United States Senate Committee on Finance

Bipartisan Chronic Care Working Group
Policy Options Document

January 26, 2016

Comments for the Record
Submitted by ASHP

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The American Society of Health-System Pharmacists (ASHP) respectfully submits the following comments for the record to the Senate Finance Committee's Bipartisan Chronic Care Working Group (working group) on the policy options document released on December 18, 2015. ASHP supported the formation of the working group in July 2014 and applauds their commitment to addressing the unmet needs of an aging population with increasing chronic conditions.

ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's more than 43,000 members include pharmacists, student pharmacists and pharmacy technicians. For over 70 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety. For more information about the wide array of ASHP activities and the many ways in which pharmacists advance healthcare, visit ASHP's website, www.ashp.org, or its consumer website, www.safemedication.com.

ASHP's comments focus on the unique and critical role that pharmacists serve in the treatment of patients with chronic conditions. We also comment directly on a number of the specific chronic conditions and options listed in the policy options document.

As a member of the Patient Access to Pharmacists' Care Coalition (PAPCC), ASHP recommends that the working group leverage the expertise of pharmacists in managing complex patient cases by including the provisions of S. 314, the "Pharmacy and Medically Underserved Areas Enhancement Act," which would recognize pharmacists as providers under Part B of the Medicare program. S. 314 was introduced on January 29, 2015 by Senators Grassley, Kirk, Casey, and Brown and currently has 41 cosponsors. A companion bill, H.R. 592 was introduced on January 28, 2015 and is overwhelmingly supported in the House of Representatives with 262 cosponsors.

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The Role of Pharmacist in the Management of Chronic Conditions

Pharmacists should be a required member of inter-professional teams that are providing chronic disease management. All patients across the continuum of care should have access to an inter-professional team to address all complex medical management concerns. Complex medical management should include those disease states that may require input from multiple providers of differing backgrounds (e.g., medicine, pharmacy, nursing, social work, physical therapy, occupational therapy, case management). Health conditions may span from diabetes requiring co-management with a primary care provider and pharmacist to a more complex advanced dementia patient requiring long-term care and management from several providers on the inter-professional team.

Medications are a cornerstone in the successful management of chronic disease; however, their misuse is associated with significant morbidity and mortality. The Institute of Medicine estimates that 1.5 million preventable ADEs occur annually in the United States resulting in an estimated 7,000 deaths.[1] Medication-related morbidity is estimated to cost $177 billion annually.[2]

An additional risk associated with the medication use process is underutilization of medications. Underutilization may be a result of patient non-adherence or non-adherence by providers to

[1] Preventing Medication Errors: Quality Chasm Series Institute of Medicine (IOM). To Err Is Human: Building a Safer Health System. Washington, DC: National Academy Press; 1999. Available at: http://www.nap.edu/catalog/11623.html. Accessed April 7, 2014.

[2] Ernst FR, Grizzle AJ. Drug-related morbidity and mortality: Updating the cost-of-illness model. J Am Pharm Assoc. 2001;41:192–9.

evidence-based treatment guidelines. The New England Healthcare Institute has estimated the cost of medication-related adverse events and non-adherence to total $290 billion annually.[3]

As a result of their specialized medication knowledge and patient skills, inclusion of pharmacists as members of the healthcare team has been demonstrated to decrease drug related morbidity, mortality, and costs.[4] For every dollar invested in clinical pharmacy services in all types of practice settings (hospital, clinics, government, etc.), an average savings of $4.00 is realized to the health system.[5] Many examples of the impact of pharmacists being included in the healthcare team have been discussed in the literature. The 2011 Report to the U.S. Surgeon General provides a comprehensive review of the types of services and the impact of advanced pharmacy services that are provided by pharmacists throughout the United States.[6] We believe the ideal complex medical management model includes the services of appropriately trained pharmacists across the continuum of care and integrated with the entire inter-professional team.

As members of the inter-professional patient care team, pharmacists who provide complex medical management services, subject to state scope of practice laws: perform patient assessments; modify and/or initiate medication therapy via collaborative drug therapy management or through formalized

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3 New England Healthcare Institute**.** Thinking Outside the Pillbox: A System-wide Approach to Improving Patient Medication Adherence for Chronic Disease. Cambridge, MA: New England Healthcare Institute;2009.

4 Bond, C. A. and Raehl, C. L. Clinical Pharmacy Services, Pharmacy Staffing, and Hospital Mortality Rates. Pharmacotherapy, 2007;27:481–493.

5 Schumock GT, Butler MG, Meek PD, et al. Evidence of the Economic Benefit of Clinical Pharmacy Services: 1996–2000. Pharmacotherapy 2003;23:113–32.

6 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. Available at: http://www.usphs.gov/corpslinks/pharmacy/documents/2011advancedpharmacypracticereporttotheussg.pdf

credentialing and privileging processes in hospitals; order, interpret, and monitor medication therapy-related tests; coordinate care and other health services for wellness and prevention of disease; provide education to patients and caregivers incorporating principles of health literacy and cultural sensitivity; and document care processes in the medical record.

Pharmacists are the ideal healthcare provider to identify underutilization and overutilization of medications. In addition, pharmacists also are effective in identifying inappropriate medications. Optimization of medication therapy, including through evidence-based prescribing and medication adherence, results in better outcomes, reduces the frequency of medication errors, and reduces future medical costs. Pharmacists also facilitate evidenced-based selection of cost-effective medications. As such, the payment model should incentivize evidenced-based patient-specific selection of appropriate medications and support medication adherence.

The 2011 Report to the U.S. Surgeon General provides a comprehensive review of the types of services and the impact of services that are provided by pharmacists throughout the United States. Pharmacists have shown to improve patient care outcomes, increase access to care, shift time for physicians to focus on more critically ill patients in need of physician-based care, improve patient and provider satisfaction, assure patient safety, enhance cost-effectiveness, and clearly advance and improve healthcare delivery.

As the U.S. population is ages and baby boomers transition into the geriatric segment of the population, people are living longer, being prescribed more medications, and taking medications that are more powerful. Therefore, the use of a pharmacist who is practicing at the top their license is essential. Pharmacists are not “physician extenders.” Rather they bring a unique body of knowledge,

an in-depth knowledge of medications, into the healthcare arena. Many appointments with a physician, nurse practitioner (NP) or physician's assistant (PA) involve discussion centered around the pathophysiology of a disease or chronic condition. At the end of the visit, the patient is then handed a prescription for a medication. One of the most powerful interventions healthcare providers have, medication, is discussed to a much lesser degree than the disease process. We believe that pharmacists should have a prominent role and responsibility in medication selection and modification, patient education, follow up and monitoring of medication and overall medication and chronic disease management.

How Pharmacists Can Achieve the Goals of the Draft Policy Options

The working group outlines a number of potential items for Medicare reform in the policy options document. We believe that there are a multitude of examples of pharmacist services contributing to improvement in patient outcomes in a variety of healthcare settings on many of these specific areas of disease

The following are a few specific examples of these services and patient care outcomes in the ambulatory care setting:

The Asheville Project® is a novel community based, payer-driven, patient-centered health care model established in 1996 by the City of Asheville, North Carolina to provide education and personal oversight for chronic disease state management including diabetes, asthma, hypertension and dyslipidemia. Patients with a variety of chronic diseases were teamed with specially trained community pharmacists to receive pharmaceutical care services providing education, long-term

pharmacist follow up, clinical assessment, goal setting, monitoring and collaborative drug therapy management with physicians.

Asheville Project: Diabetes Care: Ongoing pharmaceutical care services by specially trained community pharmacists significantly improved mean hemoglobin A1c values showing a decrease at each follow up visit with more than 50% of patients demonstrating improvements over time. The number of patients with optimal hemoglobin A1c values increased. Total mean direct medical costs decreased by $1,200-$1,872 per patient per year and one employer estimated an increase in $1,800 annually in productivity based on decreased days of sick time.[7]

The Diabetes Ten City Challenge is a community-based, payer-driven, patient-centered healthcare model established in 2005 at 10 American cities providing pharmacy health management services for diabetic patients. Patients were teamed with community pharmacists to receive pharmaceutical care services providing education, long-term pharmacist follow up, clinical assessment, goal setting, monitoring, and collaborative drug therapy management with physicians. The pharmacists were part of an interdisciplinary health care team and communicated regularly to optimize patient care.

Ongoing pharmacy management services significantly decreased hemoglobin A1c from 7.5% to 7.1%, decreased mean LDL from 98 mg/dl to 94 mg/dl and decreased mean systolic blood pressure from 133 to 130 mmHg over a mean of 14.8 months. Average total healthcare costs per patient per year were reduced by $1,079.[8]

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[7] Cranor CW, Bunting BA, Christensen DB. The Asheville Project: long-term clinical and economic outcomes of a community pharmacy diabetes care program. JAPhA. 2003;43:173-84.

[8] Fera T, Blumi BM, Ellis WM. Diabetes Ten City Challenge: final economic and clinical results. JAPhA. 2009;49:383-391

Project Impact: Diabetes is a national diabetes self-management program launched in 2010 to improve the health of underserved populations with limited access to quality care in 25 communities disproportionally affected by diabetes. Pharmacy care services were provided including medication-related coaching, goal setting, education, diet education and one-on-one counseling as a part of an interdisciplinary health care team including 126 pharmacists. Practice settings included community pharmacy practices, employer worksites, federally qualified health centers, homeless clinics, and county health departments. Patients enrolled in the project had statistically and clinically significant decreases in glycosylated hemoglobin (A1C), an important clinical indicator of diabetes, after receiving team-based diabetes care that included pharmacists. Pharmacists were the common link for improved patient outcomes in all 25 communities.[9]

Developing Quality Measures for Chronic Conditions: Medication-related metrics that influence chronic disease clinical outcomes and healthcare utilization such as those already identified by the Centers for Medicare and Medicaid (CMS) Star ratings, the Healthcare Effectiveness, Data, and Information Set (HEDIS), and the Pharmacy Quality Alliance should be incorporated whenever possible to assess safety and effectiveness. In addition, consumer satisfaction and patient experience measures should also be included.

Telehealth: Patients in rural and underserved areas frequently lack access to care. Therefore, we would encourage utilization of telehealth infrastructures to extend access to inter-professional teams that require inclusion of pharmacists. An example of a telehealth model that extends the care of an inter-professional team including a pharmacist is Project ECHO (Extension for Community Healthcare

[9] Benjamin M. Bluml; Lindsay L. Watson; Jann B. Skelton; Patti Gasdek Manolakis; Kelly A. Brock. J Am Pharm Assoc (2003) 2014;54:477-485.

Outcomes). Payment models should address incorporation of innovative inter-professional telehealth models such as Project ECHO as well.[10]

Chronic Care Management Services: On November 13, 2014, the Centers for Medicare & Medicaid Services (CMS) published a final rule that changed incident-to billing rules for chronic care management (CCM) provided to Medicare beneficiaries outside of normal physician office hours. Beginning in CY 2015, physicians can use their provider number to bill Medicare for a non-physician clinician services even if the clinical professional is not directly employed by the provider. Additionally, direct supervision is no longer a prerequisite for CCM services provided "after hours" by a non-physician clinician. As with other recent changes, CMS is recognizing that pharmacists, among other non-physician practitioners, should be able to practice at the top of their license. This is evidence that the agency recognizes the importance of the pharmacist as a key member of the interdisciplinary healthcare team and that physicians should be able to use pharmacists' services as part of the CCM billing code. ASHP supports changes to the CCM codes that would account for patients with more severe chronic conditions. We believe that pharmacists can greatly improve the well-being of these Medicare beneficiaries. However, we still urge Congress to enact S. 314 which is the still the only way to ensure that pharmacists can be explicitly recognized for direct patient care.

Additional Examples of Pharmacist Intervention for Conditions not Addressed in the Draft Policy Options Document

Pain management in an integrated health-system: Pharmacist clinicians with prescribing authority for controlled substances have provided chronic non-cancer related pain medication management

[10] Harkins MS, Raissy H, Moseley K, Luttecke K, Arora S. "Extension for Community Healthcare Outcomes Project – Asthma Specialty Consultation Via Telehealth to Improve Asthma Care in rural New Mexico, " US Respiratory Diseases. 2011;7(1):7-9.

services in a for-profit integrated health system. In a one-year time period the pharmacist clinicians were able to show an improvement in mean visual analogue scale pain scores and save the health system over $450,000.[11]

Depression management in a staff model health maintenance organization: A randomized controlled trial was conducted to measure the impact of a collaborative care model that emphasized the role of clinical pharmacists to provide drug therapy management and treatment follow-up in patients with depression. In this collaborative model, after 6 months, those patients with depression randomized to the services of a pharmacist compared with the control group, had a significantly higher medication adherence rate (67% vs 48), higher patient satisfaction, and favorable changes in resource utilization.[12]

Asheville Project: Asthma: Ongoing pharmaceutical care services by community pharmacists significantly improved FEV1 and asthma severity classification. The proportion of patients with asthma action plans increased from 63% to 99% and emergency department visits due to asthma exacerbations decreased from 9.9% to 1.3% and hospitalizations from 4.0% to 1.9%. Estimated direct cost savings averaged $725 per patient per year and estimated indirect cost savings averaged $1,230 per patient per year.[13]

Asheville Project: Hypertension/hyperlipidemia: Ongoing pharmaceutical care services by community pharmacists increased the percentage of patients with an at goal blood pressure from

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[11] Dole EJ, Murawski MM, Adolphe AB, Hochstadt B, Aragon FD. Provision of pain management by a pharmacist with prescribing authority. Am J Health-Syst Pharm. 2007;64:85-9.

[12] (Finley PR, Rens HR, Pont JT et al. Impact of a collaborative pharmacy practice model on the treatment of depression in primary care. AJHP. 2002;59:1518-26.)

[13] Bunting BA, Cranor CW. The Asheville Project: long-term clinical, humanistic, and economic outcomes of a community-based medication therapy management program for asthma. JAPhA. 2006;46:133-47.

40.2% to 74.6% and percentage of patients with an at goal LDL level from 49.9% to 74.6%. Cardiovascular-related medical costs decreased from 30.6% of total healthcare costs to 19% and an observed greater than 50% decrease in risk of a cardiovascular-related emergency department visit occurred.[14]

HRSA PSPC Collaborative: The U.S. Health Resources and Services Administration's (HRSA's) Patient Safety and Clinical Pharmacy Services (PSPC) Collaborative is an effort to improve the quality of health care across America by integrating evidence-based clinical pharmacy services into the care and management of high-risk, high-cost, complex patients. Additional information available at: www.hrsa.gov

Conclusion

ASHP is encouraged by the work of the bipartisan working group and the draft policy options document and we believe that our members can play a critical role in achieving the goals of the working group. Currently, however pharmacists are not recognized as healthcare providers under the Social Security Act. This recognition at a federal level would increase direct patient care and result in better care management for those Medicare beneficiaries suffering from chronic disease. Please do not hesitate to contact us at gad@ashp.org or at301-664-8710 should you wish to discuss our comments in greater detail.

[14] Bunting BA, Smith BH, Sutherland SE. The Asheville Project: clinical and economic outcomes of a community-based long-term medication therapy management program for hypertension and dyslipidemia. JAPhA. 2008;48:23-31.

Additional references and examples:

Arora S, Kalishman S, Dion D, Som D, Thornton K, Bankhurst A, Boyle J, Harkins M, Moseley k, Murata G, Komaramy M, Katzman J, Colleran K, Deming P, Yutzy S. "Quality Profile: Partnering Urban Academic Medical Centers and Rural Primary Care Clinicians to Provide Complex Chronic Disease Care," Health Affairs. 2011 Jun;30(6): 1176-84.

Arora S, Thornton K, Murata G, Deming P, Kalishman S, Dion D, Parish B, Burke T, Pak W, Dunkelberg J, Kistin M, Brown J, Jenkusky S, Komaromy M, Qualls C. "Outcomes of Treatment for Hepatitis C Virus Infection by Primary Care Providers" N Engl J Med. 2011 Jun;364:2199-207.

Borenstein JE, Graber G, Saltiel E et al. Physician-pharmacist comanagement of hypertension: a randomized, comparative trial. Pharmacotherapy. 2003;23(2): 209-16.

Bozovich M, Rubino CM, Edmunds J. Effect of a clinical pharmacist-managed lipid clinic on achieving National Cholesterol Education Program low-density lipoprotein goals. Pharmacotherapy. 2000;20(11): 1375-83.

Brooks AD, Rihani RS, Derus CL. Pharmacist membership in a medical group's diabetes health management program. AJHP. 2007;64:617-21.

Chisholm-Burns MA, GraffSivin JS, Lee JK, et al. Economic effects of pharmacists on health outcomes in the United States: a systematic review. Am J Health Syst Pharm 2010;67:1624-34.

Cioffi ST, Caron MF, Kalus JS et al. Glycosylated hemoglobin, cardiovascular, and renal outcomes in a pharmacist-managed clinic. Ann Pharmacother. 2004;38(5): 771-5.

Dole EJ, Murawski MM, Adolphe AB, Hochstadt B, Aragon FD. Provision of pain management by a pharmacist with prescribing authority. Am J Health-Syst Pharm. 2007;64:85-9.

Finley PR, Rens HR, Pont JT et al. Impact of a collaborative pharmacy practice model on the treatment of depression in primary care. AJHP. 2002;59:1518-26.

Gattis WA, Hasselblad V, Whellan DJ, et al. Reduction in heart failure events by the addition of a clinical pharmacist to the heart failure management team: results of the Pharmacist in Heart Failure Assessment Recommendation and Monitoring (PHARM) Study. Arch Intern Med. 1999;159(16): 1939-1945.

Kiel PJ, McCord AD. Pharmacist impact on clinical outcomes in a diabetes disease management program via collaborative practice. Ann Pharmacother. 2005;39(11): 1828-32.

Leal S, Glover JJ, Herrier RN, et al. Improving quality of care in diabetes through a comprehensive pharmacist-based disease management program. Diabetes Care. 2004;27(12): 2983-84.

Lee JK, Grace KA, Taylor AJ. Effect of a pharmacy care program on medication adherence and persistence, blood pressure, and low-density lipoprotein cholesterol: a randomized controlled trial. JAMA. 2006;296(21): 2563-2571.

Morello CM, Zadvorny EB, Cording MA et al. Development and clinical outcomes of pharmacist-managed diabetes care clinics. AJHP. 2006;63:1325-31.

Murawski M, Villa KR, Dole EJ et al. Advanced-practice pharmacists: practice characteristics and reimbursement of pharmacists certified for collaborative clinical practice in New Mexico and North Carolina. AJHP. 2011;68(24): 2341-50.

Rothman R, Malone R, Bryant B, et al. Pharmacist-led, primary care-based disease management improved hemoglobin A1c in high-risk patients with diabetes. Am J Med Qual. 2003;18(2): 51-8.

Shane-McWhorter L, Oderda GM. Providing diabetes education and care to underserved patients in a collaborative practice at a Utah community health center. Pharmacotherapy. 2005;25(1): 96-109.

Touchette DR, Doloresco F, Suda KJ, et al. Economic evaluations of clinical pharmacy services: 2006-2010. Pharmacotherapy 2014 Mar 19. Epub 2014 Mar 19.

Traywick Till L, Voris JC, Bourne Horst J. Assessment of clinical pharmacist management of lipid-lowering therapy in a primary care setting. JMCP. 2003;9(3): 269-73.