

Comments of the American College of Clinical Pharmacy and the College of Psychiatric and Neurologic Pharmacists

**Submitted to the
Committee on Energy and Commerce
Subcommittee on Health:**

**“Examining the Medicare Part D
Medication Therapy Management Program”**

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The American College of Clinical Pharmacy (ACCP) and the College of Psychiatric and Neurologic Pharmacists (CPNP) appreciate the opportunity to provide the following statement to the House of Representatives Committee on Energy and Commerce, Subcommittee on Health related to the October 21, 2015 hearing entitled, “Examining the Medicare Part D Medication Therapy Management Program.”

ACCP is a professional and scientific society that provides leadership, education, advocacy, and resources enabling clinical pharmacists to achieve excellence in patient care practice and research. ACCP's membership is composed of over 16,000 clinical pharmacists, residents, fellows, students, scientists, educators and others who are committed to excellence in clinical pharmacy practice and evidence-based pharmacotherapy.

CPNP is an association of specialty pharmacists who work to improve the minds and lives of those affected by psychiatric and neurologic disorders. These professionals apply their clinical knowledge in a variety of healthcare settings and positions ranging from education to research with the goal to apply evidence-based, cost efficient best practices in achieving patient recovery and improving quality of life.

Beginning with the introduction of the Medicare Prescription Drug, Improvement, and Modernization Act (also referred to as the Medicare Modernization Act or MMA) in 2003, ACCP and CPNP worked closely and diligently with Congress to ensure that the proposed prescription drug benefit not only enhanced beneficiary access to needed medications, but that the program's operational and quality standards assured that therapeutic outcomes will be fully optimized through the delivery of medication therapy management (MTM) services by pharmacists as a substantial and integral part of the overall drug benefit.

Following the passage of the MMA, a group of eleven pharmacists' professional associations worked to develop a consensus definition of MTM services. Our organizations were at the forefront of the regulatory rulemaking process, working to help develop an MTM program within the newly established Part D benefit that we hoped would deliver on its aims, assuring that covered Part D drugs prescribed to targeted beneficiaries are appropriately used to optimize therapeutic outcomes through improved medication use.

In the preamble to the Part D final rule, CMS stated its belief that the MTM Program would be a “cornerstone of the Medicare Prescription Drug Benefit.” MTM was intended to be a “patient-centric and comprehensive approach to improve medication use, reduce the risk of adverse events, and improve medication adherence.”¹ However, recently CMS has acknowledged that it has not been possible to fully demonstrate the value and success of the Part D MTM Program.²

Following the implementation of the Part D benefit and the launch of the MTM program, pharmacists across all practice settings worked tirelessly to deliver high quality patient care to beneficiaries within the Part D MTM structure and sought to make the program a success. Now, after almost a decade of experience, we are concerned that the Part D MTM program as it is currently structured – delivered primarily through prescription drug plans and detached from the patient's health care team and medical records – fails to support this patient-centric comprehensive approach and will never fully realize the full potential of effective, team-based medication management in terms of improved outcomes and lower costs.

This concern is shared by the Medicare Payment Advisory Commission (MedPAC). In a February 28, 2014 comment letter to CMS in response to the Fiscal Year 2015 Medicare Prescription Drug Benefit proposed rule, MedPAC stated that, “after seven years, it may be time to question whether MTM programs offered through PDPs – without the cooperation and coordination of a beneficiary's care team – have the capacity to significantly improve beneficiaries' drug regimens.” The Commission went on to suggest that better medication management might be achieved through programs offered by ACOs,

medical homes, and other team-based delivery models, since providers working within these care models have more incentive to improve their patients' medication regimens and eligible patients may be more likely to participate in MTM programs and follow the advice they receive.

Like MedPAC, ACCP & CPNP support the Committee's commitment to improving medication management services for Medicare beneficiaries but question whether improvements to the Part D MTM program, as it is currently structured, is the most effective way to achieve this broader goal. Part D MTM is an administrative benefit delivered by the patient's Part D plan sponsor, rather than a comprehensive medical benefit coordinated through the patient's health care team. Part D MTM is largely driven using drug claims data and is narrowly focused on issues such as duplications in therapy, gaps in adherence, use of certain classes of medications, and generic substitution. Experience has shown that physicians may be reluctant to accept recommendations from drug plans with which they have no direct relationship.

ACCP & CPNP believe that medication management services, delivered in a comprehensive manner targeting high-cost, high-risk beneficiaries can result in significant improvements in drug therapy outcomes and contribute to lower overall health care spending by reducing hospitalizations and avoidable emergency room and physician visits. However, we remain concerned that the Part D MTM program as it is currently structured cannot ensure a true team-based, patient-centered approach to health care consistent with evolving delivery and payment models such as the patient-centered medical home (PCMH) and will ultimately fall short of realizing the full potential of effective, team-based medication management in terms of improved outcomes and lower costs.

We therefore urge the Committee to include reforms to the Medicare program that provide for coverage of comprehensive medication management (CMM) services provided by qualified clinical pharmacists as members of the patient's health care team. This team-based service of CMM is supported by the Patient Centered Primary Care Collaborative, (PCPCC), in which ACCP as well as the major primary care medical organizations are actively involved. CMM helps ensure that seniors' medication use is effectively coordinated, and in doing so enhances seniors' health care outcomes, contributing directly to Medicare's goals for quality and affordability. CMM can "get the medications right" as part of an overall effort to improve the quality and affordability of the services provided to Medicare beneficiaries.

CMM is a collaborative, team-based approach to patient care delivered by clinical pharmacists operating under formal collaborative practice agreements or clinical privileges granted by the health care setting in which the pharmacist practices. Effective CMM saves overall health care costs by reducing unnecessary use of more costly health care services. By helping ensure that seniors' medication use is effectively coordinated, this service is a benefit that enhances seniors' health care outcomes and contributes directly to Medicare's goals for quality and affordability.

Patients benefit from the delivery of CMM in terms of improved outcomes due to the increased individualized attention to medications and the role they play in the patient's therapeutic care plan. In addition, physicians and other care team members benefit when pharmacists apply their pharmacotherapeutic expertise in a collaborative process to help manage complex drug therapies.

CMM also contributes to enhanced productivity for the entire health care team, allowing other team members to be more efficient in their own patient care responsibilities. Physicians are able to dedicate more time to the diagnostic and treatment selection process, enabling them to be more efficient, see more patients, and spend more time providing medical care. Team members are freed up to practice at the highest level of their own scopes of practice by fully utilizing the qualified clinical pharmacist's skills and training to coordinate the medication use process as a full team member.

The central role that medications play in the care and treatment of chronic diseases is undeniable. According to data from the Centers for Medicare and Medicaid Services (CMS), medications are the fundamental treatment intervention in each of the eight most prevalent chronic conditions in Medicare patients. For the typical Medicare beneficiary, four of every five medical encounters result in a prescription order (new or refill) and 60% of seniors are taking 3 or more discrete prescription or non-prescription medications at any point in time. Furthermore, the importance of medications in the care and treatment of chronic illness will only increase as advances in biomedical research and innovation and breakthroughs in digital and personalized medicine bring new life-saving drugs and devices to patients and a new generation of cures and treatments.

Despite these facts, traditional practice models and payment policies result in disjointed prescribing and distribution of medications from unconnected professional “silos.” No effective incentives currently exist in Medicare to support a coordinated medication management service for beneficiaries delivered by an effective inter-professional health care team. When combined with the continuing growth in the number and categories of medications -- and greater understanding of the genetic and physiologic differences in how people respond to their medications -- the current system, including the Part D MTM benefit, consistently fails to deliver the full promise medications can offer. We therefore urge the Committee to consider opportunities to integrate coordinated, team-based CMM delivered across all care settings (e.g. hospital, outpatient practice, managed care), and during transitions between care settings, throughout the entire Medicare program.

The burden of chronic physical and mental health conditions has far reaching implications for the Medicare program. Over 68% of Medicare beneficiaries have two or more chronic conditions and over 36% have four or more chronic conditions. In terms of Medicare spending, beneficiaries with two or more chronic conditions account for 93% of Medicare spending, and those with four or more chronic conditions account for almost 75% of Medicare spending.³

Currently, millions of complex, chronically ill Medicare beneficiaries receive care in a delivery system that is fragmented and insufficiently focused on quality and outcomes. This program deficiency not only fails to adequately meet patient needs but threatens the long-term structural and financial viability of the Medicare program. We applaud the leadership of the Committee in holding this hearing to explore opportunities to strengthen the Medicare Part D MTM program for both patients and for the Part D plans.

But in order to enhance access to high-quality care and to ensure the sustainability of the Medicare program as a whole, it is essential that progressive payment and delivery system improvements that have emerged and are being actively utilized in both public and private-sector integrated care delivery systems be facilitated and aggressively promoted -- especially those that measure and pay for quality and value, not simply volume of services, and that fully incentivize care that is patient centered and team based.

For more information on why a modernized, integrated Medicare program needs to systematically address medication use through the incorporation of CMM as a covered benefit, please refer to Appendix A. For more information on the potential for cost savings through the incorporation of CMM as a Medicare benefit, please refer to Appendix B.

Summary

As the committee continues its effort to examine opportunities to strengthen and enhance medication management services available to Medicare beneficiaries, ACCP and CPNP urge you to focus on models that promote and incentivize a truly patient-centered and inter-professional approach to medication related clinical care and medication safety.

ACCP and CPNP are dedicated to advancing a quality-focused, patient-centered, team-based approach to health care delivery that helps assure the safety of medication use by patients and that achieves medication-related outcomes that are aligned with patients' overall care plans and goals of therapy through the provision of CMM. Clinical pharmacists, working collaboratively with physicians and other members of the patient's health care team, utilize a consistent process of direct patient care that enhances quality and safety, improves clinical outcomes and lowers overall health care costs.

As part of the process of exploring opportunities to improve the quality of medication management services available to seniors, Congress should enact reforms to the Medicare program that provide for coverage of CMM services provided by qualified clinical pharmacists as members of the patient's health care team within its broader payment reform efforts. We would welcome the opportunity to provide further information, data, and connections with successful practices that provide CMM services to help further inform the committee about this service in the context of specific improvements to the Part D MTM program as well as the broader debate over Medicare payment and delivery system reform that will modernize and sustain the program for the future.

¹ CMS Memo to all Part D Sponsors. CY 2015 Medication Therapy Management Program Guidance and Submission Instructions. May 7, 2014. Accessed October 15, 2015. Available here: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoContractYear2015MedicationTherapyManagementProgramSubmission050714.pdf>

² CMS Memo to all Part D Sponsors. CY2013 Part D Reporting Requirements – Request for Comments. January 13, 2012. Accessed October 15, 2015. Available here: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/ReqforCommentson2013ReportingRequirements_01102012.pdf

³ CDC Report - Prevalence of Multiple Chronic Conditions Among Medicare Beneficiaries, United States, 2010. Available at: http://www.cdc.gov/pcd/issues/2013/12_0137.htm. Accessed October 15, 2015

Appendix A

Coverage for Comprehensive Medication Management Services for Medicare Patients:

“Getting the medications right” in a reformed and modernized program

The American College of Clinical Pharmacy (ACCP) and the College of Psychiatric and Neurologic Pharmacists (CPNP) urge Congress to enact legislation to provide Medicare patients with coverage for comprehensive medication management (CMM) within the Part B medical benefit. This direct patient care service, provided by qualified clinical pharmacists working as formal members of the patient’s health care team, has been demonstrated to significantly improve clinical outcomes and enhance the safety of medication use by patients.

Effective CMM also saves overall health care costs by reducing unnecessary use of more costly health care services. By helping ensure that seniors’ medication use is effectively coordinated, this service is a benefit that enhances seniors’ health care outcomes and contributes directly to Medicare’s goals for quality and affordability.

A needed benefit that contributes to more cost effective and patient-centered care

The importance of “getting the medications right” is widely recognized by health policy analysts and quality experts as a key to more efficient, cost-effective and patient-centered care.^{1 2} This is particularly critical for seniors because the central role that medications play in their care and treatment is undeniable:

- The typical Medicare beneficiary sees two primary care providers and five medical specialists in any given year. Four of every five medical encounters result in a prescription order (new or refill);³
- 66% of Medicare beneficiaries have two or more chronic diseases; 40% have four or more;⁴
- 60% of seniors are taking 3 or more discrete prescription or non-prescription medications at any point in time.⁴

Despite these facts, traditional practice models and payment policies result in disjointed prescribing and distribution of medications from unconnected professional “silos.” No effective incentives currently exist in Medicare Part B to support a coordinated medication management service for beneficiaries delivered by an effective inter-professional health care team. When combined with the continuing growth in the number and categories of medications -- and greater understanding of the genetic and physiologic differences in how people respond to their medications -- the current system consistently fails to deliver the full promise medications can offer.

The too-common result -- particularly in Medicare seniors -- is a range of medication-related problems that frequently are either unrecognized or inadequately addressed:

- dosing “mistakes” that can result in either under treatment or preventable adverse events – or both;

¹ Smith, MA et.al. Why pharmacists belong in the medical home. Health Affairs 2010;29(5):906-13. (May 2010)

² Isetts, BJ et.al. Managing drug-related morbidity and mortality in the patient-centered medical home. Med Care 2012;50:997-1001 (November 2012)

³ Pham, HH et al. Care patterns in Medicare. NEnglJMed 207:356:1130-1139. (March 2007) ⁴ CMS Chartbook 2012. Centers for Medicare and Medicaid Services.

⁴ CDC/NCHS Statistical Data Brief. September 2010.

- inappropriate, ineffective, or unnecessarily costly medication choices for the established goals of care;
- duplicative or interacting medications;
- avoidable side effects;
- inconsistent adherence or other patient challenges or issues that directly reduce treatment success.

In short, the current medication use “non-system” fails to get the medications right far too often.⁵

Comprehensive Medication Management “gets the medications right”

CMM is a service provided directly to patients by qualified clinical pharmacists who practice as members of functional inter-professional teams. This care occurs in some health care settings today, including integrated private sector delivery systems, the Veterans Administration, some community health centers and other settings. But it is only rarely available to most Medicare beneficiaries – the people most in need and most likely to benefit from the service.

In the emerging environment of patient-centered medical homes (PCMH), the practice of CMM is now recognized as a core strategy to achieve better clinical outcomes and quality. The Patient-Centered Primary Care Collaborative (PCPCC) supports the practice of team-based CMM and has published a resource guide to assist with the integration of this service into clinical practice in the PCMH.⁶ Medicaid programs in North Carolina and Minnesota now support CMM within the practice and service components of their primary care delivery systems.⁷

What is comprehensive medication management and how does it work?

Working in formal collaboration with physicians and other members of the patient’s health care team, qualified clinical pharmacists:

- identify and document medication-related problems of concern to the patient and all members of the care team, using a consistent care process that assures medication appropriateness, effectiveness and safety;
- initiate, modify, monitor, and discontinue drug therapy to resolve the identified problems and achieve medication-related outcomes that are aligned with the overall care plan and goals of therapy; and
- engage and educate patients and families in fully understanding their medication regimen, supporting active patient engagement in the successful use of their medicines to achieve desired health outcomes.

In “getting the medications right,” CMM also contributes to enhanced productivity for the entire health care team, allowing other team members to be more efficient in their own patient care responsibilities. Team members are freed up to practice at the highest level of their own scopes of practice by fully utilizing the qualified clinical pharmacist’s skills and training to coordinate the medication use process as a full team member.

⁵ Parekh, AK et.al. The challenge of multiple comorbidity for the US health care system. JAMA 2010;303(13):1303-1304 (April 7, 2010)

⁶ Integrating comprehensive medication management to optimize patient outcomes. PCPCC Resource Guide, Second Edition June 2012. Available at www.pcpcc.net

⁷ Minnesota statute 256B.0625 Subd. 13h, 2005. Available at www.revisor.mn.gov/statutes/?id=256B.0625

Who is a “qualified clinical pharmacist?”

A qualified clinical pharmacist:

- has a doctor of pharmacy degree (Pharm.D.) or possesses equivalent clinical training/experience;
- has a formal collaborative drug therapy management (CDTM) agreement with a physician/medical group or has been granted clinical privileges to provide the service by the care setting in which (s)he practices;
- is certified or eligible for certification in a pharmacy practice specialty recognized by the Board of Pharmacy Specialties (BPS).

Why is this benefit important to add to Medicare Part B?

In addition to the data previously described, there are additional reasons why this service can be of particular value to Medicare Part B beneficiaries:

- Nearly half of all Medicare beneficiaries’ medication use is “disconnected” from their medical benefits under Medicare Part B because they choose not to enroll in a Medicare Part D drug plan.
- While Part D plans offer a “medication therapy management” (MTM) program for limited numbers of beneficiaries, these programs are, by law, administrative in purpose and scope. Part D plan administrators – not patients or clinicians - determine who can access an MTM program.
- The benefit would be available for all Part B-enrolled beneficiaries regardless of how they access or pay for their prescription medications, including creditable coverage from private and/or supplemental plans.
- The benefit would provide improved outcomes and quality achievement in Medicare Part B, AND contribute directly to goals for cost savings within Medicare Part A, including reduction in avoidable hospitalizations, readmissions, and emergency department visits.

Action needed

“Getting the medications right” is an essential objective for a modernized, cost-effective and quality-focused Medicare program. Congress should enact legislation to reform Medicare Part B to cover comprehensive medication management services provided by qualified clinical pharmacists as members of the patient’s health care team.

Appendix B

THE EVIDENCE FOR VALUE OF COMPREHENSIVE MEDICATION MANAGEMENT SERVICES: “GETTING THE MEDICATIONS RIGHT” RESOLVES REAL PROBLEMS AND IMPROVES OUTCOMES

Growing evidence demonstrates the care quality and economic benefits of a **comprehensive approach to team-based medication management**. It also reveals that some commonly cited “medication problems” for patients, including seniors, are often not the leading reasons for treatment failures and incomplete achievement of clinical goals. “Medications” include prescription and non-prescription products, herbals, and vitamins/supplements.

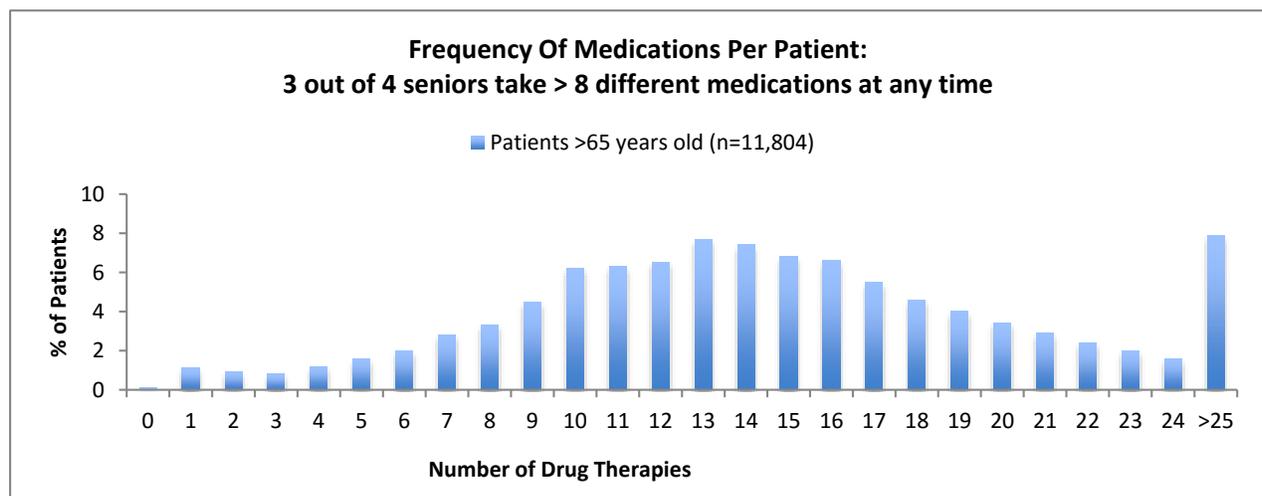
The data represented below reflect aggregated results from 19 distinct medication management service practices, provided by qualified pharmacists within settings such as community-based pharmacies, hospital-based clinics, free-standing medical clinics, and health systems. In all cases, a consistent and comprehensive process of care was used in the provision of the service. Data reflect 11,804 patients (over 65 years old) with 21,213 documented encounters. All patients received services between April 2006 and September 2010.¹

2 out of 3 Medicare Beneficiaries Need Access to Comprehensive Medication Management (CMM) Services

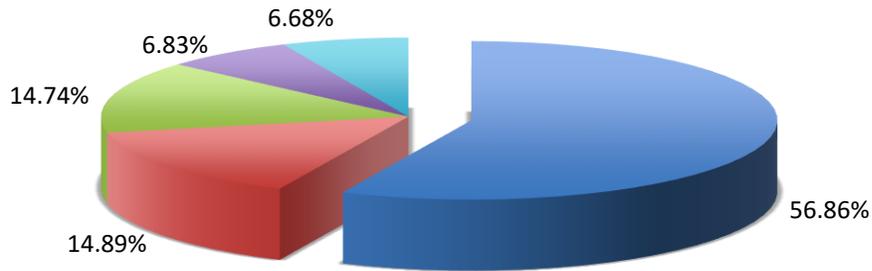
Of the 11,804 patients documented, 2 out of 3 seniors had 3 or more medical conditions and 2 out of 3 seniors were identified with 2 or more drug therapy problems.

Providing coverage for CMM services could help the Medicare program avoid:

Almost 6 million physician office visits, saving more than \$1 billion annually
670,000 emergency room visits, saving more than \$500 million annually



**Types of Drug Therapy Problems:
Almost half of problems result from improper medication use.**



Category of Drug Therapy Problem

- Improper Use (Dose too low/Different or additional drug needed/Wrong drug)
- Non-Adherence
- Adverse reaction
- Dose too high
- Unnecessary

HEALTH CARE SERVICES SAVINGS FROM CMM SERVICES

	11,804 patients (over 65 years old) 21,213 encounters			Medicare Part B Population Projections	Medicare Part B Population Projections**
Health care savings*	# of events avoided	# of referrals	\$ net savings	# of events avoided	\$ Gross Savings
Office visit (\$182)	9,146	838	\$1,512,056	23,789,053	4,329,607,646
Specialist visit (\$564)	549	149	\$225,600	1,427,967	805,373,388
Urgent care (\$182)	263	7	\$46,592	684,072	124,501,104
Emergency department visit (\$821)	1,033	12	\$838,241	2,686,868	2,205,918,628
Hospital admission (\$29,046)	69	15	\$1,568,484	179,471	5,212,914,666
Totals			\$4,190,973		

*Health care event savings and referral costs based on 2008 U.S. averages from Expenses per Visit for Ambulatory Visits and Inpatient Stay for 2008, Agency for Healthcare Research & Quality-Center for Financing, Access, and Cost Trends, 2010 and Genworth 2011 Cost of Care Survey, Genworth Financial 2011.

** Projections based on data collected over period: April 2006 to September 2010