



American Pharmacists Association[®]

Improving medication use. Advancing patient care.

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[Submitted electronically to chronic_care@finance.senate.gov]

Senate Committee on Finance
Chronic Care Working Group

RE: Chronic Care Working Group Policy Options Document

Dear Senators Hatch, Wyden, Isakson & Warner:

The American Pharmacists Association (“APhA”) appreciates the opportunity to provide our perspective on the Senate Committee on Finance’s Chronic Care Working Group’s (“Working Group”) policy options document. APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 62,000 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.

APhA is committed to working with the Senate Committee on Finance, including the Committee’s Chronic Care Working Group, and other health professionals and stakeholders to identify policy options to improve care for the millions of Americans managing chronic illness. We believe solutions will require the unified efforts of many diverse stakeholders, including health care professionals, patients and caregivers, community-based organizations, and federal, state, and local governments. Thus, we appreciate the Working Group’s decision to seek public comment regarding policy options.

Because medications play such an important role in the treatment of chronic conditions, pharmacists are well positioned to play an important role in optimizing medications, including promoting safe and effective medication use. Below we have highlighted our suggestions on policy options addressing the following requested topics: receiving quality care in the home, advancing team-based care, innovation and technology, identifying the chronically ill population and ways to improve quality, advancing care delivery in ACO models, empower individuals and caregivers in care delivery, advancing care delivery in accountable care organizations, prediabetes education, and other policies to improve care.

I. Receiving Quality Care in the Home

a. Policy option: Expanding the Independence at Home (IAH) Model of Care

As a long-time advocate for team-based approaches to care, APhA encourages expanding the IAH model into a permanent, nationwide program. Not only does the IAH program focus on enhancing team-based care, the program has demonstrated improved outcomes and cost savings. Primary care teams that include pharmacists consistently report savings, in addition to achieving results, such as improving medication adherence, clinical outcomes, patient understanding and satisfaction, and quality-of-life.^{1,2,3,4} While APhA supports expanding the model, we believe that there should be a greater emphasis on including pharmacists on care teams given their value to patients and demonstrated savings.

Pharmacists' medication-related expertise, helps meet pay-for performance measures, and prevent hospital readmissions.⁵ For example, a pharmacist on the team of the Virginia Commonwealth University House Calls Program, part of the Mid-Atlantic Consortium, performs services such as medication reconciliation to identify drug interactions and other drug therapy problems, educates patients about their medications, works with patients to remove unnecessary medications in the home, and provides complex chronic disease management consultations. The pharmacist also meets with other clinic team members to discuss patient progress. This example highlights the importance that pharmacists' medication-related expertise brings to team-based care and why pharmacists should be included on teams in the IAH and other government-sponsored programs.

APhA suggests that there be greater promotion of the IAH program to increase participation by providers and patients. In addition, provider participation can be increased through the development of a mechanism to connect health care providers, such as pharmacists, interested in participating in the IAH Model of Care.

II. Advancing Team-Based Care

a. Policy option: Improving care management services for individuals with multiple chronic conditions

(i) *Establishing a new high-severity chronic care management code*

¹ See, Chisholm-Burns, M.A., Kim Lee, J., Spivey, C.A., Slack, M., Herrier, R.N., Hall-Lipsy, E., Graff Zivin, J., Abraham, I., Palmer, J., Martin, J.R., Kramer, S.S. & Wunz T. (2010). US Pharmacists' Effect as Team Members on Patient Care: Systematic Review and Meta-Analyses, *Medical Care*, 48(1), 923-933.

² See also, Hunt, J.S., Siemienczuk, Pape G., Rozenfeld, Y., MacKay J., LeBlanc, B.H. & Touchette, D. (2008). A Randomized Controlled Trial of Team-Based Care: Impact of Physician-Pharmacist Collaboration on Uncontrolled Hypertension, *Journal of General Internal Medicine*, 23(12). 1966-1972.

³ See also, Carter, B.L., Rogers, M., Daly, J., Shimin, Z., & James, P.A. (2009). The Potency of Team-Based Care Interventions for Hypertension, *Journal of the American Medical Association: Internal Medicine*, 169(10), 1748-1755.

⁴ See also, DeBar, L.L., Kindler, L., Keefe, F.J. Green, C.A., Smith, D.H., Deyo, R.A., Ames, K. & Feldstein, A. (2012). A primary care-based interdisciplinary team approach to the treatment of chronic pain utilizing a pragmatic clinical trials framework, *Translational Behavioral Medicine*, 2(4), 523-530.

⁵ See, Avalere Health (2014) *Few Medicare Beneficiaries Receive Comprehensive Medication Review Services*. Available at: http://avalere-health-production.s3.amazonaws.com/uploads/pdfs/1408370417_20140807_MTM_Part_D_Release.pdf. Last accessed: January 24, 2016, finding that while 25 percent of beneficiaries are eligible for MTM, only 11 percent of all Part D enrollees were part of a MTM program in 2012.

APhA appreciates the Working Group's willingness to accept feedback as it considers establishing a new high-severity chronic care management (CCM) code that clinicians could bill under the Physician Fee Schedule. APhA supports additional coding for CCM services that more accurately depict the complexity of the service provided. Additional severity code(s) could help better stratify, document, and account for the costs related to the services delivered. Since CMS's Physician Fee Schedule rule for 2015 relaxed some of the requirements around incident to billing for CCM, medical practices are now able to bill Medicare for CCM services provided by a pharmacist or other nonphysician personnel under general vs. direct supervision. It is important that the Working Group remember and specifically recognize pharmacists in addition to the other practice team members when developing chronic care policy⁶ because of the importance and value that pharmacists and their medication-related expertise bring to the delivery of CCM and other chronic care services.

The new flexibility of incident to billing for CCM facilitates participation of pharmacists working in physician office practices, community pharmacies or consulting practices. Pharmacists' involvement in the provision of coordinated, team-based care, such as in the management of chronic conditions and the medications associated with them, expands access to CCM and other needed services. When providing CCM services, APhA's members indicate that they provide 25-30 minutes of non-face-to-face CCM services per beneficiary per month. Because some patients with complex conditions require significantly more time per month, APhA supports the idea of developing new severity code(s) that adequately account for the level of services required to manage beneficiaries with complex multiple chronic conditions or new time-based code that can be added to account for the additional time required to care for and treat complex patients.

APhA members expressed concern that the high-severity code's proposed eligibility criteria of 5 or more chronic conditions may not accurately capture the patients most in need of higher intensity CCM services. According to the Working Group's document, the reason this policy is being considered is because the current structure may be insufficient to capture the time needed for a clinician to manage a complex patient's care. Patients may need more CCM services due to a variety of factors, such as disease severity, the types of diseases, language barriers, demographic factors and cost (e.g. risk of hospital readmission). Consequently, we recommend using proven risk stratification methods already in practice, such as the Centers for Medicare & Medicaid Services (CMS)-Hierarchical Conditions Category (HCC) Risk Adjustment Model, to identify patients for high-severity CCM services. For risk stratification to work, diagnoses must be correctly documented, thus efforts to better capture correct documentation of diagnoses are needed.

(ii) Providers allowed to bill for CCM services

Pharmacists are highly trained health care professionals whose services are integral to improving patient health. Pharmacists help patients by managing medications, monitoring chronic conditions and improving overall health and wellness. In fact, studies show the quality of care provided and health outcomes achieved are better when pharmacists are a member of a patient's health care team.

APhA believes that mechanisms should be created to allow for better use of providers in team-based care by establishing payment mechanisms to account for the contributions of team members providing CCM services, including pharmacists. Given that in some practices large percentages (up to

⁶ See, Senate Finance Committee, Chronic Care Working Group Policy Options Document (2015), 11, not including pharmacists in the list of potential team members, "Managing multiple chronic conditions requires increased levels of patient and provider interaction beyond the typical in-person visit that often includes practice team members such as social workers, dieticians, nurses, and behavioral health specialists."

80% in one practice) of CCM services are medication-related and that pharmacists are medication experts, allowing pharmacists to directly bill CCM services that are coordinated with providers on the patient's team, rather than requiring incident to billing for services, , will improve patient access to these services.

(iii) Instituting a new code

APhA recommends basing reimbursement for CCM services on the time and complexity of the care delivered. APhA is supportive of mechanisms to account for the cost of care for patients with multiple chronic diseases whose care needs are often complex and require the coordination of care by multiple providers, which is resource- and time-intensive. However, risk stratification and other strategies for identifying patients in need of a specific service are still evolving so APhA recommends allowing for flexibility in making changes to these codes as well as continuing their evaluation. Additionally, APhA is also aware that designating codes as temporary may prevent providers and practices from investing in and making the infrastructure changes necessary to provide CCM services for fear the service is not viable in the long-term. APhA supports giving the Secretary of Health and Human Services authority to continue, discontinue, or modify the code based on effectiveness, feedback, code utilization, and other factors.

b. Policy option: Addressing the Need for Behavioral Health among Chronically Ill Beneficiaries

APhA supports the proposal for the Government Accountability Office (GAO) to conduct a study on the current status of the integration of behavioral health and primary care among private sector Accountable Care Organizations (ACOs), public sector ACOs, and ACOs participating in the Medicare Shared Savings Program (MSSP), as well as private and public sector medical homes. Depression is common among people who have many chronic illnesses, including diabetes, cardiovascular disease, stroke, and Parkinson's Disease. People with depression are at risk for other chronic illnesses.⁷ Also, pain is commonly experienced in individuals with chronic illnesses, and there is a strong link between chronic pain and depression. As the policy options related to comprehensively integrating care are considered, it is important that the Working Group include chronic pain in any study because of the legitimate need of patients with chronic illness to have access to appropriate and effective chronic pain treatment.

III. Identifying the Chronically Ill Population and Ways to Improve Quality

a. Policy option: Increasing beneficiaries' participation in and access to chronic care management services

APhA appreciates that the Working Group has suggested waiving the beneficiary co-payment associated with the current chronic care management code. Many of our members stated that patients are less inclined to utilize CCM services because the copayment presents a financial barrier. Given the importance of CCM and its benefit to patients' long-term health and the Working Group's goal to

⁷ See, National Institute of Mental Health, *Clinical Illness and Mental Health: Recognizing and Treating Depression*, NIH Publication No. 15-MH-8015. Available at: http://www.nimh.nih.gov/health/publications/chronic-illness-mental-health-2015/nih-15-mh-8015_151898.pdf. Last accessed: January 24, 2016.

increase utilization, we encourage the Working Group to also consider other factors that may be limiting utilization, in addition to the patient copayment.

Our members have indicated that the consenting process, which occurs as part of a patient visit, can be quite onerous, limiting beneficiary use of CCM services. Finding the time during a health care visit to fully educate and obtain a patient's consent for CCM services can be very difficult, especially given the amount of information that must be exchanged before CCM services can be provided. If a beneficiary does not fully understand a service (particularly one that carries a copayment), he or she is less likely to utilize it, despite possible benefits. For example, the utilization rates for medication therapy management (MTM) programs remain extremely low due in part to a lack of beneficiary awareness and the corresponding skepticism beneficiaries exhibit toward services that they do not understand.⁸

Members expressed that the number of providers participating in CCM services may be lower due to the complex rules dictating how physicians' offices are to bill for CCM services, and onerous health information technology requirements are also barriers to uptake of CCM. Thus, to encourage overall uptake of CCM, we suggest targeting resources not only toward evaluating and removing barriers related to beneficiary participation in CCM services (e.g. lack of awareness, co-pay) but include resources and effort focused on barriers related to provider participation.

b. Policy option: Developing quality measures for chronic conditions

APhA strongly supports the use of quality metrics that target the unique needs of individuals with chronic diseases, including outcomes, patient experience, care coordination, and appropriate use of services' measures. APhA recommends the Institute of Medicine's Vital Signs: Core Metrics for Health and Health Care Progress as a framework for identifying quality metrics for chronic conditions.⁹ Pharmacists contribute to meeting quality metrics by engaging the patient in appropriate self-management of medications; coordinating care with other providers, including sharing goals of therapy to best achieve outcomes of collaborative team-based care; and contributing to optimal health and medication outcomes. Because medications are integral to the treatment of chronic conditions, metrics focused on appropriate medication use across the general categories raised by the Finance Committee should be considered in the quality measures plan.

Currently, the Pharmacy Quality Alliance (PQA), of which APhA is an active member, is examining medication-related patient reported outcomes (PROs) measures and patient reported outcomes performance measures (PRO-PMs). PQA would be an excellent resource in any quality-related initiative. PQA is a consensus-based measure developer with over 175 member organizations representing a diverse group of stakeholders that develop measures to meet identified measure gaps. PQA's measures are included in multiple federal performance programs, including Medicare Part C and D Star Ratings. Many of the measures PQA is currently developing are for use in addressing the medication management issues associated with chronic diseases.

⁸ See, Avalere Health (2014) *Few Medicare Beneficiaries Receive Comprehensive Medication Review Services*. Available at: http://avalere-health-production.s3.amazonaws.com/uploads/pdfs/1408370417_20140807_MTM_Part_D_Release.pdf. Last accessed: January 24, 2016.

⁹ See, Institute of Medicine (2015) *Vital Signs: Core Metrics for Health and Health Care Progress*. Available at: <http://iom.nationalacademies.org/Reports/2015/Vital-Signs-Core-Metrics.aspx>. Last accessed: January 26, 2016.

IV. Advancing Care Delivery in ACO Models

a. Policy option: Providing ACOs the ability to expand use of telehealth

APhA supports ACOs having the ability to expand the use of telehealth and recommends that pharmacists be recognized as provider of ACO services, including telehealth. Pharmacists are not a provider specifically enumerated in the Medicare statute's definition of "ACO Professionals," which has effectively limited them from full participation in some Medicare ACOs due to the concern that a pharmacist's participation would make a service ineligible for Medicare reimbursement. While CMS has indicated that pharmacists are not excluded from participating in Medicare ACOs, we believe the omission of pharmacists in the federal statute is a barrier to effective and coordinated team-based care, and recommend appropriate and practical guidelines be developed to clarify that pharmacists can provide services, including telehealth services, in ACOs.

b. Policy option: Maintaining ACO flexibility to provide supplemental services

APhA supports clarifying that ACOs participating in the MSSP may furnish a social service, transportation service, or remote patient monitoring service for which payment is not made under fee-for-service Medicare. In addition to allowing ACOs to provide these supplemental services, such as remote monitoring, APhA advocates that these services should be able to be provided by pharmacists. Pharmacists have consistently demonstrated that they save money and improve patient outcomes when included on a care team. However, integrating pharmacists is constrained by current payment models since pharmacists and their patient care services are not recognized within the Social Security Act. The lack of payment to pharmacists for services provided within their state scope of practice unnecessarily limits patient access to certain health care services and the contributions pharmacists can make to patient health and outcomes, especially given health care provider shortages and an increasing demand for services.

Recent research found that pharmacist delivered, outpatient-focused medication therapy management programs using a remote blood glucose meter upload device can improve care; however, lack of reimbursement for remote monitoring services acts as a barrier to utilization.¹⁰ Thus policies providing flexibility to provide supplemental services should also clarify that pharmacists can be reimbursed for these services.

V. Prediabetes Education

a. Policy option: Expanding access to prediabetes education

APhA appreciates the Working Group's interest in helping people with prediabetes reduce their risk of developing diabetes and we offer suggestions in support of that goal. APhA believes that Medicare should provide payment for evidence-based lifestyle interventions that help individuals with prediabetes reduce their risk of developing diabetes. We support efforts to educate individuals at risk of developing diabetes, but are concerned that challenges in identifying individuals for prediabetes education may limit the effectiveness and sustainability of such programs. We suggest that a referral

¹⁰ See Schenk, R.J.Jr. & Schenk, J. (2011). Integration of Remote Blood Glucose Meter Upload Technology into a Clinical Pharmacists Medication Therapy Management Service, *Journal of Diabetes Science and Technology*, 5(1), 188-191.

from a health care professional, including a pharmacist, be required to better target patients for prediabetes education.

In addition, APhA supports a requirement for prediabetes education providers to meet specific qualifications such as the criteria under the National Diabetes Prevention Program to ensure consistency and effectiveness of the program. We also believe that qualified health care professionals such as pharmacists should be eligible to provide prediabetes education as long as they meet program requirements. Organizations that may be authorized to administer these programs, such as non-profit organizations and departments of health, should be required to have a link to a qualified health professional. Requiring links to a health care professional could help address unique patient concerns, add legitimacy to the program, and better connect individuals to the care community. Lastly, APhA believes that before expanding the entities that can provide prediabetes education, policies should be implemented so diabetes education programs are effective and appropriately provided to best impact patients and their health outcomes.

VI. Other Policies to Improve Care

a. Policy option: Study on medication synchronization

APhA supports the policy option requiring a study on medication synchronization and offers additional suggestions to further benefit patients with chronic diseases. Medication synchronization is a valuable service offered by pharmacists for patients living with chronic conditions who are on complex medication regimens. Medication synchronization allows for maintenance medications to be filled or refilled at the same time on a regular interval. Since patients tend to fill prescriptions on the day they are prescribed, without medication synchronization, patients routinely fill different prescriptions on different days of the month. By coordinating patients' medication refills and visits to pharmacies, medication synchronization can improve adherence to treatment regimens, while reducing costs and burdens of patients living with chronic health conditions.

Based on the description provided in the policy options document, medication synchronization is narrowly described as dispensing multiple medications to a beneficiary on the same day. We believe that effective medication synchronization involves the technical component of refill timing and prorated billing, and is enhanced by a clinical component, which includes services such as comprehensive medication reviews, adherence barrier identification, possible corrective action, and counseling.¹¹ Pharmacists play a proactive role when synchronizing medications, often calling patients a week before their scheduled refill day to review medications, discuss current therapies and identify any issues that may impact the patient's care and/ or medication regimen. The policy option does not adequately reference these additional services, and simply notes that pharmacist counseling would be an incidental benefit of medication synchronization, rather than a proactive, planned benefit integral to a comprehensive and effective service. Based on member feedback, medication synchronization cannot be separated to include only the technical component. Consequently, limiting the study to the technical component only will not accurately depict medication synchronization or the benefit it can have on patients, especially those with chronic conditions. APhA strongly supports studying both the technical and clinical services pharmacists commonly provide to patients synchronizing their medications to better understand how this service can be structured to best benefit patients. Such a

¹¹ See American Pharmacists Association Foundation, Pharmacy's Appointment Based Model (2013). Available at: <http://www.aphafoundation.org/sites/default/files/ckeditor/files/ABMImplementationGuide-FINAL-20130923.pdf>, last accessed: January 22, 2016.

study should measure primary outcomes correlated to Pharmacy Quality Alliance (PQA) measures of medication adherence (PDC), primary medication non-adherence (PMN), and patient outcomes, including total cost of care, emergency room utilization, and hospital admission rates.

b. Policy option: Study on obesity drugs

APhA supports a study focused on coverage of obesity drugs for beneficiaries in MA-PD plans and agrees that ‘prescription drug treatments may be an effective policy intervention’ for the treatment of obesity. Because behavioral and lifestyle interventions are important components of weight reduction and are usually indicated as adjunct therapy to prescription obesity drugs, we encourage the Committee to consider examining the use of obesity drugs as part of an integrative approach to addressing obesity. Pharmacists can play an important role in educating and working with patients across multiple strategies being employed. In addition, pharmacists can identify certain medications that may cause weight gain as a side effect and recommend alternative therapies for the patient as another mechanism of facilitating weight loss. Thus APhA suggests that the study evaluate a comprehensive, integrative team-based approach to address obesity, and that pharmacists be included as service providers.

Thank you for your leadership and work on this issue. We look forward to supporting your efforts and working with you as the Guideline is refined. If you have any questions please contact, Jenna Ventresca, Associate Director for Health Policy, by email jventresca@aphanet.org or phone (202) 558-2727.

Sincerely,



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