NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

By Electronic Submission via www.regulations.gov

December 31, 2019

The Honorable Joanne Chiedi
Office of Inspector General
Department of Health and Human Services
Attention: OIG–0936–AA10–P
Room 5521, Cohen Building
330 Independence Avenue SW
Washington, D.C. 20201

Re: OIG–0936–AA10–P: Proposed Rule Regarding Fraud and Abuse Revisions to Safe Harbors Under the Anti-Kickback Statute and Beneficiary Inducements CMP

Dear Inspector Chiedi

I. Introduction

The National Association of Chain Drug Stores (NACDS) thanks the Department of Health and Human Services Office of the Inspector General (OIG) for the opportunity to comment on your proposal to modernize and clarify regulations that interpret the federal Anti-Kickback Statute and beneficiary inducement provisions of the civil monetary penalty law. 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.

As you work through the HHS "Regulatory Sprint to Care" to improve patient outcomes, produce health system efficiencies, lower costs, and transform our Nation's healthcare system to better pay for value, we urge you to consider how community pharmacies are helping to accelerate your efforts. Moreover, we urge you to consider how community pharmacies could further accelerate your efforts through recognition in this proposed rule.

II. Proposed Rule Section III.B.5: VBE Participant

Under section 1001.952 of the Proposed Rule, the term "value-based enterprise participant" or "VBE participant" would include "an individual or entity that engages in at least one value-based activity as part of a value-based enterprise." OIG states, however, that the agency is "considering excluding pharmacies (including compounding pharmacies) from the definition of 'VBE participant'." OIG "acknowledge[s] that some pharmacies (and pharmacists) have the potential to contribute to the type of beneficial value-based arrangements this rulemaking is designed to foster (e.g., through medication adherence programs or educational services for patients with diabetes)." OIG believes that pharmacies

"primarily provide items" and the agency is "concerned that their participation in value-based arrangements may not further the care coordination purposes of this rulemaking."[1]

OIG's concern is entirely misplaced. ***Community pharmacies can and do play a critical role in coordinating and managing care for patients. As evidenced throughout our comments below, community pharmacies should be included in the definition of "VBE participant." We urge OIG to remedy this misconception in the final rule.***

A. Maximize the Entire Care Continuum to Improve Value

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. NACDS urges OIG, instead of looking to exclude entities, consider opportunities to take advantage of the unique positions, roles, and value of all players to meaningfully drive HHS' mission on quality and to improve care coordination. Innovative strategies that elevate and align the entire continuum to synergistically advance quality and value are imperative to broad and meaningful victories. Excluding certain sectors of the healthcare continuum from being considered VBE participants will unjustly deprive patients of necessary advancements in transformational care delivery, hamper care coordination, and dissolve tremendous opportunities to improve healthcare in America. Hence, instead of excluding community pharmacy, HHS should leverage community pharmacy embedded in neighborhoods across the nation and correspondingly the multiple patient touch points to drive outcomes and population health.

B. Community Pharmacies are Essential to Advancing Value-based Care for Patients

Community pharmacies deliver a wide range of accessible clinical care services that advance, support, and drive the value transformation of healthcare, strongly aligned with the "triple aim" to improve outcomes, patient experience, and reduce costs. Over the last several decades, community pharmacies have flourished and evolved into patient-centered healthcare destinations, providing care such as medication adherence interventions, chronic disease management, preventive care, and much more. 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.[2,3,4,5] Community pharmacies provide clinical healthcare services in most neighborhoods across the country, sometimes as the only healthcare provider within walking or driving distance, offering solutions to address unmet needs related to healthcare quality, health inequality and social determinants of health. Community pharmacies are valuable and essential partners in quality and value-based work, especially given that nearly 9 out of 10 Americans live within 5 miles of a community

[1] 84 Fed. Reg. 55694, 55704 (Oct. 17, 2019).
[2] 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/
[3] 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
[4] 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
[5] Milosavlijevic A, et al. Community pharmacist-led interventions and their impact on patients' medication adherence and other health outcomes: a systematic review. International Journal of Pharmacy Practice. June 2018. https://onlinelibrary.wiley.com/doi/full/10.1111/ijpp.12462

pharmacy.[6] And in fact, a study of **high-risk Medicaid patients** found that patients visited pharmacies **35 times per year**, compared to seeing their primary care doctors only 4 times per year, and specialists 9 times per year.[7]

Further, because pharmacies are well integrated into the communities they serve, pharmacists are able to deliver essential clinical interventions to advance quality of care, with an understanding of the regional, social, and economic challenges uniquely faced by that population. The important positioning of pharmacists embedded into communities lends well to moving the needle on HHS' goals and objectives to advance healthcare value; and in fact, national and federal agencies, such as the CDC and the U.S. Surgeon General, have encouraged and recognized the value of pharmacists in efforts to collaboratively improve quality and healthcare outcomes.[8] Additionally, federal programs like the Public Health Service and the Veterans Health Administration have proven that greater inclusion of pharmacists in direct patient care leads to less administrative burden on other healthcare providers, improved cost efficiency, more cohesive healthcare teams, and most importantly, improved patient outcomes.[9]

Considering all of these factors, NACDS believes excluding pharmacies as part of the modernized healthcare world and as VBE participants would be tremendously harmful to patients seeking clinical care in accessible, convenient community pharmacy locations. Instead of exclusion, HHS/OIG should leverage and maximize the value of pharmacies as part of the value transformation of healthcare by duly recognizing community pharmacies as VBE participants.

C. Community Pharmacy Care Is Flourishing: As Alternative Health Destinations, They Provide Far More than Medication Dispensing

Community pharmacies provide a variety of evidence-based clinical care to drive value and improve outcomes, including chronic care management and disease state monitoring, smoking cessation programs, transitions of care coordination, minor ailment care, immunization screening and delivery, chronic and acute disease screening, mental and behavioral health services, medication management, health and wellness programs, lifestyle counseling, and more. These initiatives and care services are directly aligned with the goals of 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.

A myriad of evidence supports the clinical effectiveness of pharmacists to move the needle on healthcare quality, outcomes, and value. For example, a CMMI-funded, pharmacy-led chronic care management initiative was designed to serve an underserved population through collaboration with University of Southern California and AltaMed. This initiative aimed to optimize patient health and

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[6] Kelling SE. Exploring Accessibility of Community Pharmacy Services. Innovations in pharmacy. Vol 6 No 3. 2015. https://pubs.lib.umn.edu/index.php/innovations/article/view/392
[7] 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.
[8] A Program Guide for Public Health: Partnering with Pharmacists in the Prevention and Control of Chronic Diseases. CDC. August 2012. https://www.cdc.gov/dhdsp/programs/spha/docs/pharmacist_guide.pdf
[8] 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
[9] 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.

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.**[10] Other examples of pharmacist impacts on healthcare quality and value are highlighted in the following chart:

[10] 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 ; Chen SW. 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

The Proven Clinical 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
The results for 6-month systolic blood pressure 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 blood pressure 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;" *Journal of the American Pharmacists Association*; 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.
Pharmacy care program for elderly patients led to increases in medication adherence, medication persistence, and clinically meaningful reductions in blood pressure. After 6 months of intervention, medication adherence increased from baseline of 61.2% to 96.9% and associated with significant improvements in systolic BP (133.2 to 129.9) and LDL-C levels (91.7 to 86.8).	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; Available at https://jamanetwork.com/journals/jama/fullarticle/204402.
Improved Medication Adherence	
Patients receiving the pharmacist adherence intervention increased between baseline and the end of the study (86.0% vs 96.5%) whereas the control group did not have a significant change (86.5% vs 85.4%). The odds of **adherence to antihypertensive drug therapy in the pharmacist group was three times higher** than the control group.	Fikri-Benbrahim N, et al.; :Impact of a community pharmacists' hypertension-care service on medication adherence."; *The AFenPA study. Research in Social and Administrative Pharmacy*. Available at https://www.ncbi.nlm.nih.gov/pubmed/23391845. Last Accessed June 13, 2018.
A review of 22 studies showed that **community pharmacist-led interventions improve patients' adherence and contribute to improved blood pressure control, cholesterol management, and chronic obstructive pulmonary disease and asthma control.**	Milosavljevic A, Aspden T, Harrison J. Community pharmacist-led interventions and their impact on patients' medication adherence and other health outcomes: a systematic review. International Journal of Pharmacy Practice. 2018; 26(5).
Patients receiving the pharmacist adherence intervention increased between baseline and the end of the study (86.0% vs 96.5%) whereas the control group did not have a significant change (86.5% vs 85.4%). The odds of **adherence to antihypertensive drug therapy in the pharmacist group was three times higher** than the control group.	Fikri-Benbrahim N, et al.; :Impact of a community pharmacists' hypertension-care service on medication adherence."; *The AFenPA study. Research in Social and Administrative Pharmacy*. Available at 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. Health Affairs 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."; *Journal of the American Pharmacists Association*; June 2015. https://www.sciencedirect.com/science/article/pii/S1544319115300558
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. Ann Pharmacother. 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. Am. J. Manag. Care. 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 immunizatio**n each year.	Patel AR, Breck AB, Law MR. The impact of pharmacy-based immunization services on the likelihood of immunization in the United States. Journal of the American Pharmacists Association. August 2018. https://www.japha.org/article/S1544-3191(18)30231-0/pdf
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. Preventive Medicine. 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 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.	Rosser S, Frede S, et al. Development, Implementation, and Evaluation of Pharmacist-Conducted Screening Program for Depression. Journal of the American Pharmacists Association. Feb 2013. https://www.sciencedirect.com/science/article/pii/S1544319115302831?via%3Dihub
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."; *Journal of the American Pharmacists Association*; 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;" *Journal of the American Pharmacists Association*; 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.

D. The Tremendous Value of Community Pharmacy Will be Sorely Missed; Costing the Nation Way Too Much

It was recently estimated that up to $21.9 billion could be saved within the US healthcare system by optimizing medication use.[11] Further, it has been estimated that lack of medication adherence causes 125,000 deaths, at least 10% of hospitalizations, and hundreds of billions of preventable healthcare spending.[12] Healthcare spending on non-optimal medication therapy is estimated at $528.4 billion per year[13] and medication non-adherence is estimated to cost the system $290 billion per year.[14]

Importantly for Medicare beneficiaries, it was recently estimated that medication nonadherence for diabetes, heart failure, hyperlipidemia, and hypertension resulted in billions of Medicare fee-for-service expenditures, millions in hospital days, and thousands of emergency department visits that could have been avoided. If the 25% of beneficiaries with hypertension who were nonadherent became adherent, Medicare could save $13.7 billion annually, with over 100,000 emergency department visits and 7 million inpatient hospital days that could be averted.[15] Further, in the context of an aging population, increasing prevalence of chronic disease and rising medication use, the proposal to exclude medication experts – pharmacists – seems misplaced. In fact, 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.[16]

The proven ability of pharmacists and community pharmacies to optimize medication use, improve medication adherence, better manage disease, advance preventive care, and therefore improve outcomes and reduce costs is well documented. See the chart below for some salient examples of evidence demonstrating the tremendous economic effectiveness of pharmacy to advance and drive healthcare value. The compelling evidence clearly demonstrates that better medication use and management in America is an urgent and critically important aspect of truly improving healthcare quality in this country. Community pharmacists across the nation stand ready and able to improve medication use in the context of value-based care. However, HHS must take the first key step to better deploy the power and expertise of community pharmacies, by accurately recognizing community pharmacies as VBE participants.

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

[12] 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

[13] 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

[14] 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.

[15] 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.

[16] 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.

The Proven Economic Value of Community Pharmacy Care	
Economic Result of Pharmacist Intervention	Source
Chronic Disease Outcomes	
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.
Improved Medication Adherence	
The intervention, which included pharmacist-led screening across 283 pharmacies for medication non-adherence and counseling for those at an increased risk, led to statistically significant improvement in medication adherence, and an **annual per patient cost savings of $241 dollars for improved adherence to oral diabetes medications and $341 related to improved adherence to statin medications.**	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.
Pharmacists provided counseling for adherence to diabetes medications and recommendations for other medications often used in tandem with diabetes medications aimed at reducing the risk of cardiovascular disease (ACE-inhibitors or ARBS and/or statins). **The return on investment of the initiative was estimated at 3:1.**	Brennan TA, et al.; "An Integrated Pharmacy-Based Program Improved Medication Prescription and Adherence Rates in Diabetes Patients.;" Health Affairs; Available at https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2011.0931?url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org&rfr_dat=cr_pub%3Dpubmed; Last Accessed June 13, 2018.
Patients who received the outpatient pharmacy clinical service program were more likely to be adherent with their diabetes medications (53.5% compared to 37.4%). This group was also more likely to continue taking their medication, less likely to have an emergency department visit, and **the return on investment for this program was estimated at 5.79:1.**	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; Available at https://www.jmcp.org/doi/10.18553/jmcp.2014.20.10.1036; Last Accessed June 13, 2018.
Pharmacist-led Medication Monitoring and Optimization results: For osteoporosis, therapy discontinuation after 1 year was 16.1% in the pharmacist group, compared with 31.7% in the control group and was found to be cost-effective in 52,000 patients yearly, initiating osteoporotic therapy with an incremental cost-effectiveness. For dyslipidemia, the therapy discontinuation rate was 13.6% in the pharmacist cohort and 25.9% in the control group. **The cost-effective aspect was favorable for the primary prevention population and significant for the secondary prevention population (lower costs and more health gains).**	Van Boven JF, 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; Available at https://www.jmcp.org/doi/10.18553/jmcp.2014.20.8.786. Last Accessed June 13, 2018.
A comprehensive medication management program, led by pharmacists, targeted at high-risk individuals, resulted in 33% reduction in readmission rate, 31.5% reduction in costs, and an average of 12:1 ROI overall.	https://www.chcs.org/media/Slides-CMMC-National-webinar-3.1.19.pdf
In 2012, a Medicaid managed care plan established a collaborative MTM program for nearly 1,000,000 Ohio Medicaid beneficiaries. By the end of 2013,	Ben Urick, Patrick Brown, and Jon C. Easter. Achieving Better Quality and Lower Costs in Medicaid Through Enhanced Pharmacy Services

pharmacists at 1,500 pharmacies had provided over 100,000 MTM interventions, 40% of which were associated with medication adherence. In a program evaluation, **the managed care plan reported a 4.4:1 return on investment for total health care expenditures.**	North Carolina Medical Journal May-June 2017 78:188-189; doi:10.18043/ncm.78.3.188
Transitions of Care	
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. J Manag Care Spec Pharm. 2018;24(2):90-96.
Preventive Care and Screening	
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. Journal of the American Pharmacists Association. 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. The American Journal of Managed Care. April 2012. https://europepmc.org/abstract/med/22554040

Accordingly, the mistaken concept of excluding pharmacies as VBE participants will have the serious, unintended consequence of depriving patients of convenient and effective quality of care, and severely undermining HHS' mission of putting patients first and driving outcomes and value. To more effectively and efficiently reach HHS' goals on quality and value in healthcare, NACDS urges HHS to duly recognize pharmacies as VBE participants.

E. As VBE Participants, Community Pharmacies Are in the Best Position to Advance Care Quality

As the most accessible and frequently visited member of the healthcare team, [17] community pharmacists complement the care provided by others by facilitating convenient access to affordable and high-quality interventions. As shown in charts above, pharmacists have a proven ability to improve clinical outcomes, especially associated with chronic conditions, optimized medication use, and preventive services, which are core components of existing quality programs. By including community pharmacies as VBE participants and supporting pharmacists to provide evidence-based interventions and care, primary care physicians, nurse practitioners, and physician assistants are better able to focus on providing care for patients that require their unique expertise.

For example, 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. [18] This is especially important when you consider workload and time constraints of primary care physicians. Notably, it has been observed that general practitioners have about 2 minutes per clinic visit to properly

[17] Hemberg N, Huggins D, et al. Innovative Community Pharmacy Practice Models in North Carolina. North Carolina Medical Journal. June 2017. http://www.ncmedicaljournal.com/content/78/3/198.full
[18] 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/

implement preventive care, leading to a care deficit of over 5 hours per day for preventive care.[19] To buttress this point, it has been estimated that 1,773 hours of a physician's annual time, or 7.4 hours per working day, would be needed to fully satisfy the United States Preventive Services Task Force (USPSTF) recommendations for these preventive services.[20]

Therefore, including community pharmacies as VBE participants to provide interventions, such as preventive care and chronic disease management, can alleviate unnecessary strain on other providers, and help all providers across the continuum of care to better manage, focus on, and meet quality objectives that they are best suited, positioned, and qualified to tackle.

F. Physician Shortage & Rural Access Concerns Diminished if Pharmacies Are VBE Participants

The inclusion of community pharmacies as VBE participants is even more critical given the projected shortage of physicians. Approximately 65 million people live in regions without adequate primary care[21] and experts estimate a shortage of providers: up to 122,000 physicians by 2032 within the United States.[22] Better leverage 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. As the most accessible healthcare provider, 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.[23] Patients are already visiting their community pharmacies more than other healthcare providers[24] 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 clinic hours, and many of these patients do not have a primary care provider. [25,26,27,28,29] As demonstrated, community pharmacies help reduce unmet care needs and are critically important to advancing HHS' mission on quality. As such, to advance quality, value, and care coordination across the continuum, HHS should duly recognize community pharmacies as VBE participants.

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[19] 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
[20] 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/
[21] 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
[22] 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
[23] 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
[24] Hemberg N, Huggins D, et al. Innovative Community Pharmacy Practice Models in North Carolina. North Carolina Medical Journal. June 2017. http://www.ncmedicaljournal.com/content/78/3/198.full
[25] 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
[26] Klepser DG, Klepser ME, Smith JK, Dering-Anderson AM, Nelson M, Pohren LE. Utilization of influenza and streptococcal pharyngitis point-of-care testing in the community pharmacy practice setting. Research in Social and Administrative Pharmacy. 2018;14(4):356-359. doi:10.1016/j.sapharm.2017.04.012
[27] Klepser DG, Klepser ME, Dering-Anderson AM, Morse JA, Smith JK, Klepser SA. Community pharmacist–physician collaborative streptococcal pharyngitis management program. Journal of the American Pharmacists Association. 2016;56(3):323-329.e1. doi:10.1016/j.japh.2015.11.013
[28] 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
[29] 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

G. Impressive Examples of Community Pharmacy Value-based Payment Models

Pharmacies and pharmacists face many challenges to bill for and sustain clinical care services, limiting their ability to more broadly expand the reach of healthcare delivery. However, despite these challenges, many impressive examples of value-based payment models exist in the community pharmacy space.[30] A number of payors have recognized the value of pharmacy to improve quality and value, and hence, are participating and incentivizing pharmacies to deliver clinical care, outside of dispensing prescriptions. Given the observed successes, HHS should leverage community pharmacies as VBE participants and support, develop, and implement similar models of care that align incentives for pharmacies to deliver and drive HHS' initiatives on quality and value. A subset of examples of value-based/pay-for-performance models in community pharmacy are included below, and this is not an exhaustive list:

1. Wellmark Blue Cross Blue Shield Value Based Pharmacy Program (VBPP)

Payors: Medicare, Medicaid, and Commercial

Background: In 2015, Wellmark began conversations with community pharmacists and a 12-month pilot was launched with 62 high performing independent and chain pharmacies in the Midwest from 12 organizations in 2017. Project objectives are to improve patient care/outcomes by optimizing pharmacist involvement given the quality impact of pharmacists, and especially focused on better serving patients with chronic disease. Goals of this program include ensuring that the patient is on the right drug and is adherent, and in the longer-term, to reduce emergency department visits, hospital readmissions, and total cost of care.

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

Eligible members for the program include those with ≥1 chronic medication or diagnosed with a chronic condition. Example metrics[31] to evaluate pharmacy performance vary by disease state and include:

- Medication adherence
- Medication persistency
- Use of high-risk medications
- Diabetes – blood sugar control and blood pressure control
- Cardiovascular risk – cholesterol goals, is patient on correct statin intensity?
- Asthma – assess how often patient is utilizing rescue inhaler
- Potentially preventable emergency department visits and admissions

[30] https://www.pharmacytoday.org/article/S1042-0991(16)00353-4/fulltext
[31] https://www.chcs.org/media/Slides-CMMC-National-webinar-3.1.19.pdf

- Total healthcare costs

Payment Structure: Wellmark's VBPP network is structured outside of the Pharmacy Benefit Manager (PBM) relationship. VBPP payment structure is per member per month (PMPM) with bonuses. Bonus from shared savings is received based on Wellmark's evaluation of a value-based performance score.

Results: Impacts of this program were evaluated in early 2019, and results[32] include:

- 4.6% decrease in total per member per month costs
- 9.3% decrease in potentially preventable admissions
- 1.7% decrease in potentially preventable emergency department visits
- Biggest impact on cost of care was for patients with heart disease
- 17,000 clinical interventions by pharmacists with 50% of interventions resulting in pharmacists identifying a drug therapy problem, and 60% of interventions were not directly related to the specific drug being dispensed because pharmacists took time to ask about *other* medications the person was taking.[33]

The Continuous Medication Monitoring (CoMM) pharmacy pilot, which informed the creation of the ongoing Wellmark VBPP model, also had significant results.

- The pilot results demonstrated lower total costs of care and meaningfully better medication adherence: **per member per month (PMPM) costs were approximately $300 lower for patients** who received medications only from the pharmacy offering the CoMM program as compared to patients receiving medications from other pharmacies. This pilot validated that paying pharmacists to proactively address the safety, effectiveness, and adherence of medications at the time of dispensing can support optimization of medication therapy and decrease costs.[34]

2. Wisconsin Pharmacy Quality Collaborative (WPQC)[35]

Payors: Medicaid, Medicare Part D, Medicare, Commercial, and SeniorCare

Background: Established in 2008, the WPQC is an initiative of the Pharmacy Society of Wisconsin (PSW), which connects community pharmacists with patients, physicians, and health plans to improve the quality and reduce the cost of medication use across Wisconsin. In 2012 the PSW received a $4.1 million Health Care Innovation Award from the Centers for Medicare & Medicaid Services (CMS) to expand the WPQC statewide.[36] Currently, over 500 pharmacists are actively certified through WPQC. Current health plan partners include the Wisconsin Medicaid and SeniorCare programs and the United

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[32] https://pqa.memberclicks.net/assets/library/PQA_Quality_Forum_Webinar_2019-10-03.pdf

[33] https://join.healthmart.com/clinical-performance/create-new-revenue-streams/

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

[35] http://www.pswi.org/wpqc
http://www.pswi.org/WPQC/About-WPQC/About-WPQC
https://www.dhs.wisconsin.gov/publications/p01558.pdf
http://www.pswi.org/WPQC/WPQC-Payers/Benefits-to-Payers
http://www.pswi.org/Portals/17/WPQC/Wisconsin%20Pharmacy%20Quality%20Collaborative%20Medication%20Therapy%20Management%20Services%20Program.pdf?ver=2015-09-21-120558-607

[36] http://www.wisconsinmedicalsociety.org/_WMS/publications/wmj/pdf/113/3/95.pdf

Way of Dane County, representing approximately 20% of the state population, or over 1 million Wisconsin lives.

Program Details: WPQC is a network of pharmacies with pharmacists who provide medication therapy management (MTM) services, such as comprehensive medication reviews (CMRs) to complex, high-risk patients. This model leverages pharmacists to reduce medication complexity and errors, improve adherence, and empower patients to safely manage their medication regimens. WPQC and its health plan partners facilitate the provision of MTM services for patients taking multiple medications to treat chronic conditions, those at risk of falls and adverse drug events (ADEs), and those recently discharged from the hospital. The UWDC CMR program supports community and senior center case managers to identify older adults at risk of falls and ADEs and intervene by scheduling WPQC-provided CMRs and offering home falls safety assessments. Services can also be provided at the pharmacy or the patient's residence. Similarly, a partnership in Milwaukee between WPQC pharmacies and UniteMKE trains community health workers in medication adherence screening. The community health workers then make CMR referrals to WPQC pharmacies.

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

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

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

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

3. Community Care of North Carolina – Enhanced Pharmacy Services Network[37]

Payor: Medicare and Medicaid Innovation Grant

Background: The following $15.6 million CMMI project led by North Carolina Community Care Networks, Inc. (CCNC), Optimizing the Medical Neighborhood: Transforming Care Coordination through the North Carolina Community Pharmacy Enhanced Services Network, tested a model focused on community-based pharmacists who delivered medication management services to Medicaid, Medicare, and dually eligible Medicare-Medicaid and NC Health Choice beneficiaries with at least one chronic condition and had over 80% of their medications filled within the last 100 days at one of 275 participating pharmacies. This project was one of 39 awardees for a 3-year cooperative agreement known as Round Two of the Healthcare Innovation Awards (HCIA R2). While the impact analysis for the CCNC project is still underway, the project reached 92% of its enrollment goal – 328,806 participants[38] with more than 70% of enrolled patients being Medicare-Medicaid dual eligible.

This model tested the use of a value-based approach to incentivize pharmacists to move from filling prescriptions to providing enhanced services that address gaps in patient care for the most at-risk patients. Of the 39 awardees – only two reported their program had been replicated by others - with 15 other pharmacy networks replicating the CCNC project and another 25 or more requesting technical assistance to do so. This model has garnered substantial interest across the pharmacy community and payors, and more demonstration work needs to be done to further refine the quality program tested and press toward larger scale sustainability and replicability across Medicare and state Medicaid programs. Further, CCNC reported working closely with the North Carolina Division of Medical Assistance to incorporate the program into a Medicaid reform effort.

Program Details: Participating pharmacies are given access to CCNC information that allows pharmacists to review prescription claims data, adherence data, and population management tools. Pharmacies are allowed to participate in the CPESN-NC framework as long as they deliver enhanced services, document interventions, and meet minimum established criteria. CPESN-NC pharmacies must provide a proactive waste management program that prevents medication waste by verifying patient need prior to each fill, patient counseling and adherence coaching, and assistance with medication reconciliation especially after hospital discharge. Primary goals of this grant were to improve quality and reduce costs while enhancing the ability of the primary care provider (PCP) to improve care outcomes for patients with chronic diseases.

Preliminary Results: Based upon preliminary results, high-risk Medicaid patients supported by CPESN pharmacies are:

- 45% less likely to have an inpatient hospitalization admission,
- 35% less likely to have a preventable hospital admission or readmission,
- 15% less likely to experience an emergency department visit,

[37] https://www.communitycarenc.org/
https://www.cpesn.com/
https://issuu.com/iowapharmacyassociation/docs/2016q2_journal_web
https://cpesn.com/payors
http://www.ncmedicaljournal.com/content/78/3/188.full

[38] This is the number of participants who sought any service at participating pharmacies. https://downloads.cms.gov/files/cmmi/hcia2-yr3evalrpt.pdf

- 25% more likely to engage their primary care provider (PCP), and
- 20% more adherent to their medications.

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

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

4. Community Pharmacy Enhanced Services Network of United States of America (CPESN-USA)[39]

Results of the CMMI grant have informed the creation of CPESN-USA, which is made up of 1,600 pharmacies and owned by a partnership of the National Community Pharmacists Association (NCPA) and Community Care of North Carolina (CCNC). Goals are to encourage state networks of pharmacies to provide enhanced services such as MTM, adherence packing, and more, and to offer guidance on establishing value-based payment contracts. The company contains a growing network of 35 local networks in 32 different states in varying stages of implementation or pre-implementation. One example of a functional state-based network participating in CPESN, USA is CPESN-Iowa.

5. Community Pharmacy Enhanced Services Network of Iowa (CPESN-IA)

Payors: Medicare, and others

Background: CPESN-IA was the second state to join CPESN-USA after CPESN-NC. As of July 2018, CPESN-IA consists of 91 pharmacies across Iowa including independently owned, small chains, and large chains, and has a core service set that every pharmacy must agree to provide as part of the network.

Program Details: The Iowa CPESN core service set includes medication reconciliation, clinical medication synchronization, adherence packaging, immunizations, and complete medication reviews with chronic care management.

Payment Structure: CPESN-IA has local contracts with Tabula Rasa and with ClaritasPSM. For the Tabula Rasa contract, pharmacists utilize their MedWise Advisor Platform to assess patients' regimens and complete Medication Safety Reviews. The ClaritasPSM contracts with preferred pharmacies to provide enhanced services to hospice patients. Core services are available to all patients who utilize CPESN-IA pharmacies. Patients enrolled in Medicare Blue Rx Part D plan are eligible for the Tabula

[39] https://www.cpesn.com/

Rasa EMTM program. Eligible patients for ClaritasPSM are hospice patients for whom ClaritasPSM is the claims processor.

CPESN-IA is a fee-for-service payment structure with bonuses. There are 2 bonus pools - if the pharmacy reaches 50% approval on doctor recommendations and/or 70% positive patient satisfaction based on brief survey. CPESN-IA mainly focuses on patient safety. Metrics include the following: patient recognizes enhanced service based on a survey, factors that require patients to spend more time with pharmacists, reduction in emergency department visits and hospital admissions, assuring the patient is taking medication at the correct time of day, reducing medication side effects, and confirm patient is on a safe therapy regimen.

Preliminary Data: Data outcomes are not yet available.

6. Inland Empire Health Plan (IEHP) Pharmacy P4P Program[40]

Payors: Medi-Cal and Medicare

Background: In 2013, IEHP, a Medi-Cal and Medicare health plan that provides managed care for more than 1.2 million California residents, developed the IEHP Pharmacy Pay-For-Performance (P4P) Program – one of the first programs of its kind – designed to improve pharmacy services through IEHP's 450 community pharmacy providers. The main focus of the program aimed to validate the roles of community pharmacies in promoting healthcare quality and define a pharmacy payment model for outcome-based services while improving members' health, reducing costs, and increasing the plan's star rating. IEHP has a Pharmacy Quality Star Ratings system created to help IEHP members locate high-quality pharmacies based on data collected. The searchable system displays the rating of each participating pharmacy. The ratings range from 1 to 5 stars, with 5 stars being the best.

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

[40] https://ww3.iehp.org/en/providers/pharmaceutical-services/pharmacy-p4p-program
https://ww3.iehp.org/providers/?redirect=pharmserv
https://www.pharmacytoday.org/article/S1042-0991(16)00353-4/fulltext
http://www.ncmedicaljournal.com/content/78/3/188.full

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

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

7. Express Scripts Performance-based Retail Pharmacy Network[41]

The Express Scripts Performance-based Retail Pharmacy Network is a 12-month pilot launched in the fall of 2018. The pilot will examine the impact of rewarding pharmacies that fill prescriptions for Express Scripts members and demonstrate a positive improvement on individual members' medication adherence for conditions such as diabetes, hypertension, and asthma. It is designed to optimize medication therapy, improve medication adherence, and promote better outcomes. Participating pharmacies will be able to track their own performance and identify gaps in care via a web portal. For this pilot, participating plan sponsors, such as employers and health plans, will have the ability to select the four therapy classes where they would like to see an improvement in medication adherence - for example, diabetes, cholesterol, hypertension or asthma - which will be used to measure each pharmacy's performance.

8. Healthfirst of New York Program

Healthfirst, a regional payor in New York serving Medicare beneficiaries, had a pay-for-performance program for other providers, who may have the chance to see members only a few times a year. But Healthfirst quickly took note that members were going to pharmacies on a monthly basis and saw this as an opportunity to support and build upon the provider incentive.[42] A pay-for-performance program was launched for pharmacies in 2014.[43] The model is based on adherence measures, and the payment structure is a combination of payment for program commitment and for reaching performance goals.[44] While formal results have not been reported to our knowledge, Healthfirst saw benefit and extended the program another year at least until December 2016.

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[41] https://www.prnewswire.com/news-releases/express-scripts-launches-innovative-pilot-program-for-performance-based-retail-pharmacy-network-for-commercial-plans-300628608
[42] https://www.pharmacytoday.org/article/S1042-0991(16)00353-4/fulltext
[43] https://www.performrx.com/sites/default/files/Panel-Pay%20for%20Performance%20and%20the%20Changing%20Landscape%20for%20Pharmacy.pdf
[44] Ibid.

9. Caremark-Silver Script Network Performance Program[45]

SilverScript announced in 2014 the implementation of a network performance program for pharmacies serving Medicare Part D SilverScript enrollees. This program is designed to pay pharmacies for their performance in improving adherence and compliance with clinical guidelines. The goal of this type of program is to encourage better performance by rewarding higher scoring pharmacies through performance payments. The payment structure is based on a combination of payment for gap closures delivered through Mirixa and bonus on reaching performance goals[46] with bonus payments to top-performing pharmacies.[47] Quality metrics for this model are listed below, however results of this program have yet to be published.

Quality Metrics:

- Adherence to diabetes, antihypertension, and cholesterol medications
  - 70% weighting
- Appropriate drug therapy for patients with diabetes and hypertension (ACE/ARB/DRI)
  - 15% weighting
- Percent of CMS Stars drugs dispensed as extended day supply
  - 7.5% and compared to state-wide average
- Overall generic dispensing rate
  - 7.5% and compared to state-wide average

10. Humana Rx Quality Network

This pilot program launched in 2015 in Texas and Florida with a limited group of pharmacies.[48] As of 2019, the program is still in existence and focuses on the health outcomes of patient care related to medication adherence, in addition to rewarding pharmacies for medication adherence performance in targeted drug classes: diabetes, hypertension, and cholesterol. The quality-based network rewards pharmacies on performance and establishes their pharmacy in-network/preferred for PDP/MAPD plans.[49] The payment structure is as follows: $5 is withheld for each Medicare pharmacy claim and there is a $2, $6 payback opportunity for each Medicare pharmacy claim based on performance. If the pharmacy fails to hit 50th percentile of PDC (Proportion of Days Covered, a measure of medication adherence), there will be no payback. If the pharmacy hits 50th percentile of PDC, payback will be $2 of the $5 collected. If the pharmacy hits 80th percentile of PDC, payback will be the entire $5 collected plus $1, for a total payback of $6.[50] Results of this program have yet to be published.

[45] https://imedicare.com/articles/medicare-part-d-star-ratings-and-pharmacy-performance/
[46] https://www.performrx.com/sites/default/files/Panel-Pay%20for%20Performance%20and%20the%20Changing%20Landscape%20for%20Pharmacy.pdf
[47] https://www.pharmacytoday.org/article/S1042-0991(15)30339-X/fulltext
[48] https://www.performrx.com/sites/default/files/Panel-Pay%20for%20Performance%20and%20the%20Changing%20Landscape%20for%20Pharmacy.pdf
[49] https://progressivecareus.com/progressive-care-inc-subsidiary-pharmco-llc-earns-top-performance-scores-from-humana-inc/
[50] https://www.tnpharm.org/wp-content/uploads/08701_GCHJLWSEN_FlyNC_8.5x11_4C.pdf

11. HealthPartners – Partners in Excellence Program[51]

Background: As of 2018, this program is available for pharmacies dispensing at least 6,500 prescriptions for HealthPartners members in Minnesota and Iowa. The goals of this program are to:

- Promote safe, effective, timely, patient centered, equitable and efficient care
- Provide financial and public recognition to pharmacies for excellent performance, designated as gold and silver recognitions
- Reinforce: prevention, population-based care, evidence-based care, continuous improvement, and efficient care

Program Details: Pharmacies achieve performance targets based on antidepressant medication persistency, asthma medication adherence, diabetes medication adherence, and cholesterol medication – continuous persistency.[52] For the MTM program, targets are based on the percentage of members engaged in medication therapy management services.

Preliminary Results: In 2018, for antidepressant medication persistency, 2 pharmacies met gold target with at least 70% of members persistent, 3 pharmacies met silver target with at least 65% of members persistent. For asthma medication adherence, 4 pharmacies achieved gold target with at least 65% of members adherent and 2 pharmacies achieved silver status with at least 55% of members adherent. For diabetes medication adherence, 3 pharmacies achieved gold target with 90% of members adherence, 3 pharmacies achieved silver status with at least 86% of members adherent. For cholesterol medication adherence, 4 pharmacies achieved silver target with at least 62% of members persistent.

Also, HealthPartners notes, the collaborative pay-for-performance program between HealthPartners and a mid-size regional pharmacy chain resulted in **impressive outcomes for quality and affordability**, according to a 2019 report. Improvements in adherence, statin use in patients with diabetes, and blood pressure engagement were noted.[53]

Payment Structure: The payment structure for this program is based on achievement of targets. For gold target achievement, 100% of bonus pool percentage is paid, and for silver, 25% of bonus pool percentage is paid. For the MTM program, gold target achievement results in $50.00 per enrolled targeted member up to a max of $20,000, and $25 for silver with a max of $10,000. [54]

In addition to those already listed above, other payors who have started to engage in limited innovative value-based models with pharmacy include United Healthcare, SCAN, Aetna, Anthem, among others.

[51] https://www.healthpartners.com/ucm/groups/public/@hp/@public/documents/documents/entry_191059.pdf
[52] https://www.healthpartners.com/ucm/groups/public/@hp/@public/documents/documents/entry_197084.pdf
[53] https://www.healthpartners.com/ucm/groups/public/@hp/@public/documents/documents/entry_191059.pdf
[54] https://www.healthpartners.com/ucm/groups/public/@hp/@public/documents/documents/entry_197083.pdf

H. Community Pharmacy's Proven Benefit to Advance Current Quality Metrics

Pharmacists, as medication experts, are well suited to impact many quality metrics existing in federal quality programs today, as demonstrated below. And in fact, pharmacists may in some cases be best positioned to influence a certain metric given their expertise on medications, accessibility within communities, and ongoing face-to-face clinical touchpoints with patients. For example, within the MIPS and 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.[55] 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.[56]

Similarly, many APM quality metrics are dependent upon improvements affected by optimized medication use. These include metrics include controlling high blood pressure, comprehensive diabetes care, preventive care, tobacco use, and more. Furthermore, many ACOs' top priority quality metrics can be impacted by medication optimization.[57] And, using the Agency for Healthcare Research and Quality (AHRQ) National Guidelines Clearinghouse, it has been estimated that there are 79 clinical quality metrics for which pharmacists have or should have primary responsibility as the health professionals most closely involved in service delivery - many of which involve medication management, adherence, and medication safety.[58] Further, using CMS' measure inventory[59] of finalized and implemented measures, NACDS offers the following examples of metrics that pharmacists are particularly well suited to influence across a variety of programs:

[55] "Payment Methods in Outpatient Team-based Clinical Pharmacy Practice, Part 2: MACRA for Pharmacists."; American College of Clinical Pharmacy; October 2017.
[56] "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
[57] 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
[58] 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
[59] https://cmit.cms.gov/CMIT_public/ListMeasures

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

I. Summing it Up: Community Pharmacies as VBE Participants

As detailed above, community pharmacies' inclusion as VBE participants is essential to improve outcomes and control costs within our health care system. However, community pharmacy participation in VBEs is only possible if their participation in such arrangements is protected and consistent with applicable law. **As such, we recommend that in finalizing the definition of VBE participant, OIG include community pharmacies.**

In the preamble to the Proposed Rule, OIG notes that its proposal to exclude certain entities from the definition of VBE participant is based on historical enforcement and oversight experience, and in particular its concern that some of the entities proposed to be excluded might misuse the safe harbors as a means of offering remuneration to practitioners and patients to market their products, rather than as a means to create value for patients and payors by improving the coordination and management of patient care, reducing inefficiencies, or lowering health care costs.[60] OIG is also concerned that these entities might create arrangements styled as value-based arrangements in order to "tether" clinicians or patients to a particular service or product when a different service or product could be more clinically effective for the patient.[61]

We strongly support a legal framework that protects against fraud and abuse; however, community pharmacies are no more likely to be involved in arrangements involving abuse than entities OIG is not seeking to exclude. Creating categorical exclusions based on the type of entity, rather than focusing on the arrangement and appropriate safeguards, results in an overly broad approach that is likely to limit the number and type of innovative arrangements to improve care for patients. If permitted to be VBE participants, community pharmacies will be subject to the appropriate safeguards OIG has proposed under the value-based arrangement safe harbors, including appropriate monitoring of activities. **We strongly urge OIG ensure appropriate safeguards are included in the VBE safe harbors rather than creating categorical exclusions that will prevent care coordination with all appropriate healthcare stakeholders.**

[60] 84 Fed. Reg. 55703-4.
[61] 84 Fed. Reg. 55703-4.

III. Proposed Rule Section III.D: Value-Based Arrangements with Substantial Downside Financial Risk (1001.952(ff))

The proposed new safe harbor for value-based arrangements with substantial downside financial risk requires, among other standards, that the VBE assume substantial downside financial risk from a payor. In the proposed rule, OIG has proposed to define substantial downside financial risk based on specific methodologies or benchmarks, and it solicits comments on the same, including whether the proposed benchmarks should be higher or lower to ensure appropriate incentive.[62]

Based on our experience, the proposed benchmarks for substantial downside financial risk are too high. For example, under the proposed definition of substantial downside financial risk, one of the categories is that the capitated payment reflects a discount equal to at least 60 percent of the total expected fee-for-service payments. Such a proposal is unrealistic and excessive. As proposed, parties will be prohibited from taking advantage of the protections offered under the new safe harbor because they will be unable to realistically assume the definitional risk proposed. At the levels of risk proposed by OIG under this new safe harbor, whole groups of providers and entities will be practically excluded from participating in these proposed value-based arrangements. We recommend that in the final rule, the benchmarks included in the definition of substantial downside financial risk are adjusted to more realistic levels.

IV. Conclusion

Community pharmacies offer unparalleled value in improving quality and efficiency in our Nation's health care delivery system. Community pharmacies are already essential components of value-based care initiatives. Recognizing community pharmacies as VBE participants under this rule could accelerate community pharmacies' abilities to achieve even greater value to patients, payors, and other healthcare providers. Conversely, excluding community pharmacies in the final rule would likely serve as a hindrance to their participation in newer and even more innovative VBEs in the future. We urge OIG to include community pharmacies as VBE participants and to consider our additional recommendations for VBE safe harbors and appropriate downside risk.

Sincerely,

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

[62] 84 Fed. Reg. 55717.