March 7, 2014

[Submitted electronically to www.regulations.gov]

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS–4159–P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: CMS–4159–P Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Proposed Rule

Dear Sir/Madam:

APhA is pleased to submit these comments regarding the proposed changes to the Part D program for CY 2015 (the “Proposed Rule”). Founded in 1852 as the American Pharmaceutical Association, APhA represents more than 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

We thank CMS for its recognition of the value of pharmacists’ services and the importance of patient access to these services, which improve overall health and well-being. Overall, APhA strongly supports a number of the provisions in the Proposed Rule. Specifically, APhA believes that the Medication Therapy Management (“MTM”) expansion provision, the “any willing pharmacy”/preferred cost-sharing provision, and the changes to mail-order services represent fundamental, much-needed reform that will greatly benefit beneficiaries. However, APhA, like many other groups, has concerns regarding the proposed changes to the protected drug classes. As such, we strongly encourage CMS to retain the MTM, “any willing pharmacy”/preferred cost-sharing, and mail-order provisions in the Final Rule, and to remove or substantially revise the protected drug classes provision in the Final Rule. Below we will provide CMS with some additional constructive feedback that we hope can be used to perfect the above provisions in the Final Rule.

I. Medication Therapy Management

APhA would again like to take this opportunity to express our thanks to CMS for recognizing the important role pharmacist-led MTM plays in improving patient outcomes and enhancing care transitions in a cost-conscious manner. Because the Proposed Rule includes changes like the MTM...
expansion, which is a fundamental, much-needed reform that will greatly improve access to MTM services for Part D beneficiaries, we encourage CMS to include this provision in the Final Rule.

We agree with CMS that MTM must “become a cornerstone of the Medicare Prescription Drug Benefit.” Medication-related problems have a significant detrimental impact on patient safety in the U.S. health care system, and MTM services are a mechanism to improve both the quality and cost of medication-related outcomes and overall health care. Further, some studies indicate that for every $1 spent on MTM services, up to $12 is potentially saved—in addition to costs savings, patients also realize significant improvements in key health measures. As such, we believe that by broadening the criteria for MTM eligibility—criteria that will allow many more Medicare beneficiaries to benefit from MTM services—CMS is taking an important step toward improving patient health in a cost-conscious manner. Variation in plans’ MTM eligibility criteria creates confusion for providers and beneficiaries alike, and the new criteria included in the Proposed Rule create consistent eligibility standards that should lead to a more uniformly administered and widely-used MTM benefit that is much more likely to meet CMS’s goals for the program.

A. Eligibility Criteria, “Core” Chronic Diseases, and Cost Threshold

As stated above, APhA supports the eligibility criteria laid out in the Proposed Rule. We believe the proposed criteria are better aligned with successful MTM models such as the Minnesota Medicaid program. Setting the requirements for eligibility at two chronic diseases and two Part D medications will reduce the variability in Part D plan sponsors’ beneficiary targeting criteria. This should result in a more consistent and coordinated benefit for beneficiaries who previously might have qualified for MTM services in one Part D plan but not in another. Furthermore, standardizing the requirement that at least one of the chronic diseases must be one from a core list of core chronic diseases will help significantly reduce confusion regarding beneficiary eligibility among beneficiaries, and providers.

As CMS continues to evaluate the core chronic disease list in the future, we recommend that the agency seek and consider the input of pharmacists who regularly provide MTM services. We also recommend that CMS consider testing a process that would allow pharmacists and physicians to identify and refer patients who may require and/or may benefit from MTM services, but who may not have one of the targeted conditions or who do not meet other eligibility criteria.

APhA also strongly supports the reduction in annual cost threshold to $620. Most studies point to the number of medications, rather than the cost of those medications, as the most significant risk factor related to medication use. Thus, lowering the legally-required cost threshold removes a barrier that had prevented some beneficiaries with high-risk, low-cost medication regimens from participating in the MTM program. The cost reduction is likely to result in increased eligibility for patients who use lower-cost generic medications and, importantly, is likely to help to address racial and ethnic disparities in meeting MTM eligibility criteria.


Additionally, we urge CMS to ensure any definition of “core chronic disease” be treated consistently across all plans. We are concerned that plans may include more restrictive criteria to define a disease state in order to limit eligibility. For example, it could be possible for a plan sponsor to limit beneficiary eligibility for MTM services by defining restrictive criteria for a core chronic disease. A plan sponsor could define “diabetes” restrictively and limit eligibility to beneficiaries with a diagnosis code of five digits rather than the more common three digit code. The definition for each core chronic disease should be specific enough to prevent undue flexibility for plans. In the past, flexibility in MTM criteria has led to a less-than-optimal uptake of MTM services—clear and consistent definitions will safeguard beneficiary access to MTM services.

B. Parameters for Service Provision

As an organization that represents pharmacists who provide MTM services on a daily basis, we wish to ensure that the MTM services are expanded in the manner most likely to result in the greatest benefits for patients. Specifically, the Proposed Rule specifies targets for eligibility, but does not include parameters regarding the actual provision of MTM services.

We strongly encourage CMS to consider including criteria for MTM service delivery in the MTM expansion section of the Final Rule. In the Proposed Rule’s preamble, CMS cited the Center for Medicare and Medicaid Innovation (“CMMI”) MTM study a number of times, noting that “high-performing MTM programs” leveraged “trusted relationships” between pharmacists and patients and close coordination between pharmacists and prescribers. We support CMS’s recommendation that Part D sponsors “must have an outreach strategy designed to effectively engage all at-risk beneficiaries enrolled in the plan.” Further, we are very encouraged by CMS’s recognition that “incorporating the pharmacies that targeted individuals utilize into the MTM program may be a particularly effective strategy for successful outreach that will lead to enrollment in MTM programs that is more broadly representative of the breadth of demographic segments in the targeted population.” These trusted relationships between patients and health care professionals are foundational to patients’ engagement in the health care system. Thus, we urge CMS to require that, as CMS proposed to do for cost-sharing terms and conditions (see Section III below), Part D sponsors expand contracting opportunities for pharmacists in the community to provide MTM services to their patients with whom they have trusted relationships.

Further, in order to expand the MTM program effectively, we strongly encourage CMS to require plans to increase patient and prescriber outreach and education efforts regarding MTM services. During discussions with our members, many have noted that patients are often entirely unaware that MTM services are available to them as part of their plan benefit. In some plans, pharmacists may be required to call beneficiaries to determine their interest in receiving MTM. In many instances, beneficiaries receiving these calls have no previous experience with MTM and are suspicious that these are “sales” calls or scams. This perception may account for many MTM opt-outs. However, if patients were better informed and plans were required to provide beneficiaries with information regarding MTM in advance of these calls, as well as on an on-going basis, it is likely that

5 Id.
more beneficiaries would take advantage of the services provided. Additionally, prescribers do not always receive information relevant to MTM services. As a result, pharmacists providing MTM are left to explain the benefit to prescribers, which can negatively impact coordination of care and patient outcomes. As more beneficiaries have access to this service, a small investment in patient and prescriber education on MTM could result in improved utilization of services, and as a result, improved patient outcomes.

i. Comprehensive Medication Reviews

Comprehensive Medication Reviews (“CMRs”) are an essential element of successful MTM. In the preamble to the Proposed Rule, CMS notes that “annual CMRs may be one of the more crucial elements of MTM.” We agree with this assertion, but caution that an annual CMR should be considered a minimum requirement. In some instances, patients benefit significantly from additional CMRs, especially during care transitions and when changes to medication therapy are initiated—thus, we suggest that CMRs be provided, as determined by the beneficiary’s providers, including the beneficiary’s pharmacist.

In this vein, we also encourage CMS to implement criteria for pharmacist and prescriber referrals into MTM programs. As CMS notes, the CMMI study identified “establishing proactive and persistent CMR recruitment efforts” as a major component of a “high-performing” MTM programs. However, at present, MTM is available based only on plan determinations of eligibility, and the providers who are most familiar with a beneficiary’s medical history are not permitted to refer them for MTM services. Allowing pharmacists and prescribers to use their expertise and patient knowledge to identify beneficiaries who would benefit from MTM, particularly when the patient is undergoing a care transition or beginning a new medication, could result in significant increases in the number of appropriate and highly-beneficial MTM interventions and would improve coordination of care across the system. Incorporating CMRs and follow-up MTM services into a patient’s regular care increases the likelihood of more appropriate medication regimens and increased medication adherence while decreasing the chances of adverse drug events.

ii. Targeted Medication Reviews

Many plans employ a “check-the-box” approach to MTM, which allows essential MTM elements, including targeted medication reviews (“TMRs”), to be completed on paper without direct contact with the patient. The “Core Elements of an MTM Service Model” states that in addition to an annual comprehensive medication therapy review, patients receive “additional targeted medication therapy reviews (“MTRs”) to address new or ongoing medication-related problems.” Significant events, such as the important changes in the patient’s medication needs or resources, changes in the patient’s health status or condition, a hospital admission or discharge, an emergency department visit, or an admission or discharge from a long-term care or assisted living facility would necessitate additional comprehensive MTRs. In contrast, the current Medicare Part D requirements for TMR

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service delivery (i.e., follow-up) do not require person-to-person interaction. This approach is less costly for plans and may not achieve desired outcomes.

As demonstrated in other robust medication management programs, ongoing person-to-person monitoring is necessary to achieve clinical goals, especially in complex high-risk patients. Furthermore, requiring quarterly TMRs may not be the most effective approach. Especially with the new eligibility criteria, some targeted beneficiaries may not need successive quarterly follow-up TMRs whereas others may need more frequent TMRs. Once a beneficiary is enrolled in an MTM program and a CMR is completed, follow-up medication reviews (i.e., comprehensive or targeted) should be provided based on the specific needs of the patient as determined by the pharmacist working collaboratively with the prescriber to meet the patient’s clinical goals. Thus as we suggested for CMRs in Section I(B)(i), we encourage CMS to test alternative approaches to follow-up medication reviews that use a person-to-person approach with the frequency of follow-up determined by the pharmacist based on patient need and justified by appropriate documentation. We anticipate that beneficiaries taking fewer medications may need less follow-up (i.e., person-to-person TMRs) than those taking more medications, and using an approach based on individual patient needs would allow limited resources to be allocated most effectively and efficiently. In order to ensure that TMRs provide the highest level of benefit for patient health and outcomes, we recommend that CMS consider creating specifications that TMRs should be person-to-person, with varying levels of intensity and frequency of delivery based on individual patient needs.

iii. Payment Model

Another barrier to more effective MTM delivery is the current payment model. In the assumptions set forth in the Effects section of the Proposed Rule’s preamble, CMS states that it assumes CMRs will take 35 minutes to complete and will cost $120 to deliver, with $70 of costs associated with direct labor. This payment level is higher than the payments that many providers are able to receive for contracted MTM services, and we hope that plans will use it in calculation of bid submissions. However, we caution that CMS should monitor the actual completion time within the context of the new eligibility criteria (e.g., CMS could implement MTM completion time surveys similar to the cost-of-dispensing surveys they have previously used). With the current criteria, many of our members report that a CMR takes approximately 45-60 minutes, on average, to complete. With the broader eligibility criteria, a CMR average of 35 minutes may be appropriate if the delivery of the benefit is allocated between community pharmacies and Part D plans in a fair manner.

APhA strongly encourages CMS to implement models that allow pharmacists in the community the opportunity to provide MTM services. Opening MTM services provision up to more providers aligns with CMS’s goals of promoting competition (as stated in the “any willing provider” section of the Proposed Rule) and also better positions MTM services for incorporation into integrated care delivery models (as discussed in Section I(B)(iv) below). We are concerned that plans may implement tiered approaches that funnel beneficiaries taking fewer medications to the Part D plan’s in-house MTM program, while more complex patients are referred to pharmacists in the community for services. This approach may be appropriate for increasing access and uptake for MTM services, but would not yield payment sufficient to cover costs for complex patients if the above payment

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9 Proposed Rule at p. 2096.
parameters are used. However, if pharmacists in the community also regularly provide MTM for less complex cases, this could decrease the average time spent on MTM provision and help offset costs. In order to ensure that payments for MTM are sufficient to cover provider costs, we suggest that CMS explore other payment models, such as a severity-based payment plans, which have been employed with some success.10

iv. Integrating MTM with Other Health Care Services

The lack of coordination and integration of MTM with the beneficiaries’ other health care services has presented some obstacles to effective MTM provision. The MTM benefit provided through Part D is siloed and is not well-coordinated with the clinical services of other health professionals on a patient’s health care team. Better integration of MTM services and the pharmacists who provide them with the rest of the health care team would better align clinical goals for the patient, better coordinate the care provided, avoid confusion, and ultimately contribute to more efficient and effective care. As demonstrated by the successes in longstanding integrated care delivery programs like Kaiser Permanente, the Veterans Administration, and Geisinger Health System, including MTM services delivered by pharmacists as part of team-based care results in improved health outcomes for patients. We strongly recommend that CMS continue to explore mechanisms for better integrating MTM with beneficiaries’ other health care services. Requiring better coordination and communication with the beneficiary’s prescriber(s) within all MTM programs and as stated earlier, leveraging trusted community relationships between pharmacists and prescribers for the delivery of MTM services would facilitate better coordination of MTM services within the health care system. APhA would welcome the opportunity to work with CMS to better coordinate MTM with other health care services.

v. Health Information Technology

Pharmacists providing MTM have indicated to APhA that the lack of access to health information and appropriate Health Information Technology (“HIT”) when providing MTM services is a major challenge. Most pharmacists providing MTM services do not have access to pharmacy management systems or other electronic record systems that have electronic health record (“EHR”) functionality, operate using Health Level 7 (“HL-7”) standards, or have the functionality to effectively communicate with other EHR systems through health information exchanges (“HIEs”). As a result, pharmacists are unable to send and receive electronic information effectively between EHRs using structured electronic documents. Thus, pharmacists cannot send or receive continuity of care documents (“CCDs”), pharmacy care notes (“PCNs”) or other structured documents between entities using HL-7, which limits the ability of pharmacists providing MTM to maximize patient care and other benefits to the Part D program. Systems currently in place rely on faxed information or phone calls, leading to ineffective and often inefficient communication and patient management. Given the considerable focus on HIT upgrades in both the American Recovery and Reinvestment Act of 2009 and the Patient Protection and Affordable Care Act of 2010, reliance on faxes for sharing information with other providers seems antiquated and burdensome. Thus, we recommend that, to the extent possible, CMS provide support and incentives for the implementation and adoption of systems with built-in EHR functionality for pharmacists providing MTM. Additionally CMS is encouraged to advise state- and regional-based HIEs to actively include and integrate pharmacies with EHR functionality into their infrastructure.

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Finally, HIEs should be advised to remove any potential barriers that may currently prevent pharmacists or pharmacies from participating in or connecting with these HIE systems.

It is also important to note that in some cases, on the basis of Health Information Portability and Accountability Act (“HIPAA”) compliance concerns, pharmacists are being told that they cannot access appropriate clinical information contained in other providers’ EHR systems that is necessary for the provision of MTM and other patient care services. This type of information-sharing is explicitly covered by HIPAA, so we encourage CMS to work with the U.S. Department of Health and Human Services (“HHS”) to ensure that all providers and health care organizations are well-versed on HIPAA legal requirements so that the information-sharing necessary for effective coordinated care is not compromised. Permitting pharmacists HIPAA-compliant access to relevant clinical information and electronic documents will enable pharmacists to effectively contribute to improved patient outcomes, to coordinate care, and to maximize the impact of MTM to Part D and the health care system.

Pharmacists hope to continue working closely with CMS to identify and implement MTM best practices, including standards related to HIT, which will allow CMS to recognize a substantial return on its investment in MTM services. On behalf of pharmacists, we again thank CMS for recognizing the value of pharmacist-led MTM services to high-quality patient care.

II. Mail-Order Services

APhA supports the Proposed Rule’s changes to both cost-sharing and fulfillment requirements. We believe that these provisions will place community pharmacies and mail-order pharmacies on a more equal playing field.

A. Mail-Order Cost-Sharing

We commend CMS for requiring equal cost-sharing for one-month supplies of the same medications, regardless of whether they are provided via mail-order or by a community (i.e., retail) pharmacy. APhA supports a level playing field that allows beneficiaries to obtain medications from a pharmacist with whom they have a trusted relationship, much like the one they have with their physician. In de-incentivizing mail-order for new and routine 30-day prescriptions, CMS is increasing the chances that beneficiaries will fill those prescriptions at a community pharmacy that can provide direct access to a pharmacist, who can answer any questions the beneficiary or caregiver may have. Additionally, we agree that filling 30-day prescriptions at a community pharmacy decreases the opportunity for gaps in therapy caused by delayed refill requests and/or delayed shipping. Taken together, these two requirements may increase medication adherence and beneficiary health.

APhA also supports the limits on cost-sharing for extended days’ supplies. Our understanding is that the prices for mail-order extended supply and community pharmacy extended supply do not need to be equal, but that mail-order cost sharing cannot be less than standard cost-sharing at a community pharmacy. Therefore, beneficiaries are free to access the pharmacy services that best meet their needs, rather than defaulting to mail-order on the basis of cost alone. While we recognize that mail-order services are essential for certain beneficiaries, they are not appropriate in all instances, and this Proposed Rule should improve patient choice in accessing pharmacy services.

11 See 45 C.F.R. § 164.506.
B. Fulfillment Requirements

As with the changes to mail-order cost-sharing, APhA also supports the Proposed Rule’s changes to Section 423.120. Requiring mail-order services, whether provided by a mail-order pharmacy or through a community pharmacy’s home delivery program, to adhere to a specific timetable for fulfillment reduces the likelihood that beneficiaries who rely on mail-order to receive medications will experience gaps in therapy.

APhA believes that the changes to the cost-sharing requirements and the fulfillment requirements will cut down on utilization of mail-order services on the basis of cost only. Leveling cost-sharing requirements and creating clear timelines for the provision of mail-order services will benefit beneficiaries, offering them greater access to pharmacy services and to pharmacist guidance, which may result in improved outcomes for patients and reduced costs for the system as a whole. Thus, we encourage CMS to maintain these provisions in the Final Rule.

III. “Any Willing Pharmacy” and Preferred Cost-Sharing Provision

APhA applauds CMS for recognizing the detrimental effects of preferred pharmacy networks on competition in the Part D program. Our community pharmacist members have repeatedly voiced concern about the substantial adverse impact of preferred networks on their businesses, patient access, and continuity of care. In some cases, pharmacists are forced to close pharmacy locations because they are shut out of the preferred network in a service area. When pharmacies close, patients lose important access points for medications. Thus, we strongly recommend that CMS retain this provision in substantially this form in the Final Rule.

In particular, we believe the “any willing pharmacy” provision will increase transparency and competition. In the past, some plans have refused to even allow pharmacies an opportunity to consider their terms and conditions. CMS’s requirement that each plan provide standard terms and conditions at each level of cost-sharing will allow community pharmacies the opportunity to consider plan terms and exercise judgment about whether they can meet those terms. The Proposed Rule will prevent plans from arbitrarily excluding pharmacies from participation in their service areas.

Additionally, APhA considers the cost-sharing changes to be a much-needed reform to Part D. Imposing a ceiling on “preferred” cost-sharing that explicitly requires preferred cost-sharing rates to fall below the standard cost-sharing rates, particularly for mail-order claims, has a two-fold impact—it allows beneficiaries more access to lower cost-sharing while stopping the “race to the bottom” for plans. Under the new requirements, it will be more difficult for plans to push cost-sharing so low that pharmacies can no longer compete in service areas. While plans and pharmacy benefit managers (“PBMs”) may argue that restrictions on the number of cost-sharing tiers will impede flexibility in designing plan benefits, we believe that fewer cost-sharing tiers will lead to less confusion in determining plan benefits. Furthermore, while plan sponsors must offer all pharmacies the opportunity to meet preferred cost-sharing terms and conditions, not all pharmacies will be able to accept them. Thus, plans will still be able to offer preferred cost-sharing (just in more pharmacies) and they will retain sufficient flexibility to design appropriate benefits.

Further, APhA believes that the “any willing provider” provision and the associated cost-sharing changes will be highly beneficial to patients. Preferred networks limit beneficiary access. If more pharmacies are able to participate in plans, more beneficiaries will have access at the same cost-sharing levels they would have encountered in the preferred networks. This change will be especially valuable for those beneficiaries who reside in rural areas. In the past, some of those beneficiaries were forced to
travel long distances in order to pick up prescriptions at preferred pharmacies. If the Proposed Rule’s provision becomes final, beneficiaries will have more choice and more access to essential pharmacy services.

IV. Protected Drug Classes

While APhA supports many provisions of the Proposed Rule discussed above, we have serious concerns with the changes to the protected drug classes. APhA respects CMS’s need to constrain costs, but we believe that the removal of antidepressants, antipsychotics, and immunosuppressants from the protected drug classes does so at the expense of beneficiary well-being.

In reviewing the statements CMS made regarding the protected classes during the February 26, 2014 Energy and Commerce hearing, it seems unlikely that the protections in place to ensure that beneficiaries smoothly transition to new drugs if formularies are changed are insufficient. During the hearing, Principal Deputy Administrator Jonathan Blum noted that even without the protections afforded by protected classes, most formularies include “79% of the drugs in each class”.\(^{12}\) Even if 79% of the drugs in a class are covered, that still means that 21% of drugs will not be covered. Patients often struggle to find medications that work well for them, and once stabilized; changing formularies could result in detrimental patient-safety issues.

Given that most patients will prefer to remain on the medication that is working for them, there will likely be a substantial number formulary appeals. Pharmacists and physicians will bear the brunt of communicating formulary restrictions to beneficiaries and facilitating formulary exceptions. While pharmacists will assist patients in every way they can, considering the sheer volume of beneficiaries who may be impacted by the changes, it may be difficult for pharmacists to fill this role for every patient during the short transition period.

Each plan has its own formulary exception and appeals process and very few of these processes are fast (Deputy Administrator Blum acknowledged that a prescriber must provide written or verbal attestation for a formulary exception), which will impede speedy transitions to new medications. Further, the transition supply for beneficiaries is “30 days of medication during the first 90 days of the plan year.”\(^{13}\) When the beneficiary communication and appeals aspects are taken together, it seems highly unlikely that beneficiaries will be transitioned to new medications without substantial disruptions to therapy.

In the interests of patient health and safety, we encourage CMS to remove this provision from the Final Rule. However, if the provision is retained, we strongly recommend that CMS revise the transition supply requirements to allow for delayed formulary exceptions and appeals determinations that are likely to result from the high volume of requests.

V. Opioid Prescribing Changes

APhA supports all efforts to combat abusive prescribing and dispensing patterns related to hydrocodone-combination products. We appreciate CMS’s recognition that all providers in the system have a responsibility to work to combat the problem. However, the change in Section 423.120(5)(ii)(B), which reads “[a] Part D sponsor must deny or require its PBM to deny a pharmacy claim for a Part

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13 Id.
D drug if the physician or eligible professional—(1) Is not enrolled in the Medicare program in an approved status; and (2) Does not have a valid opt-out affidavit on file with an A/B MAC”, raises serious concerns for pharmacists.\textsuperscript{14} While this provision appears to place the onus on the Part D plans for determining Medicare enrollment, if there is an error in the claim related to Medicare enrollment, plans should be required to cover the costs associated the charge-back. We respectfully request that CMS consider requiring that the cost for verification and correction of any claims be borne by the plan through their administrative costs.

**Conclusion**

APhA strongly supports the “any willing pharmacy”/preferred networks provision, the changes to mail-order services, and the MTM expansion provision in the Proposed Rule, which we believe will be highly beneficial to beneficiaries and the health system as a whole. Thus, we encourage CMS to include the foregoing provisions in the Final Rule. While we appreciate the costs associated with the protected drug classes, because we are concerned that the proposed changes present a serious threat to patient safety, we respectfully request that CMS remove or substantially revise the protected drug classes provision. We look forward to working with CMS as it implements these changes. On behalf of pharmacists, we again thank CMS for recognizing the value of pharmacist services, including MTM services, to high-quality patient care. It is a privilege to work with you to meet the needs of current and future Medicare beneficiaries.

Thank you for the opportunity to provide comments on the Proposed Rule. If you have any questions or require additional information, please contact Jillanne Schulte, JD, Director of Regulatory Affairs, at jschulte@aphanet.org or by phone at (202) 429-7538.

Sincerely,

Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO

cc: Stacie S. Maass, RPh, JD, Senior Vice President, Pharmacy Practice and Government Affairs
Anne Burns, Vice President, Professional Affairs

\textsuperscript{14} Proposed Rule at p. 2063.