August 12, 2019

[Submitted electronically via www.regulations.gov]

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS–6082–NC
P.O. Box 8016
Baltimore, MD 21244–8016

Re: Request for Information; Reducing Administrative Burden to Put Patients Over Paperwork [CMS–6082–NC] RIN 0938–ZB54

Dear Administrator Verma:

The American Pharmacists Association (APhA) is pleased to submit these comments regarding the Centers for Medicare & Medicaid Services' ("CMS") "Request for Information; Reducing Administrative Burden to Put Patients Over Paperwork," (hereinafter the "RFI"). APhA, founded in 1852 as the American Pharmaceutical Association, represents 60,000 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, physicians' offices, hospitals, specialty pharmacies, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services.

APhA shares CMS's goal of putting additional focus on patient-centered care, innovation and outcomes in the Medicare and Medicaid programs. APhA appreciates CMS's continued efforts "…to eliminate overly burdensome and unnecessary regulations and subregulatory guidance in order to allow clinicians and providers to spend less time on paperwork and more time on their primary mission—improving their patients' health." Pharmacists are medication experts who provide care to patients in many different settings, as described above. As payment models shift towards value-based care, the need to integrate pharmacists into different delivery models, including access to health records is growing, but several barriers can delay or prevent pharmacists from being effectively utilized.

To assist CMS accomplish the stated goals of the RFI, APhA respectfully submits the following recommendations for regulatory, subregulatory, policy, practice, and procedural changes.

A. Modification or streamlining of reporting requirements, documentation requirements, or processes to monitoring compliance with CMS rules and regulations

APhA recommends CMS clarify whether physicians and other eligible nonphysician practitioners can bill for "incident-to" services provided to Medicare beneficiaries by pharmacists at levels higher than Evaluation and Management (E/M) code 99211. APhA is aware of varying interpretations as to whether physicians and other eligible nonphysician practitioners can bill for E/M services provided to Medicare beneficiaries by pharmacists at levels higher than E/M code 99211. In 2014, the American Academy of Family Physicians (AAFP) petitioned CMS for clarification on whether a physician may bill for services provided by a pharmacist as "incident to" services.[1] Then CMS Administrator Marilyn Tavenner's response stated that, "provided all requirements of the 'incident to' statute and regulations, including applicable state and local laws, were met, such billing would be wholly permitted."[2] Therefore, communication from CMS in 2014 confirmed this interpretation of "incident to" billing provisions. Despite this guidance from CMS, APhA continues to receive reports of difficulties associated with "incident to" billing of E/M services when provided by pharmacists.

APhA appreciates the RFI's references to CMS's "Sample Accomplishments," improving the Medicare Program Integrity Manual Chapter with the "…instructions, policies and procedures for Medicare Administrative Contractors (MAC) that administer the Medicare program in different regions of the country, as well as guidance for stakeholder engagement in the process." Various MACs have provided differing interpretations of permissible billing practices, and even on an institutional leadership level, there is reluctance to permit physicians to bill for pharmacists' services at a level above E/M code 99211, even though the complexity of most services delivered by pharmacists meet the requirements for physicians to bill at higher billing levels (E/M codes 99212-215). Continued uncertainty is a detriment to desired team-based care. Therefore, APhA requests clarification from CMS on this issue and continues to request a meeting with the appropriate individuals at CMS to discuss these issues where we can provide a more detailed overview and examples of these challenges. Further, clarifying this issue will help reduce burden and improve access to care in practices where health care practitioners are currently challenged to utilize pharmacists for more complex patient care needs.

B. Aligning of Medicare, Medicaid and other payer coding, payment and documentation requirements, and processes

a. Align Payment Requirements

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[1] American Academy of Family Physicians letter to Centers for Medicare & Medicaid Services, (Jan 2014), available at: https://www.accp.com/docs/positions/misc/AAFP%20MTM%20Letter%20to%20CMS%5E2.pdf

[2] Centers for Medicare & Medicaid Services response to American Academy of Family Physicians, (March 2014), available at: https://www.accp.com/docs/positions/misc/CMS%20Response%20to%20AAFP%20MTM%20Billing%20Letter.pdf, *stating,* "In your letter, you ask that we confirm your impression that if all the requirements of the "incident to" statute and regulations are met, a physician may bill for services provided by a pharmacist as "incident to" services. We agree."

As CMS is aware, pharmacist-provided patient care services are not currently covered by Medicare Part B but are covered by other payers, including several Medicaid programs. APhA strongly agrees with several of the Administration's recommendations in the recent report "Reforming America's Healthcare System Through Choice and Competition," including the recommendation to allow pharmacists and other health care providers to practice to the top of their license, utilizing their full skill set and training. Further, it encourages the federal government and states to consider legislative and administrative proposals to allow nonphysician providers, including pharmacists, to be paid directly for their services.[3] Accordingly, APhA recommends CMS take advantage of any discretion to remove regulatory barriers to payment for pharmacist-provided patient care services. Team-based, patient-centered payment and delivery structures lower the administrative burden and assist eligible clinicians to achieve maximum quality scores. Such action would align Medicare with the many states and Medicaid programs that are already turning to pharmacists to improve patients' health and outcomes and lower medication-related costs.[4] In addition, increased recognition of pharmacists and payment for the patient care services they provide would align pharmacists with other health care professionals' services covered under Medicare Part B.

b. Align supervision requirements for remote physiologic monitoring (RPM) with chronic care management (CCM) services.

APhA is very pleased that CMS issued a technical correction on March 14 clarifying that RPM under CPT code 99457 may be furnished by auxiliary personnel, which can include pharmacists, working under the direct supervision of the physician or eligible nonphysician practitioner. The newest code for remote patient monitoring, CPT code 99457, which took effect in January 2019, offers Medicare reimbursement for "Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified healthcare professional time in a calendar month requiring interactive communication with the patient/caregiver during the month." The change now allows RPM services to better mirror CCM services (CPT code 99487, 99489, and 99490). Similarly, APhA is also pleased CMS recently included a provision in the "CY 2020 Revisions to Payment Policies under the Physician Fee Schedule," proposed rule clarifying CPT codes 99457 and 994X0 may be furnished as "designated care management services" under general supervision rather than direct supervision. Accordingly, APhA urges CMS to finalize this proposed rule to align the supervision requirements of RPM with CCM for auxiliary personnel to allow more patients to access the quality-improving benefits of remote physiologic patient monitoring.

C. New recommendations regarding when and how CMS issues regulations and policies and how CMS can simplify rules and policies for beneficiaries, clinicians, and providers.

When pharmacists partner with physicians and other health care professionals they streamline and improve care, but rules and regulations that lag behind state scope of practice

[3] U.S. Departments of HHS, the Treasury, and Labor. Reforming America's Healthcare System Through Choice and Competition. November 30, 2018, available at: https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf
[4] CMS/ CMCS Informational Bulletin. State Flexibility to Facilitate Timely Access to Drug Therapy by Expanding the Scope of Pharmacy Practice using Collaborative Practice Agreements, Standing Orders or Other Predetermined Protocols. January 17, 2017. Available at: https://www.medicaid.gov/federal-policy guidance/downloads/cib011717.pdf

laws add extra barriers that limit patient access to care. When state laws and regulations expand, it is important that federal regulations adapt to allow health care practitioners to contribute fully to patient care. As noted above, lack of CMS coverage of pharmacist-provided care services, unnecessarily rigid supervision requirements and unclear coverage policies for incident-to services create unnecessary layers of complexity for health care providers and patients. In addition to the recommendations noted throughout this letter, APhA encourages CMS's rulemaking process to consider advances in state scope of practice for health care practitioners, including pharmacists, when determining eligibility and coverage for patient care services. APhA also requests that CMS continue to examine, through notice and comment rulemaking, patient care services that could be delivered under general supervision in "incident-to" arrangements.

D. Improve the accessibility and presentation of CMS requirements for quality reporting, coverage, documentation, or prior authorization.

a. Standardize and Streamline Prior Authorization

As CMS is aware, prior authorization and other utilization management tools (e.g., quantity limits, step therapy) can pose administrative hurdles that delay patient access to medical services or their medication(s). There is a significant need for CMS to take a more standardized approach to prior authorization policies to improve patient access and reduce significant administrative burden on health care practitioners, including pharmacists. In January 2017, APhA partnered with the American Medical Association (AMA) and a number of other health care organizations to create 21 principles to reform prior authorization and utilization management requirements.[5] In addition, APhA along with the American Hospital Association, America's Health Insurance Plans, AMA, Blue Cross Blue Shield Association and Medical Group Management association released a consensus statement on improving prior authorization which offered opportunities for improvement in prior authorization programs and processes.[6] Accordingly, APhA strongly recommends CMS utilize work completed by key stakeholders and incorporate these 21 consensus principles and consensus statement into prior authorization policies.

While the principles and consensus statement address many of APhA's concerns, it is also important for CMS to be aware of issues related to prior authorization that are unique to community pharmacists. Often, pharmacists will inform their patients that a prescription requires prior authorization and communicate with a patient's prescriber regarding prior authorization needs. However, information about prior authorization may not be easily determined by the pharmacist, and pharmacists may spend additional time contacting the plan or pharmacy benefit

[5] AMA, American Academy of Child and Adolescent Psychiatry, American Academy of Dermatology, American Academy of Family Physicians, American College of Cardiology, American College of Rheumatology, American Hospital Association, American Pharmacists Association, American Society of Clinical Oncology, Arthritis Foundation, Colorado Medical Society, Medical Group Management Association, Medical Society of the State of New York, Minnesota Medical Association, North Carolina Medical Society, Ohio State Medical Association and Washington State Medical Association. (January 2017). Prior Authorization and Utilization Management Reform Principles. Available at: https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/principles-with-signatory-page-for-slsc.pdf.

[6] APhA, American Hospital Association, America's Health Insurance Plans, AMA, Blue Cross Blue Shield Association and Medical Group Management, Consensus Statement on Improving the Prior Authorization Process, available at: https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc-public/prior-authorization-consensus-statement.pdf.

manager for more information. Pharmacists may initiate the prior authorization process by contacting the prescriber, often using automation, fax or telephone. After this, pharmacists are often kept in the dark regarding the status of the prior authorization. On a daily basis, many pharmacies attempt to process prescriptions requiring prior authorization until the claim is accepted, incurring transaction fees with each attempt. It is also common for patients, who have been informed by their prescriber that the prior authorization has been approved, to arrive at the pharmacy expecting their prescription to be filled, when the pharmacy is not aware of the approval. Implementing policies that require pharmacies to be informed when prior authorizations have been approved would improve timely access to care for beneficiaries and efficiencies within the pharmacy.

Pharmacists are the health care practitioner patients see most frequently and, in some circumstances, can play a more expansive role in helping streamline prior authorization requests based on their medication expertise and knowledge about a patient. However, plans generally require the prescriber to submit the prior authorization request. While APhA is very sensitive to policies that place additional burdens on pharmacists, especially when those requirements are not covered by payers, there may an opportunity to better utilize pharmacists and proactively provide pharmacists with easier access to information about a patient's prior authorization request.

To address several of these issues, APhA requests a more standardized approach to prior authorization and other utilization management requirements that would be more transparent, user-friendly, and function more efficiently. Currently, each MA plan and PBM has different requirements for prescribers and pharmacists when a medication requires prior authorization. While some requirements are similar, even minor variability makes it more difficult for prescribers and pharmacists to complete the prior authorization in accordance with a plan's or PBM's specific policies. When documentation issues occur, valuable, unreimbursed additional time is spent by health care practitioners to identify why a prior authorization request was not accepted and then to resolve the issue. All these additional steps delay patient's access to their medically necessary services or prescribed medications and detract from the practitioner's capacity to provide care directly to the patient.

E. Address specific policies or requirements that are overly burdensome, not achievable, or cause unintended consequences in rural settings

Currently, payment models that preclude participation from health care practitioners qualified to provide care have the unintended consequence of limiting access to care, including care in community pharmacies, in rural settings. Physicians and other health care practitioners are challenged to meet the growing demand for patient care services. According to the Association of American Medical Colleges (AAMC), the estimated shortage of physicians due to workforce aging, population growth and increased demand for health care services will range from 40,000 to 90,000 by 2025.[7] The effects of shortages will be exacerbated in rural

[7] Association of American Medical Colleges, Physician Supply and Demand Through 2025: Key Findings. 2015, available at: https://www.aamc.org/download/450420/data/physiciansupplyanddemandthrough2025.pdf

communities which already struggle to meet patient needs.[8] One important mechanism physician practices can employ to greatly increase their capacity to meet patient demand is to use a coordinated, team-based, patient-centered approach to care and delegate appropriate clinical responsibilities to non-physician practitioners.[9]

There are over 300,000 pharmacists in the U.S., many of whom are underutilized in their capacity to mitigate these unmet health care needs. As medications are becoming more complex and the population ages, optimizing patients' medications will be crucial under the Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs). Therefore, recognizing the unique and essential contributions that pharmacists make on patient care teams is fundamental to sustaining new payment systems and models. Given pharmacists' ability to reduce the possible $528 billion spent annually on medication-related issues,[10] pharmacists are critical to bending the Medicare cost curve by encouraging the delivery of high-quality, low-cost care. Improving the utilization of pharmacists as part of patient-care teams, particularly in rural and medically underserved areas will help address the need to provide access and care in rural settings and improve quality. Therefore, APhA recommends CMS incorporate and/or test an alternative model in rural and medically underserved areas focused on optimizing medication use and health outcomes as part of coordinated care delivery through the use of pharmacists.

In addition, APhA notes an unintended consequence of rural pharmacy closures as payment models advance that do not include pharmacists. As of March 2018, 630 rural communities that had at least one community pharmacy in March 2003 had no community pharmacy" in March 2018.[11] The decline has been attributed to low and late reimbursement from Part D prescription drug plans, including factors such as direct and indirect remuneration (DIR) fees.[12] The closure rate of community pharmacies is accelerating and demands decisive action. APhA urges CMS to reform DIR, starting with moving DIR fees to the point-of-sale to add transparency as APhA outlined in past comments and anticipated in the Medicare Advantage and Part D Drug Pricing Final Rule.[13]

Community pharmacists, like their counterparts in other practice settings, are also eager to provide patient-care services that are covered through Medicare Part B, including in underserved areas. Community pharmacy closures negatively impact hospitals, clinics, other care settings, medication adherence, patient safety and leave significant gaps in to important services

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[8] Petterson S.M., Phillips R.L., Jr., Bazemore A.W. & Koinis G.T.. (2013). Unequal distribution of the U.S. primary care workforce. *American Family Physician* ,87(11), available at: http://www.aafp.org/afp/2013/0601/od1.html.

[9] Bodenheimer, T.D. & Smith, M.D. (2013). Primary Care: Proposed Solutions to the Physician Shortage Without Training More Physicians, *Health Affairs*, available at: https://doi.org/10.1377/hlthaff.2013.0234

[10] Watanabe, J.H., McInnis, T. & Hirsch, J.D. (2018). Cost of Prescription Drug-Related Morbidity and Mortality, *Annals of Pharmacotherapy*, https://doi.org/10.1177/1060028018765159

[11] Rural Policy Research Institute & Rural Health Research & Policy Centers, (2018). Rural Policy Brief – Update: Independently Owned Pharmacy Closures in Rural America, 2003-2018. Available at: https://rupri.public-health.uiowa.edu/publications/policybriefs/2018/2018%20Pharmacy%20Closures.pdf

[12] *Id.*

[13] *See* American Pharmacists Association, (January 2019) Comments to CMS: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses [CMS–4180–P] RIN 0938–AT92, available at:

such as vaccine administration.[14,15,16,17] Patients are limited in options to obtain their medications or receive clinical patient care services due to challenges in the Medicare program. Therefore, in the interest of a patient-centered approach to care, APhA urges CMS to carefully consider how pharmacists across all practice settings can be included in different aspects of Medicare.

Thank you for the opportunity to provide feedback on the RFI and for your consideration of our comments on your efforts to reduce the administrative burden on our nation's pharmacists and other providers. If you have any questions or require additional information, please contact, Michael Baxter, Director of Regulatory Affairs, at mbaxter@aphanet.org or by phone at (202) 429-7538.

Sincerely,

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

cc: Mitchel C. Rothholz, RPh, MBA, APhA Chief Strategy Officer

[14] Qato, D.M., Alexander, G.C., & Chakraborty, A. (2019). Association Between Pharmacy Closures and Adherence to Cardiovascular Medications Among Older US Adults, *Journal of the American Medical Association*, 2(4):e192606.
[15] Traynor, A.P., Sorenson, T.D. & Larson, T. (2011). The Main Street Pharmacy: Becoming an Endangered Species, *Rural Minnesota Journal*, 2(1).
[16] Bartch, S.M., Taitel, M.S., DePasse, J.V., Cox, S.N., Smith-Ray, R.L., Wedlock, P., Singh, T.G., Carr, S., Siegmund, S.S. & Lee, B.Y. (2018). Epidemiologic and economic impact of pharmacies as vaccination location during an influenza epidemic, *Vaccine*, 34(46), 7054-7063.
[17] Rural Policy Research Institute & Rural Health Research & Policy Centers, (2017). Issues Confronting Rural Pharmacies after a Decade of Medicare Part D, available at: https://rupri.public-health.uiowa.edu/publications/policybriefs/2017/Issues%20confronting%20rural%20pharmacies.pdf