

**Summary: *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses*  
(CMS-4180-P)**

**Publication Date: November 30, 2018**

**Comments Due: January 25, 2019**

On November 26, The Centers for Medicare and Medicaid Services (CMS) issued a [new proposed rule](#) outlining potential policies that are intended to lower the cost of prescription drugs through tools that allow prescription drug plans to negotiate prices and by improving access to costly drugs through reduction of out-of-pocket costs for beneficiaries. Numerous provisions in the proposed rule are intended to implement strategies set in the Administration's [Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs](#) (Drug Pricing Blueprint) released in May 2018.

Major Provisions in the proposed rule include:

- Providing Part D Prescription Drug Plan (PDP) flexibility to negotiate discounts for drugs in protected classes.
- Utilizing Real Time Benefits Tools (RTBT) in the Part D Program to increase drug price transparency at the point of prescribing.
- Codifying a policy to allow step therapy in Medicare Advantage for Part B Drugs.
- Amending regulations related to the Part D Explanation of Benefits (EOB) that plans send to beneficiaries to include drug pricing information and lower cost alternatives.
- Implementing a statutory provision prohibiting the use of gag clauses in pharmacy contracts.
- Considering a policy that would re-define negotiated price as the baseline, or lowest possible, payment to a pharmacy in future plan years as early as 2020.

AMCP shares the Administration's concern about the rising costs of medications and the impact on patients, payers, and providers. In July, 2018, AMCP offered [comments](#) to the Department of Health and Human Services (HHS) on its Drug Pricing Blueprint. Comments focused on AMCP's proactive engagement with HHS to solve some of the more difficult issues associated to medication management, patient care services and ways to consider innovative and high cost medications.

AMCP is reviewing this proposal to provide formal comments to CMS on proposed provisions and is seeking feedback from members to help develop its comments and ensure the perspective of managed care pharmacy is voiced.

Comments on this proposal must be submitted to CMS by January 25, 2019. You may provide feedback via email to Afton Wagner, Director of Regulatory Affairs at [awagner@amcp.org](mailto:awagner@amcp.org) by January 9, 2019 on any provisions included in the proposed rule. AMCP's final comments will be available on the AMCP website and included in the Legislative-Regulatory Briefing Newsletter that is distributed to all AMCP members.

The following is a summary of key sections in the proposed rulemaking that may be of interest to AMCP members:

**A. Providing Plan Flexibility to Manage Protected Classes**

- a. Currently, all Part D plans must include all drugs in the six protected classes on their formularies: antidepressants, antipsychotics, anticonvulsants, immunosuppressants for the treatment of transplant rejection, antiretrovirals, and antineoplastics.
- b. CMS will not be eliminating any of the protected classes, but is proposing the following three exceptions to this mandatory coverage of protected classes:
  - Wider use of utilization tools such as prior authorization (PA) and step therapy (ST) for drugs in these classes.
    - CMS is proposing to permit PA for protected classes for both new starts and existing therapy.
    - CMS is seeking comment on if this exception should be limited to new starts only.
  - Excluding a drug in one of these protected classes from a formulary if the drug is a new formulation of an existing single-source product that does not provide a unique route of administration, even if the older formulation is removed from the market.
    - CMS would make amendments to specify drug or biological products that are rated as (1) therapeutically equivalent under the Orange Book and (2) interchangeable under the Purple Book, to account for the introduction of interchangeable biologics in the market.
  - Excluding a drug in one of these classes from a formulary if the wholesale acquisition cost (WAC) increases beyond the rate of inflation, relative to the price in a baseline month and year.
    - The rate of inflation would be calculated based on the Consumer Price Index for all Urban Consumers (CPI-U).
    - CMS seeks comment on whether an alternative pricing threshold to the CPI-U should be considered and whether an increase in price other than the drug's WAC should be used to determine if the protected class drug should be excluded from a Part D formulary.
- c. CMS is also proposing to allow indication-based formulary design under the first exception.
  - Indication-based formulary design would allow determination of formulary coverage based on the indication of a drug, instead of covering the drug for all FDA indications.
- d. These proposals would be applicable beginning with the 2020 contract year and formularies that use these new provisions would still be subject to CMS' annual review process which includes review of utilization tools.
- e. CMS is seeking comment on whether there are additional considerations for the three proposed exceptions that might be necessary to minimize interruptions in existing therapy of protected class drugs for protected class indications.
- f. CMS is also seeking comment on other tools that could be utilized to minimize interruptions such as electronic prior authorization (e-PA) during e-prescribing and targeting protected class drugs in Medication Therapy Management (MTM) programs.

AMCP has long supported the ability of plans to manage medications in all categories and classes, including medications in protected classes, and has [commented](#) to CMS on this topic in the past. Specifically, AMCP has commented on support for further management of protected classes, including through appropriate prior authorization, indication- based formulary design, medication therapy management, and other utilization management. We are reviewing the pricing provisions proposed. AMCP supports using pharmacists as the primary health care professional to provide MTM in conjunction with nurses and physicians in health plans.

## **B. Prohibition Against Gag Clauses in Pharmacy Contracts**

- a. The proposed rule codifies a provision recently passed in [statute](#) that prohibits the use of gag clauses in the Medicare Part D program, beginning with plan year 2020.

AMCP opposes any contracts between pharmacy benefit managers, health plans, and pharmacies that prevent pharmacists from discussing lower out-of-pocket costs options with beneficiaries. On October 10, 2018, legislation prohibiting the use of gag clauses in contracts was signed into law by President Trump.

## **C. E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards**

- a. CMS is proposing to require that PDP sponsors implement an electronic real-time benefit tool (RTBT) that is capable of being integrated with the e-prescribing (eRx) systems and electronic medical record (EMR) systems used by providers.
  - RTBTs would include cost, formulary alternatives and utilization management requirements.
- b. CMS believes that RTBTs would improve the cost-effectiveness of the Part D benefit by making patient-specific coverage information visible at the point-of-prescribing.
- c. CMS is proposing that each PDP implement at least one RTBT of its choosing to be used with the patient's consent.
  - CMS believes that there are currently no industry-wide electronic standards for RTBTs; however, it acknowledges that they are in development.
- d. Each Part D Plan would need to carefully review existing drugs on the formulary to determine if any alternatives exist and how these alternatives can be presented in a way that will be helpful to prescribers making clinical decisions.
- e. CMS is encouraging plans to use the RTBTs to show each drug's full negotiated price in addition to the beneficiary's out-of-pocket costs to provide prescribers with additional decision support but is *not* making it a requirement at this time.
- f. PDPs would be required to choose and implement a RTBT by January 1, 2020.
- g. CMS welcomes comment on this proposal, including the feasibility for plans to meet the proposed deadline.
- h. If there is indication that a RTBT standard would become available before the 2020 effective date of this proposed rule, CMS would review the standard and consider it for a proposal in its 2021 rulemaking.

AMCP supports federal and state legislative provisions that require the use of electronic prescribing. Electronic transmission of prescription information improves patient safety, enhances the collection and analysis of patient data, and increases operational efficiencies. In addition, AMCP

supports the adoption of the NCPDP eRx standard as a standardized and secure means of transmitting electronic prescriptions. AMCP is examining the RTBT provisions contained in the proposed rule to provide feedback to ensure that it provides streamlined benefit checks.

#### **D. Medicare Advantage and Step Therapy for Part B Drugs**

- a. This proposed rule reaffirms CMS's [prior announcement](#) in August 2018 stating that Medicare Advantage (MA) plans may implement utilization therapy tools, such as prior authorization and step therapy, for Part B drugs in an effort to control costs across the Medicare program while ensuring access to medically-necessary Medicare-covered benefits.
- b. CMS expects MA plans to work closely with the provider community to adopt best practices that streamline requirements and reduce the burden of implementing utilization tools.
  - CMS also encourages continued development and advancement of electronic prior-authorization (e-PA) processes.
- c. When applying step therapy to Part B drugs, MA plans would be required to disclose that Part B drugs may be subject to step therapy requirements in the plan's Annual Notice of Change (ANOC) and Evidence of Coverage (EOC) documents.
- d. CMS is proposing to include a requirement for plans to establish policies and procedures to educate and inform health care providers and enrollees about its step therapy policies.
- e. MA plans would be required to use a Pharmacy and Therapeutics (P&T) committee to review and approve step therapy programs that could include any existing Part D P&T committees established by the MA-PD plan.
  - This requirement is consistent with Part D requirements for a P&T committee.
  - CMS is seeking comment on this proposal to require a P&T committee for MA plans with step therapy programs.
- f. Step therapy would only be applied to new prescriptions for enrollees not currently taking the impacted medication to not disrupt enrollees' ongoing therapies.
- g. To determine if the enrollee is taking a Part B medication, MA plans would be required to have a look back period of 108 days, consistent with Part D policy with respect to transition requirements for new prescriptions.
- h. CMS is proposing to allow MA plans to require an enrollee to try and fail an off-label medically-accepted indication before providing access to a drug for an FDA-approved indication, consistent with Part D guidelines, and is soliciting comment on this proposal.
- i. MA plans would be prohibited from using a non-covered drug as a step in the step therapy program.
  - MA plans that also offer prescription drug coverage (MA-PD plans) may use step therapy to require a Part D drug therapy prior to allowing a Part B drug therapy since the Part D drug would be covered by the plan.
- j. Any step therapy requirements would be subject to CMS review and approval as part of its formulary review and approval process.
- k. CMS is proposing that requests for Part B drugs, including drugs subject to step therapy, be processed under the same adjudication timeframes as used in the Part D drug program to allow MA-PD plans to better coordinate their drug benefits.
  - CMS is *not* proposing that adjudication timeframes for Part B drugs could be extended as it is not permitted under the Part D program and CMS does not feel that it is warranted for Part B. CMS is seeking comment on this decision.

- I. Currently, an MA organization must notify an enrollee of an expedited organization determination no later than 72 hours after receiving the request and within 14 calendar days with respect to pre-service standard organization determinations.
  - For expedited organization requests for Part B, CMS is proposing that an MA organization must make its determination and notify the enrollee of its decision no later than 24 hours after receipt of the request.
  - For pre-service standard organization determinations for Part B drugs, CMS is proposing that a MA organization must notify the enrollee of its determination no later than 72 hours after the request.
  - CMS is soliciting comment on these shorter proposed timelines for determination related to Part B drugs.
- m. MA organizations must disclose prior authorization or step therapy requirements that condition or limit coverage and must be met in order to ensure payment for services.
- n. A MA plan can determine if an enrollee should be exempt from step therapy requirement for medically necessary reasons.
- o. CMS is proposing to modify Part C independent review entity (IRE) adjudication time periods for organizations determinations and appeals involving Part B drugs.
- p. CMS is soliciting comments on all of the proposals in this section that would allow MA plans to apply step therapy as a utilization management tool for Part B drugs in 2020 and beyond.

AMCP generally supports the addition of this provision to allow greater management of Medicare Part B medications through Medicare Advantage plans. During Nexus, AMCP hosted a focused group that included health plans, pharmacy benefit management companies, and health IT stakeholders to receive feedback on the provisions of CMS' previously released memo. AMCP and participants are finalizing a review of this focus group and will be releasing the information shortly. AMCP will also use these findings as a basis for comments to HHS.

#### **E. Part D Explanation of Benefits (EOB)**

- a. CMS is proposing to require that negotiated drug pricing information and lower cost alternative are included in the Part D Explanation of benefits with the intention of providing beneficiaries with greater transparency and encouraging lower costs.
- b. The proposed rule would require Part D EOBs to include the following:
  - The item or service for which payment was made and the amount of the payment;
  - Notice of an individual's right to an itemized statement;
  - Cumulative, year-to-date total amount of benefits provided;
  - Cumulative, year-to-date total of incurred costs;
  - Any applicable formulary changes.
- c. CMS is also proposing to require that Part D sponsors provide information about drugs that are therapeutic alternatives with lower cost-sharing, when available as determined by the plan, from the applicable approved plan formulary for each prescription drug claim.
  - The plan may also include therapeutic alternatives with the same copayments if the negotiated price is lower.
  - Lower-cost therapeutic alternatives would not be limited to therapeutically equivalent generics if the original prescription fill is for a brand drug.

- Alternatives could also include a different drug, not within the same category or class, but one that has a medically-accepted indication to treat the same condition.
- CMS would encourage, but not require, information about formulary therapeutic alternatives available at lower cost sharing to be beneficiary-specific and acknowledges that alternatives may not be available.

## **F. Pharmacy Price Concessions in the Negotiated Price**

### *Negotiated Price*

- a. CMS states that the agency is considering, for a future year, which could be as soon as 2020, a new definition of “negotiated price” for drugs covered under Part D.
  - The “negotiated price” is the benchmark price used to determine beneficiary cost-sharing, as well as the beneficiary’s progression through the four phases of the Part D benefit and is meant to represent the price the plan sponsor ultimately pays for a drug.
- b. CMS is considering creating a new definition of “negotiated price” to include the maximum amount of pharmacy price concessions received by the plan sponsor and to reflect the lowest price that the plan sponsor could pay for the drug.
  - The new definition of “negotiated price” would require that all price concessions from network pharmacies be reflected in the negotiated price that is made available at the point of sale, even when price concessions are contingent upon performance by the pharmacy.
  - At the end of the year, if the actual price paid to the pharmacy is higher than the reported negotiated price, the plan sponsor would report the difference as negative direct and indirect remuneration (DIR).

### *Price Concessions*

- c. Additionally, CMS is considering adding a definition of “price concession” into Part D regulations to be implemented for 2020 or another future year to avoid confusion from inconsistent terminology.
  - Price concessions are the net of all pharmacy incentive payments and are negotiated between pharmacies and sponsors or their Pharmacy Benefit Managers (PBMs), independent of CMS.
  - Currently, there is no regulatory definition of price concession.
  - The definition under consideration by CMS would be broad include all forms of discounts, rebates, and indirect and direct price concessions, that serve to reduce costs incurred under PDPs by Part D sponsors.
- d. CMS is seeking comment on whether it should move forward with adopting this proposal in the final rule and whether to make this change for contract year 2020.

AMCP supports greater transparency for patients in medication costs. AMCP is carefully examining this section, including on provisions related to negotiated price and price concessions falling outside of CMS’ oversight under the “Medicare Modernization Act’s” non-interference clause.