

**Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce  
Out-of-Pocket Expenses  
[CMS-4180-F]**

**Summary of Final Rule**

On May 16, 2019, the Centers for Medicare & Medicaid Services (CMS) put on public display at the *Federal Register* a final rule providing for revisions to the Medicare Advantage (MA) and Voluntary Prescription Drug Program (Part D) regulations to support plan negotiations for lower drug prices and lower out-of-pocket costs for enrollees of MA and Part D plans.

Major changes finalized in the rule include:

- Permitting plan sponsors to use prior authorization and step therapy for protected class drugs (other than antiretrovirals) only for new starts, including to confirm that the use is for a protected class indication;
- Requiring plan sponsors to implement an electronic real-time benefit tool (RTBT) that can integrate with at least one prescriber's e-Prescribing (eRx) or electronic medical record (EMR) systems by 2021;
- Allowing Medicare Advantage Prescription Drug (MA-PD) plans to impose step therapy utilization management practices on beneficiaries initiating therapy (new starts) of Part B drugs; and
- Requiring MA and Part D plan sponsors to provide enrollees with information about drug price changes and lower-cost therapeutic alternatives.

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

Section 1860D-4(b)(3)(G) of the Social Security Act (the Act) requires Part D sponsors to include in their plan formularies all Part D drugs in classes and categories of clinical concern identified by the Secretary using criteria established through rulemaking; these are referred to as the protected classes. Section 1860D-4(b)(3)(G) also establishes protected classes of drugs which are to apply until the Secretary identifies drug categories or classes of clinical concern through rulemaking; these are anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection.

Section 1860D-4(b)(3)(G) also permits the Secretary to create exceptions that permit plan sponsors to limit access or exclude from their formularies a protected class drug; the current exceptions permit plan sponsors to exclude therapeutically equivalent drugs, to apply utilization management edits for safety, and to exclude other drugs CMS specifies through a public process. CMS did not propose to change or remove any of the protected classes established by statute.

In the proposed rule, CMS stated that the protected class policy increases drug prices due to lack of competition and potentially facilitates overuse of drugs within the protected classes. Part D sponsors believe the policy reduces leverage in price negotiations with manufacturers which

results in higher Part D costs.

CMS had proposed to:

1. Expand the purposes for which sponsors may impose prior authorization and step therapy requirements for protected class drugs, including to determine use for protected class indications;
2. Permit the exclusion of specific protected class drugs from plan formularies if they are a single-source drug or biological product for which the manufacturer introduces a new formulation with the same active ingredient or moiety that does not provide a unique route of administration, regardless of whether the older formulation remains on the market; and
3. Permit the exclusion of single-source drugs or biological products whose prices increase beyond a specified threshold over a specified look-back period.

CMS finalizes the first proposal to permit prior authorization and step therapy for protected class drugs with some modifications. Antiretrovirals are exempted from this policy. CMS says the final policy is a codification of current policy and does not place additional limits on beneficiary access to protected class medications. CMS does not finalize its other two proposals to permit exclusion of protected class drugs from formularies.

Many commenters objected to all three proposals believing that they would compromise beneficiary access to needed therapy which would adversely affect health outcomes and, in the case of HIV, endanger public health. CMS believes that beneficiary access to protected class drugs is maintained through its access requirements (i.e. formulary transparency; formulary requirements under statute and regulations, including the annual formulary submission and review process; reassignment formulary coverage notices; transition supplies and notices; and expedited coverage determinations and decisions) as well as its initiatives to inform beneficiaries of appeal rights and its efforts to monitor grievances and appeals. CMS also dismisses assertions that its proposals violated the statutory nondiscrimination provision, especially as it applies to enrollees who take high-cost protected class drugs or HIV patients; it argues that its policies would not substantially discourage enrollment by certain individuals eligible for Part D and thus are not discriminatory.

#### *Broader Use of Prior Authorization for Protected Class Drugs*

CMS had specifically proposed to—

1. Permit Part D sponsors to use prior authorization as is currently allowed for all other drug categories and classes; this would have included implementing step therapy for protected class drugs or to determine use for protected class indications, or both, without distinguishing between new starts or existing therapies; and
2. Permit indication-based formulary design and utilization management for protected class drugs.

Because many commenters expressed significant concern for potential disruption of ongoing therapy of protected class drugs used for protected class indications, CMS concludes that the risks of inappropriately interrupting therapy for stabilized patients by permitting prior authorization or step therapy policies for plan sponsors outweigh the benefits of potential cost

savings or potential clinical benefits from switching therapies. Thus it finalizes what it describes as a codification of its current policy pursuant to which plan sponsors may use prior authorization and step therapy for five of the six classes of Part D protected class drugs only for new starts and for one (or more) of the following purposes: (i) To determine if a drug's intended use is for a protected class indication; (ii) to ensure clinically appropriate use; or (iii) to promote utilization of preferred formulary alternatives. Prior authorization and step therapy are prohibited for antiretroviral drugs. For enrollees on existing therapies, CMS clarifies that plan sponsors may not require prior authorization to confirm that a drug's intended use is for a protected class indication if the drug does not otherwise have a high likelihood of use intended for a non-medically accepted indication that is not coverable under Part D. Plan sponsors generally will have to rely on other approaches (such as retrospective DUR) to confirm the intended use is for a protected class indication.

CMS clarifies that it considers medically accepted indications consistent with protected drug class categories or classes to be protected class indications; thus, "when a Part D drug is used for a protected class indication, we consider it to be a protected class Part D drug." Additionally, Part D drugs with multiple medically accepted protected class indications are protected for each such indication, even where the indications are in more than one protected class. However, for Part D drugs with both protected class and non-protected class indications, CMS says it may permit different prior authorization requirements or formulary inclusion for non-protected indications, depending on clinical appropriateness and its policies on indication-specific utilization management and formulary design. Plan sponsors are expected to note differential inclusion for drugs with respect to protected class versus non-protected class indications. In response to a comment about protected class therapies started for a patient as a hospital inpatient or pursuant to treatment in an emergency care setting, CMS expects plan sponsors to treat that patient as continuing an existing therapy when the prescription for the protected class drug is presented to the pharmacy.

CMS notes that under current policy it will not approve prior authorization criteria that are not clinically supported and that new utilization management edits are reviewed as part of the annual formulary review and approval process. Commenters expressed concerns about CMS' references to clinical criteria, including the lack of specificity about the criteria that will be applied to formulary review and that clinical criteria should not override clinician decisions about the best therapy for an individual patient. CMS responds by noting that it uses FDA-approved labeling and widely accepted guidelines to determine clinical appropriateness of prior authorization and step therapy formulary requirements and that pharmacists are included on the review and approval teams.

CMS previously clarified that its policy has always been to require retrospective drug utilization review of protected class drugs; the rule does not modify or eliminate that requirement. It further clarifies that sponsors must take appropriate action upon determining that protected class drugs were not prescribed for a particular individual for a medically-accepted indication or that the prescribing may have been fraudulent.

### *New Formulations*

Part D sponsors must include all or substantially all drugs in the six protected classes on their formularies; substantially all means all drugs and unique dosage forms are expected to be included on the formulary with certain exceptions. These exceptions include (1) multiple source drugs of the identical molecular structure, (2) extended-release products when the immediate-release product is included, (3) products with the same active ingredient or moiety, and (4) dosage forms that do not provide a unique route of administration. CMS also codified an exception for drug products that are rated therapeutically equivalent.<sup>1</sup>

CMS had proposed to allow Part D sponsors to exclude from their formularies a protected class single-source drug or biological product for which the manufacturer introduces a new formulation with the same active ingredient or moiety that does not provide a unique route of administration. Part D plans are not required to include a new formulation of a drug on their formularies when the older formulation is still available; the proposal would have extended this policy to protected class drugs.

As noted above, CMS does not finalize the proposal. CMS agrees with commenters that the proposal would have left enrollees without access to new formulations of needed protected class drugs in the situation where other formulary requirements did not obligate Part D sponsors to have the new formulation on their formulary.

CMS does finalize its proposal to update the regulations to accommodate the introduction of interchangeable biological products to the market. Thus, the regulatory exception for therapeutically equivalent drugs noted above will also include an exception for biological products rated as interchangeable.

### *Pricing Threshold for Protected Class Drug Formulary Exclusions*

CMS had proposed to allow Part D sponsors to exclude from their formularies any single-source drug or biological product that is a protected class drug whose price increases, relative to the price in a baseline month and year, beyond the rate of inflation calculated using the Consumer Price Index for all Urban Consumers (CPI-U). Thus, if the wholesale acquisition cost for a protected class single-source drug or biological product increases from a baseline date to any point in an applicable period by more than the cumulative increase in the CPI-U over the same period, the sponsor would have been permitted to exclude the drug from its formulary.

As noted above, CMS does not finalize this policy after taking into consideration commenter concerns about beneficiary access to protected class drugs, the impact of the proposal on launch prices for protected class drugs, and other concerns. CMS believes its proposals would have incentivized manufacturers to increase prices for their drugs at launch. Additionally, commenters informed CMS that contracts between plan sponsors and manufacturers may include price protections which would negate the efficacy of the exception.

Some commenters believe the proposal was a departure from established policy of basing exceptions on scientific evidence, medical standards or clinical practice; basing these policies on cost considerations is inconsistent with past practice and would create discrimination in Part D.

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<sup>1</sup> See 42 CFR 423.120(b)(2)(vi)(A).

CMS counters that an exception based on a pricing threshold does not conflict with its regulatory requirements for exceptions to be based on scientific evidence and medical practice standards; the agency believes it may do both without any discriminatory impact.

#### *Comment Solicitation for Special Considerations*

CMS sought comment on additional considerations necessary to minimize interruptions in existing therapy of protected class drugs as well as to minimize increases in program spending for increased utilization of services secondary to adverse events from interruptions in therapy. CMS also asked for comment on whether existing protections are inadequate as well as on specific patient populations, individual patient characteristics and specific protected class drugs or drug classes that require additional special transitions or other protections. It also asked about other tools that could be used to minimize interruptions in existing therapy.

While commenters expressed concerns about access issues, detrimental patient outcomes and increased costs to Medicare overall by reason of the proposals (due to greater numbers of visits to hospital emergency departments or inpatient admissions), CMS complains that no specific suggestions were provided to address the issues other than to exempt “virtually all of the applicable enrollees from the exceptions” proposed by the agency. CMS acknowledges the importance of access and continuity of care which it says will be taken into account when approving prior authorization and step therapy formulary requirements. CMS also strongly rejects claims that its existing protections (e.g., appeals processes) do not ensure access to medically appropriate protected class drugs, and states that it will continue to closely monitor appeals activity through audits and the Complaints Tracking Module.

#### *Regulatory Impact*

Because the only protected class exception policy finalized in this rule is a codification of current policy, CMS does not anticipate any material impacts from the use of prior authorization and step therapy utilization management tools for the five classes where it will be allowed. Additionally, CMS does not estimate any material impact from excluding antiretroviral drugs from this exception because it does not believe such a policy would generate returns for plan sponsors’ increased administrative burden. CMS does not anticipate any adverse effects on enrollee access to protected class drugs.

### **II. Prohibition Against Gag Clauses in Pharmacy Contracts (§423.120(a)(8)(iii))**

CMS finalizes its proposal to implement the Know the Lowest Price Act of 2018 (P.L. 115-262) without change. Thus, effective January 1, 2020, Part D sponsors may not restrict their network pharmacies from telling plan enrollees that they would be charged less for a drug if they paid cash than if they got the drug through their insurance.

CMS amends existing pharmacy contract requirements at §423.120(a)(8) by adding a requirement that states 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.

Many commenters strongly supported the provision. Some commenters suggested that enrollee cash purchases should be reported electronically and automatically to their plan sponsors so the cost may be counted towards TrOOP and benefit deductible accumulations; CMS responds that the comments were outside the scope of the proposed rule.

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

Part D plan sponsors and MA-PD plans must comply with electronic prescription drug program e-prescribing (eRx) standards established by CMS. The agency periodically updates these standards taking into account new knowledge, technology and other considerations. Providers and dispensers must use the latest implementation guide version of the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard for communication of prescriptions or prescription-related information for certain transactions. Part D sponsors must convey electronic formulary and benefits information using Version 1.0 or 3.0 of the National Council for Prescription Drug Programs (NCPDP) Formulary and Benefits (F&B) Standard Implementation Guides. CMS states that these standards are critical components of the Part D programs; however, neither standard can convey patient-specific real-time cost or coverage information that includes formulary alternatives or utilization management data to the prescriber at the point of prescribing.

CMS proposed to require all Part D sponsors to implement a real-time benefit tool (RTBT) to be used with a patient's consent. CMS finalizes the proposal, with some modifications, which will be effective January 1, 2021 (one year later than proposed).

The RTBT must integrate with automated prescriber systems (eRx or EMR) to present a list of formulary alternatives to a prescriber along with (1) the patient's cost sharing for each alternative drug and (2) any applicable utilization management requirements for each alternative. The goal is to permit the prescriber to consider both the clinical appropriateness and the patient-specific copayment of a drug at the point of prescribing.

CMS notes that several Part D plans offer RTBT inquiry and response capabilities to some physicians. While CMS acknowledges that there is no industry-established transaction standard for RTBTs, it nonetheless believes the policy is sufficiently important to require implementation using available technologies. The majority of commenters expressed concern about the lack of an industry standard and the proposed effective date of January 1, 2020. While the effective date of the finalized proposal is January 1, 2021, CMS nonetheless encourages plans to facilitate earlier use of RTBT. Some commenters objected to requiring the RTBT before the establishment of an industry standard because the costs of integrating multiple RTBT systems into EHRs would be prohibitive; these commenters also cautioned that those costs may be passed on to prescribers. CMS responds that should an industry standard become available in the future, it will address requiring it in rulemaking. CMS also cautions that prescribers will be less likely to adopt RTBT if it represents a significant financial burden.

Part D sponsors must select or develop an RTBT capable of integration with at least one prescriber's EMR and eRx systems. Each response value must show an accurate reflection of

how the prescription claim will be adjudicated given the information submitted and the claims history of the patient with that plan at the time the prescriber query is made. Real-time values for patient cost-sharing and additional formulary alternatives are also required.

CMS encourages plans to show each drug's negotiated price in addition to beneficiary out-of-pocket cost information, but it does not require this functionality since the majority of commenters opposed it. CMS also believes the RTBT plan benefit information should include patient-specific utilization requirements (e.g., prior authorization or step therapy requirements) that must still be satisfied at the time of the prescription. CMS also expects the data to be both timely and accurate.

Acknowledging that the policy implicates patient privacy rights under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy regulations (because information about services or treatment may be disclosed to the plan by the RTBT), CMS had proposed that the prescriber should first check whether the patient will pay for the drug or service out-of-pocket in full. Commenters warned that this additional patient consent requirement would require prescribers to modify their workflow and systems to capture that explicit consent; they believe that no less than 18 months would be required to adopt, implement, test and resolve any issues. CMS reevaluates its position on this issue and determines that RTBT use will fall within HIPAA health care treatment disclosures that are generally permissible without patient authorization. While no specific patient consent will be required for use of the RTBT, CMS nonetheless encourages prescribers to use the tool judiciously and always permit the enrollee to tell the prescriber not to use the tool.

#### *Regulatory Impact*

CMS acknowledges its RTBT policy has unclear costs and impacts, and the comments submitted did not provide the agency sufficient information to quantify the burden for purposes of the Paperwork Reduction Act. CMS will publish stand-alone 60- and 30-day Federal Register notices to revisit the burden issues, solicit public comment, quantify the burden, and obtain OMB approval.

CMS believes its proposal will yield savings through encouraging the prescription of drugs and biologicals on lower cost-sharing tiers. CMS also believes that lower prices would equate to better medication adherence. Based on comment, CMS no longer believes plans will write their own RTBT software and thus does not attempt to estimate those costs in the final rule.

However, because of both lack of data and complexity of the required data, CMS does not quantify the impact. However, it states that the provision scores as a qualitative savings.

#### **IV. Part D Explanation of Benefits (§423.128)**

CMS finalizes its proposal to add two items to §423.128(e), a section which describes the items that must be included in the explanation of benefits (EOB). In the only change from its proposal, plan sponsors will be required to include the new information beginning for contract year 2021 instead of 2020 as proposed. The EOB must include information about any negotiated price changes for each drug provided as well as any lower-cost therapeutic alternatives. CMS states that these additions will increase price transparency and better inform beneficiaries.

The EOB is presently required to be provided to enrollees no later than the end of the month in which an enrollee used their prescription drug benefit and must include:

- The item or service for which payment was made and the amount of payment;
- Notice of an individual's right to an itemized statement;
- Cumulative, year-to-date total amount of benefits provided (including the deductible, initial coverage limit, and the annual out-of-pocket threshold for the current benefit year);
- Cumulative, year-to-date total incurred costs; and
- Any applicable formulary changes.

In this final rule, CMS redesignates section 423.128(e)(5) and (e)(6) as (e)(6) and (e)(7) and specifies a new (e)(5) requiring sponsors to include information about any negotiated price changes and any lower-cost therapeutic alternatives. With respect to reporting any negotiated price changes, plans will need to report the cumulative percentage change in the negotiated price of the drug since the first day of the current benefit year for each prescription drug claim in the EOB.

With respect to reporting lower-cost therapeutic alternatives, plan sponsors must include information on therapeutic alternatives from the formulary that have lower cost sharing. Plans may also include therapeutic alternatives from the formulary with the same copayments if the negotiated price of the drug is lower. CMS notes that this reporting is not limited to therapeutically equivalent generics. A different drug with a medically-accepted indication, even one in a different category or class, to treat the same condition may be reported.

CMS received feedback that it did not provide sufficient definition of the term “lower-cost therapeutic alternative.” CMS points out that lower-cost therapeutic alternatives for this purpose will be determined by the plan sponsor based on its formulary and the term is not limited to therapeutically-equivalent generic drugs. Other commenters raised concerns that the drug cost information would not be actionable or useful because it would be provided after the prescription has already been filled. CMS believes there is value in providing the information even after the prescription has been filled insofar as it provides information for a dialogue between a patient and his or her providers.

## **V. Medicare Advantage and Step Therapy for Part B Drugs (§§422.2 and 422.136)**

CMS finalizes its proposal to codify the ability of MA plans to use step therapy as a utilization management tool for Part B drugs beginning with plan years that start on or after January 1, 2020 with several changes as described further below. CMS notes that because the rule is finalized in advance of the 2020 bid deadline, MA plans must include any savings from such a policy in their bids for 2020 and future years.

The final policy is largely consistent with guidance issued in August of 2018 establishing that step therapy and other utilization management tools were permitted to apply to Part B drugs

covered by MA plans beginning with the 2019 plan year.<sup>2</sup> Unlike under the 2018 guidance, however, where plans were required to use those savings for rewards and incentives, the final rule requires all plan savings resulting from step therapy to be incorporated in the plan's bid amount.

As proposed, “step therapy” is defined in new §422.2 to mean a utilization management policy for coverage of drugs that begins medication for a medical condition with the most preferred or cost effective drug therapy and progresses to other drug therapies if medically necessary. CMS does not specify standards for exemptions from the policy nor movement within a step therapy program and notes that MA plans continue to be responsible to provide all medically necessary covered services and items under the Medicare fee-for-service program.

CMS finalizes new §422.136 with a significant change to the timeline for determining an ongoing course of treatment. To ensure that a step therapy program does not interfere with an ongoing course of treatment, it may only apply to new administrations of Part B drugs. CMS had proposed a lookback period of 108 days, however, in response to commenters who argued that 108 days was too short and others who provided specific examples of drug therapies that would not be identified as pre-existing within a 108 day look-back period, CMS extends this period to *at least 365 days*.

Other safeguards intended to ensure that enrollees have access to all medically necessary Part B medications are finalized as proposed.

- Consistent with the proposed rule, an MA plan must have policies and procedures in place to educate and inform providers and enrollees about its step therapy policy.
- Also consistent with the proposed rule, a step therapy program is required to be reviewed and approved by the plan’s pharmacy and therapeutic (P&T) committee before it is implemented. A MA-PD plan may use an existing Part D P&T committee.

Final §422.136(b) further describes the P&T committee requirements. CMS points out that this section mirrors the Part D requirements for such committees at §423.120(b). As finalized, CMS replaces several references to the more broad “utilization management requirements” or “prior authorization” with more specific text that refers to “step therapy.”

The P&T committee must:

- (1) Include a majority of members who are practicing physicians or pharmacists.
- (2) Include at least one of each of a practicing physician and a practicing pharmacist who are independent and free of conflict with the MA organization, its plans, and pharmaceutical manufacturers.

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<sup>2</sup>Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage (August 2018), [https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA\\_Step\\_Therapy\\_HPMS\\_Memo\\_8\\_7\\_2018.pdf](https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf).

- (3) Include at least one of each of a practicing physician and a practicing pharmacist who are experts in the care of elderly or disabled individuals. CMS encourages plans to include P&T members that represent various clinical specialties.
- (4) Articulate and document processes to ensure that the requirements §422.136(b) are met, including those related to conflicts of interest.
- (5) Base clinical decisions on scientific evidence and standards of practice, including peer-reviewed literature, pharmacoeconomic studies, outcomes research, and other information as appropriate.
- (6) Consider whether the inclusion of a particular Part B drug *step therapy program* (instead of a “utilization management program, such as step therapy” as proposed), has any therapeutic advantages in terms of safety and efficacy.
- (7) Review policies that guide exceptions and other *step therapy processes* (instead of “utilization management processes, including drug utilization review, quantity limits, generic substitution, and therapeutic interchange” as proposed.)
- (8) Evaluate and analyze treatment protocols and procedures related to the plan's step therapy policies at least annually.
- (9) Document in writing decisions regarding the development and revision of *step therapy activities* (instead of “utilization management activities” as proposed) and make the documentation available to CMS on request.
- (10) Review and approve all *step therapy criteria* (instead of “clinical prior authorization criteria, step therapy protocols, and quantity limit restrictions” as proposed) applied to each covered Part B drug.
- (11) Meet other requirements consistent with written policy guidelines and CMS instructions.

CMS finalizes without change new §422.136(c) permitting a MA plan to include a drug for a medically accepted off-label indication as part of a step therapy protocol if that use is supported by widely used treatment guidelines or clinical literature that CMS considers to be best practices. In response to commenters who requested that CMS clarify what is meant by widely used treatment guidelines or what CMS considers to be best practices, CMS provides an example of a widely used treatment guideline: the National Cancer Center Network guidelines.

In §422.136(d), CMS finalizes its proposal to prohibit a non-covered drug from being included as a component of a step therapy protocol. This provision ensures that a step therapy protocol is not used as a barrier to accessing covered benefits. CMS notes in the preamble that a MA-PD plan could require a Part D drug prior to a Part B drug or the reverse as long as such requirements are clearly outlined in the Part D prior authorization criteria. Consistent with the finalized proposal permitting the application of prior authorization including step therapy for drugs in protected classes (described above), beginning in 2020, plans may also require step therapy for Part B drugs before Part D drugs in the protected classes.

CMS points out that certain existing requirements applicable to MA plans also apply in the case of Part B drugs subject to step therapy:

- Care coordination activities that are sufficient to promote positive health outcomes at §§422.112(b) and 422.152.
- Existing determination and appeals processes (However CMS proposes new timelines specifically for those related to Part B drugs as described in more detail below.)
- Disclosure requirements in §422.111 under which plans are required to disclose to enrollees any prior authorization rules or review requirements that must be met in order to ensure payment for services.
- Existing requirements to educate and fully inform contracted health care providers regarding policies on utilization management (although, as described above, CMS proposes a specific requirement of this type for step therapy in §422.136(a)).
- Existing rules at §422.206 that prevent plans from interfering with the ability of a treating physician to advise enrollees about treatment options.
- The existing requirement at §422.202(b)(1) that MA organizations must formally consult with contracted physicians when developing utilization management guidelines.

As in the preamble to the proposed rule, CMS repeats that PPOs cannot use prior authorization including step therapy with respect to out-of-network coverage. PPOs may only use step therapy for a Part B drug provided by an in-network provider.

Some commenters expressed concerns that the policy could lead to negative health outcomes, restricted or delayed access to care, or benefits that are more restrictive than under original Medicare. Others recommended additional study before CMS finalizes the provisions. Concerns about increased administrative costs and insufficient administrative oversight were raised as well. In response, CMS reviews the new and existing protections that apply (largely as noted above). In addition, CMS reviews its justification for allowing step therapy, points out that plans must continue to comply with national and local coverage determinations, and describes its plans to monitor beneficiary complaints, determinations, and appeals related to Part B drugs.

CMS acknowledges the potential administrative burden and in response encourages plans to continue to develop and advance electronic prior authorization processes. In response to recommendations for increased transparency of step therapy requirements, CMS notes that it intends to seek additional comment through sub-regulatory guidance about how such requirements should be displayed in Annual Notice of Change and Explanation of Coverage documents. In response to commenters' concerned that some beneficiaries could be financially disadvantaged if a Part D drug is used as a step to a Part B drug because Part D does not include a maximum out-of-pocket limit, CMS notes that premiums should be reduced because of step therapy program savings.

### *Determinations and Appeals for Part B Drugs*

CMS proposed timeframes for the adjudication of Part B drugs that are parallel to Part D timelines at the applicable appeals stages and states that because of the clinical circumstances that typically accompany requests for Part B drugs, CMS proposed to not permit MA plans to extend those timelines. In addition, CMS requested feedback on whether the same or different timelines should be finalized for D-SNPs with integrated grievance and appeals provisions.

CMS finalizes its proposed adjudication timeframes for determinations and appeals for Part B drugs without substantive changes:

- In §422.568 (standard timeframes and notice requirements for determinations) an MAO must notify an enrollee (and their physician or prescriber as appropriate) of a determination related to a Part B drug as expeditiously as the enrollee's health requires, but no later than 72 hours after receipt of the request. This 72-hour period cannot be extended. In addition, Part B drugs are added to the existing provision requiring notification of a service denial to describe the reconsideration and remaining appeals processes and the enrollee's right to request expedited reconsideration.
- In §422.572(a) (timeframes and notice requirements for expedited determinations) a MA organization that approves an expedited request is required to make its determination known to the enrollee (and physician or prescriber as appropriate) as expeditiously as the enrollee's health requires but no later than 24 hours after receiving the request. This timeline cannot be extended.
- In §422.590(c) (timeframes and notice requirements for standard reconsiderations) the MAO must issue its determination as expeditiously as the enrollee's health requires but no later than 7 calendar days from the date it receives the request. That period cannot be extended. If the MAO makes a reconsidered determination that affirms its adverse organization determination, it must provide a written explanation and send the case file to the independent entity no later than 7 calendar days from the date it receives the request for a standard reconsideration.
- In §422.590(e)(2) (timeframes and notice requirements for expedited reconsiderations), a MAO that approves a request for an expedited reconsideration of a Part B drug is required to complete its reconsideration and provide notice of the decision as expeditiously as the enrollee's health requires but no later than 72 hours after receiving the request. This timeline cannot be extended.

CMS finalizes its proposal to add references to determinations relating to Part B drugs in §§422.584(d), 422. 618(a) and (b), and 422.619(a), (b) and (c). These provisions incorporate references to Part B drugs into existing requirements relating to handling of requests for expedited reconsiderations, effectuating reconsidered decisions, and effectuating expedited reconsiderations.

Other cross references and technical conforming changes are finalized as proposed. In addition, throughout these regulations regarding appeals, CMS adds the word "items," to better reflect that appeals for benefits may be related to *items or services*.

CMS did not receive comments regarding timeframes for Part B drug coverage decisions made as part of the integrated grievance and appeal provisions for certain D-SNPs with aligned enrollment with Medicaid managed care plans. In the final rule, however, CMS finalizes the following provisions requiring integrated plans to use the same Part B organization determination and appeals timeframes as described above:

- In §422.629(a) (which sets out the general requirements for grievance and appeal processes for applicable integrated plans) such plans are required to use the Part B drug rules;
- In §422.631(a) (regarding the process for integrated organization determinations) specifying the applicability of Part B drug rules to integrated organization determinations; and
- In §422.633(f) (regarding reconsidered determinations and notification about such determinations) specifying the applicability of Part B drug reconsideration timelines to the integrated reconsideration process.

#### *Regulatory Impact*

CMS states that step therapy is a widely accepted tool for utilization management. In 2014, 75 percent of large employers used step therapy. In addition, 18 states have step therapy laws most of which provide protection to beneficiaries against the misuse of step therapy.

CMS provides a qualitative discussion on the expected impact of step therapy programs on “front-end” negotiated prices. It expects that the ability to use step therapy will increase the effectiveness of plans’ price negotiations with manufacturers and therefore result in savings on the price of drugs. CMS also, however, provides citations to studies that describe the potential costs and ill-effects of step therapy:

- Research indicates that some enrollees become discouraged by step therapy and do not pursue their medications once a claim is rejected at the point of service; and
- Step therapy, which generally requires a person to “fail-first” on a particular course of treatment before moving to the next treatment in the step protocol, has been found to result in worsening health care conditions, and to increase non-drug health care costs for those subject to step therapy.

CMS states that step therapy will, therefore, result in both savings and costs.

In addition, CMS provides estimates of the impact on “back-end negotiations” and the resulting savings to the trust fund and enrollee cost sharing attributable to the additional use of lower-cost biologicals and lower-cost therapeutic equivalents. Those factors are estimated to result in savings of 1.6 percent of the aggregate annual cost of Part B drugs under MA plans or \$145 million in 2020, and almost \$2 billion over the 2020 to 2029 period. Beneficiaries are estimated to save \$5 million in 2020 and \$62 million over that period. These savings are expected to be partly offset by an increase to plans in the number and therefore the cost of appeals. CMS estimates those costs to be \$1.0 million in 2020 and \$11.2 million over the 2020 to 2029 period.

## **VI. Pharmacy Price Concessions in the Negotiated Price (§423.100)**

In the preamble of the proposed rule, CMS requested feedback on policies that it is considering proposing in the future to address concerns regarding the growing amount of pharmacy price concessions and the impact on the program and on beneficiaries that those price concessions are rarely included in the price at the point of sale. Two alternative ways of changing the definition of “negotiated prices” were described:

- (1) To eliminate the clause permitting those prices to exclude contingent pharmacy payment adjustments that cannot reasonably be determined at the point of sale.
- (2) To define “negotiated price” to be the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug under its contract with the Part D sponsor or the sponsor’s intermediary. Under this proposal, the negotiated price for a covered Part D drug would include all pharmacy price concessions and any dispensing fees, and exclude additional contingent amounts such as incentive fees if these amounts increase prices.

CMS states that it received over 4,000 comments on these policies. It will review and take them into consideration as it continues its efforts to address rising drug costs.