



Academy of
Managed Care
Pharmacy®

January 25, 2019

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
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]

Dear Administrator Verma:

The Academy of Managed Care Pharmacy (AMCP) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide comments in response to the proposed rule “*Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses [CMS-4180-P]*” published in the *Federal Register* on November 30, 2018. AMCP supports efforts by CMS to reduce drug prices and commends CMS for considering how the Medicare Advantage and Part D prescription drug programs can be transformed to lower drug prices and reduce costs for Medicare beneficiaries. AMCP offers comments on the following CMS proposals for the Medicare Part D (Part D) and Medicare Advantage (MA) Programs, which seek to improve regulatory framework and reduce out-of-pocket spending for beneficiaries:

- I. Providing Plan Flexibility to Manage Protected Classes
- II. Prohibition Against Gag Clauses in Pharmacy Contracts
- III. E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards
- IV. Part D Explanation of Benefits
- V. Medicare Advantage and Step Therapy for Part B Drugs

AMCP is the nation’s leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of healthcare dollars. Through evidence- and value-based strategies and practices, the Academy’s 8,000 pharmacists, physicians, nurses and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

Providing Plan Flexibility to Manage Protected Classes (§423.120(b)(2)(vi))

For the benefit year 2020, CMS is proposing three exceptions to its protected class policy in the Part D program. AMCP has long supported the ability of Medicare prescription drug plans (PDPs) to manage medications in all categories and classes, including the classes of clinical concern (the “protected classes”). The protected classes reduce the ability of plans to negotiate lower prices for these medications, thereby increasing costs to beneficiaries and the government. Specifically, AMCP supports CMS’s proposal to implement broader use of prior authorization (PA) and step therapy for protected class drugs.

Implementation of well-designed, evidence-based utilization management tools, such as PA and step therapy, optimizes patient outcomes by ensuring patients receive the most appropriate medications while reducing waste, errors, adverse effects, and unnecessary prescription drug use and cost. PA is an effective method to ensure that drug benefits are administered as they have been designed, and that plan members receive the medication therapy that they need while ST encourages the use of clinically proven and cost-effective medications prior to using newer medications that often have a shorter history of clinical effectiveness and a higher cost.

Utilization tools are reviewed by pharmacy and therapeutics (P&T) committees that compare medications by therapeutic classifications or upon similarities in clinical use. When two or more medications produce similar effectiveness and safety results in patients, then business elements like cost, supplier services, ease of delivery or other unique properties of the agents are considered when determining which agent to include on the formulary. Moreover, utilization management tools are based on clinical need, therapeutic rationale, and the desired outcome for the patient. Studies¹ show that choice of the most appropriate drug results in fewer treatment failures, reduced hospitalizations, better patient adherence to the treatment plan, fewer adverse side effects, and better overall outcomes. Such efficient and effective use of health care resources helps to keep overall medical costs down, improves the consumer’s access to more affordable care, and provides the patient with an improved quality of life.

Formulary placement determinations for cost sharing also relate to plans’ P&T committee evaluation of the safety profile of medications. Often, newer medications are placed on higher formulary tiers which require beneficiaries to pay additional costs whereas products already on the market that are placed on lower tiers have a more established track record of safety and effectiveness outside of the clinical trial environment and are often available at a lower cost. If a beneficiary requires a medication not covered by the formulary, the Part D program requires plans to have a formulary exceptions process in place to ensure the beneficiary can access the

¹ 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. December 2011. Available at: https://dcp.psc.gov/osg/pharmacy/sc_comms_sg_report.aspx. Accessed January 24, 2019.

medication.² Given these protections and CMS's formulary review process, continued restrictions for certain clinical classes of medications by the Part D program on plan management of agents in the protected classes are unnecessary. Beneficiaries may access necessary medications even if not covered under the formulary by using the exceptions process required by Medicare.

AMCP also supports CMS's proposed exception that would allow a PDP sponsor to exclude from its formulary a new formulation of a single-source drug or biological product when a manufacturer introduces a product with the same active ingredient or moiety that does not provide a unique route of administration. The proposed exception would help to discourage circumstances where a manufacturer discontinues a certain formulation of a product prior to the launch of an approved generic and exclusively markets the reformulated brand product. This practice often results in patients being switched to the new brand name reformulation and then requires prescribers to specifically prescribe the generic of the previous formulation once it becomes available or requires the pharmacy to seek authorization from the prescriber prior to dispensing the generic medication. This often results in unnecessary delays for patients to receive a lower cost, safe and effective generic medication.

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

CMS proposes to implement the prohibition of "gag clauses" in PDP sponsors' contracts with their network pharmacies as signed into law in October 2018 as the "Know the Lowest Price Act of 2018." AMCP opposes any provisions in contracts between pharmacy benefit managers, health plans, and pharmacies that prevent pharmacists from discussing lower out-of-pocket costs options with beneficiaries and therefore supports this proposal.

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

In its proposal, CMS would require prescribers and dispensers to use the NCPDP SCRIPT standard, Implementation Guide Version 2017071 beginning on January 1, 2020. Additionally, CMS proposes to require PDP Sponsors to make a real time benefit tool (RTBT) available to prescribers that is capable with integrating with prescribers' e-prescribing and Electronic Medical Record (EMR) systems and providing patient-specific coverage information at the point of prescribing.

² Medicare Prescription Drug Benefit Manual Chapter 6 – Part D Drugs and Formulary Requirements. Accessed on January 15, 2016. Available at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>. Accessed January 14, 2019.

AMCP supports moving from the current required NCPDP SCRIPT standard, Implementation Guide Version 10.6 to requiring prescribers and dispensers to use NCPDP SCRIPT standard, Implementation Guide Version 2017071, beginning January 1, 2020. This standard was approved in 2017 to provide for communication of prescription or prescription related-information between prescribers and dispensers for the older named transactions and a handful of new transactions listed at §423.160(b)(2)(iv). 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.³

AMCP agrees that furthering prescription drug price transparency is critical to lowering overall drug costs, and patients' out-of-pocket costs. Generally, we are in support of the use of real-time benefit tools (RTBTs) in the Part D program that would allow beneficiary-specific out-of-pocket cost information to be viewed at the point of prescribing. However, we are concerned that the proposed requirement for PDP sponsors to implement one or more RTBTs by January 1, 2020, may do more harm than good in the short-term because currently a balloted and recognized standard for real time benefit checking (RTBC) does not exist. Requiring adoption of non-standardized RTBT solutions does not align with the Administration's goals or ongoing Health and Human Services' efforts to promote interoperability. This requirement would potentially place PDP sponsors, PBMs and intermediaries in the position of needing to maintain several separate proprietary solutions and or configurations for the different electronic prescribing (eRx) networks and EMR vendors to enable connectivity.

Adoption and implementation of new health IT functionality, including testing and debugging takes, at a minimum, 18 months. The 18-month period would allow PDPs time to educate and prepare providers on the requirements for a RTBT. Given the existing circumstances, AMCP believes that a January 1, 2020 implementation requirement would be extremely challenging.

The National Council for Prescription Drug Programs (NCPDP) has a task group, "Real Time Prescription Benefit Standard Task Group," focused on developing an industry wide standard for RTBC. We recommend that CMS work with NCPDP to accelerate development and balloting of a national interoperable standard for RTBC. Additionally, CMS should coordinate with the Office of the National Coordinator for Health IT (ONC) to include certification requirements and testing for a RTBT in the health IT certification programs. The burden for meeting certification requirements for a RTBT should lie with the technology vendors, not the PDP sponsors who rely on vendors to provide usable functionality.

³ National Council for Prescription Drug Programs. NCPDP SCRIPT Version 2017071 ePrescribing Testing Tool Now Available. September 13, 2018. Available at <http://www.ncdp.org/NCPDP/media/pdf/pressrelease/SCRIPT-v-2017071Testing-Tool-Now-Available-091318.pdf>. Accessed January 4, 2019.

If CMS continues to require implementation of a non-standardized RTBT, please note the following additional concerns.

1. In its proposal, CMS is encouraging PDPs to use RTBTs to promote full drug cost transparency by showing each drug's negotiated price, in addition to the beneficiary's out-of-pocket cost information. Inclusion of full negotiated drug prices is out of scope for point of care clinical decision making. While patient co-pays and financial sharing are related to patient outcomes such as medication adherence, negotiated drug prices are not directly linked to clinical care and are often based on contractual terms and arrangements that should not impact a patient-provider medical decision.
2. The requirement to "include relevant indications that could impact coverage, at the time the prescriber query is made" should not be the responsibility of the PDP sponsor. The indication for use comes from the prescriber and can be shared with the pharmacist and health plan using the NCPDP SCRIPT transaction for eRx. There is no requirement for prescribers to include indication on the eRx so this field is routinely left blank. The 2015 Edition EHR Certification Requirements optionally allow EHR vendors to support transmission of the indication on the eRx. We encourage CMS to work with the provider and health IT vendor community to facilitate routine transmission of the indication for use along with the prescription. This information will be critical for the PDP sponsor's ability to provide therapeutic alternatives based on the intended use.
3. Patient consent for sharing of information through the eRx workflow should reside with the prescriber, not the PDP sponsor. As mentioned, once the prescription is sent and the claim adjudicated, the sponsor and any intermediaries will automatically have the patient's medical and prescription information. The appropriate point for consent is at the point of prescribing where the request for patient information is made. The PDP sponsor has no control over who will prescribe or request what information. In the scenario presented where a patient does not want the PDP to know about self-pay prescriptions, CMS can work with ONC to create certification requirements for RTBTs that provide the necessary point of care consent options for patients to review with their prescriber.

Part D Explanation of Benefits (§423.128)

Under this proposal, PDPs would be required to include information in an Explanation of Benefits (EOB) to beneficiaries regarding changes in the negotiated price from the first day of the benefit year, as well as information on lower-cost therapeutic alternatives.

AMCP supports the need to improve drug price transparency and in general, support efforts that would improve beneficiary education. We recognize that providing beneficiaries with additional

information about negotiated drug price changes could be helpful but we have concerns that providing a retroactive negotiated price may lead to beneficiary confusion over actual drug prices. In section §423.160 of this proposal, CMS would require PDPs to utilize a RTBT that would provide beneficiary-specific out-of-pocket cost information at the time of prescribing. AMCP encourages CMS to continue to look to RTBTs to provide the most current, beneficiary-specific cost information once a RTBT standard has been established.

Additionally, AMCP supports the concept of patient engagement and providing patients with information about alternative treatment options. However, providing information about low-cost alternative options to a patient on an EOB after a transaction has occurred does not allow the beneficiary to participate in a shared decision-making process with their health care provider and may be counterproductive to CMS's goals.

Medicare Advantage and Step Therapy for Part B Drugs (§423.160)

In August 2018, CMS announced in a memo that MA Plans would have the choice to implement step therapy and prior authorization for Medicare Part B (Part B) drugs beginning in January 2019.⁴ In this proposal, CMS outlines requirements under which MA plans may apply step therapy as a utilization management tool for Part B. Generally, AMCP supports the addition of this provision to allow greater management of Part B medications through MA plans. The flexibility to implement well-designed, evidence-based utilization management tools optimizes patient outcomes by ensuring that patients receive the most appropriate medications while reducing waste, errors, adverse effects, and unnecessary prescription drug use and cost. AMCP believes that after CMS provides further clarification, including allowing sufficient time for implementation, this change is a positive step to balance affordability and accessibility of Part B-covered products.

Utilization management tools, such as step therapy, have been critical to decreasing costs, improving quality, and increasing value in the Part D Program and the commercial market. They also play a critical role in ensuring clinical appropriateness of medications. Furthermore, the proposed rule would implement safeguards that ensure beneficiaries have timely access to all medically necessary Part B medications such as an appeals process under new proposed time frames that are similar to those applicable for Part D coverage determinations and an exemption process through MA organization policies.

AMCP supports CMS's proposal to require MA plans to utilize any existing Part D pharmacy and therapeutics (P&T) committees established by the Part D plan to review and approve step

⁴ Centers for Medicare & Medicaid Services. Medicare Advantage Prior Authorization and Step Therapy for Part B Drugs. August 7, 2018. Available at <https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-prior-authorization-and-step-therapy-part-b-drugs>. Accessed January 10, 2019.

therapy programs. Currently, the Part B statute and CMS regulations do not allow for the use of P&T committees established by health plans and pharmacy benefit managers to develop formularies for Medicare Part B or allow for the use of utilization management tools.

P&T committees and utilization management have been key to the success in decreasing costs, improving quality, and increasing value in Part D and the commercial market. Use of health plan or PBM-established formularies and allowance for utilization management tools are necessary for the success of initiatives to improve outcomes and lower costs. AMCP supports the use of well-designed and evidence-based formularies that enhance the quality of pharmaceutical care while lowering medication costs. A formulary is a continually updated list of prescription medications that represents the current clinical judgment of providers who are experts in the diagnosis and treatment of disease.

Generally, a formulary is developed and maintained by a P&T Committee comprised of physicians, pharmacists, and other health care professionals, that meets regularly to review and evaluate the medical and clinical evidence from the literature, relevant patient utilization and experience and economic data, and provide recommendations to determine which drugs are the safest, most effective, and produce the best clinical outcomes. Since a formulary is a dynamic and continually revised document, the P&T Committee regularly evaluates the formulary and adjusts it to reflect the best medical practices, newly marketed medications, and new clinical and economic evidence that may have an impact on which medications are included or excluded. Additionally, formularies often contain additional prescribing and clinical information that assist health care professionals as they promote high quality, affordable care to patients.

AMCP appreciates that CMS is also actively considering expanding the role of MA P&T committees to require that all MA plans with utilization management policies, such as step therapy programs and prior authorization, be required to have P&T committees. However, we are concerned that requiring the development of new committees without providing for an adequate implementation timeline to ensure proper committee composition and sound ethical considerations would potentially undermine CMS's intent. AMCP also cautions that costs to implement such committees must also be taken into consideration before requiring implementation in rulemaking. We agree with CMS that existing Part D P&T committee requirements are adequate to ensure MA plans implement step therapy for Part B drugs if medically appropriate and there is a benefit to initially utilizing such established committees.

In its proposal, CMS would only allow step therapy to be applied to new prescriptions or administrations of Part B drugs with a look-back period of 108 days, consistent with Part D policy for transition requirements for new prescriptions. AMCP observes that PDPs do not always have the historical basis to know if the prescription is new or if the patient is new to the plan so there may be confusion surrounding a "new start" day. Therefore, the 108-day look-back

period as proposed is inadequate for determining the start date. AMCP is also concerned that without full interoperability, plans may be prohibited from retrieve medical data on Part B medications from the beneficiaries Electronic Health Record (EHR) to make an informed clinical decision on implementing step therapy or identifying eligible patients.

While AMCP is generally supportive of utilization management in Part B, we have identified a need for both provider and patient education, especially given that this is an optional program. We recommend that CMS carefully consider the development of further guidance on how step therapy should align with existing care coordination programs and how education on step therapy will be provided to both providers and patients so that continuity of care is preserved and there are appropriate patient engagement strategies in place to support step therapy programs.

Conclusion

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing work on these issues with CMS. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-684-2600 or scantrell@amcp.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Susan Cantrell", with a long horizontal flourish extending to the right.

Susan A. Cantrell. RPh, CAE
Chief Executive Officer