[Submitted electronically via CMMI_NewDirection@cms.hhs.gov]

November 20, 2017

Amy Bassano, Acting Deputy Administrator for Innovation and Quality and Director, Center for Medicare & Medicaid Innovation
Arrah Tabe-Bedward, Deputy Director
U.S. Centers for Medicare & Medicaid Services
7500 Security Boulevard, Baltimore, MD 21244

Re: Centers for Medicare & Medicaid Services: Innovation Center New Direction, Request for Information (RFI)

Dear Acting Deputy Administrator Bassano:

The American Pharmacists Association (APhA), American Association of Colleges of Pharmacy (AACP), and National Alliance of State Pharmacy Associations (NASPA) appreciates the opportunity to provide feedback in response to the Centers for Medicare & Medicaid Services (CMS): Innovation Center New Direction, Request for Information (RFI).

APhA, founded in 1852 as the American Pharmaceutical Association, represents 64,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, physicians' offices, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services.

Founded in 1900, AACP is the national organization representing pharmacy education in the United States. The mission of AACP is to lead and partner with our members in advancing pharmacy education, research, scholarship, practice and service to improve societal health. AACP is comprised of all accredited colleges and schools with pharmacy degree programs accredited by the Accreditation Council for Pharmacy Education, including more than 6,400 faculty, 62,500 students enrolled in professional programs and 5,100 individuals pursuing graduate study.

NASPA, founded in 1927 as the National Council of State Pharmacy Association Executives, is dedicated to enhancing the success of state pharmacy associations in their efforts to advance the profession of pharmacy. NASPA's membership is comprised of state pharmacy associations and over 70 other stakeholder organizations. NASPA promotes leadership, sharing, learning, and policy exchange among its members and pharmacy leaders nationwide.

We are including our responses on the relevant focus areas included in the RFI: (1) Advanced Alternative Payment Models (APMs), (4) Prescription Drug, (6) State-Based and Local Innovation, including Medicaid-focused Models and (7) Mental and Behavioral Health.

Potential Models

1. Increased participation in Advanced Alternative Payment Models (APMs)

Do you have comments on the guiding principles or Expanded Opportunities for Participation in Advanced APMs?

Our organizations are supportive of the CMMI's guiding principles and refocused efforts to test new models to expand opportunities in Advanced Alternative Payment Models (APMs). We strongly believe policies that facilitate and expand pharmacists' participation in Advanced APMs will address a number of the RFI's guiding principles, including increasing choice, improving competition and facilitating patient-centered care.

As our nation continues to move towards more accountable care and outcome-based APMs, we applaud CMS's and CMMI's continued recognition of the value of pharmacists and the implementation of policies that allow for pharmacists to increase health care access and contribute to efficiencies in care delivery. Such examples include transitional care management (TCM) services, chronic care management (CCM), Part D Enhanced Medication Therapy Management (MTM) models, Comprehensive Primary Care Plus (CPC+)[1] and Transforming Clinical Practice Initiative (TCPI).

As drugs become more and more expensive, complex, and personalized, the need to optimize their impact also increases. The United States spends nearly $300 billion annually on medication-related problems, including nonadherence.[2] Consequently, in order to get the greatest benefit from medications, patients must understand how to use their medications safely and effectively. Pharmacists have more medication-related education and training than any other health care professional. Pharmacists can and do assist patients in optimizing the impact of medications and decreasing patients' overall health care costs by providing services focused on safe and appropriate medication use. For example, pharmacists provide medication management services, which are especially important for patients who have complex medication regimens and care plans, take multiple drugs from multiple prescribers, or have chronic conditions. Additionally, to address hospital readmissions, pharmacists help patients transition between care settings—a time when patients can be at increased risk of medication-related problems. Medication management services delivered by pharmacists need to be an integral part of Advanced APMs to address medications and medication-related problems, many of which are preventable.

Unfortunately, despite the fact that many states and Medicaid programs are turning to pharmacists to increase access to health care and address medication-related costs, Medicare Part B does not cover the services pharmacists can provide. While Congress and CMS have created and implemented various new care delivery models, such as Accountable Care Organizations (ACOs), to promote value and team-based care, many of these models' payment and related policies primarily rely on Fee-for-Service (FFS) statutes and definitions of qualifying providers, disincentivizing the use of pharmacists in these models. All pharmacists are educated and trained to provide a wide variety of services including medication management, chronic disease management, and preventive services. Despite ninety-one

[1] CMMI. CPC Program Year 2015. Implementation and Milestone Reporting Summary Guide. December 2014. Available at: https://innovation.cms.gov/Files/x/CPCI-ImplementationGuidePY2015.pdf
[2] New England Healthcare Institute. Thinking Outside the Pillbox: A System-Wide Approach to Improving Patient Adherence for Chronic Disease. August 2009. Available at: http://www.nehi.net/publications/17-thinking-outside-the-pillbox-a-system-wide-approach-to-improving-patient-medication-adherence-for-chronic-disease/view

percent of Americans living within five miles of a community pharmacy[3] (with extended hours allowing broad access to a health care professional), and many of our nation's seniors being medically underserved, the Medicare program fails to optimize the pharmacist's role in team-based patient care and improving patient outcomes. Pharmacists are an underutilized health care resource which can positively affect beneficiaries' care and the entire Medicare program.

The potential impact of pharmacists and their medication expertise is evident by the significant number of measures in CMS/CMMI programs related to or impacted by medications. For example, a significant number of the thirty-one required quality measures in Medicare's ACO programs are impacted by appropriate medication use. [4]

What Expanded Opportunities for Participation in Advanced APMs model designs should the Innovation Center consider that are consistent with the guiding principles?

We ask that CMMI test models that remove the statutory and regulatory barriers preventing pharmacists from participating in Advanced APMs. While pharmacists are impacting a number of quality measures, because Advanced APMs are generally built on the Medicare FFS model, these APMs are disincentivized from hiring or contracting with pharmacists, who are not named providers for participation, such as an "eligible clinician" or "ACO professional." Health care delivery can be more effective and efficient by utilizing and optimizing the skills and expertise of qualified health care providers to benefit patients. Not only will this help improve overall quality, but utilizing providers, like pharmacists, in patient care can increase health care access.

Do you have suggestions on the structure, approach, and design of potential Expanded Opportunities for Participation in Advanced APM models? Please also identify potential challenges or risks associated with any of these suggested models.

Our organizations believe that the creation of opportunities for pharmacists to directly bill Medicare under Advanced APMs, like other "eligible clinicians," under the Quality Payment Program (QPP), will facilitate the integration of pharmacists into team-based care models and Advanced APMs to increase patient access, improve choice and competition, and reduce costs.

Potential Challenges/Risks

Suboptimal and siloed health information technology (HIT) systems continue to be a barrier to the exchange of pertinent health information necessary for optimal coordination of care in various practice settings. For example, unless pharmacists are part of an integrated system or practice, pharmacists are frequently blocked from the electronic exchange of relevant clinical and billing information with other health care providers, insurers, etc. Such restrictions impede the ability of patients, the health care system and payors like Medicare, to benefit from coordinated, team-based care. Pharmacists are the most accessible health care professional and may be the only one in many communities. CMMI needs to consider innovative approaches to provide pharmacists the ability to access and exchange information through Electronic Health Records (EHRs) – essential to team-based coordinated care.

[3] NCPDP Pharmacy File, ArcGIS Census Tract File. NACDS Economics Department.
[4]RTI International. Accountable Care Organization 2017 Program Quality Measure Narrative Specifications. January 5, 2017. Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/2017-Reporting-Year-Narrative-Specifications.pdf

CMMI could test Advanced APM models that tie pharmacist access and ability to exchange information via EHRs with "eligible clinicians'" performance on quality metrics/ outcomes. This approach would ensure incentives are aligned between providers and make cooperation more meaningful between community pharmacists and eligible clinicians.

What options might exist beyond FFS and MA for paying for care delivery that incorporate price sensitivity and a consumer driven or directed focus and might be tested as a model and alternative to FFS and MA?

New health care models cannot continue to consider drug and medical coverage, and their related costs and outcomes, separately if we are to achieve true value in health care. Therefore, we recommend that CMMI models, including Advanced APMs, incorporate medications (e.g., Medicare Part D) when designing and testing models. Medications are often carved out when including them would permit better management of all aspects of a patient's care across the continuum. Pharmacists are well-positioned to manage both access to cost-effective medications and their appropriate use, in both lower and higher risk-based, models such as Advanced APMs. Breaking down the many silos within our health care system will help address that $300 billion dollars spent on medication-related problems—many of which are preventable.

As stated earlier, facilitating the incorporation of pharmacists in patient care, whether in FFS, MA or Advanced APMs, will help increase access, choice, and quality as well as address total health care cost. Models including and measuring the impact of the pharmacist need to be tested.

How can CMS further engage beneficiaries in development of Expanded Opportunities for Participation in Advanced APM models and/or participate in new models?

Our organizations suggest providing co-pay waivers for medications and services and performance incentives for patients meeting treatment goals as mechanisms to better engage beneficiaries. Additionally, patients may be more adherent to treatments if allowed to seek care from their pharmacists because he or she may be more conveniently located and accessible due to hours and availability.

We encourage CMMI's and CMS's help in the training of health care team members in being patient-centered and providing patient-centered care, as well as beneficiary education on how to engage. Not only could CMS develop resources, but CMMI could test models incorporating patient-centered principles and beneficiary education into their models.

Are there payment waivers that CMS should consider as necessary to help healthcare providers innovate care delivery as part of a model test?

Yes. CMS should waive the current restriction on recognizing/ reimbursing pharmacists as providers in Medicare, including in Part B and APMs. Additionally, our organizations recommend CMMI test the value of incentive models such as per member per month (PMPM) payments for pharmacists longitudinally managing medications for targeted patients with ties to specific quality metrics as opposed to FFS models.

Are there any other comments or suggestions related to the future direction of the Innovation Center?

Yes. Multiple studies have found evidence that pharmacist-led processes could prevent medication discrepancies and potential Adverse Drug Events (ADEs) after discharge.[5] Our organizations repeat our ask that CMMI test models which remove the statutory and regulatory barriers preventing or discouraging pharmacists' participation in Medicare and Medicaid.

In addition, it is difficult to isolate and quantify the value of pharmacists in team-based models, particularly those that are value-based. This inability to specifically attribute pharmacists' value, impedes policies encouraging their incorporation due to lack of evolving evidence or data. As the complexity and use of medications continues to increase, so will the role proper medication management plays in APMs and health care generally. Consequently, recognizing the unique and essential contributions of pharmacists, the medication experts on the health care team, is fundamental to assisting CMS to meet its goals of improving the quality of care and reducing costs.[6] Therefore, our organizations strongly urge CMMI and CMS to seek mechanisms for appropriate attribution and recognition of pharmacists' services in new models as well as identify appropriate quality measures and payment codes for those services.

CMMI also needs to review provider reporting and other administrative requirements related to participation in Medicare. While we are supportive of the movement to value-based care, the burden being placed on providers with regard to Medicare participation, including quality and other metric measurement and reporting, should not be overlooked or minimized. We urge CMMI and CMS to assess the impact of measurement and reporting requirements on providers, including whether it takes away from patient care, and how to make them more efficient and effective. CMMI could also create Requests for Proposals (RFPs) on research from quality measurement organizations, such as the Pharmacy Quality Alliance (PQA), to determine which metrics are most consequential to improving outcomes in order to create a set of core evidence-based medication measures that significantly impact value. In addition, CMMI and CMS should address technology requirements that limit providers' ability to provide comprehensive patient care, such as barriers for all practitioners (including pharmacists seeking information on patient history, diagnoses, laboratory values, etc.) to EHRs.

4. Prescription Drug Models

When considering new delivery models and reforms, it's important to look beyond isolated components of health care. Because health coverage is frequently analyzed by the benefit type such as inpatient, outpatient, and drug coverage, a patient's overall services, costs and outcomes may never be reviewed comprehensively. Policies cannot continue to consider drug and medical coverage, and their related costs and outcomes, separately if we are to achieve true value in health care. Current coverage and payment policies related to prescription drugs place incentives on the short-term, focusing on cost containment for the product rather than weighing the overall clinical benefit to the patient and the

[5] See Kilcup, M. Et. al. Postdischarge pharmacist medication reconciliation: impact on readmission rates and financial savings. *Journal of the American Pharmacists Association.* 2003. 2013 Jan-Feb; 53(1). Available at: http://www.ncbi.nlm.nih.gov/pubmed/23636160. *See* Mueller, SK. Et.al. Hospital-based medication reconciliation practices: a systematic review. Arch Intern Med. 2012;172:1057-1069. Available at: https://psnet.ahrq.gov/resources/resource/24689. Also, See Shekelle, PG. Et al. Making Health Care Safer II: An Updated Critical Analysis of the Evidence for Patient Safety Practices. Rockville, MD: Agency for Healthcare Research and Quality; March 2013. AHRQ Publication No. 13-E001-EF. Available at: https://psnet.ahrq.gov/resources/resource/25758

[6] HHS. National Strategy for Quality Improvement in Health Care. Report to Congress. Agency for Healthcare Research and Quality (AHRQ). March 2011. Available at: http://www.ahrq.gov/workingforquality/nqs/nqs2011annlrpt.pdf

impact to their medical costs. Breaking down the many silos within our health care system, and integrating care with pharmacists, the medication experts on the team, will help address the $300 billion dollars spent on medication-related problems—many of which are preventable. In 2012, the Congressional Budget Office (CBO) published a guidance document with its estimate that increased use of prescription drugs lowers overall medical cost: specifically, every 1.0 percent increase in the number of prescriptions filled by Medicare beneficiaries leads to a net decrease in medical spending of 0.2 percent.[7] When evaluating broader pharmacist patient care services as a whole, up to $4 in benefits is expected for every $1 invested.[8]

As CMMI considers alternative prescription models we ask CMMI to study the impact of certain Medicare prescription drug plans' practices have on patients and the program as a whole – Direct and Indirect Remuneration (DIR) fees, narrow networks and limited distribution. CMS has acknowledged a notable growth in DIR fees, which have more than tripled in recent years.[9] DIR fees are imposed by Medicare Part D plan sponsors and their pharmacy benefit managers (PBMs) to retroactively reduce payment submitted by pharmacies. Originally designed to capture rebates and other mechanisms not included at the point-of-sale, these fees are now being used beyond their original purpose to retroactively adjust pharmacies' payment months after the sale, sometimes below the price paid by the pharmacy. Moreover, DIR fees do not positively impact what patients pay, but rather increase the point-of-sale price, which can result in the beneficiary paying more because the patient's cost-sharing may be based on sales prices.

The inability of a pharmacy to enter into contracts with health plans (i.e., narrow networks) has been a growing problem facing pharmacists. Our organizations believe there is a need for Part D plans to be required to contract with any pharmacy willing to accept their contractual terms and conditions. Increasing patient choice will not only improve patients' access to benefits and services, but will likely positively impact patient satisfaction and outcomes, such as adherence. A related issue is limited distribution of some medications. As more costly and complex medications are being developed, some manufacturers, clinics, practitioners' offices and pharmacies have entered into contracts that effectively limit the distribution of certain medications. To address these issues, our organizations encourage CMMI to examine the impact the policies are having on patients' access, outcomes and satisfaction as well as the impact they have on the Medicare program overall and CMS oversight due to the lack of transparency.

6. State-Based and Local Innovation, including Medicaid-focused Models

What Expanded Opportunities for State-Based and Local Innovation, including Medicaid-focused Models should the Innovation Center consider that are consistent with the guiding principles?

Our organizations strongly recommend that CMMI focus on expanding state-based and local innovations that recognize pharmacists as providers and value pharmacists' services in addressing unmet health needs. These services align with patient-centered care and could increase the amount of

[7] CBO. Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services. November 2012. Available at: http://www.cbo.gov/sites/default/files/cbofiles/attachments/43741-MedicalOffsets-11-29-12.pdf
[8] Schumock GT, Butler MG, Meek PD, et al. Evidence of the economic benefit of clinical pharmacy services: 1996-2000. Pharmacotherapy. 2003;23(1):113-132. : 116. Available at: https://www.accp.com/docs/positions/positionStatements/pos029.pdf : Perez A, Doloresco F, Hoffman JM, et al. ACCP: economic evaluations of clinical pharmacy services: 2001-2005. Pharmacotherapy. 2009;29(1):128. Available at: https://www.accp.com/docs/positions/whitePapers/EconEvalClinPharmSvcsFinalkjsedit-gts.pdf
[9] See, Wakely Consulting Group analysis of S. 413/H.R. 1038. 2017. Available at: http://www.ncpa.co/pdf/wakely-report.pdf

provider choices for Medicare/ Medicaid beneficiaries available in the marketplace. In January 2017, the Center for Medicaid and CHIP Services (CMCS) recommended that states use their 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.[10] We recommend CMMI consider testing for scalability several payment and delivery models outlined below, which have lowered overall patient costs and increased patients' access to health care by successfully engaging pharmacists. Our organizations welcome the opportunity for a face-to-face meeting to share specific information with CMMI and CMS on our own internal analyses of how and where pharmacists can contribute to these new models. We would include pharmacists who are practicing in these models and working with physicians and other eligible clinicians to influence quality and outcomes to share their experiences, successes, and impacts with CMMI and CMS.

Do you have suggestions on the structure, approach, and design of State-Based and Local Innovation, including Medicaid-focused Models? Please also identify potential challenges or risks associated with any of these suggested models.

Expanding Sustainable Community Pharmacy Care Management

Given the accessibility of community pharmacies and the medication expertise of pharmacists, our organizations request that CMS/CMMI test and evaluate for scalability a community pharmacy care management service that effectively integrates electronic health record (EHR) capability using a pharmacist e-care plan.[11] Community pharmacists' enhanced patient care services can contribute to optimizing medication use and improving health outcomes, yet lack a financially viable incentive model to sustain this practice. Community pharmacists are in an excellent position to review and monitor all of the medications a patient is taking across all providers and work with providers to optimize medication use. However, community pharmacists experience significant access barriers to clinical information needed to care for patients, and facilitating scalable EHR integration for sharing of information amongst pharmacies, physicians and other providers, payors and others would address an important barrier to optimal care of patients.

Community pharmacy care management is a "whole patient" approach to addressing patients' medication-related needs, including accounting for social determinants of health that impact appropriate medication use. Various pharmacy staff, including pharmacy technicians, can be leveraged to assist the pharmacist(s) in patient management. Instead of a focus on an individual prescription, the pharmacist would be incentivized to monitor the patients' medications on an ongoing basis, including during care transitions. The services provided by pharmacists would be supported by functional EHR infrastructure, measured using targeted quality metrics, and incentivized through value-based payment. Care would be coordinated with other members of the patient's health care team as needed. A coordinated mechanism to monitor patients would be provided through the Appointment-Based Model[12] (includes medication synchronization with a specific proactive outreach to the patient/caregiver prior to each visit to the pharmacy). The pharmacist would submit the pharmacist

[10] CMS. CMCS Informational Bulletin. 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 17, 2017, *available at:* https://www.medicaid.gov/federal-policy-guidance/downloads/cib011717.pdf
[11] See, Pharmacist eCare Plan. HealthIT.gov Available at: https://www.healthit.gov/techlab/ipg/node/4/submission/1376
[12] See, APhA Foundation's "PHARMACY'S APPOINTMENT BASED MODEL (ABM)." August 30, 2013. Available at: https://www.aphafoundation.org/appointment-based-model

eCare plan to facilitate measurement of the value of services provided. The following factors provide a framework for the service:

- Target audience: pharmacists practicing in community pharmacies under their respective state scope of practice
- Target patient population: patients with chronic condition(s) that are medication-centric
- Care delivery: face-to-face and telephonic/telehealth
- Credentials: minimum registered pharmacist; additional training requirements depending on the service
- Potential services included in community pharmacy care management:
    - Appointment-based model
    - Medication reviews and monitoring
    - Medication adherence services
    - Medication education
    - Care transitions services
    - Chronic condition monitoring where medications are used (e.g., diabetes, cardiovascular disease, respiratory health, pain management, medication assisted treatment (MAT))
    - Behavioral health – medication monitoring/adherence to antipsychotic/antidepressant medications
- Payment: consider a PMPM, FFS with incentives to meet quality metrics, or a FFS with a shared savings component to the pharmacist/pharmacy
- Infrastructure: EHR capability, use of Pharmacist eCare Plan
- Quality metrics (depending on the service)
    - Medication adherence
    - Clinical metrics depending on the disease or condition
    - Patient satisfaction/patient engagement
    - Provider satisfaction
    - Impact on total cost of care (medications and medical care including hospitalizations)
    - Uptake of EHR capability
        - Ability to generate an eCare Plan
        - Ability to receive clinical information (patient goals, diagnoses, laboratory values, etc.)
        - Ability to exchange eCare plan with other providers/payors

Specific examples of current programs that utilize some or all of the features of the proposed community pharmacy care management program and could be scaled more broadly include:

- The Pennsylvania Pharmacist Care Network, which is currently contracted with Gateway Health, a Medicaid Managed Care organization, for their network of pharmacists to provide services to Medicaid members that have at least one chronic medication filled at a network pharmacy. Patients are eligible for a medication review and up to 6 follow-up appointments. Over 80 pharmacies are participating statewide. Payment is tied to 16 Healthcare Effectiveness Data and Information Set (HEDIS) measures. Pharmacists in the network

document in an EHR-compliant pharmacist eCare plan and submit their care plans for payment utilizing the STRAND platform from Creative Pharmacist.[13]
Patient Care Numbers:

- 66 pharmacies participating in 1st month of payor contract – 23 more to join.
- 110 patients cared for as of September 30, 2017.
- 82% of pharmacies have seen at least 1 patient in the 1st month.
- Opportunity to care for over 10,000 patients.

More specific data points will be available in January, 2018.

- The Wellmark Value-based Pharmacy Program in Iowa and South Dakota, which has a goal of measuring, recognizing and rewarding pharmacists' management of patients with chronic conditions for improved health care and lower costs. The focus of this project is on actual patient outcomes (total cost of care, preventable hospital admissions and emergency department visits) and selected clinical metrics that focus on appropriate medication management activities in patients with certain chronic medical conditions (e.g., appropriate statin dosing intensity to reduced cardiovascular risk, appropriate use of controller therapy in patients with asthma, and ensuring adherence with selected therapeutic categories). It also includes improved access to information by pharmacists and collaboration between members of health care teams.

  The network involves a 60+ performance network of pharmacies and approximately 50,000 patients. Included patients must have a chronic condition and/ or be on a chronic medication with a focus on frequent use of emergency departments. Chronic conditions included are hyperlipidemia, diabetes, depression or asthma.

  Results for a time-period from May 2016-April 2017, which could be considered baseline, compared high performance network pharmacies with Iowa and South Dakota pharmacies not in the network.

  Results to Date:

  - 1.7% decrease in total cost of care.
  - 11.6% decrease in potentially preventable hospital admissions.
  - 3.7% decrease in potentially preventable emergency department visits.

  This project is an extension of an initial pilot project of Wellmark with one community pharmacy in Iowa that focused on continuous medication monitoring and demonstrated significantly lower costs of care and better medication adherence.[14]

[13] Please, reference the attached poster (.PDF). Early Implementation of the Pennsylvania Pharmacists Care Network Initial Payor Contract. October 2017. McGivney MS1,2, Kozminski M1,2, Coley K1, Antinopoulos B1,2, Carroll J1, Leon N2,3, Pope D4, Berenbrok L1, Epple P2. 1. University of Pittsburgh School of Pharmacy; 2. Pennsylvania Pharmacists Association; 3. Jefferson College of Pharmacy; 4. Creative Pharmacist.
[14] William R. Doucette, Randal P. McDonough, Fischer Herald, Amber Goedken, Jenn Funk, Michael J. Deninger. Pharmacy performance while providing continuous medication monitoring. JAPhA. November–December, 2017. Volume 57, Issue 6, Pages 692–697. Available at: http://www.japha.org/article/S1544-3191(17)30788-4/pdf

- The North Carolina Community Pharmacy Enhanced Services Network (CPESN) is part of a 3-year grant funded by CMMI to test new reimbursement models for community pharmacies serving Medicaid, Medicare, dually eligible, and NC Health Choice beneficiaries. There are 272 pharmacies participating, and pharmacists and support staff manage risk-stratified patients and are paid using a PMPM payment model based on patients' risk scores and performance on 11 quality metrics. Pharmacists submit pharmacist eCare plans that are EHR compliant for payment.

  Early Results:

  - Early results suggest a 4%–5% increase in medication adherence over time (since 2015) among patients working with CPESN pharmacies (unpublished data).[15]
  - Patients that did not have a "pharmacy home" – a community pharmacy where they regularly fill prescriptions – were 20-25% more likely to be hospitalized in the ensuing year.[16]
  - The CPESN team performed a panel across all community pharmacies in North Carolina, where the attribution criteria included patients who had filled at least one chronic medication within the last 90 days, and with 80% or more of their fills/refills at a single pharmacy. A patient's likelihood of falling out of that panel – meaning that switched pharmacies or didn't refill their prescription – was up to four times greater in pharmacies that didn't provide enhanced services.[17]

Challenges/Risks

- It is likely networks of pharmacies/pharmacists will be necessary to deliver these services, which is not easy to accomplish unless it is done under a coordinated effort. While many states are developing networks through CPESN and other models, not all are. The maturity of the network will be an important factor in carrying out the services and related infrastructure.
- How patients are targeted for services would still need to be determined and the similarities between the programs outlined above could be informative in this process.
- Training may be necessary regarding managing a population of patients and also for specific services, especially those related to chronic care management.
- Implementation of the EHR requirements and ability to exchange information may be a barrier due to costs and data sharing challenges between pharmacists and other providers.

Expanding Access to Care through the ECHO Model Using Pharmacists

Project ECHO (Extension for Community Healthcare Outcomes) is a guided practice model that enhances medical education and increases workforce capacity to provide specialty care and reduce health disparities using successful, evidence based practices. The heart of the ECHO model™ is its hub-and-spoke knowledge-sharing networks, led by expert teams who use multi-point videoconferencing to

[15] Ronald E. Gaskins. Innovating Medicaid. The North Carolina Experience. North Carolina Medical Journal. January-February 2017. vol. 78 no. 1 20-24. Available at: http://www.ncmedicaljournal.com/content/78/1/20.full
[16] AHRMM. Pharmacies Focused on Patients Instead of Prescriptions: the Community Pharmacy Enhanced Services Network. Case Study. July 24, 2017. Available at: http://www.ahrmm.org/knowledge-center/resources/case-study/ccnc-enhanced-services-network-case-study-2017
[17] Ibid.

conduct virtual clinics with community providers. This model allows local providers to learn to provide specialty care to patients in their own communities.[18] The mission of Project ECHO is to develop the capacity to safely and effectively treat chronic, common and complex diseases in rural and underserved areas, and to monitor outcomes of this treatment.

In late 2016, Congress passed the *Expanding Capacity for Health Outcomes* or *ECHO* Act directing the U.S. Department of Health and Human Services (HHS) to examine technology-enabled collaborative learning and capacity building models and issue a report within 2 years.[19] Currently, Project ECHO focuses on 65 diseases and conditions in 23 countries using a hub-and-spoke approach. Specialists train primary care providers using a case-based telehealth approach in a series of sessions. Pharmacists serve as faculty trainers in some ECHO hubs and can also participate in the training as a primary care provider.

Our organizations encourage CMS/CMMI to test and evaluate payment models supporting sustainable mechanisms for pharmacists to contribute their medication expertise to primary care service delivery that is enhanced through participation in specific Project ECHO programs. Various Project ECHO programs are available for pharmacists' participation, and combining an evidence-based training model (Project ECHO) with a payment mechanism, would expand access to care, especially in underserved areas.

- Target audience: pharmacists practicing in community health centers, community pharmacies, and telehealth practices under their respective state scope of practice who also participate in specific Project ECHO programs
- Target patient population: patients with chronic condition(s) that are medication-centric and whose condition(s) is included in a Project ECHO program who live in health professional shortage areas, medically underserved areas or who are medically underserved populations
- Care delivery: face-to-face or telehealth
- Education/training: required pharmacist participation in the relevant Project Echo program
- Potential Project ECHO programs that could benefit from pharmacists' expertise:
    - Antimicrobial stewardship
    - Chronic pain and opioid management
    - Complex care
    - Endocrinology (specific focus on diabetes)
    - Hepatitis C community
    - Opioid addiction
- Payment: consider a PMPM, FFS with incentives to meet quality metrics, or a FFS with a shared savings component to the pharmacist/pharmacy
- Quality metrics: increased access (measured by visits, etc.), medication adherence, clinical metrics depending on the disease or condition, patient satisfaction, patient engagement, provider satisfaction, impact on total cost of care (could also focus on total medication cost)

[18] See, https://pharmacy.unm.edu/clinical-innovation-practice/patient-care-services/project-echo.html. Also, See, https://echo.unm.edu/
[19] See, https://www.congress.gov/bill/114th-congress/senate-bill/2873/text?overview=closed

Challenges/Risks

- A systematic approach would have to be created that would tie payment to participation in a Project ECHO program.
- Need to resolve if a network of pharmacists/pharmacies is necessary.
- How patients are targeted for services would still need to be determined.
- Training may be necessary regarding managing a population of patients.
- Need to decide the method of sharing information with payors and other providers. This project could include an EHR requirement with the ability to exchange information as described in the previous project, although there could be barriers due to costs and data sharing challenges between pharmacists and other providers.

Given that ninety-one percent of Americans live within five miles of community pharmacy and pharmacists also practice in physician office practices, clinics, health systems, long term care facilities, federally qualified community health centers, and other federal facilities, our organizations believe further inclusion of pharmacists in state-based and local innovation will be impactful for patients and the system. Our organizations welcome the opportunity for a face-to-face meeting to share specific information with CMMI and CMS on our own internal analyses of how and where pharmacists can contribute to these new models. We would include pharmacists who are practicing in these models and working with physicians and other eligible clinicians to influence quality and outcomes to share their experiences, successes, and impacts with CMMI and CMS.

7. Mental and Behavioral Health Models

New delivery and payment models open up opportunities to better integrate mental health and primary care, which is much needed. Due to their medication expertise, ability to coordinate medications amongst different providers, and accessibility, pharmacists are well-poised to improve this integration. Pharmacists are already providing chronic care management (CCM) and transitional care management (TCM) for Medicare beneficiaries, which could be expanded to behavioral health. The importance of medications, is often overlooked, and no other health care professional is more knowledgeable about medications than pharmacists. Given that the cost of mental health treatment is expected to total $280.5 billion in 2020, and that State Medicaid programs will bear the brunt of the costs, where "average outlays were four times as high as those for beneficiaries with a diagnosed mental health disorder ($13,303 vs. $3,564)," [20] there is reason to integrate more pharmacist-provided care into the system. Accordingly, our organizations recommend CMS/CMMI test and evaluate for scalability a community pharmacy care management service that effectively integrates electronic health record (EHR) capability using a pharmacist e-care plan that includes pharmacist-provided services for behavioral health – medication monitoring/adherence to antipsychotic/antidepressant medications. CMMI can reference our previous comments to this RFI on the Wellmark Value-based Pharmacy Program in Iowa and South Dakota that focuses on patient outcomes (total cost of care, preventable hospital admissions and emergency department visits) for monitoring medications used to treating mental health conditions and could also include depression screening and referral services. In addition,

[20] Haiden A. Huskamp, Ph.D., and John K. Iglehart. Mental Health and Substance-Use Reforms — Milestones Reached, Challenges Ahead. N Engl J Med 2016; 375:688-695. August 18, 2016. Available at: http://www.nejm.org/doi/full/10.1056/NEJMhpr1601861. Also, *See* Medicaid and CHIP Payment and Access Commission (MACPAC). Report to Congress on Medicaid and CHIP. Chapter 4: Behavioral Health in the Medicaid Program—People, Use, and Expenditures. Page 94. June 2015. Available at: https://www.macpac.gov/wp-content/uploads/2015/06/June-2015-Report-to-Congress-on-Medicaid-andCHIP.pdf.

the Pennsylvania Pharmacist Care Network, mentioned in our earlier comments, ties 7 HEDIS measures related to behavioral health care to pharmacist payment.[21]

We also encourage CMS/CMMI to test models that incorporate specialty pharmacists into mental health/substance use disorder clinics/physician office practices using a team-based care approach. These pharmacists are equipped to manage complex patients who often have both mental health and other chronic conditions that result in highly complex medication regimens spanning multiple prescribers. We recommend testing a medication management fee such as a PMPM for targeted patients and tied to specific quality metrics for comprehensive care delivered by pharmacists. Research on an existing model produced an estimated total net cost savings of $90,484.00, with a mean savings of $586.55/patient (for every $1 spent on providing the service, $2.80 was estimated to be saved).[22] Our organizations would welcome the opportunity for a face-to-face meeting to share specific information with CMS on our own internal analyses on how and where pharmacists can contribute to these new models to integrate mental and behavioral health with primary care. We would include pharmacists in this meeting who are practicing in these models and working with physicians and other eligible clinicians to influence quality and outcomes measures to share their experiences, successes, and impacts.

Thank you for the opportunity to comment on the RFI. Our organizations look forward to working with CMMI to implement the above recommendations. If you have any questions or require additional information, please contact Michael Baxter, Director of Regulatory Affairs, at mbaxter@aphanet.org or by phone at (202) 429-7538.

Sincerely,

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cc: The Honorable Seema Verma, Administrator, CMS

[21] Behavioral health related HEDIS measures, include: Adherence to antipsychotic medications for individuals with schizophrenia; Diabetes monitoring for people with diabetes and schizophrenia; Diabetes screening for people with schizophrenia or bipolar disorder who are using antipsychotic Medications; Cardiovascular monitoring for people with cardiovascular disease and schizophrenia; Metabolic monitoring for children and adolescents on antipsychotics; Use of multiple concurrent antipsychotics in children and adolescents; and Antidepressant medication management.

[22] Cobb, C.D. (2014). Optimizing medication use with a pharmacist-provided comprehensive medication management service for patients with psychiatric disorders. *Pharmacotherapy, 34*(12), 1336-40. Available at: https://www.ncbi.nlm.nih.gov/pubmed/25329409