HEALTHCARE LEADERSHIP COUNCIL

October 21, 2015

House Energy and Commerce Committee
Subcommittee on Health
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515-6115

Dear Chairman Pitts and Ranking Member Green:

The Healthcare Leadership Council respectfully submits this statement for the record regarding the hearing entitled, "Examining the Medicare Part D Medication Therapy Management Program." Members of the Healthcare Leadership Council (HLC), a coalition of chief executives from all disciplines within American healthcare, applaud the committee for examining the existing Medicare Part D Medication Therapy Management (MTM) Program to make it more effective for patients. We agree with the subcommittee that "the program's incentives are not aligned and adherence to prescriptions is not as strong as possible."

Opportunities to strengthen MTM
HLC members are concerned that the way Medicare MTM is currently structured does not effectively reach patients. We suggest the following areas for improvement:

- **Revisit Eligibility Criteria:** MTM services currently target beneficiaries who have multiple chronic conditions, take multiple medications, or are likely to incur annual costs above a predetermined level. This criteria, as CMS has noted in its recent announcement of a Part D Enhanced Medication Therapy Management Model, may "both over-identify and under-identify beneficiaries who are either experiencing or at-risk of experiencing medication-related issues and could benefit from MTM interventions." Since the causes of non-adherence are myriad—and often depend on factors outside of the existing eligibility criteria (e.g., cost sharing, regimen complexity, medication beliefs, and depression[1])—it is important that plan sponsors be given the flexibility to better target the patients who need MTM services most. Special attention should be paid to patients with chronic conditions (particularly, those with multiple chronic conditions) as well as patients with low levels of health literacy. Other groups of people who may benefit the most include those who use several medications, those who have several health conditions, those who have questions about or problems with their medications, those who are taking medications that require close monitoring,

[1] Walid F. Gellad, Jerry Grenard, Elizabeth A. McGlynn. A Review of Barriers to Medication Adherence: A Framework for Driving Policy Options. Cited from Page 5. RAND: Santa Monica. 2009.

those who have been hospitalized, and those who obtain their medications from more than one pharmacy.

- **Data Sharing:** The lack of information sharing between different parts of the Medicare program inhibits the ability of plan sponsors to use best practices to improve medication adherence. With better data linkage, plans would be able to monitor patient use of medical services and target patients who need the most assistance. It would be especially helpful to share information on patients as they change venues of care and reach various disease state milestones.

- **MTM Activities:** The issue of patient adherence has been extensively researched, but the rates of non-adherence have not improved much in the past three decades. The current MTM program hampers this even more by requiring uniform service offerings for any MTM program. It is important that MTM allow flexibility for plan sponsors to better tailor interventions to suit the unique needs and challenges of different patients as well as develop new and innovative ways of more effectively reaching patients.

- **Areas of Overlap:** Because of the patient care imperative to ensure the best medication use possible, as well as the existence of many incentive and quality programs that promote MTM activities, it is possible that patients may be enrolled in multiple MTM programs. HLC is concerned that being part of multiple programs may confuse or frustrate patients, thereby negating the benefits of such programs. We encourage the committee to keep in mind the full spectrum of care providers (from standalone prescription drug plans (PDPs) to pharmacists to doctors to community health workers) and be aware that all sectors contribute expertise and insight to patient care.

- **Incentives:** As CMS noted, "Competitive market dynamics and Part D program requirements and metrics encourage investment in these activities only at a level necessary to meet minimal compliance standards." The way the program is structured creates disincentives for PDPs to offer innovative, robust MTM programs because savings created by improved medication use are often realized in the form of reduced hospitalizations and other clinical spending not related to the Part D program. We urge the committee to closely examine these incentives.

Part D Enhanced Medication Therapy Management Model

Given the challenges outlined above, HLC members are encouraged by CMS's recent Announcement to develop an Enhanced MTM Model. We strongly support the proposal's emphasis on "right sizing" MTM and testing innovative regulatory flexibility and payment incentives to target high-risk beneficiaries and provide them with the appropriate level and intensity of services.

In response to CMS's request for feedback on the proposed model, HLC submitted the following comments:

- **Regulatory flexibility:** HLC strongly supports CMS's efforts to test innovations in the Medicare Part D program. The Enhanced MTM Model's emphasis on regulatory flexibility will allow participating plans to stratify MTM services by beneficiary risk and offer different levels and types of MTM services, which should improve outcomes by targeting high-risk beneficiaries and providing them with the appropriate level and intensity of services. HLC favors incentivizing the early identification of risk factors for chronic illness, and the concept of the Enhanced MTM Model aligns with this vision.

  We support the proposal's emphasis on "right sizing" MTM and also its decision to offer waivers that would allow various providers to offer interventions of a type that are not usually furnished in traditional MTM programs. While we believe the role of a pharmacist is fundamental to the clinical development of any medication management program, we look forward to drawing on the expertise of physician and nonphysician providers from all parts of the healthcare system as they work together to address barriers to optimized drug therapy.

  HLC also strongly supports the notion of cost sharing assistance for financially needy enrollees because it aligns with HLC's vision of improving patient access to quality healthcare.

- **Geographic Scope:** The Announcement states that, "CMS intends to conduct the model test in the following Part D Regions: Region 7 (Virginia), Region 11 (Florida), Region 21 (Louisiana), Region 25 (Iowa, Minnesota, Montana, Nebraska, North Dakota, South Dakota, Wyoming), and Region 28 (Arizona)." Unfortunately, the way the model is designed creates a large competitive disadvantage for plan sponsors outside of the designated regions by limiting the geographic locations where these benefits will be available, despite the fact that they are available and successful today in other lines of business for sponsors operating outside of the designated regions. The design does not address the value of being able to offer these benefits to all Part D members to achieve better alignment of PDP sponsor and government financial interests and optimize therapeutic outcomes. As proposed, exclusion from the model will result in a potential delay of seven to ten years from today since the model does not start until 2017, runs for five years, and will be evaluated before making it available to a broader geographic area.

  HLC recommends that CMS reconsider limiting the Part D Enhanced MTM model to only five regions. We recommend that qualified plan sponsors in other states be permitted to participate to enable them to offer the same range of benefits and incentives to their members to improve health quality and lower cost.

- **Payment incentives:** HLC welcomes the use of plan-specific prospective payments to support care management as well as performance payments as part of the Enhanced MTM model. HLC believes that a misalignment of incentives for

the standard MTM program has discouraged plans' investment in the program beyond meeting minimum CMS requirements. HLC supports performance payments as a way of offering plans greater reward in exchange for increased performance-based risk. HLC urges CMS to invest in research to determine whether these payment incentives will offset participating plan sponsors' increased resources in the Enhanced MTM model.

- **Stakeholder outreach:** HLC supports CMS's emphasis on seeking out strategies to individualize beneficiary and prescriber outreach and engagement. In particular, HLC is a proponent of using health information technology to facilitate more efficient and impactful interactions among prescribers, pharmacists, and beneficiaries. For example, the Announcement calls for "[g]reater reliance on clinical pharmacist screening or mediation of communications with prescribers," "[p]roviding beneficiary medication histories to physicians or other providers in accessible and clinically relevant formats," "[e]nabling physicians to order pharmacist consults directly from a standardized list of services on electronic medical record order entry screens," "[p]rospective medication refilling and pre-notification of prescription ordering, or prescription refill synchronization." All of these components will allow plans to better serve patients and provide high quality care.

- **Data Interoperability:** HLC welcomes CMS's efforts to develop MTM-specific code sets, because it aligns with ONC's vision of prescription drug data interoperability. HLC urges that CMS provide participating plans with an opportunity to participate in the process of developing the quality indicators that comprise the uniform set of MTM data elements. HLC also applauds CMS for attempting to link clinical and MTM data.

- **Learning Systems:** HLC appreciates CMS's emphasis on learning activities in this model, and supports the promulgation of lessons that can place all participating plans on a path to high performance. HLC members support knowledge-sharing broadly, but we request that CMS be more explicit about how plans' proprietary information can be appropriately protected while meaningfully participating in the Enhanced MTM model. In addition, we support broader sharing activities so that plan sponsors in states not permitted to participate in the model are not at a competitive disadvantage if and when the model is expanded to additional regions.

- **Stakeholder Collaboration:** HLC urges CMS to reconsider its stance regarding manufacturer and health plan collaborations. The announcement's restrictions on PDP sponsors' ability to make use of personnel affiliated with a manufacturer, manufacturer-financed coupons or discounts provided to a beneficiary or manufacturer-supplied educational materials is short-sighted. HLC believes that some types of interaction between PDPs and manufacturers are appropriate. Manufacturers have a great deal of expertise, and experience in dealing with issues of disease awareness and adherence and incentives in Part D and it is

important that all stakeholders (from pharmacists to industry) be able to share best practices. (Additionally, since PDP plans are at risk, it is unlikely that plans will use manufacturer collaboration to increase costs.) We encourage CMS to think creatively about ways stakeholders can work together to increase medication adherence.

- **Measure Development:** HLC appreciates CMS's acknowledgement that the final quality metrics for the program will need to be selected and developed collaboratively. To that end, HLC encourages CMS to rely on measures that have been developed through an intensive, transparent development and evaluation process such as the processes employed by national quality organizations like the Pharmacy Quality Alliance (PQA) and the National Quality Forum (NQF). These processes are designed precisely to provide validation of the rigor of the measure and ensure that measures reflect stakeholder consensus. In selecting measures, CMS should aim to include a range of measures that meet the above standards and reflect patient outcomes. In addition, HLC encourages CMS to work with stakeholders to choose measures that address clinical outcomes for the conditions selected by plans for enhanced MTM services to determine any potential effect that these services have on overall quality of care.

  Finally, HLC encourages CMS to work with a broad range of stakeholders as it identifies measures and develops reporting specifications to assess plan performance and the overall impact of the demonstration. In addition to more direct stakeholder engagement, this will be best achieved through a public comment process that allows a full range of stakeholders to provide input into the final measure set, performance standards (e.g., for purposes of determining performance-based payments), and evaluation methods.

HLC's National Dialogue for Healthcare Innovation (NDHI) Initiative

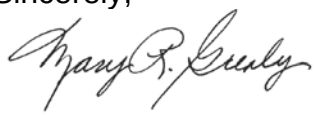
As part of HLC's National Dialogue for Healthcare Innovation (NDHI), established to bring together leaders from industry, government, academia, patient organizations, and all sectors of healthcare to discuss and develop consensus approaches to challenges affecting the course of healthcare innovation, HLC has formed a patient engagement and adherence workgroup. The workgroup, comprised of NDHI summit participants (HLC members and other diverse organizations from across the healthcare spectrum) will have a unique perspective and ability to develop comprehensive recommendations that will be beneficial to the patient.

The patient adherence workgroup has finalized its workplan, which includes a focus on how patient adherence can be supported throughout the care continuum, in acute and chronic care settings. We look forward to working on a set of care plan best practices to share with you as you work on The Care Planning Act" (S. 1549) to help patients manage their chronic care planning and improve care coordination through care plans.

The workgroup will also seek to streamline federal medication therapy management (MTM) programs to make the current system more effective. The workgroup will meet throughout the fall and we look forward to sharing our findings from this and other workgroups with you when they are finalized.

Thank you again for the opportunity to provide a statement for the record. If you have any questions, please do not hesitate to reach out to me or Debbie Witchey at dwitchey@hlc.org or 202-449-3435.

Sincerely,



Mary R. Grealy
President