January 25, 2019

[Submitted electronically via www.regulations.gov]

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4180-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses [CMS–4180–P] RIN 0938–AT92

Dear Administrator Verma:

APhA is pleased to submit comments to the Centers for Medicare and Medicaid Services' ("CMS") proposed rule, "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses," (hereinafter "Proposed Rule"). APhA, founded in 1852 as the American Pharmaceutical Association, represents 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.

General Comments

APhA strongly supports patient access to affordable and cost-effective medications and appreciates CMS's continued efforts to look at ways to improve efficiencies and reduce patients' rising prescription drug costs. However, APhA wants to underscore the need for CMS to look comprehensively at expenditures across the Medicare Program when evaluating the cost effectiveness of medication-related policy changes. Because of the fragmentation of the Medicare program (i.e, Part A, Part B, Part C, Part D), in order to truly assess the cost impact of Part D policies, CMS must include the effect such changes will have on medical expenditures under Part A and B as well. Furthermore, when developing mechanisms to lower drug costs, APhA reminds CMS about the need to consider separately the reimbursement of the product, which is fixed for pharmacists, from any related patient care service or performance incentive payment. Finally, APhA reiterates its call for Medicare to cover patient care services by pharmacists, the medication expert on the health care team, to make sure medications are

appropriate and taken/ used correctly and thus, maximizing the Program's significant investment in patients' medications.

Providing Plan Flexibility to Manage Protected Classes (§ 423.120(b)(2)(vi)) Pgs. 62154-62164

APhA is pleased CMS is "…not proposing to change or remove any of the protected classes identified in section 1860D–4(b)(3)(G)(iv) of the Act…" in the Proposed Rule. Although, we remain concerned regarding the language allowing prescription drug plan (PDP) sponsors to: "(1) Implement broader use of prior authorization (PA) and step therapy (ST) for protected class drugs, including to determine use for protected class indications; (2) exclude a protected class drug from a formulary if the drug represents only a new formulation of an existing single-source drug or biological product, regardless of whether the older formulation remains on the market; and (3) exclude a protected class drug from a formulary if the price of the drug increased beyond a certain threshold over a specified look-back period." While APhA appreciates CMS clarifying its intent that these proposed exceptions "…would not introduce interruptions for enrollees on existing therapy of protected class drugs for protected class indications," we offer the following comments to address our concerns.

Proposed Additional Exceptions to the Formulary

APhA respects CMS's need to constrain costs. However, it is important to note the cost of the actual product is only a portion of the expenditures related to drugs in the Medicare Program. The United States spends a possible $672 billion annually on medication-related problems and nonoptimized medication therapy, including nonadherence. [1] APhA is concerned the potential removal of medications from the protected drug classes does so at the expense of beneficiary well-being and may actually increase costs which may result from treatment changes. In a February 26, 2014 U.S. House Energy and Commerce hearing, on a related proposal from the past Administration, Principal Deputy Administrator Jonathan Blum noted most formularies only maintain a "…79% inclusion rate on average" of the drugs in each class,[2] indicating 21% of drugs are not covered. Often, a significant amount of time, effort and money (e.g., office visits, medication cost, etc.) is expended to find the appropriate medication and correct dose to optimize a patient's health. Accordingly, once stabilized, changing formularies can be much more than an inconvenience for patients; it may impact their health, safety and costs.

An additional negative consequence of this policy is its burden on prescribers and pharmacists. Pharmacists and physicians will bear the brunt of communicating formulary restrictions to beneficiaries, facilitating formulary exceptions and helping reestablish patients on a new medication and appropriate dose to achieve optimal outcomes. For pharmacists and prescribers, the time spent navigating utilization management requirements is done without compensation. Given most patients will prefer to remain on their current medication, there will likely be a substantial number of formulary appeals. Each PDP has its own formulary exceptions

[1] Watanabe, Jonathan H. Et. al. Cost of Prescription Drug–Related Morbidity and Mortality. Annals of Pharmacology. First Published March 26, 2018. Available at: http://journals.sagepub.com/eprint/ic2iH2maTdI5zfN5iUay/full

[2] Jonathan Blum, Testimony before the U.S. House Committee on Energy & Commerce, Subcommittee on Health (Feb. 26, 2014) at p. 6. Available at: https://docs.house.gov/meetings/IF/IF14/20140226/101788/HHRG-113-IF14-Wstate-BlumJ-20140226.pdf

and appeals process with a number of required steps, such as prescribers supplying a written or verbal attestation for a formulary exception. While the Proposed Rule provides for a month's supply to account for the transition to a new medication, upon implementation of a final rule, APhA believes more time will be needed as it may be difficult for providers to meet the needs of patients in a timely manner. Accordingly, in the interests of patient health, safety and effective care, we encourage CMS to remove this provision from the final rule. Although, if the provision is retained, we strongly recommend CMS revise the transitional supply requirements to longer than a 30-day supply due to the number of patients that will be affected and monitor the impact of prior authorization and other similar drug utilization policies on patients and providers.

Solicitation of Comment for Special Considerations

CMS is also asking for comments on "…other tools that could be used to minimize interruptions in existing therapy of protected class drugs for protected class indications during prior authorization processes, for example…targeting protected class drugs in Medication Therapy Management (MTM) programs…" APhA is grateful for CMS's ongoing recognition of the value of MTM and its encouragement of PDP sponsors to go beyond statutory requirements that trigger offering MTM services. [3] While MTM services do provide costs savings, both for patients and the Medicare program, its primary purpose is to optimize the impact of patients' medications. APhA reiterates the need for CMS to revisit the cost threshold which excludes many beneficiaries with complex conditions, but smaller drug spends, who could benefit from MTM services. APhA also urges CMS to support legislative changes related to MTM eligibility criteria (e.g., the number of medications and chronic conditions) in order to maximize the service's benefits to both patients and the larger health care system.

Prior Authorization

APhA appreciates CMS's sensitivity "…on whether there are additional considerations that would be necessary to minimize: (1) Interruptions in existing therapy of protected class drugs for protected class indications during prior authorization processes…." APhA's House of Delegates policy states, in part, "APhA opposes prior authorization programs that create barriers to patient care."[4] As you may know, 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] The overwhelming consensus from the authors of these principles is "[s]trict or bureaucratic oversight programs for drug or medical treatments have delayed access to necessary care, wasted limited health care resources and antagonized patients and physicians alike." APhA strongly recommends CMS incorporate these 21 consensus principles into its prior authorization policies to minimize the negative impacts they can have on patients and providers and prevent unintended costs to the system.

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[3] CMS. Center for Medicare and Medicaid Innovation. Evidence Supporting Enhanced Medication Therapy Management. Last updated 12/04/2018. Available at: https://innovation.cms.gov/initiatives/enhancedmtm/

[4] APhA House of Delegates. Current Adopted Policy Statements 1963-2017. Available at: https://www.pharmacist.com/sites/default/files/files/16898%20CURRENT%20ADOPTED%20POLICY%20MANUAL%20-%20FINAL.pdf

[5] AMA, etc. Prior Authorization and Utilization Management Reform Principles. January 25, 2017. Available at: https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/principles-with-signatory-page-for-slsc.pdf

Prohibition Against Gag Clauses in Pharmacy Contracts (§ 423.120(a)(8)(iii)) Pg. 62164

APhA strongly supports the provision in the Proposed Rule to "…amend the set of pharmacy contracting requirements at § 423.120(a)(8) by adding a paragraph (iii) that provides that a Part D sponsor may not prohibit a pharmacy from, nor penalize a pharmacy for, informing a Part D plan enrollee of the availability at that pharmacy of a prescribed medication at a cash price that is below the amount that the enrollee would be charged to obtain the same medication through the enrollee's Part D plan." APhA is grateful for CMS's continued efforts to remove barriers preventing pharmacists from assisting patients in reducing their medication costs.

E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards (§ 423.160) Pgs. 62164-62167

In the Proposed Rule, CMS proposes requiring PDP sponsors to implement an electronic real-time benefit tool (RTBT) capable of integrating with prescribers' e-prescribing (eRx) and electronic medical record (EMR) systems.[6] APhA appreciates CMS's efforts to enhance electronic prescribing and supply more information about a patient's benefits. As new tools are developed, it is important to remember the broad range of providers, such as pharmacists, who can prescribe and different settings in which prescribing occurs. APhA also requests CMS monitor and evaluate the accuracy and impact, including time expended and value, of tools created.

As demonstrated in the Proposed Rule's regulatory history regarding eRx, standard development and implementation are crucial components in regulatory efforts to streamline and improve electronic communications. APhA recognizes implementation and development of standards, including those associated with eRx and real-time benefits, is labor and time intensive. APhA is also aware of forthcoming changes impacting PDPs, pharmacists and patients, including NCPDP SCRIPT Standard v2017071 adoption[7] and policies in the SUPPORT for Patients and Communities Act (Public Law No:115-271). APhA believes consistent use of standards in various health care settings, including within community pharmacies, helps improve communication between PDPs, prescribers, pharmacists and patients and improve care. Although, providing sufficient time to develop, test and implement standards is crucial to their effectiveness and uptake. APhA is concerned rushing adoption of RTBTs can have negative unintended consequences across different care settings, such as the adoption of RTBTs which are not capable of integrating with pharmacy systems or are more difficult to integrate in various systems. Therefore, APhA encourages CMS to consider other forthcoming changes (e.g., NCPDP RTPB Standard publication, SUPPORT for Patients and Communities Act implementation) and provide PDPs other flexibilities, such as extending the RTBT compliance deadline, when finalizing the Proposed Rule. APhA also supports comments submitted by the Pharmacy Health Information Technology Collaborative which address eRx and RTBT adoption.

[6] APhA also recognizes CMS's acknowledgement in the proposed rule that "[b]oth physicians and pharmacists would be needed to identify clinically equivalent drugs," and would require PDPs to use at least "two pharmacists" before implementing an electronic RTBT.

[7] Version 2017071, which is now available for testing, also contains electronic prior authorization (ePA) transactions, as well as transactions for new prescription requests, transfers, and Risk Evaluation and Mitigation Strategy (REMS) requests and responses.

Medicare Advantage and Step Therapy for Part B Drugs (§§ 422.136, 422.568, 422.570, 422.572, 422.584, 422.590, 422.618, and 422.619) Pgs. 62168-62174

APhA is supportive of CMS requiring "…the majority of members comprising the P&T committee would be required to be practicing physicians and/or practicing pharmacists" for MA plans under the Proposed Rule. However, APhA has concerns about expanding the use of step therapy protocols due to the concerns we stated above related to other drug utilization mechanisms like prior authorization. These programs can be particularly problematic for patients who change health insurance on an annual basis. Forcing patients to abandon effective treatment and repeat therapy that has already been proven ineffective under other plans' step therapy protocols delays care and may result in negative health outcomes, as noted previously.[8] Consequently, APhA would again point CMS towards the 21 consensus recommendations, mentioned above, such as not requiring patients to repeat step therapy protocols or retry therapies failed under other benefit plans before qualifying for coverage of a current effective therapy.[9] In addition, APhA requests a more standardized approach to prior authorization/ step therapy requirements that would be more user-friendly and function more efficiently. Currently, each MA plan/ PBM has different hurdles/ steps for prescribers and pharmacies, which are similar but not the same, and often make it difficult to get approval.

Pharmacy Price Concessions to Drug Prices at the Point of Sale (§ 423.100) Pgs. 62174-62180

Point-of-Sale

As adopted by APhA's House of Delegates (HOD) "APhA opposes retroactive direct and indirect remuneration (DIR) fees and supports initiatives to prohibit such fees on pharmacies."[10] Accordingly, APhA supports CMS's proposal to require "price concession[s]" between pharmacies and PDP sponsors or their PBMs (e.g., DIR fees and/or similar policies/terminology, such as "true up" practices) be reflected in the "negotiated price" made available at the time a medication is dispensed at the point-of-sale. APhA also supports CMS's definition of "negotiated price" which excludes additional contingent amounts, such as "incentive fees," to "high performing" pharmacies. According to CMS estimates, this proposed policy change would reduce net beneficiary costs by $10.4 billion and give community pharmacies greater predictability regarding reimbursement rates.[11] CMS has stated "[w]hen pharmacy price concessions are not reflected in the price of a drug at the point of sale, beneficiaries might see lower premiums, but they do not benefit through a reduction in the amount they must pay in cost-sharing, and thus, end up paying a larger share of the actual cost of a drug."

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[8] AMA, etc. Prior Authorization and Utilization Management Reform Principles. January 25, 2017. Available at: https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/principles-with-signatory-page-for-slsc.pdf

[9] Ibid.

[10] APhA House of Delegates. Current Adopted Policy Statements 1963-2017. Available at: https://www.pharmacist.com/sites/default/files/files/16898%20CURRENT%20ADOPTED%20POLICY%20MANUAL%20-%20FINAL.pdf

[11] CMS. Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program. Proposed Rule. November 28, 2017. Table 11. Available at: https://www.regulations.gov/document?D=CMS-2017-0156-0046

Pass through Savings

Based on CMS's acknowledgement that savings from price concessions between manufacturers and PBMs, or to PBMs generally, have not been passed on to beneficiaries, APhA supports requiring Part D sponsors to pass these savings onto beneficiaries.[12]

Additional Considerations

APhA supports CMS's intent to consider "…an option to develop a standard set of metrics from which plans and pharmacies would base their contractual agreements." In response to CMS's request for feedback on the "…most appropriate agency or organization to develop these standards...," APhA strongly urges CMS to build upon its current work with the Pharmacy Quality Alliance (PQA). As you know, PQA was initially established by your agency as a public-private partnership in 2006 for the purpose of developing measures for Medicare Part D. APhA supports PQA's measure development due to its proven track record of developing, and more importantly, testing evidence-based metrics for their intended use (i.e., level of analysis and populations of focus), to ensure they are feasible, valid and reliable.

APhA supports CMS's continued work to spend health care dollars more cost-effectively for the benefit of the Medicare Program and its beneficiaries. We also reiterate the need for CMS to look beyond the cost of the product when looking at drug pricing policies. As CMS moves forward, we hope you will use APhA as a resource. Thank you again for the opportunity to provide information on this important issue. 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: Stacie S. Maass, RPh, JD, Senior Vice President, Pharmacy Practice and Government Affairs
The Honorable Alex Azar, Secretary, HHS
John O'Brian, PharmD, Senior Advisor to the Secretary for Drug Pricing Reform

[12] See, CMS. Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program. Proposed Rule. 82 FR 56336. ''Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale,'' (82 FR 56419 through 56428) - which states "…less than 1 percent of plans have passed through any price concessions to beneficiaries at the point of sale, and the amount that is passed through is less than 1 percent of the total price concessions those plans receive." November 28, 2017. Available at: https://www.federalregister.gov/documents/2017/11/28/2017-25068/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare