January 26, 2016

Senator Orrin Hatch, Chairman
Senator Ron Wyden, Ranking Member
United States Senate Committee on Finance
Washington, D.C. 20510

Re: Senate Finance Committee Chronic Care Working Group Policy Options

Chairman Hatch, Ranking Member Wyden, and members of the Senate Finance Committee,

As the Committee working group solicits feedback on proposed policy options to improve chronic care, the National Community Pharmacists Association (NCPA) appreciates the opportunity to provide our perspective and response to the proposals which have the potential to improve the health outcomes of millions of Medicare beneficiaries in a higher quality, cost-effective manner. We would also like to thank the Committee for its consideration of our initial set of comments from 2015 and including NCPA in stakeholder meetings.

NCPA represents the interests of America's community pharmacists, including the owners of more than 22,000 independent community pharmacies. Together they represent an $81.4 billion health care marketplace and employ more than 314,000 individuals on a full or part-time basis. Additionally, about 40% of the long term care (LTC) market is serviced by independent community pharmacy. Over half of our LTC members have a service area that is over a 50 mile radius, thus having far reach into many rural communities who rely on the special services LTC pharmacies provide. Independent community pharmacists are proud to play a vital role in the Medicare Part D program, and have been on the front lines of providing medications, related counseling, and assistance with plans since the inception of the program.

NCPA will be providing feedback on the following areas:

- Expanding the Independence at Home Model of Care
- Improving Care Management Services for Individuals with Multiple Chronic Conditions
- Expanding Access to Prediabetes Education
- Study on Medication Synchronization

Overall we have the following observations and recommendations:

- We are encouraged to see the Committee's commitment to advancing team-based care. Our recommendation is to include pharmacists as essential health care providers on chronic care teams and the designated lead in coordinating safe and effective medication management. Pharmacists are often the health care professional patients see more often than their physician or specialists, and yet are currently a vastly underutilized health care provider. Pharmacists have the medication expertise and training in disease state management (e.g. smoking cessation, obesity, asthma) to be an extremely valuable team member. NCPA continues to advocate for pharmacists as formal providers who can independently bill for services to fill gaps in chronic care, especially in rural, medically underserved areas.
- CMS can better coordinate the care of beneficiaries by improving data sharing and implementing innovative payment strategies among Parts A, B, and D by looking at the total cost of care, rather than individual benefits separately. In fact, the Center for Medicare & Medicaid Innovation (CMMI) has recognized the importance of aligned incentives across the Medicare program to better coordinate chronic care. CMMI recently announced a new demonstration model to examine enhanced changes to the Medication Therapy Management

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(MTM) program within Part D. These changes are intended to maximize the value of MTM services and improve health outcomes by better aligning the financial interests of standalone prescription drug plan (PDP) sponsors, and creating incentives for more flexibility and innovation in designing and delivering the MTM benefit. This was a concept championed by NCPA in our first set of comments to the Committee, and we believe the demonstration is a positive enhancement to the MTM program.

- In defining the parameters for managing chronic care, it is important not to establish criteria that is too rigid and may miss a subset of patients who could benefit from services. Even having one chronic disease, such as diabetes could require a patient to be on multiple medications across different classes of drugs. It's important to keep patient goals and outcomes in perspective and not be bound by strict standards that may be set too high. We would like to reiterate our support for S. 776, the *Medication Therapy Management Empowerment Act of 2015*, which has bi-partisan support from the Finance Committee.
- Encourage and empower patients to take an active role in managing their chronic care by taking control of medication use through personalized, coordinated refill programs. There is evidence that supports a positive correlation between refill coordination and improving medication adherence, which in turn could provide greater savings on medical expenditures due to reduced complications or hospital admissions. Plan sponsors should be required to provide appropriate payment for professional pharmacy services related to refill synchronization, not just the dispensing of the medication, via a formal structure within the Medicare Part D program

Pharmacists provide and fill gaps in patient care, especially in underserved areas

NCPA strongly believes that community pharmacists play a vital role on an integrated health care team, as we work together with our allied partners in delivering safe, high-quality and cost-effective care to the Medicare population, and there is positive evidence to support the expanded role of the pharmacist. A white paper from the National Governors Association notes that integrating pharmacists into chronic-care delivery teams, has the potential to improve health outcomes because of the critical role medication management plays in treating chronic disease.[1] However, there are also barriers in the current fee-for-service program, preventing pharmacists from being able to provide their services to Medicare beneficiaries. In a 2011 Report to the Surgeon General, the Office of the Chief Pharmacist noted that "pharmacists may be the only health professionals (who manage disease through medications and provide other patient care services) who are not recognized in national health policy as health care providers or practitioners."[2]

We are pleased with the bi-partisan support from Congress for pharmacists' services to be formally recognized, including members of the Finance committee, who serve as original co-sponsors of S 314, the *Pharmacy and Medically Underserved Areas Enhancement Act*. S 314, if enacted, would permit pharmacists to perform patient care services consistent with their state's scope of practice if their pharmacy is located in a medically underserved area, health professional shortage area, or medically underserved population. More than any other segment of the pharmacy industry, independent pharmacies are often located in the underserved and rural areas that are home to many Medicare recipients. In fact, independent pharmacies represent 52% of all rural retail pharmacies and there are over 1,800 independent community pharmacies operating as the only retail pharmacy within their rural communities.[3] This could alleviate issues with primary care provider shortages in rural areas, and provide enhanced preventative services as well.

Expanding the Independence at Home Model of Care

NCPA supports the concept of 'aging in place', so Medicare beneficiaries can continue to carry out their daily activities and feel more comfortable staying in their own home and communities if they have the ability to remain independent. We are in favor of expanding the current Independence at Home demonstration, and believe that initial results are encouraging. As the program continues to evolve and expand, we would strongly urge the

[1] National Governors Association. The Expanding Role of Pharmacists in a Transformed Health Care System. 2015.
[2] 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.
[3] Based on NCPA Analysis of National Council for Prescription Drug Programs (NCPDP) data, Rural Urban Commuting Area (RUCA) \ Codes, and 2000 U.S. Census data.

inclusion of a community pharmacist as part of this care team. Nearly 80% of independent pharmacies provide delivery services, which can include a visit by a pharmacist to perform a medication review in the patient's home.[4] In addition, many pharmacies provide specialized medication adherence packaging and medication reconciliation services during transitions between care settings, which can reduce medication errors and prevent patients from being readmitted to the hospital or other acute care settings. The home visits from a pharmacist a few days after discharge from the hospital can provide the critical counseling and education the patient needs to recover in the comfort of their home, versus being readmitted due to an adverse event or medication error. Expanding the independence at home project to include pharmacists could produce further savings in overall medical expenditures that have been realized up to now.

In addition to involving community pharmacists in transitions of care for Medicare beneficiaries, allowing the recognition of pharmacists involved in beneficiaries living at home instead of going to an institutional setting, such as a skilled nursing facility, assisted living facility or other change of residence, can assist in decreasing costs and providing better outcomes. Providing special packaging to aid in medication adherence, coordination with prescribers, medication management with the beneficiary and/or care giver are examples of how pharmacists can impact these beneficiaries in a positive manner.

Improving Care Management Services for Individuals with Multiple Chronic Conditions

We are supportive of the addition of a complex chronic care management (CCCM) code that clinicians could bill under the Physician Fee Schedule, and would recommend its temporary use on a trial basis during which time CMS could gather data on its effectiveness and utilization of the code. In establishing patient eligibility criteria for these potential new CCCM codes, we believe that the proposed criteria of five or more chronic conditions is high. If the focus is on early detection, intervention, and prevention of complications, we would not recommend waiting until a beneficiary has five chronic conditions before care management is provided.

We can understand the need to ensure that increased Medicare payments correlate with quality improvement. While CPT codes are designed for billing, there are also ways to capture and document care. The Systematized Nomenclature of Medicine–Clinical Terms (SNOMED-CT) is a comprehensive clinical coding nomenclature used to document patient care in the electronic health record (EHR) and added to electronic care plans for the electronic exchange of clinical health information in a standardized manner. SNOMED-CT codes could be utilized to differentiate the eligible provider or clinician including pharmacists who provided the high-severity chronic care management service. For example there are over 250 SNOMED-CT codes specific to medication therapy management by pharmacists. These codes can be used to capture and exchange patient agreed medication-related goals of care.

NCPA also believes that pharmacist-provided medication management services should be included under the CCCM code. Pharmacists spend time reviewing a patient's medication history to optimize their medication use, including monitoring for allergies, potential drug interactions, duplicate therapies, ways to reduce pill burden and improve adherence such as combination products, and identifying cost-saving alternatives. This preparation work is performed ahead of an appointment with the patient, without a face-to-face encounter and is likely to require more than 20 minutes a month, especially for patients with more complex regimens. Ideally pharmacists would be recognized as a 'qualified health care professional' and able to bill independently for these services with their own provider number, rather than incident-to and under the supervision of a physician. Allowing greater flexibility for pharmacists to document and bill for such services also dovetails with the independence at home demonstration, and could aid with more eligible professionals providing CCM services, thereby illustrating the need for formal provider status for pharmacists.

Expanding Access to Prediabetes Education

We applaud the working group for recognizing that prediabetes can often serve as a warning sign of further disease progression and complications associated with other chronic conditions. Greater efforts focused on earlier lifestyle modifications and management with medications as soon as patients are diagnosed with prediabetes can

[4] 2015 NCPA Digest sponsored by Cardinal Health

improve their quality of life and reduce overall health care spending. Therefore NCPA is supportive of the proposal to expand coverage for diabetes self-management training (DSMT) to beneficiaries with a diagnosis of prediabetes.

In the Committee's consideration of expansion of diabetes education, we would strongly urge consultation and coordination with the nation's leading groups on diabetes self-management education. There are existing cooperative partnerships between these organizations and the Centers for Disease Control and Prevention (CDC) with established networks of diabetes educators and nationally certified DSMT locations to implement the National Diabetes Prevention Program (DPP), which could serve as a blueprint for high quality, cost effective models in diabetes care management. However, for purposes of the policy proposals under consideration, we would like to clarify that the DPP and DSMT programs are separate and distinct.

The working group has asked for feedback on whether a program like the DPP should be expanded to include entities not currently listed as providers under the Medicare statute. First and foremost, we would like to note that the term "diabetes educator" is not currently defined under Medicare statute, and we would recommend that this be rectified prior to expansion of such services. We are supportive of another bill introduced in the Finance Committee, S. 1345, *Access to Quality Diabetes Education Act of 2015*, which would provide the formal recognition of diabetes educators and bring greater awareness to DSMT. Secondly, increasing the number of providers may not necessarily solve the issue of beneficiary access to DSMT. The sites which are currently facilitated to provide DSMT for patients with diabetes can extend these services to those diagnosed with prediabetes. Some of the inherent issues are related to payment, and NCPA believes that greater access to DSMT services can be improved with better consistency in Medicare Part B billing practices.

NCPA would like to highlight the extraordinary need that community pharmacists are ready and willing to fulfill in providing DSMT services, but they just are not able to. As we've pointed out, community pharmacies are often located in underserved areas of the country, with approximately 6,700 independently owned rural pharmacies, and over a quarter of those serving as the only pharmacy and likely health care resource in their community.[5] Based on our members' experience, an overwhelming majority of them have indicated interest in becoming an accredited site for DSMT, which could provide incredible reach into these rural communities; however reimbursement and billing challenges and restricted provider networks have stalled these efforts. We would like to take this opportunity to share the experiences of our members which have posed barriers to billing for such services, and limited the extent to which they can provide these programs.

The American Association of Diabetes Educators (AADE) currently has 149 pharmacies accredited nationwide, but over the past three years over 60 locations have had to give up their accreditation due to the inability to be able to service patients, with pharmacies citing the lack of reimbursement due to complicated enrollment and billing processes. There could be a much healthier supply of accredited pharmacies; however a large number of local Medicare administrative carriers (MACs) are still unable to efficiently process 855B enrollment applications from accredited DSMT pharmacies. This effectively discourages already accredited DSMT providers from continuing the process and the problem lies in how pharmacies are enrolled in Medicare Part B.

Historically most pharmacies are enrolled with Medicare as a 'mass immunizer', and DSMT services cannot be added to a mass roster billing number, the provider must change their mass immunizer number to a pharmacy type number. In order to make the change, MAC contractors must issue a new provider transaction access number (PTAN), resulting in the provider paying an additional enrollment fee. Additionally, if the PTAN is not correctly set up, this can result in denied claims, and also negatively affect the pharmacy providers other Part B claims (such as durable medical equipment (DME)). While pharmacy providers are accredited and trained to provide DSMT, the barriers to entry are daunting and often become a deterrent, which other providers are likely to face as well if additional entities are included as eligible providers.
Community pharmacies have also been receiving support from the CDC to obtain facility accreditation to provide DSMT, but their efforts to provide these services are hampered by payers and insurers who are limiting their

[5] RUPRI Center for Rural Health Policy Analysis. Update: Independently Owned Pharmacy Closures in Rural America, 2003-2013. June 2014.

provider panels. Plan sponsors may claim that they offer such training, yet significantly limit the eligible providers in their network and are often excluding community pharmacies as participating providers. As an example, there is a community pharmacy that is an accredited provider in Sparta, TN that was unable to service the beneficiary because they were enrolled in a managed care plan. That patient had to travel 100 miles round-trip to Nashville's Vanderbilt Hospital to get the training that she needed. Greatly limiting provider networks for this population will only cause greater harm to the beneficiaries who could most benefit from such services.

While NCPA is supportive of the working group's proposal to expand access to prediabetes education to eligible beneficiaries, and believe it is the right thing to do to improve patient care, there are hurdles which remain in place and could prevent DSMT programs from realizing their full potential.

Study on Medication Synchronization

For many chronic illnesses, medications are the most cost-effective course of treatment. And yet patients routinely miss doses, fail to fill or refill a prescription, take a lower or higher dose than prescribed, or stop taking a medication without consulting a health care professional. These actions constitute medication non-adherence, the economic costs of which are estimated at nearly $300 billion a year.[6] In addition, studies have found that higher rates of medication adherence result in significantly fewer hospitalizations and lower health care costs, and that these savings are greater for patients over age 65, further amplifying the problem in Medicare beneficiaries.[7][8]

Medication synchronization is increasingly being recognized as a tool to improve adherence, and we greatly appreciate the working group's proposal for a study on medication synchronization, the process of a pharmacy coordinating all of a patient's chronic prescription medications to be filled on the same date each month. NCPA and its members have seen positive outcomes thus far from these services, with over 2,500 community pharmacies nationwide providing medication synchronization programs and more than 100,000 patients enrolled. Given our experience with such programs, we would like to offer additional recommendations for how the study can be structured, additional research questions, and policy discussions for consideration.

We believe the feasibility of expanding medication synchronization programs within Medicare is relatively high, with the application of daily cost-sharing requirements already implemented in Part D. There is also the electronic messaging infrastructure in place for pharmacies to communicate to plan sponsors their reasoning for 'short fills' which may become necessary in order to align a patient's medications to come due on a certain date. There is also growing evidence on the correlation between refill alignment in fostering improved adherence. Patients enrolled in an appointment-based refill model, whereby they met with a pharmacist monthly to discuss medication-related problems in addition to the synchronization of their refills, were 3.4 to 6.1 times likelier to remain adherent compared with control patients with no pharmacist intervention. Patients in the control group were 52 to 73% more likely to stop taking their chronic medications over one year.[9]

For purposes of the study being proposed by the Committee, an important distinction needs to be made between appointment-based, refill coordination programs and automated refills (or auto-fills). Refill coordination programs include high-touch, personalized patient consultations each month, when a personal outbound call is made from the pharmacy to the patient to review all of their medications, and any notable changes that have occurred in the past month. This medication reconciliation process is a cornerstone of the model and allows the community pharmacist to identify any recent hospitalizations, especially those that may have resulted in changes in therapy (such as new medications, discontinuations, or dosage adjustments) during care transitions. In order to achieve this, the pharmacist initially performs a comprehensive review of the patient's medication regimen to determine the appropriateness of each therapy and the patient receives a personal call each month to review their

[6] NEHI. Thinking Outside the Pillbox – a system-wide approach to improving patient medication adherence for chronic disease. 2009

[7] Roebuck MC, Liberman JN, Gemmill-Toyama M, Brennan TA. Medication adherence leads to lower health care use and costs despite increased drug spending. *Health Affairs* 2011;30(1):91-9.

[8] Sokol MC, *McGuigan* KA, *Verbrugge RR.* Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost. *Med Care* 2005;43(6):521–30.

[9] Holdford DA, Inocencio TJ. Adherence and persistence associated with an appointment-based medication synchronization program. *J Am Pharm Assoc*. 2013;53(6):576–583.

medications prior to filling them to ensure no changes have been made and to confirm the patient is still taking the medication. This level of service does not exist with automated refills.

It will also be critical that the proposed study on medication synchronization be focused on coordination and management of chronic care and improved patient outcomes (e.g. blood pressure, hemoglobin A_1C, lipid panels, weight at goal). The data sources cannot and should not be based solely on claims data, as prescription refills may not be the most accurate indicator of true patient adherence. If study endpoints such as proportion of days covered (PDC) or medication possession ratio (MPR) are used to measure success, plan sponsors will revert to methods used today to boost their quality measures for adherence such as auto-fill and large quantity fills of 90-day supplies that could be used to inaccurately reflect positive "adherence" and thus medication synchronization success. The core of the coordinated refill program is not in the process of aligning the medications, but the opportunity for a monthly and thorough review of a patient's medication regimen.

To capture this data, a SNOMED-CT code has been established to document the procedure that a pharmacist has provided medication synchronization, and early adopters plan to utilize this code to demonstrate pharmacist clinical services at the time the patient visits their community pharmacist when the medications are synchronized. The working group could consider tying SNOMED-CT codes for medication synchronization and/or MTM and relate medication management services to a beneficiary's hospitalizations (or lack thereof) and reduction in overall health care spend.

Coordinated refill programs are an example of a scalable, innovative model of care delivery that can achieve more coordinated, patient-centered care. They provide high-touch monitoring of medication regimens and empower the patient to be an engaged participant in their care. Recent evidence from both CMS data and the Congressional Budget Office (CBO) confirms the positive impacts associated with comprehensive medication reviews, not only in relation to improved adherence and health outcomes, but also in medical savings.[10,11] In addition to studies conducted by CMS and CBO, additional studies have shown that adherence services can lead to a reduction in overall healthcare expenditures. We believe the study question of, "do medication synchronization programs improve adherence" has already been answered with a resounding "yes". We would hope that this study on medication synchronization has parameters that are more directly tied to achieving patient goals and demonstrating outcomes in order to examine the impact of adherence on chronic care.

Ultimately what we would like to accomplish through this proposed study on medication synchronization is a realization of the true benefits of working closely with a pharmacist to manage a patient's medication profile to optimize health outcomes and improve chronic care. Given the time involved in the monthly review and comprehensive counseling, NCPA would like to see this become a recognized benefit under the Medicare Part D program with coverage for the service which could be billed monthly, not just the application of a daily cost-sharing rate for beneficiaries. NCPA believes that prevention is the best medicine, and whether it's catching a medication error before it leads to a hospitalization or effective chronic disease management, adherence services and the corollary counseling present opportunities to improve patient care while providing greater efficiencies within the healthcare system.

Conclusion

We would like to commend Committee staff for holding the stakeholder meetings, compiling feedback, and distilling those ideas into the proposals put forth. NCPA appreciates the opportunity to share our perspective on the working group's policy options for improving chronic care.

[10]CMS Center for Medicare & Medicaid Innovation ,Medication Therapy Management in Chronically Ill Populations: Final Report, August 2013

[11] Congressional Budget Office, Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services, November 2012.