clinical outcomes and significantly lower rates of hospitalization and emergency department visits , compared to a control group.	Krumme A. Glynn, R., Schneeweiss, S. et al. (2018). Medication Synchronization Programs Improve Adherence to Cardiovascular Medications and Health Care Use. <i>Health Affairs</i> 37(1)125-133.
Transitions of Care	
Patients who received medication therapy management services from the pharmacist experienced significantly fewer readmissions than patients who received usual care . Approximately 20% of patients who received usual care were re-admitted within 30 days compared to 6.9% of the patients who received pharmacist care.	Luder HR, et al.; "TransitionRx: Impact of Community Pharmacy Postdischarge Medication Therapy Management on Hospital Readmission Rate."; <i>Journal of the American Pharmacists Association</i> ; June 2015. https://www.sciencedirect.com/science/article/pii/S1544319115300558
A budget impact analysis of a pharmacist-provided transition of care program predicts a potential cost savings of \$25 million to a managed Medicaid plan over a period of 2 years, corresponding to over \$4 per member per month .	Ni W, Colayco D, Hashimoto J, et al. Budget impact analysis of a pharmacist-provided transition of care program . <i>J Manag Care Spec Pharm</i> . 2018;24(2):90-96.
A meta-analysis of 32 articles found that, compared to usual care, pharmacy-supported transitions of care programs resulted in a significant 32% reduction in the odds of readmission	Rodrigues, C.R., Harrington, A.R., Murdock, N. et al. Effect of pharmacy-supported transition-of-care interventions on 30-day readmissions: a systematic review and meta-analysis . <i>Ann Pharmacother</i> . 2017; 51: 866–889
A community pharmacy-based transitions of care program demonstrated that patients' risk of readmission can be decreased by 28% and 31.9% at 30 and 180 days, respectively, when pharmacists are added to usual care . In this program, pharmacist interventions focused on patient education, resolving medication-related problems, and facilitating access to post-discharge appointments and medications	Ni W., Colayco D., Hasimoto J., Komoto K., Gowda C., Wearda B., McCombs J. Impact of a pharmacy-based transitional care program on hospital readmissions . <i>Am. J. Manag. Care</i> . 2017;23:170–176.
Preventive Care and Screening	
Five years after national implementation of pharmacist-administered immunizations, it is estimated that 6.2 million additional influenza immunizations and 3.5 million additional pneumococcal immunizations are attributable to pharmacy-delivered immunization each year.	Patel AR, Breck AB, Law MR. The impact of pharmacy-based immunization services on the likelihood of immunization in the United States. <i>Journal of the American Pharmacists Association</i> . August 2018. https://www.japha.org/article/S1544-3191(18)30231-0/pdf
The cost effectiveness of a pharmacist-directed smoking cessation program that achieved abstinence of at least 1 year in 25% of patients was studied. Depending on the smoker's age at the time of cessation, the incremental discounted cost-effectiveness was \$720- 1,418/life-year saved .	Patel AR, Breck AB, Law MR. The impact of pharmacy-based immunization services on the likelihood of immunization in the United States. <i>Journal of the American Pharmacists Association</i> . August 2018. https://www.japha.org/article/S1544-3191(18)30231-0/pdf
Community pharmacists used a rapid antigen detection test for strep throat and provided medication for positive results through the research project. The cost associated with providing the treatment was compared to 5 physician-provided treatment strategies for strep throat. Pharmacist treatment of strep throat was the most cost effective .	Klepser D, Bisanz SE, Klepser ME. Cost-effectiveness of pharmacist-provided treatment of adult pharyngitis. <i>The American Journal of Managed Care</i> . April 2012. https://europepmc.org/abstract/med/22554040
The provision of preventive services at community pharmacies is shown to be effective at increasing immunization rates, supporting smoking cessation, managing hormonal contraceptive therapies, and identifying patients at high risk for certain diseases .	San-Juan-Rodriguez A, Newman TV, Hernandez I, et al. Impact of community pharmacist-provided preventive services on clinical, utilization, and economic outcomes: An umbrella review. <i>Preventive Medicine</i> . 2018. https://www.ncbi.nlm.nih.gov/pubmed/30145351
3,726 patients were screened for depression by pharmacists during the study period . A total of 67 (1.8%) patients screened positive on the PHQ-2. Of the patients who completed the PHQ-9, approximately 25% met the criteria for consideration of diagnosis and were referred to their physician. Five patients presented with suicidal thoughts and were referred for urgent treatment. Approximately 60% of patients with a positive PHQ-9	Rosser S, Frede S, et al. Development, Implementation, and Evaluation of Pharmacist-Conducted Screening Program for Depression. <i>Journal of the American Pharmacists Association</i> . Feb 2013. https://www.sciencedirect.com/science/article/pii/S1544319115302831?via%3Dihub

had initiated or modified treatment at the time of follow-up. Using the PHQ, pharmacists were able to quickly identify undiagnosed patients with symptoms of depression.	
Pharmacist-initiated HCV screening in community pharmacy assists with identifying patients at risk for HCV infection and provide patients with linkage to care.	Isho N, et al.; "Pharmacist-initiated hepatitis C virus screening in a community pharmacy to increase awareness and link to care at the medical center."; <i>Journal of the American Pharmacists Association</i> ; March 2017. https://www.japha.org/article/S1544-3191(17)30136-X/pdf
In Michigan, a pharmacist-provided HIV testing model, which incorporated rapid HIV testing, counseling, and linkage to confirmatory HIV testing services, was developed and implemented. Approximately 42% of the participants stated it was their first HIV test, many of whom reported high-risk behaviors in prior 6 months. This project demonstrated the acceptability and feasibility of pharmacist-provided rapid HIV testing and increase access of care within the community.	Darin KM, et al.; "Pharmacist-provided rapid HIV testing in two community pharmacies;" <i>Journal of the American Pharmacists Association</i> ; Feb 2015. https://www.japha.org/article/S1544-3191(15)30015-7/pdf
A literature review showed that community pharmacy conducted and analyzed point-of-care tests had satisfactory analytical quality . This review further supports that community pharmacies are well positioned to deliver a wide range of point-of-care tests and will allow for patients to have increased access to various screenings.	Buss V.H., Naunton M. Analytical quality and effectiveness of point of care testing in community pharmacies: A systematic literature review . Res. Soc. Adm. Pharm. 2019;15:483–495. doi: 10.1016/j.sapharm.2018.07.013.

Appendix #4: State Opportunities for Pharmacy Care (vastly underutilized by Medicare to date)		
Preventive Care	Chronic Care	Acute Care
Immunizations <i>Immunization rates continue to hit below national benchmark goals. With numerous, convenient locations and extended hours, pharmacists provide an ideal option for patients to receive their vaccines and quality care.</i>	Statin Therapy for Diabetes <i>With access to patients' medication history records, and occasionally patients' diagnoses, pharmacists are able to identify patients who have not filled a statin or have not appropriately continued therapy. Pharmacist interventions have shown to improve statin uptake and adherence.¹⁵¹</i>	Test and Treat for Seasonal Influenza and Group A Streptococcal Pharyngitis <i>Expanded authority to test and treat for influenza and strep throat increases access to care and supports community antibiotic stewardship efforts. Sixteen (16) states allow pharmacists to test and treat patients as a result of a CLIA-waived test.</i>
Tobacco Cessation Services <i>Pharmacist-led smoking cessation interventions have been shown to be an effective approach to reduce smoking.¹⁵² Twelve (12) states allow expanded pharmacist authority to initiate tobacco cessation aids.</i>	Medical Devices <i>It is not often realized that prescriptions are needed to purchase medical devices via insurance. At point of dispensing and counseling, pharmacists are knowledgeable which devices are necessary for patients, thus expanded pharmacist authority prevents unnecessary delay in patient access and poor medication administration.</i>	Treat Uncomplicated Minor Ailments <i>When dealing with acute, minor conditions, convenient and accessible care is desired by most. Pharmacists are not only accessible, but well-positioned to provide prompt and affordable care.</i>
Hormonal Contraceptives <i>Expanded pharmacist authority to initiate hormonal contraceptives increases access to care. Currently, ten (10) states/jurisdictions allow pharmacists to initiate contraceptives without a collaborative practice agreement.</i>	Additional Services: Diabetes Management Hypertension Management Anticoagulation Asthma/COPD Mental Health Pain Management	Additional Services: Travel Health Services Cough/Cold Management
HIV Prevention <i>Many states, including New Mexico, Iowa, and Washington, have piloted studies that show pharmacist-run, or pharmacist-involved, PrEP clinics are an effective way to increase uptake of the medication, which can then</i>		

¹⁵¹ Bui A, Kwon J, Kim J, Lucas, A. Overcoming Barriers to Statin Adherence. June 2019. <https://www.uspharmacist.com/article/overcoming-barriers-to-statin-adherence>

¹⁵² 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>

lead to decreased HIV transmission.^{153,154,155} To improve access to emergency PEP, New York allows pharmacists, through a non-specific patient order, to provide 7 days of PEP to patients without a prescription.¹⁵⁶		
Naloxone States across the nation recognize the impact pharmacists can provide in helping improve access to care related to substance abuse. Currently, all 50 states authorize pharmacists to dispense naloxone, of which 28 states have expanded pharmacist authority to initiate naloxone.¹⁵⁷		
Additional Services: Health Screenings Health and Wellness Services		

¹⁵³ Ryan K, Lewis J, Sanchez D, et al. The Next Step in PrEP: Evaluating Outcomes of a Pharmacist-Run HIV Pre-Exposure Prophylaxis (PrEP) Clinic. ID Week 2018 Poster Abstract Session. Oct 2018. <https://idsa.confex.com/idsa/2018/webprogram/Paper72194.html>

¹⁵⁴ Hoth A, Shafer C, et al. Iowa TelePrEP: A Public-Health-Partnered Telehealth Model for HIV Pre-Exposure Prophylaxis (PrEP) Delivery in a Rural State. Sexually Transmitted Diseases. May 2019. <https://www.ncbi.nlm.nih.gov/pubmed/31157732>

¹⁵⁵ Tung EL, Thomas A, Implementation of a community pharmacy-based pre-exposure prophylaxis service: a novel model for pre-exposure prophylaxis care. Sex Health. Nov 2018. <https://www.ncbi.nlm.nih.gov/pubmed/30401342>

¹⁵⁶ New York State Education Department, Pharmacy Unit. §6801. Definition of practice of pharmacy. <http://www.op.nysed.gov/prof/pharm/article137.htm>

¹⁵⁷ NASPA 2019. <https://naspa.us/resource/naloxone-access-community-pharmacies/>

Appendix #5:

Quality Metrics in CMS Programs Suited for Pharmacist Influence

Measure Topic	Measure Examples	CMS Programs
Chronic Disease Outcomes		
Chronic Disease Assessment and Management	Blood pressure control A1c control Depression remission Osteoarthritis function assessment	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	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	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	30 Day All Cause Readmissions	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 Screening		
Immunization Assessment and Delivery	Childhood Immunization Status Immunizations for Adolescents Pneumococcal Vaccination Status for Older Adults Preventive Care and Screening: Influenza Immunization Zoster (Shingles) Vaccination	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 and intervention for alcohol use and/or tobacco use DEXA scans Functional status and cognitive assessments Spirometry HIV screening Falls risk assessment/screening Blood pressure and/or diabetes screening	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