DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 423

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Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule amends the Medicare Advantage (MA) program (Part C) regulations and Prescription Drug Benefit program (Part D) regulations to support health and drug plans' negotiation for lower drug prices and reduce out-of-pocket costs for Part C and D enrollees. These amendments will improve the regulatory framework to facilitate development of Part C and Part D products that better meet the individual beneficiary's healthcare needs and reduce out-of-pocket spending for enrollees at the pharmacy and other sites of care.

DATES: These regulations are effective on January 1, 2020, except for the amendments to §§ 422.629, 422.631, 422.633, 423.128, and 423.160, which are effective January 1, 2021.

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SUPPLEMENTARY INFORMATION:

I. Executive Summary and Background

A. Purpose

This final rule amends regulations to support Medicare health and drug plans' negotiation for lower drug prices and to reduce out-of-pocket costs for Part C and D enrollees. Although satisfaction with the MA and Part D programs remains high, these provisions are responsive to input we received from stakeholders while administering the programs, as well as through our requests for comment.

The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (May 16, 2018, 83 FR 22692) sought to find out more information about lowering drug pricing using these four strategies: Improved competition, better negotiation, incentives for lower list prices, and lowering out-of-pocket costs. We are finalizing a number of provisions that implement these four strategies in an attempt to lower out-of-pocket costs. There is also a particular focus in this final rule on strengthening negotiation leverage for MA and Part D plans and increasing competition in the market for prescription drugs. We are finalizing policies that provide more tools to MA plans that negotiate with manufacturers of Part B drugs, so these plans are equipped with similar negotiation capabilities that group health plans and issuers have in the commercial market. We sought to drive robust competition among health plans and pharmacies, so consumers can shop based on quality and value. These provisions align with the Administration's focus on the interests and needs of beneficiaries, providers, MA plans, and Part D sponsors. We are also finalizing policies that will increase transparency of drug pricing and drug price increases, giving beneficiaries and prescribers tools to help improve adherence, lower prescription drug costs, and minimize beneficiary out-of-pocket costs.

B. Summary of the Major Provisions

1. Providing Plan Flexibility To Manage Protected Classes (§ 423.120(b)(2)(vi))

Except in limited circumstances, current Part D policy requires Part D sponsors to include on their formularies all Part D drugs in six categories or classes: (1) Antidepressants; (2) antipsychotics; (3) anticonvulsants; (4) immunosuppressants for treatment of transplant rejection; (5) antiretrovirals; and (6) antineoplastics. We proposed three exceptions to this protected class policy that would allow Part D sponsors to: (1) Implement broader use of prior authorization (PA) and step therapy (ST) for protected class Part D drugs, including to determine use for protected class indications; (2) exclude a protected class Part D 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 Part D drug from a formulary if the price of the drug increased beyond a certain threshold over a specified lookback period. This regulatory provision finalizes one of the three proposed exceptions with modifications: The first exception related to PA and ST.

The first exception permits Part D sponsors to use PA and ST for protected class Part D drugs. We are finalizing this exception with modifications. As modified, the exception is a codification of existing policy and does not place additional limits on beneficiary access to medications. Specifically, the exception will permit PA and ST only for new starts (that is, enrollees initiating therapy), including to confirm the use is for a protected-class indication, for five of the six protected classes (that is, all protected classes except for antiretroviral medications). PA and ST will not be permitted for antiretrovirals under this exception. This exception will permit indication-based formulary design and utilization management for new starts in five of the six protected classes, allowing Part D sponsors to exclude a protected class Part D drug in these five classes from the formulary for non-protected class indications only. As is required for all other Part D drug categories or classes, these formulary design and utilization management edits will be subject to CMS review and approval as part of our annual formulary review and approval process, which includes reviews of PA and ST edits that restrict access, ST criteria, PA outliers, and PA criteria. (For an extensive description of our annual formulary checks see section II.A.1. of this final rule.)

The second exception would have permitted Part D sponsors to exclude from the formulary a protected class Part D drugs that is a new formulation of a protected class Part D drug, even if the older formulation is removed from the market. That is, Part D sponsors would have been permitted to exclude from their formularies a protected class Part D drug that is a new formulation that does not provide a unique route of administration, regardless of whether the older formulation remains on the market. Based on comments, we are not finalizing this exception.

The third exception would have permitted Part D sponsors to exclude from the formulary any protected class Part D drug whose price increases, relative to the price in a baseline month and year, beyond the rate of inflation calculated based on the Consumer Price Index for all Urban Consumers (CPI–U). Based on comments, we are not finalizing this exception.

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

This final rule requires under section 1860D–4(e)(2)(D) of the Social Security Act (Act) that Part D plan sponsors implement an electronic real-time benefit tool (RTBT) capable of integrating with at least one prescriber's electronic prescribing (eRx) system or

electronic health record (EHR). We believe that this requirement is appropriate given the Act's support of interactive real-time standards whenever feasible, and for standards that improve the cost-effectiveness of the Part D benefit. RTBTs currently used in the industry have the ability to make beneficiary-specific drug coverage and cost information visible to prescribers who want to consider that information at the point-of-prescribing. Because there currently are no industry-wide electronic standards for RTBTs, we are finalizing a requirement that each Part D plan implement at least one RTBT of its choosing that is capable of integrating with at least one prescriber's eRx system or EHR to provide prescribers who care for its enrollees complete, accurate, timely and clinically appropriate patient-specific real-time formulary and benefit (F&B) information (including cost, formulary alternatives and utilization management requirements) by January 1, 2021. However, we strongly encourage plans to start implementing this provision prior to 2021.

3. 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)

This final rule provides requirements under which MA plans may apply step therapy as a utilization management tool for Part B drugs and adopts new adjudication timeframe requirements for organization determinations and plan reconsiderations related to requests for Part B drugs. In addition, CMS will incorporate the shorter adjudication timeframes for Part B drug requests into the contract deadlines that apply to Part C Independent Review Entity (IRE) reconsiderations under § 422.592(b). In this final rule, we reaffirm MA plans' existing authority to implement appropriate utilization management and prior authorization programs (meaning policies and procedures) for managing Part B drugs to reduce costs for both beneficiaries and the Medicare program. The use of utilization management tools, such as step therapy, for Part B drugs enhances the ability of MA plans to negotiate Part B drug costs and ensures that taxpayers and MA enrollees face lower per unit costs or pay less overall for Part B drugs while maintaining access to medically-necessary Medicare-covered services and drugs. In order to make sure enrollees maintain access to all medically necessary Part B covered drugs, we are modifying the Part C adjudication time periods for organization determinations and appeals involving Part B drugs.

C. Summary of Costs and Benefits

TABLE 1—COSTS AND BENEFITS FOR THE MAJOR PROVISIONS

Provision	Description	Impact
Providing Plan Flexibility to Manage Protected Classes (§ 423.120(b)(2)(vi)).	We allow the following exception related to protected class Part D drugs: Use of PA and ST for new starts of five of the six protected classes, including to determine use for protected class indications.	We estimate neither cost nor savings from this provision.
E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards (§ 423.160).	We require each Part D plan sponsor to implement one or more RTBTs of its choosing that are capable of integrating with at least one provider's e-Rx system or EHR and delivering complete, accurate, timely and clinically appropriate patient-specific real- time F&B information beginning on 01/01/2021.	This provision is scored as a qualitative savings. Based on commenter response we do not believe there will be significant cost to implement RTBT since i) Based on informal conversations with plans and commenter response, 30 percent–90 percent of plans are estimated as already supporting an RTBT tool and ii) plans that do not have it are most likely to use existing intermediaries. Commenters were overwhelmingly enthusiastic on the savings potential due to reduced drug costs arising from cheaper alternatives. The Trust Fund and enrollees will save. However, this savings is classified as a transfer since a cheaper drug is being substituted for a more expensive one. Because of the complexity of prescription drug usage we are unable to meaningfully quantify this savings.
Part D Explanation of Benefits (§ 423.128).	We require the inclusion of negotiated drug pricing information and lower cost alternatives in the Part D Explanation of Benefits beginning on 01/01/2021. The intent of the provision is to provide enrollees with greater transparency, thereby encouraging lower costs.	There is an estimated cost of $4.7 million in the first year of implementation for programmers to update systems. There is an annual estimated cost in all years (including the first) of $5.7 million arising from the cost of paper, printer toner, and postage for mailing one extra page in the Part D EOB with added information about alternatives.
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).	We added certain new requirements for when MA plans may apply step therapy as a utilization management tool for Part B drugs.	The estimated savings to enrollees due to reduced out-of-pocket costs are between $5 and $8 million for 2020–2029 resulting in an aggregate savings of $62 million over 10 years. The savings to the Trust Fund are between $145 and $240 million for 2020–2029, resulting in an aggregate savings over 10 years of 1.9 billion. There is a modest cost to the government and its contractors of $1 to $1.3 million in 2020–2029 due to a projected increased in appeals, resulting in an aggregate cost of $11.2 million cost over 10 years. These estimates reflect the impact of allowing step therapy for MA organizations in 2020 and future years.

D. Background

In the proposed rule titled ''Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses'' which appeared in the November 30, 2018 **Federal Register** (83 FR 62152 through 62201), we proposed revisions to the Medicare Advantage program (Part C) regulations and Prescription Drug Benefit program (Part D) regulations that

will have the effect of lowering the cost of medications and reducing out-of-pocket costs for enrollees in the Part C and D programs. The changes, as finalized in this rule, will also streamline different aspects of the Part D program and reduce associated burden on the government and sponsoring organizations of MA plans and Part D plans.

In response to the proposed rule, we received 7,898 timely pieces of correspondence containing multiple comments each. Although we are not finalizing all of our proposals to provide plan flexibility to manage protected classes, we are finalizing all other provisions with changes varying from minor clarifications to more significant modifications, based on the comments received. We also sought comment on the possibility of adopting a new definition of ''negotiated price'' under which plan sponsors would be required to pass through all pharmacy price concessions at the point of sale. We will carefully review all input received from stakeholders on this issue as we continue our efforts to meaningfully address rising prescription drug costs for beneficiaries. We also note that some of the public comments received were outside of the scope of the proposed rule. These out-of-scope public comments are not addressed in this final rule. Summaries of the public comments that are within the scope of the proposed rule and our responses to those public comments are set forth in the various sections of this final rule under the appropriate headings.

II. Provisions of the Proposed Rule and Analysis of and Responses to Public Comments

A. Providing Plan Flexibility To Manage Protected Classes (§ 423.120(b)(2)(vi))

Section 1860D–4(b)(3)(G) of the Act requires Part D sponsors to include in their formularies all covered Part D drugs in classes and categories of clinical concern identified by the Secretary using criteria established through rulemaking. The statute specifies that until such time as the Secretary establishes the criteria to identify drug categories or classes of clinical concern through rulemaking, the following drug categories or classes shall be identified as categories or classes of clinical concern: Anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection. This policy is frequently called the ''protected class'' policy in the Part D program, with the drug categories or classes of clinical concern being the ''protected classes.'' Section 1860D–4(b)(3)(G) of the Act permits the Secretary to establish exceptions that permit a Part D sponsor to exclude from its formulary (or to otherwise limit access to such a drug, including through PA or utilization management) a particular covered Part D drug that is otherwise required to be included in the formulary. The Secretary must engage in rulemaking to establish these exceptions. Section 423.120(b)(2)(vi) currently provides three regulatory exceptions to the protected class policy that permit Part D sponsors to: (1) Exclude from their formulary therapeutically equivalent drugs, (2) apply utilization management (UM) edits for safety, and (3) exclude other drugs that CMS specifies through a medical and scientific process which also permits public notice and comment.

The protected class policy, inclusive of its current limitations on PA, is unique to the Medicare Part D program and does not appear elsewhere in other Federal programs, such as the Veterans Health Administration (VA), TRICARE, the Federal Employees Health Benefits Program (FEHBP), the Patient Protection and Affordable Care Act Essential Health Benefits (EHB) Benchmark Plans, or in commercial private health plans. We are concerned that requiring essentially open coverage of certain drug categories or classes in Part D presents both enrollee cost and welfare concerns, as well as increased costs for the Part D program as a result of overutilization (for example, antipsychotics used for sedation) and increased drug prices due to lack of competition between manufacturers to achieve inclusion on plan formularies. In our January 2014 proposed rule entitled, ''Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (79 FR 1918, hereinafter referred to as the ''January 2014 proposed rule''), we detailed concerns that the policy potentially facilitates the overutilization of drugs within the protected classes (79 FR 1938). Despite some formulary flexibility and ability to use drug UM techniques for protected class Part D drugs, Part D sponsors are not able to negotiate rebates across the protected classes at levels commensurate with other Part D drugs or prescription drugs covered in the commercial market.

Consequently, although we did not propose to eliminate any of the protected classes, we proposed to use the authority under section 1860D–4(b)(3)(G) of the Act to revise § 423.120(b)(2)(vi). Specifically, we proposed to use the authority under section 1860D–4(b)(3)(G) of the Act to establish additional exceptions to the requirement that all drugs in a protected class be included in the formulary and to permit additional use of UM. We proposed to revise § 423.120(b)(2)(vi) to permit Part D sponsors to implement PA and ST requirements for protected class Part D drugs for broader purposes than allowed currently. We also proposed to allow Part D sponsors to exclude specific protected class Part D drugs from their 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 or to exclude single-source drugs or biological products that have certain price increases beyond a certain threshold over a specified look back period. However, we noted that these exceptions will apply only to the requirement that the drug be included on the formulary because it is a protected class Part D drug. In other words, an exception from the protected class policy will not supersede our other formulary requirements in § 423.120(b)(2).

We received the following comments and our response follows:

Comment: Many commenters stated that all three of our proposals greatly compromised access to needed therapy (that is, delays and/or interruptions in therapy) for patients taking protected class Part D drugs, which would lead to adverse health outcomes for these enrollees, and, in the case of HIV, endanger public health.

Response: In considering whether to propose these exceptions, CMS took our other enrollee access protections into account, which have successfully protected beneficiary access to needed medications in the more than 12 years the Part D program has been operational. There are five such enrollee protections, which include formulary transparency, formulary requirements, reassignment formulary coverage notices, transition supplies and notices, and the expedited coverage determination and appeals processes.

The first protection is our requirement for formulary transparency to beneficiaries. Part D sponsors are required to provide comprehensive formulary drug listings to the public through their own websites and printed materials, as well as to CMS for access through the online interactive drug plan comparison tool, the Medicare Plan Finder (Plan Finder). Beneficiaries or

their representatives can complete a personalized search on the Plan Finder to locate and select a Part D plan that covers their drugs. Thus, beneficiaries who review plan formularies can select plans that cover their current medications.

The second type of protection is the Part D formulary requirements (§ 423.120(b)(2)). Our annual formulary review and approval process is designed to ensure that Part D formularies do not substantially discourage enrollment by certain beneficiaries and that the formularies include adequate representation of all necessary Part D drug categories or classes for the Medicare population. The formulary review and approval process includes the following:

- Category and Class Review (§ 423.272(b)(2)). Distinct from our other formulary checks, CMS reviews and approves drug lists that are consistent with best practice formularies currently in widespread use today. CMS evaluates the sufficiency of a Part D sponsor's formulary drug categories or classes in conjunction with the plan's formulary drug list to ensure that the formulary provides access to an acceptable range of Part D drug choices.
- Two Drugs Requirement (§ 423.120(b)(2)(i)). Each submitted formulary is reviewed for the inclusion of at least two distinct drugs from each of the submitted categories or classes, except as provided in § 423.120(b)(2)(ii).
- Formulary Tier Review (Medicare Prescription Drug Benefit Manual, Chapter 6, section 30.2.7). The tiering structure of each formulary is reviewed to ensure that each category or class generally has at least one drug in a preferred tier.
- Common Medicare Drugs Review (§ 423.120(b)(2)(iii)). Formularies are reviewed for inclusion of the drugs or drug classes that are most commonly utilized by the Medicare population. We use prior years' data to identify the drugs or drug classes with the highest utilization in Medicare Part D, and use these drugs or drug classes as the basis for our review in this area.
- Treatment Guidelines [1] Review (§ 423.120(b)(2)(iii)). We analyze formularies to determine whether appropriate access is afforded to drugs or drug classes included in widely accepted treatment guidelines.
- Vaccines Review (§ 423.100). Each formulary submission is reviewed to ensure the formulary includes Part D vaccines.
- Specialty Tier Review (§ 423.578(a)(7)). For formularies using a specialty tier, we perform an extensive review of the composition of each specialty tier. We apply a standard outlined in the annual Call Letter to determine whether drugs placed in specialty tiers meet the relevant cost criteria.
- Quantity Limits (QL) Amount Review (§ 423.153(b)). QL restrictions are reviewed for appropriateness. The standard for the review is generally based on the maximum recommended dose when such dosage limits are identified in the Food and Drug Administration (FDA)—approved labeling.
- Restricted Access Review (§ 423.153(b)). Formularies are reviewed for use of PA and ST edits across drug categories or classes. We decline to approve UM for entire drug classes, other than for those categories or classes where the UM edits are considered to be consistent with best practices, for example, for erythropoietin stimulating agents (ESAs), due to the high likelihood of Part B versus Part D coverage issues, as well as a boxed warning in the FDA labeling that warns of significant adverse events when these drugs are used outside of their approved indications and therapeutic targets.
- Step Therapy Criteria Review (§ 423.153(b)). The ST requirements are reviewed to ensure that the ST algorithms are consistent with best practices, including prerequisite drugs, current industry standards and appropriate treatment guidelines.
- Prior Authorization Criteria Review (§ 423.153(b)). We review the criteria for drugs requiring PA on the formulary submissions. We look to existing best practices, current industry standards, and appropriate treatment guidelines to check that the Part D plans' use of PA is consistent with such best practices. Submitted criteria are also compared to recognized compendia (that is, those compendia described in section 1927(g)(1)(B)(i) of the Act: American Hospital Formulary Service Drug Information and DRUGDEX Information System) and FDA-approved indications.
- Mid-year formulary change restrictions (§ 423.120(b)(5)); Chapter 6 of the Medicare Prescription Drug Benefit Manual, section 30.3.3). Except when: (1) The FDA deems a Part D drug unsafe, (2) a manufacturer removes a Part D drug from the market, or (3) in the circumstances described under § 423.120(b)(5)(iv) when a new generic drug becomes available, a Part D sponsor may not remove a covered Part D drug from its formulary, or make any adverse change in preferred or tiered cost-sharing status of a covered Part D drug, between the beginning of the annual coordinated election period described in § 423.38(b) and 60 days after the beginning of the contract year associated with the annual coordinated election period. However, prescription drug therapies are constantly evolving, and new drug availability, medical knowledge, and opportunities for improving safety and quality in prescription drug use at a lower cost will inevitably occur over the course of the year. As recognized in regulation, these new developments may require formulary changes during the year in order to provide high-quality, affordable prescription drug coverage. Moreover, CMS will not approve mid-year changes, other than the three types of changes listed here, unless the Part D sponsor grandfathers coverage for the remainder of the plan year for enrollees that are already taking the drug being removed (or subjected to an adverse change in preferred or tier cost sharing) at the time of the change.

Thus, in summary, our formulary rules both ensure that all Part D formularies contain sufficient drugs to treat all disease states in the Medicare population and protect enrollees from significant changes in formularies during the course of a coverage year.

The third type of enrollee protection is the annual notice to reassigned enrollees required under section 3305 of the Patient Protection and Affordable Care Act (PPACA, Pub. L. 111–148). Effective January 1, 2011, we provide individuals who receive the Low Income Subsidy (LIS individuals) who are reassigned to a different Part D plan with information on the differences under the new plan formulary, as well as information on the enrollee's grievance and appeal rights in the new plan. Thus, (in order to maintain access to a $0 premium) any individual who has his or her plan selection decision made through our reassignment process receives detailed coverage status information for each drug for which he or she filled a prescription between January and August of the previous year. With regard to the new plan, this notice describes for each drug whether it is on the formulary, whether the brand or generic version is covered, and whether UM may be applied. Moreover, the notice also provides a list of other available plans into which the enrollee can enroll with no premium if they

[1] The World Health Organization (WHO) defines a standard treatment guideline as a systematically developed statement designed to assist practitioners and patients in making decisions about appropriate health care for specific clinical circumstances (available at *http://www.who.int/medicines/technical_briefing/tbs/10-PG_Standard-Treatment-Guidelines_final-08.pdf*).

would prefer not to remain in the plan where they were reassigned. We send notices after the individual's reassignment and in time to allow for the LIS individual to make a voluntary selection of another plan effective January 1. Thus, any reassigned LIS individual receives advance notice of any change in formulary coverage of their medications in plenty of time to work with their prescribers if they wish to remain in the new plan, or to select a different Part D plan.

The fourth type of enrollee protection is our unique transition supply and notice requirements. A Part D sponsor must provide for an appropriate transition process for Part D drugs that are not on its formulary with respect to: (1) The transition of new enrollees into prescription drug plans following the annual coordinated election period; (2) the transition of newly-eligible Medicare beneficiaries from other coverage; (3) the transition of individuals who switch from one plan to another after the start of the contract year; and (4) in some cases, current enrollees affected by formulary changes from one contract year to the next (see § 423.120(b)(3) Chapter 6 of the Medicare Prescription Drug Benefit Manual, section 30.4). Within the first 90 days of an enrollee's enrollment in a new plan, plans must provide a temporary fill of at least an approved month's supply when the enrollee requests a fill of a non-formulary drug or a Part D drug that is on a plan's formulary but requires PA or ST under a plan's UM rules. This requirement applies beginning on an enrollee's first effective date of coverage, regardless of whether this is within the first 90 days of the contract year. Additionally, if a Part D sponsor cannot determine at the point of sale (POS) whether an enrollee is currently taking a drug (for example, a new enrollee filling a prescription for the first time), we instruct the Part D sponsor to provide the enrollee with a transition supply.

A successful transition process is contingent not only upon providing the transitional drug supply, but also upon informing affected enrollees, their caregivers, and their prescribers about the enrollee's options for ensuring that his or her medical needs are safely accommodated within a Part D sponsor's formulary. For this reason, when providing a temporary supply of non-formulary Part D drugs or Part D drugs that are on a plan's formulary but require PA or ST under a plan's UM rules, Part D sponsors must provide enrollees and their prescribers with written notice within three business days after adjudication of the temporary fill that they are receiving a transition supply and that they must take action. The temporary fill and written notice provide enrollees with a reasonable amount of time during which they and their prescribers can address the issue (by requesting a formulary exception or transitioning to a formulary drug) and prevents them from having to abruptly change or go without their medication (see Transition notice requirements (to enrollees and providers) [§ 423.120(b)(3)(iv and v); Chapter 6 of the Medicare Prescription Drug Benefit Manual, section 30.4.10]). Thus all enrollees and their prescribers have advance notice of any issue with continued coverage of a previously initiated therapy and sufficient time to resolve those issues without any lapse in appropriate therapy. The preceding formulary review and transition requirements are described in Chapter 6 of the Medicare Prescription Drug Benefit Manual (located at *http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter6.pdf*).

The fifth enrollee protection we took into account is the requirement for a robust coverage determination and appeal process, including the right of an enrollee or his or her prescriber to request an exception to the plan's UM criteria, tiered cost-sharing structure, or formulary. Part D sponsors are required to issue a coverage decision and notify the enrollee (and the prescriber, as appropriate) in writing in accordance with strict regulatory timeframes. In general, consistent with § 423.578, a plan must grant a tiering or formulary exception (for example, provide coverage for a non-formulary drug or a formulary exception to the UM criteria) when it determines that the requested drug is medically necessary, consistent with the prescriber's supporting statement indicating that preferred alternatives(s) would not be as effective and/or would have adverse effects.

We have established by regulation both an expedited adjudication timeframe if the plan or prescriber believes that applying the standard timeframe may jeopardize the enrollee's health, and a requirement that plans must issue all coverage decisions as expeditiously as the enrollee's health condition requires. The requirements at § 423.568 for coverage determinations and § 423.572 for expedited coverage determinations state that the plan must notify the enrollee ''as expeditiously as the enrollee's health condition requires, but no later than [72 or 24 hours, respectively] after receiving the request, or, for an exceptions request, the physician's or other prescriber's supporting statement.'' That is to say, if an enrollee's health condition requires a response in less than 24 hours, the plan is obligated to provide one.

If, based on the initial review of the request, the Part D sponsor expects to issue a partially or fully adverse decision based on medical necessity, the coverage determination must be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, before the Part D sponsor issues the decision on the coverage determination. If the Part D sponsor makes an adverse coverage determination, the required written notice must explain the specific reason(s) for the denial and include a description of the enrollee's right to a standard or expedited redetermination by the plan, and the rest of the five-level appeals process, including the right to request independent review. At the redetermination level of appeal, when the issue is the denial of coverage based on a lack of medical necessity, the redetermination must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. If a plan fails to make a coverage decision and notify the enrollee within the required timeframe, the request must be forwarded to the independent review entity (IRE) to be adjudicated.

Moreover, while we do not treat a claim transaction as a coverage determination, we require Part D sponsors to arrange with network pharmacies to provide enrollees with a written copy of the Office of Management and Budget (OMB)-approved standardized pharmacy notice (''Notice of Denial of Medicare Prescription Drug Coverage,'' CMS–10146) when the enrollee's prescription cannot be filled under the Part D benefit and the issue cannot be resolved at the point-of-sale (POS). The notice instructs the enrollee on how to contact his or her plan and explains the enrollee's right to request a coverage determination. Thus, all enrollees immediately receive clear, concise instructions on how to pursue their right to request a coverage determination when a prescription cannot be filled at POS. For additional information on the coverage determination, appeals, and grievance process, including information about the pharmacy notice, see 42 CFR part 423, subparts M and U, and the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, available at *https://www.cms.gov/Medicare/Appeals-and-*

Grievances/MedPrescriptDrugApplGriev/index.html.

CMS will be monitoring appeals activity to ensure Part D enrollees' requests are appropriately evaluated. Additionally, we also plan to implement a protected class-specific Complaints Tracking Module (CTM) monitoring project in 2020 to monitor access to protected class Part D drugs. Finally, as discussed elsewhere in this final rule, CMS is taking steps in 2020 and future rulemaking to include e-prescribing improvements such as real time benefit tools (RTBTs) and Part D electronic prior authorization (ePA) as required by section 6062 of the SUPPORT for Patients and Communities Act (Pub. L. 115–271), which could reduce the need for coverage determinations and appeals. Taken together, these initiatives and the five beneficiary access protections described previously will help to protect enrollees from any unnecessary or inappropriate delay in access to medically necessary drugs.

Comment: Several commenters stated that Part D sponsors already have enough tools to manage protected class Part D drugs, including PA on new starts, formulary tiering, and generic utilization. Some commenters added that by using these tools, Medicare currently only covers two-thirds of protected class Part D drugs, and plans already use PA on nearly one half of protected class Part D drugs. However, many other comments that we received expressed support for additional formulary management tools.

Response: It is unclear on what basis commenters are making the assertions regarding Medicare only covering two-thirds of protected class Part D drugs and plans already using PA on nearly one-half of protected class Part D drugs, as plans are required to include all protected class Part D drugs on their formularies, with limited exceptions as specified at § 423.120(b)(2)(vi), and the use of PA has been limited to new starts under our existing policy. Although we are not able to speak to the actual rebate values, our internal analyses of rebate data reported by Part D sponsors generally support the assertion that Part D sponsors obtain substantially smaller rebates for protected class Part D drugs than they do for non-protected class Part D drugs. Due to restrictions on disclosure of rebate data, CMS is not able to release this analysis to the public.

Comment: Some commenters claimed that proposing exceptions without previously or concurrently proposing clinical criteria is out of order, and not allowed by the plain reading of the statute.

Response: Section 1860D–4(b)(3)(G)(ii) of the Act specifies that subject to section 1860D–4(b)(3)(G)(iv) of the Act, the Secretary ''shall identify, as appropriate,'' categories or classes the Secretary determines are of clinical concern, using criteria the Secretary establishes. Section 1860D–4(b)(3)(G)(iv) of the Act states that until such time as the Secretary establishes the criteria, the existing protected class categories ''shall be identified'' under section 1860D–4(b)(3)(G)(ii) of the Act. The statute clearly contemplates that the existing protected classes—that is, those set forth in section 1860D–4(b)(3)(G)(iv) of the Act—are the identified classes for purposes of section 1860D–4(b)(3)(G)(ii)(II) of the Act, as well as section 1860D–4(b)(3)(G)(i)(I) of the Act, and therefore the Secretary need not establish criteria for identifying new or different protected classes before establishing exceptions.

Comment: Some commenters claimed that CMS's protected class proposals violate the statutory non-discrimination provision, particularly with respect to enrollees who take high-cost drugs in the protected classes. Other commenters asserted that HIV patients, LIS enrollees, and dually-eligible enrollees (particularly children) would be disproportionately affected by our proposals.

Response: The non-discrimination provision and the protected class provision are not at odds. Non-discrimination applies to all Part D enrollees, while the protected class provision establishes additional requirements for drugs in protected classes. Section 1860D–4(b)(3)(G) of the Act authorizes formulary exclusion and UM for protected class Part D drugs, which indicates that non-discriminatory formulary exclusion and UM are contemplated by the statute. Therefore, excluding a protected class drug from the formulary or imposing UM criteria would not be discriminatory in itself. Our approach to approving PA and ST criteria for protected class Part D drugs will be consistent with our discrimination analysis for all other categories or classes—that is, to ensure that these criteria, as applied, would not substantially discourage enrollment by certain Part D eligible individuals. As described previously, we conduct a discrimination review to ensure that plans' formulary designs are not likely to substantially discourage enrollment by certain Part D eligible individuals. We will conduct the same review with respect to the protected class drugs that plans wish to exclude from the formulary or for which they wish to impose PA or ST, in each case only as permitted under the exceptions we are finalizing in this rule. Moreover, there are other, non-protected categories and classes of drugs that consist of high-cost therapies (for example, drugs used to treat hepatitis C) for which CMS has been able to ensure a benefit design that is not likely to substantially discourage enrollment by certain Part D eligible individuals.

Comment: Some commenters asserted that CMS's proposals are inconsistent with Congressional intent and in conflict with our regulation. Specifically, commenters pointed to the language we adopted at § 423.120(b)(2)(vi)(C) specifying that any exception to the criteria is based upon scientific evidence and medical standards of practice (and, in the case of antiretroviral medications, is consistent with the Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV–1-infected Adults and Adolescents).

Response: Section 1860D–4(b)(3)(G)(i)(II) of the Act specifically allows the Secretary to establish exceptions that permit a Part D sponsor to exclude from its formulary a particular covered Part D drug in a category or class that is otherwise required to be included in the formulary, or to otherwise limit access to such a drug, including through PA or UM. Our existing exception at § 423.120(b)(2)(vi)(C) was adopted after enactment of the Medicare Improvements for Patients and Providers Act (MIPPA) (section 176 of Pub. L. 110–275). However, the PPACA (section 3307 of Pub. L. 111–148) removed this statutory requirement. While our existing regulations at § 423.120(b)(2)(vi)(C) discuss an exception for protected class Part D drugs that is ''based upon scientific evidence and medical standards of practice (and in the case of antiretroviral medications is consistent with the [HHS] Guidelines for the Use of antiretroviral Agents in HIV–1 Infected Adults and Adolescents),'' this is a separate and distinct exception from the exceptions proposed in this rulemaking. In other words, these exceptions can exist contemporaneously, and are not in conflict with each other.

Comment: Stakeholders provided alternative policies to lower drug prices, such as allowing copay assistance cards for Part D enrollees and other federal healthcare program beneficiaries, encouraging Part D plans to institute benefit designs that include ''select care'' tiers that would cover drugs with low or no patient cost sharing (including antineoplastic drugs), exploring new ways to encourage Part D

plans to offer supplemental benefits for enrollees, further developing demonstration models that provide supplemental benefits or reduced cost sharing for patients with specific conditions or needs, or proposing an exception that would permit Part D sponsors to exclude protected class Part D drugs when therapeutic alternatives exist.

Response: We thank commenters for their suggestions.

We are finalizing our proposal to redesignate the existing paragraph that appears at § 423.120(b)(vi)(C) that permits CMS to exempt other drugs that CMS specifies. However, because we are not finalizing our proposed exceptions regarding new formulations and price increases, paragraph § 423.120(b)(vi)(C) will be redesignated as paragraph (D), instead of (F) as originally proposed.

1. Broader Use of Prior Authorization for Protected Class Part D Drugs

Under section 1860D–4(b)(3)(G)(i)(II) of the Act, the Secretary can establish exceptions to permit a Part D sponsor to exclude from its formulary, or otherwise limit access through PA or UM, a particular Part D drug that is otherwise required to be on the formulary because it is in a protected class. This authority is specific to Part D drugs, and moreover, applies without regard to whether an enrollee is initiating therapy (new starts) or is currently taking a drug (existing therapy).

Part D coverage is limited to those drugs that meet the definition of a Part D drug in § 423.100. Therefore, regardless of a drug's potential status as a protected class drug, Part D sponsors are responsible for ensuring that coverage is limited to Part D drugs. In order to accomplish this, Part D sponsors use PA [2] on drugs that have a high likelihood of: (1) Coverage that is available under Parts A or B (versus D) for the drug as prescribed and dispensed or administered; (2) exclusion from Part D coverage (for example, a drug or drug class or its medical use that is excluded from coverage or otherwise restricted under Part D as defined in section 1927(d)(2) of the Act); or (3) use other than for a medically accepted indication as defined in section 1860D–2(e)(4) of the Act, in the Part D sponsor's experience or as directed by CMS, consistent with sections 10.6 and 30.2.2.3 of Chapter 6 of the Medicare Prescription Drug Benefit Manual. Additionally, relative to medically accepted indications, consistent with section 10.6.1 of Chapter 6 of the Medicare Prescription Drug Benefit Manual, Part D sponsors may retrospectively identify and confirm—either as part of their retrospective review programs required under § 423.153, or incident to another UM review—that a dispensed drug, including when dispensed as a transition supply, was not prescribed for a medically accepted indication for a particular individual. CMS does not consider the use of CMS-approved PA requirements for these purposes to be subject to section 1860D–4(b)(3)(G) of the Act because section 1860D–4(b)(3)(G) of the Act is specific to Part D drugs. Consequently, consistent with current policy, CMS will continue to permit Part D sponsors to apply PA for potential protected class drugs to determine whether such drugs can be covered under Part D, for both new starts and existing therapy, for those drugs with a high likelihood of being excluded from Part D for the reasons provided previously, subject to CMS review and approval.

Using the authority under section 1860D–4(b)(3)(G)(i)(II) of the Act, which applies without regard to new starts or existing therapy, we proposed to permit Part D sponsors to apply PA and ST requirements to new starts and existing therapy of protected class Part D drugs that are implemented to confirm use is intended for a protected class indication, ensure clinically appropriate use, promote utilization of preferred formulary alternatives, or a combination thereof, subject to CMS review and approval. We also solicited comment on whether PA and ST of protected class Part D drugs should be limited to new starts only.

We received the following comments and our response follows:

Comment: A number of commenters supported the proposal to expand the use of PA and ST for protected class Part D drugs from new starts only to new starts and existing therapy to confirm use is intended for a protected class indication, ensure clinically appropriate use, promote utilization of preferred formulary alternatives, or a combination thereof, subject to CMS review and approval.

Response: We thank the commenters for their support.

Comment: Many commenters asserted that treatments in the protected classes are neither interchangeable nor ''one-size-fits-all,'' adding that patients need access to the full range of therapies in these classes, and prescribers need the autonomy to make the best decision for each patient as an individual. Several commenters asserted that while clinical practice guidelines are publicly available, they are not intended to drive policy decisions. These commenters further added that while guidelines are important to give clinicians a starting point in the care of patients, it is ultimately up to the clinician who knows the full history of the individual patient to tailor treatments that will result in the best outcomes for that patient. Some commenters added that PA and ST policies intended to restrict access to physician-directed care unnecessarily prolong ineffective treatment and prevent individuals from immediately starting the treatment their prescribers believe is best. Some commenters suggested that ST requirements should not be ironclad, but instead should be suggested clinical care pathways to provide clinical decision support. Other commenters added that the lack of autonomy damages the doctor-patient relationship.

Response: Consistent with § 423.120(b)(2)(iii) and § 423.153(b), CMS conducts treatment guideline, ST criteria, and PA criteria reviews as part of the annual formulary review and approval process. CMS uses the FDA-approved labeling and widely accepted treatment guidelines to determine clinical appropriateness before approving PA or ST criteria. As discussed previously in this preamble, we will only approve PA and ST criteria that are clinically supported. These beneficiary protections, and specifically the limits we place on Part D sponsors' ability to apply PA and ST, differentiate Part D from other prescription drug benefits and help prevent the negative consequences (that is, prolongation of ineffective therapy and delaying accesses to appropriate therapy) suggested by the commenters and are designed to preserve the doctor-patient relationship. Moreover, ST requirements are not ironclad because, consistent with § 423.578, prescribers can request a formulary exception, and provided it meets the requirements at § 423.578, the supporting statement provided by a physician or other prescriber is given great weight when reviewing an exception request.

Comment: Some commenters expressed concern that CMS has not provided specificity about the clinical criteria that will be applied to its formulary review or any additional oversight and monitoring that would be appropriate to ensure the well-being of Part D enrollees with chronic conditions. Commenters recommended a system whereby CMS signs off on ST

[2] Consistent with section 10.6 of Chapter 6 of the Medicare Prescription Drug Benefit Manual, Part D sponsors should consistently use prior authorization (PA) for those drugs with the highest likelihood of non-Part D covered uses unless plans are able to reliably use tools other than PA to determine appropriate coverage for the drug.

programs for protected classes based on certain defined criteria, including that the program is evidence-based, or for areas where adequate evidence is lacking, is based on accepted standards or best clinical practice. Additionally, commenters suggested CMS should create a specialty council with expertise in the fields of the various protected class indications to review formulary decisions.

Response: As noted in response to the previous comment, consistent with § 423.120(b)(2)(iii) and § 423.153(b), CMS conducts treatment guideline, ST criteria, and PA criteria reviews as part of the annual formulary review and approval process. CMS uses the FDA-approved labeling and widely accepted treatment guidelines to determine clinical appropriateness before approving PA or ST criteria. We will only approve PA or ST criteria that are clinically supported. Please see section II.A. of the preamble to this final rule for an extensive description of our formulary review process. Consistent with § 423.578, prescribers can also request a formulary exception if a desired outcome is not met with current formulary alternatives. Additionally, the CMS formulary team reviewing Part D formularies and related PA and ST criteria is composed of pharmacists who are board-certified pharmacotherapy specialists with extensive clinical experience reviewing PA and ST criteria. These pharmacists use the FDA-approved labeling and widely accepted treatment guidelines when considering PA and ST criteria for disease states.

Comment: A number of commenters expressed concern that PA and ST policies can lead to patients' not filling their prescriptions or underutilizing medications, which leads to non-adherence. Commenters expressed concern that non-adherence, in turn, can lead to interruptions in therapy across the six classes, and in the case of HIV, would endanger public health because it is a communicable disease which can rapidly mutate and become resistant to therapy.

Response: CMS acknowledges that PA and ST requirements can potentially cause the issues cited when they are implemented without the protections provided under the Part D program. However, we believe such concerns have been mitigated in Part D based upon our more than 12 years of experience with the Part D program, including our existing policy that allows for PA and ST for new starts of protected class Part D drugs (except antiretrovirals), and the other unique Part D protections that are more robust than in comparable programs. For example, in all other Part D drug categories and classes, where wide use of PA and ST has been allowed since the beginning of the Part D program, subject to our other formulary requirements, we have no evidence to suggest that Part D enrollees routinely experience interruptions in therapy as a result of PA and ST requirements. Moreover, CMS is advancing improvements in price transparency, interoperability, and e-prescribing, such as RTBTs and Part D ePA as required by section 6062 of the SUPPORT for Patients and Communities Act (Pub. L. 115–271), that could help mitigate the kinds of administrative burdens sometimes associated with PA and ST that commenters claim could lead to underutilization.

Comment: Several commenters asserted that the PA process is complicated and labor intensive, and also, given the high approval rate—particularly for protected class Part D drugs—PA requirements do not reduce medication utilization and thus simply impose unnecessary burdens on patient care. Some commenters added that this proposal is counter to CMS's Patients over Paperwork initiative.

Response: We are concerned that the current policy potentially facilitates the overutilization of drugs within the protected classes, particularly antipsychotics.[3] [4] [5] By limiting the ability of Part D sponsors to implement UM tools (for example, PA or ST requirements) for an entire category or class, we also limit their ability to prevent the misuse or abuse of drugs that are not medically necessary. Inappropriate use of Part D drugs can lead to adverse effects that can harm the enrollee and require medical treatment that will otherwise not have been necessary, thus increasing overall Medicare costs.[6] We remain concerned there may be a link between the profitability of products not subject to normal price negotiations as the result of protected class status, such as antipsychotics, and overutilization, particularly off-label overutilization, of some of these drugs. Additionally, as discussed elsewhere in this final rule, CMS is advancing improvements in price transparency, interoperability, and e-prescribing, such as RTBTs, and Part D ePA as required by section 6062 of the SUPPORT for Patients and Communities Act (Pub. L. 115–271), that could help mitigate the kinds of administrative burdens sometimes associated with PA and ST and aligns this proposal with the Patients over Paperwork initiative.

Comment: Commenters were divided over whether we should continue to allow PA and ST for UM purposes for new starts only. Some commenters strongly supported the idea. Many commenters expressed concern that requiring enrollees to undergo ST requirements after they have already been stabilized on a treatment regimen can cause disruptions to the overall success of the enrollee's treatment and create negative treatment health care outcomes. However, other commenters opposed to limiting PA and ST for new starts only, as contrasted to permitting PA and ST for new starts and existing therapy, expressed concern that data limitations for PDP sponsors to discern new starts from existing therapy at the POS would create operational issues that would ultimately cause them not to use this exception, which would sufficiently undermine the exception and render it ineffective.

Some commenters suggested that rebate differences between the protected classes would yield greater cost savings for some protected classes, such as antipsychotics, antidepressants, and anticonvulsants, than the other protected classes (antiretrovirals, antineoplastics, and immunosuppressants). These commenters asserted that certain protected classes, like antiretrovirals to

[3] A May 2011 Department of Health and Human Services Office of Inspector General report found that of 2.1 million elderly persons who lived in nursing homes in the first 6 months of 2007, almost 305,000 had a prescription for at least one atypical antipsychotic drug. Eighty-eight percent of these prescriptions were for off-label, medically unacceptable uses and/or were associated with a specific FDA Black Box warning against their use by elderly persons with dementia. In all, unapproved uses and improperly documented claims for these drugs cost Medicare $116 million in one 6-month period. Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents. OEI–07–08–00150. *https://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf* Accessed April 17, 2019.

[4] The percentage of long-term nursing home residents being given antipsychotic drugs dropped from about 24 percent in late 2011 to under 15 in the third quarter of 2018. National Partnership to Improve Dementia Care in Nursing Homes: Antipsychotic Medication Use Data Report (January 2019). *https://www.nhqualitycampaign.org/files/Antipsychotic_Medication_Use_Report.pdf.* Accessed May 10, 2019.

[5] Advocates say even the lower rate of antipsychotic usage is excessive, given federal warnings that elderly people with dementia face a higher risk of death when treated with such drugs. February 5, 2018. Crary D. Associated Press. "New Report Details Misuse of Antipsychotics in Nursing Homes" *https://www.statnews.com/2018/02/05/antipsychotics-nursing-homes-elderly/* Accessed May 10, 2019.

[6] Prescription Drug Workgroup; American Academy of Actuaries. Issue Brief: Prescription Drug Spending the in US Healthcare System, an Actuarial Perspective. March 2018. *https://www.actuary.org/content/prescription-drug-spending-us-health-care-system* Accessed April 12, 2019.

treat HIV, do not have significant branded competition and therefore would not be expected to see significant rebating, even absent the protected classes policy.[7] Other commenters suggested that CMS should introduce automatic permission for a 7-day temporary supply while approval is sought.

Response: CMS' current policy permits PA and ST for new starts only for protected class Part D drugs, except antiretroviral medications.

We proposed to broaden the permissible use of PA and ST for protected class Part D drugs by permitting PA and ST for enrollees on existing therapy. Our goal was to provide additional flexibility so that Part D sponsors could better manage the benefit from a clinical as well as a cost savings perspective. We believe that the existing beneficiary protections, including our extensive clinical formulary review and approval process, would adequately protect enrollees from the inappropriate application of PA and ST requirements. Moreover, we would effectively limit most ST criteria to new starts as best practice, except when a change in therapy is clinically supported by the recognized compendia or widely accepted treatment guidelines. When step therapy is applied, we would expect to approve PA or ST requirements with initial treatment that is comparably supported by recognized compendia or widely accepted treatment guidelines.

Nevertheless, CMS is persuaded by comments that expressed significant concern for the potential disruption of ongoing therapy of protected class Part D drugs used for protected class indications and, after considering all the comments, we conclude that the risks associated with inappropriately interrupting therapy for stabilized patients receiving protected class drugs for protected class indications by potentially subjecting them to PA or ST requirements outweighs the potential clinical benefits that some enrollees could gain from switching therapies that might be more appropriate and the potential cost savings that would accompany the additional formulary management flexibility. Therefore, we are finalizing a codification of existing policy that allows Part D sponsors to apply PA and ST requirements for protected class Part D drugs, except for antiretroviral medications, only for new starts, to determine if a drug's intended use is for a protected class indication, ensure clinically appropriate use, promote utilization of preferred formulary alternatives, or a combination thereof, subject to CMS review and approval. PA and ST will continue to be prohibited for antiretroviral medications. Because the statutory protected class provision applies only to Part D drugs, Part D sponsors may continue to use coverage determinations, including PA or other reliable tools, to determine a drug's status as a Part D drug irrespective of such drug's status as a new start or existing therapy. However, we clarify that for enrollees on existing therapy, Part D sponsors may not require PA to confirm that a drug's intended use is for a protected class indication if the drug otherwise does not have a high likelihood of use intended for a non-medically accepted indication that would not be coverable under Part D. In other words, sponsors generally will need to rely on alternative approaches, such as retrospective DUR, to confirm the intended use is for a protected class indication for enrollees on existing therapy.

CMS thanks the commenters for their suggestion about the 7-day supply. However, because of our transition policy, which requires at least a month's approved supply, a 7-day supply is not necessary.

Comment: Some commenters expressed concern that expanded use of PA and ST will limit access to protected class Part D drugs for important uses that may not be considered a protected class indication, for example, enrollees who take various protected class Part D drugs for conditions like chronic pain or lupus. Commenters asserted that access limitations based on purported ''protected'' versus ''non-protected'' uses would be divorced from the clinical realities that exist for patients with complex and chronic conditions.

Some commenters expressed concern that expanded use of PA and ST will limit access to protected class Part D drugs that have more than one protected class indication, for example, antidepressants with dual use as anxiolytics (antianxiety medications) or antipsychotics and vice versa, or as another example, anticonvulsants with use as adjunct anxiolytics or antidepressants. Other commenters added that the proposal does not protect off-label prescribing within a protected class, for example, tacrolimus for lung transplants.

Response: A number of protected class Part D drugs have medically accepted indications for non-protected class uses. As discussed in the proposed rule, we are clarifying that we consider medically accepted indications consistent with the identified drug categories or classes of the protected classes to be ''protected class indications.'' In other words, when a Part D drug is used for a protected class indication, we consider it to be a protected class Part D drug. Using the commenter's example, tacrolimus for lung transplants would still be considered to be used for a protected class indication if use in lung transplant is a medically accepted indication. In addition, Part D drugs with multiple medically accepted protected class indications are protected for each such protected class indication, even if the indications are in more than one protected class. For example, aripiprazole has an FDA-labeled indication for acute and maintenance treatment of schizophrenia, and an FDA-labeled indication for adjunctive treatment of major depressive disorder; both of these uses are considered to be protected class indications.

As discussed in the proposed rule at 83 FR 62158, CMS is concerned that unless a Part D sponsor can use PA to determine the indication for which the drug has been prescribed, there is the potential to increase Part D program costs when there may be a less expensive alternative available to treat a particular non-protected indication that would be clinically appropriate. Therefore, we will permit Part D sponsors to use PA only for new starts in the protected classes, except for antiretrovirals, to determine if such drugs' intended use is for non-protected class indications. For those drugs that have both protected class and non-protected class indications, we may permit different PA requirements or formulary inclusion for non-protected class indications than those used for protected class indications, depending upon the clinical appropriateness and consistent with the July 25, 2018 and August 29, 2018 HPMS memos about indication-specific UM and formulary design. Additionally, to the extent that treatment guidelines for non-protected class indications include drugs with both protected class and non-protected class indications, plans will still be required to meet all established Part D formulary criteria regarding access to such drugs for non-protected class uses.

For example, for an enrollee who is a new start on topiramate, an anticonvulsant, the PA criteria used for topiramate could determine coverage and establish appropriate use in the following scenarios:

[7] See PEW Comments on Proposals to Modernize Medicare Drug Payments. *https://www.pewtrusts.org/en/research-and-analysis/speeches-and-testimony/2019/01/25/pew-comments-on-proposals-to-modernize-medicare-drug-payments* Accessed April 12, 2019.

• If use is for weight loss (an excluded, use under Part D), the Part D sponsor would deny coverage. (We remind Part D sponsors that they may deny coverage for excluded use under Part D irrespective of the enrollee's status as a new start or continuing existing therapy);

• If use is as an anticonvulsant (a protected class indication), the plan would cover the drug; or

• If use is for migraine prophylaxis (a non-protected class, indication), the Part D sponsor could—

++ Deny coverage (if this use is not on formulary) and require the enrollee to seek an exception to obtain coverage; or

++ Apply another set of PA or ST requirements for this indication.

We expect that all such issues or questions would be addressed during the coverage determination to avoid the possibility of enrollees needing to submit multiple coverage determination requests for the same drug.

Application of PA criteria to determine use for weight loss, as an anticonvulsant, or for migraine prophylaxis would be consistent with our July 25, 2018 Health Plan Management System (HPMS) memorandum entitled, ''Indication-Based Utilization Management'' and our August 29, 2018 HPMS memorandum entitled, ''Indication-Based Formulary Design Beginning in Contract Year (CY) 2020.''

Finally, in their formulary materials, we would expect Part D sponsors to note differential formulary inclusion for drugs with regard to protected class versus non protected class indications.

Comment: A few commenters suggested that, while they did not support our proposal to allow broader use of UM for protected class Part D drugs, one area in which they did support the use of such tools in the protected classes was to reduce the inappropriate prescribing of antipsychotics in the long-term care setting.

Response: We share the commenters' concerns about inappropriate prescribing of antipsychotics in the long-term care setting. Allowing PA and ST for new starts of antipsychotics will help to limit overutilization of these drugs for non-protected class indications (for example, antipsychotic use for sedation in nursing homes).

Comment: Some commenters expressed concern that expanded use of PA and ST will limit or delay access to more than one drug for an indicated use, asserting that individuals sometimes require more than one drug, or a specific combination of drugs, for a particular condition, and that this is particularly salient within the protected classes.

Response: To the extent that the FDA labeling, recognized compendia, or treatment guidelines discuss the use of multiple drugs, or a particular combination of drugs, within the protected classes for a given protected class indication, consistent with our existing formulary requirements, plans will still be required to provide coverage of such drugs for those patients. Additionally, UM and retrospective drug utilization review (DUR) can be used to ensure that combinations are clinically appropriate and comport with treatment guidelines, even if such combination is not first-line therapy, for example, retrospective DUR to ensure the use of combination therapies of HIV medications comport with the HHS HIV Guidelines.

Comment: Several commenters expressed concern that ST is not appropriate for protected class Part D drugs, particularly antineoplastics, antiretrovirals, and immunosuppressants.

Response: We agree that in most circumstances of clinically appropriate care, ST would not be appropriate for protected class Part D drugs. However, as a general statement, we disagree with the commenters. Our more than 12 years of experience with the Part D program has provided evidence of inappropriate prescribing within the protected classes, across all of the classes, and particularly for antipsychotics. Additionally, we have recently seen evidence of fraudulent prescribing and diversion of antiretrovirals. Although we are taking a more limited approach to our application of PA and ST than we proposed and excluding antiretrovirals from the exception we are finalizing at § 423.120(b)(vi)(C), we continue to believe that PA and ST are important tools to ensure clinically appropriate use of drugs, including those in the protected classes.

Comment: Some commenters suggested that CMS should require plans to list all drugs that require PA and ST.

Response: Plans are required to submit this information in their bids. Additionally, this information is available when beneficiaries search for plans by inputting their drugs into the Medicare Plan Finder. This information is also required to be available in the printed formulary, on the formulary on the plan's website, and available by calling the plan.

Comment: Some commenters noted that the Emergency Medical Treatment and Labor Act (EMTALA) requirements preclude emergency physicians from asking patients about their insurance coverage before a medical screening examination is completed, and therefore, emergency physicians do not know which type of plan and formulary the patient may have at the point of prescribing. These commenters asserted that the urgency of treatment in the emergency setting requires emergency services personnel to provide medications that may not be on a Part D plan's formulary and suggested that CMS exempt prescriptions that originate in emergency settings from this exception.

Response: Part D enrollees may be started on non-formulary medications as inpatients or in emergency settings that are subject to PA or ST requirements if continued upon discharge. If an enrollee who presented to the pharmacy a new prescription was started on protected class drugs in such a scenario, we would expect Part D sponsors to consider such enrollee to be continuing existing therapy. Additionally, as detailed previously, our transition requirements and exceptions and appeals process provides the necessary protection for enrollees that need to remain on such medications. Although Part D enrollees and prescribers may need to avail themselves of our exceptions and appeals processes, as discussed previously in this preamble and consistent with section 30.4.7 of Chapter 6 of the Medicare Prescription Drug Benefit Manual, we remind Part D sponsors that they are required to make coverage determinations and redeterminations as expeditiously as the enrollee's health condition requires.

Comment: A commenter requested that CMS allow MA plans, through a step therapy edit, to require the use of a Part B drug prior to the use of a protected class Part D drug starting in 2020.

Response: We noted in the proposed rule that the combination of our proposal to specify additional exceptions to the formulary requirements for protected class Part D drugs (section II.A. of the proposed rule, ''Broader Use of Prior Authorization for Protected Class Part D Drugs'') and our proposal for step therapy for Part B drugs (section II.F of the proposed rule, ''Medicare Advantage and Step Therapy for Part B Drugs'') would allow MA–PD plans to require step therapy of a Part B drug before a Part D drug. However, step therapy of a Part B drug before a Part D protected class drug would be allowed only under the circumstances outlined in this regulation (for example, only for new starts of five of the six protected classes) and subject to our Part D formulary review process.

We thank stakeholders for their comments on the proposed expansion of PA and ST for protected class drugs. We are redesignating the existing paragraph at § 423.120(b)(2)(vi)(C) as paragraph (D) and adding a new exception at paragraph (C), which we are modifying in response to comments: For enrollees that are not on existing therapy on the protected class covered Part D drug, and except for antiretroviral medications, PA and ST requirements that are implemented to confirm that the intended use is for a protected class indication, to ensure clinically appropriate use, to promote utilization of preferred formulary alternatives, or a combination thereof, subject to CMS review and approval. As modified, the exception is a codification of existing policy and does not place additional limits on beneficiary access to medications.

2. New Formulations

We proposed two changes to our protected class exceptions to address new formulations. First, we proposed a change to the existing exception at § 423.120(b)(2)(vi)(A) to reflect the forthcoming introduction of interchangeable biological products to the market by specifying drug or biological products that are rated as—(1) therapeutically equivalent (under the FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' also known as the Orange Book); or (2) interchangeable (under the FDA's most recent publication of the Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations).'' Second, we proposed to add a new exception at new paragraph § 423.120(b)(2)(vi)(D) that would have specified that, in the case of 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, the new formulation may be excluded from a Part D sponsor's formulary. Under our existing policy, Part D sponsors are not required to include a new formulation of a drug on their formularies when the older formulation is still available.

We received the following comments and our response follows:

Comment: Many commenters requested that CMS define the term ''new formulation.''

Response: We declined to propose a definition for ''new formulation'' because we believe Part D sponsors will be better able to make these determinations more quickly, and we saw merit and benefit in providing Part D sponsors with the flexibility to determine whether they will exclude the drug or negotiate with the manufacturer for formulary inclusion and placement.

Comment: A few commenters asked CMS to expand the application of the proposed exception for new formulations beyond brand drugs to include generic drugs.

Response: Multiple-source drugs that are therapeutic equivalents already can be excluded from the formulary in accordance with the existing exception at § 423.120(b)(5)(vi)(A).

Comment: Several commenters wanted CMS and not, as we proposed, Part D sponsors, to track which drugs would be eligible for exclusion under this exception and to publish a list of applicable drugs. Manufacturers largely wanted to limit the applicability of the exception, and plans generally wanted CMS to make the determinations for them.

Response: We did not propose that CMS publish a list of such drugs because we believed Part D sponsors will be better able to make these determinations more quickly, and we saw merit and benefit in providing Part D sponsors with the flexibility to determine whether they will exclude the drug or negotiate with the manufacturer for formulary inclusion and placement.

Comment: Some commenters expressed concern that CMS was attempting to fix a problem that has not happened yet, as there have been no instances of new formulations that that meet the proposed criteria for an exception within the protected classes. Other commenters further suggested that, while they understood CMS's attempts to fix a potential problem, our proposal, if finalized, would leave vulnerable enrollees without access to needed drugs.

Response: The purpose of our proposed exception was to specify that even if a new formulation of a single-source drug or biological product in the protected class became the only formulation available, Part D sponsors would have been able to exclude it from their formularies, except as required by our other formulary requirements in § 423.120(b)(2) and subject to our review and approval, as part of our annual formulary review process. Under our existing policy, which will still apply, Part D sponsors are not required to include a new formulation of a drug on their formularies when the older formulation is still available. CMS was persuaded by the commenters' argument because under our proposed policy, in a scenario where our other formulary requirements did not require Part D sponsors to have the new formulation on their formulary, a Part D enrollee who is stable on the old formulation could be left without access to the new formulation. Consequently, we decline to finalize this exception.

Comment: Several commenters asserted that the exception for new formulations is unnecessary if the exception for PA and ST is finalized.

Response: We thank the commenters for their suggestion. We note that we are not finalizing the new formulations exception.

Receiving no comments on the proposed change to the existing exception at § 423.120(b)(2)(vi)(A) to reflect the forthcoming introduction of interchangeable biological products to the market, we are finalizing a change to § 423.120(b)(2)(vi)(A) to allow an exception for interchangeable biological products, in addition to our existing policy of an exception for therapeutically equivalent generic drugs. We are not finalizing the proposed exception to specify that, in the case of 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, the new formulation may be excluded from a Part D sponsors' formulary.

3. Pricing Threshold for Protected Class Part D Drug Formulary Exclusions

To address Part D sponsors' assertion that they have limited ability to negotiate manufacturer rebates and achieve appreciable savings relative to drugs within the protected classes, as well as price increases for such drugs, CMS proposed, effective for plan years starting on or after January 1, 2020, to permit Part D sponsors to exclude from their formularies any single-source drug or biological product that is a protected class Part D drug whose price increases, relative to the price in a baseline month and year, beyond the rate of inflation. We proposed the rate of inflation would be calculated using the Consumer Price Index for all Urban Consumers (CPI–U), and the price would be defined as the Wholesale Acquisition Cost (WAC).

We received many comments regarding this proposal, including commenters that supported this proposed exception, and agreed with CMS that this flexibility would allow plans more negotiation power with manufacturers on protected class Part D drugs. However, we also received many

comments urging us not to finalize this proposed exception highlighting concerns with beneficiary access, and inability to adequately address rising launch prices, among other concerns. Based on the comments and responses summarized below, we are not finalizing this proposed exception.

We received the following comments and our response follows:

Comment: Several commenters supported this exception, and agreed with CMS that this flexibility would allow plans more negotiation power with manufacturers on protected class Part D drugs.

Response: While we are not finalizing the exception, we thank commenters for their support.

Comment: Many commenters stated that all three of our proposals greatly compromised access to needed therapy (that is, delays and/or interruptions in therapy) for patients taking protected class Part D drugs, which would lead to adverse health outcomes for these enrollees, and, in the case of HIV, endanger public health.

Response: In considering whether to propose these exceptions, CMS took our other enrollee access protections into account, which have successfully protected beneficiary access to needed medications in the more than 12 years the Part D program has been operational. There are five such enrollee protections, which include formulary transparency, formulary requirements, reassignment formulary coverage notices, transition supplies and notices, and the expedited coverage determination and appeals processes. While we believe our current enrollee access protects are sufficient, we appreciate commenters concerns regarding beneficiary access and protections and as a result we are not finalizing the pricing threshold exception.

Comment: Several commenters asserted that this proposed exception, since it is based on cost considerations rather than scientific evidence, medical standards, or clinical practice, represents an unexplained departure from established policy that would create discrimination in Part D. Commenters further asserted that basing exceptions to the protected classes on cost considerations is neither supported by statute nor our existing regulations at § 423.120(b)(2)(vi)(C).

Response: While a price increase could have triggered a formulary exclusion, the exception we proposed would not have superseded our other formulary requirements, including our annual clinically and scientifically based formulary review and approval process, which includes extensive checks to ultimately ensure adequate representation of all necessary Part D drug categories or classes for the Medicare population.

We would also like to clarify that we do not view an exception based on a pricing threshold as a departure from current policy. While our existing regulations at § 423.120(b)(2)(vi)(C) discuss an exception for protected class Part D drugs that is ''based upon scientific evidence and medical standards of practice (and in the case of antiretroviral medications is consistent with the [HHS] Guidelines for the Use of Antiretroviral Agents in HIV–1-Infected Adults and Adolescents),'' this is a separate and distinct exception from the exceptions we proposed in this rulemaking. In other words, these exceptions can exist contemporaneously, and are not in conflict with each other.

Finally, we remind commenters that CMS conducts a discrimination review to ensure that plans' formulary designs are not likely to substantially discourage enrollment by certain Part D eligible individuals.

Comment: Some commenters suggested that this exception policy was based on the erroneous belief that prices of protected class Part D drugs are increasing rapidly and that plans need additional leverage to negotiate prices for protected class Part D drugs, citing evidence from MedPAC's March 2017 report [8] that shows plans' ability to adequately manage utilization of protected class Part D drugs and drive enrollees toward use of generic drugs.

Response: MedPAC's finding that Part D plans ''have had success at moving enrollees toward generic drugs, which helps to slow the growth in prices, even when a drug has protected status,'' does not negate the unsustainable growth in protected class Part D drug prices or a Part D sponsor's limited ability to negotiate rebates for such drugs. For example, in addition to Part D sponsors' limited ability to negotiate rebates for protected class drugs, internal CMS analysis has also shown price trends for brand drugs are consistently higher for drugs in protected classes than such drugs in non-protected classes. On the whole, protected class drug prices have increased more than other, non-protected drug classes between 2012 and 2017. More recently, the allowed cost per days' supply increased by 24 percent for protected class brand drugs between 2015 and 2016 and by 14 percent between 2016 and 2017. In contrast, the allowed cost per days' supply increased by 16 percent for non-protected class brand drugs from 2015 to 2016, and showed no growth for such drugs from 2016 to 2017. In addition, in the March 2017 MedPAC report, MedPAC also stated ''[the drug's protected class status] may limit the amount of rebates plan sponsors are able to obtain from manufacturers in these classes,'' which supports the basis for which we proposed this exception. Although we are not finalizing the proposed exception, we remain concerned about the pricing dynamics for protected class drugs.

Comment: Some commenters suggested that if CMS finalized the exception to broaden use of PA and ST in the protected classes, then finalizing the exception based on a pricing threshold would not be necessary.

Response: As discussed earlier in this rule, we are only finalizing the exception that exists under current policy, related to the use of utilization management in the protected classes, which we believe will continue to provide Part D sponsors with the flexibility to use PA and ST in the protected classes and help them achieve negotiating leverage to realize cost savings for their enrollees. We agree that, at that this time, the pricing threshold exception is not a necessary addition to the exceptions we are finalizing.

Comment: A commenter suggested this policy exception was dangerously close to price fixing.

Response: Although we are not finalizing, this proposed policy would not have placed restrictions on how manufacturers may price their products. We also note that Part D sponsors would not have been required to exclude a protected class Part D drug from formulary under this exception, rather, we were simply proposing to provide the sponsor the flexibility to do so. However, as discussed further below, concern over whether Part D sponsors would be motivated to exercise this flexibility is one reason why we are not adopting this exception in this final rule.

Comment: Several commenters agreed with the proposal, but noted it would not limit growth in the launch prices of new drugs, which have been found to drive spending increases among specialty drugs, and might even lead to higher launch prices moving forward. Commenters also noted the potential for gaming by manufacturers to circumvent their drug being eligible for formulary exclusion under this exception.

Response: We agree with commenters that there may be an incentive for

[8] MedPAC, Report to the Congress: Medicare Payment Policy (March 2017). p. 412.

manufacturers to come in at higher launch prices for protected class Part D drugs as a result of this exception. In light of this concern and others noted previously, we are not finalizing this exception.

Comment: A commenter noted that Part D sponsors' contracts with manufacturers may include price protections, and as such, may be protected from any change in WAC during the contract year. Thus, Part D sponsors' motivation to apply this exception may be muted.

Response: We understand that all Part D sponsors may not be motivated to use this exception, particularly considering the limited savings associated with this exception. In light of this comment, we are not finalizing this exception as proposed.

Comment: We received many comments in response to these requests for comment on several specific technical and operational elements of the exception, some in support of the proposed operational and technical components of the exception, and others that suggested alternative approaches to those proposed.

Response: We thank commenters for their responsiveness to the comment solicitation, but we are not finalizing this proposed exception.

Comment: A commenter suggested that, in order to discourage potential gaming for drugs not yet on the market as of September 1, 2019, CMS establish a reference baseline price for drugs new to the market consistent with the inflation-adjusted launch prices of leading therapeutic alternatives in the class rather than allowing the manufacturer to establish its own baseline price.

Response: CMS shares the commenter's concern over the risk of potential gaming, and, thus, we are not finalizing this exception while we continue to consider how best to align incentives to encourage manufacturers to keep drug prices low of their own volition, as was intended with the proposed exception.

Comment: A commenter recommended that CMS apply this exception more broadly to include all National Drug Codes (NDCs) assigned to single-source brand drugs, single-source generic drugs, and generic drugs, as well as both protected class and non-protected class Part D drugs and biological products. The commenter asserted that if only protected class Part D drugs are excluded based upon price increases beyond a certain threshold, that over time, manufacturers will have the ability to apply egregious price increases to an NDC that applies to more than one drug, as well as non-protected classes in order to make up for any lost compensation.

Response: While we are not finalizing this exception, we remind the commenter that Part D sponsors already have the flexibility to exclude non-protected class Part D drugs from their formularies or apply PA and ST requirements to such drugs, unless the drug is required to be on formulary to be compliant with our formulary requirements. As discussed earlier in the preamble, this exception—which would have applied only to the requirement that all protected class Part D drugs be included on the formulary—does not supersede our formulary requirements at § 423.120(b)(2). Regarding multiple-source generic drugs, as discussed in the proposed rule (83 FR 62160), we declined to apply this exception to such drugs given the wide use of maximum allowable cost (MAC) pricing for such drugs which yields changes in list prices such as WAC meaningless.

Regarding potential price increases for an NDC related to multiple drugs, it is unclear what the commenter means by referring to ''an NDC that applies to more than one drug'' because an NDC is specific to a drug, the manufacturer, strength, dosage form, and quantity. However, if the commenter simply means that manufacturers will increase prices for multiple other non-protected class Part D drugs to offset limiting price increases on a specific protected class drug or drugs to the cumulative change in CPI–U, we share those concerns. Based on the comments received, we are not finalizing this proposed exception.

4. Solicitation of Comment for Special Considerations

In considering whether exceptions to the added protections afforded by the protected class policy are appropriate, we took other enrollee protections in the Part D program into account. As detailed earlier in section II.A of this final rule, there are five such enrollee protections which include formulary transparency, formulary requirements, reassignment formulary coverage notices, transition supplies and notices, and the expedited exception, coverage determination, and appeals processes. Our formulary review and approval process includes a formulary tier review, and for PA and ST, we also conduct restricted access, ST criteria, PA outlier, and PA criteria reviews. Additionally, our formulary review and approval process takes into consideration the applicable indication, proposed applicability to new or continuing therapy, and likelihood of comorbidities when reviewing PA and ST criteria submitted to CMS by Part D sponsors. We noted that best practice UM practices do not require an enrollee who has been stabilized on an existing therapy of a protected class Part D drug for a protected class indication to change to a different drug in order to progress through ST requirements, and we would not have expected Part D sponsors to require, nor would CMS have been likely to approve such requirements, unless clinically warranted (for example, an enrollee was started on clinically inappropriate therapy or received second- or third-line therapy for initial treatment of a condition, as described by the recognized compendia). Moreover, we believe our current approach, which ensures at least one drug within the class is offered on a preferred tier and free of PA and ST, is working well and should be maintained. Currently, Part D formularies frequently have more than one protected class Part D drug at a preferred cost sharing level, especially in classes with significant generic penetration, without any PA or ST requirement, and we do not expect that this policy will prompt Part D sponsors to stop including protected class Part D drugs on tiers with preferred cost sharing.

Finally, our transition policy will continue to require Part D sponsors to provide all new enrollees with at least an approved month's supply if the Part D sponsor cannot determine at the point of sale whether the enrollee is currently taking such protected class Part D drug. (For a detailed discussion of our transition requirements, see section II.A. of this final rule and regulations at § 423.120(b)(3).)

Nonetheless, it was our intent to make certain that the three proposed exceptions to the protected class policy (that is, broader use of PA, new formulations, and pricing thresholds) would not introduce interruptions for enrollees on existing therapy of protected class Part D drugs for protected class indications.

We solicited comment on whether there are additional considerations that will be necessary to minimize: (1) Interruptions in existing therapy of protected class Part D drugs for protected class indications during PA processes; and (2) increases in overall Medicare spending from increased utilization of services secondary to adverse events from interruptions in therapy. These could include, but are not limited to, for example, special transition considerations for on-formulary protected class Part D drugs for which the Part D sponsor has

established PA requirements, or as another example, for transitioning some enrollees taking protected class Part D drugs for protected class indications to alternative Part D drugs. If so, we sought comment on why our current requirements and protections are inadequate, or could be improved. In addition, we solicited comment on what specific patient population(s), individual patient characteristic(s), specific protected class Part D drugs or individual protected drug classes will require such additional special transition or other protections and how such population(s) can be consistently identified. Finally, we solicited comment on other tools that could be used to minimize interruptions in existing therapy of protected class Part D drugs for protected class indications during PA processes, for example, wider use of diagnosis codes on prescriptions, ePA during e-prescribing, targeting protected class Part D drugs in Medication Therapy Management (MTM) programs, or, as another example, expanded use of a data-sharing tool to exchange information for enrollees transitioning from one plan to another.

We received the following comments and our response follows:

Comment: Several commenters expressed concerns that our proposals would increase costs for Medicare Part D enrollees, the Part D program, and Medicare overall due to increased utilization of other healthcare services, for example, emergency department visits and inpatient admissions. Some commenters requested that we exempt various protected class indications or enrollees in LTC settings or served by LTC pharmacies from the application of the proposed exceptions, asserting these enrollees will have higher hospital admission and readmission rates due to complications from ineffective medications and consequent needs for additional treatment.

Response: CMS solicited comment on whether there are additional considerations that will be necessary to minimize increases in overall Medicare spending from increased utilization of services secondary to adverse events from interruptions in therapy but did not receive suggestions, apart from exempting virtually all of the applicable enrollees from the exceptions, to abate these concerns.

We understand the importance of access and continuity of care with these as well as all classes and will take that into consideration when approving PA and ST criteria. Our annual formulary review and approval process includes extensive checks to ensure appropriate representation of drugs for all necessary Part D drug categories or classes for the Medicare population. Our process has been working well to ensure that enrollees have access to the drugs they need for their medical conditions. Formularies will still be subject to the entire CMS formulary review criteria, and our formulary review criteria look at widely accepted treatment guidelines.

As discussed previously, we are finalizing one exception to the protected classes formulary inclusion requirements. We are finalizing an exception, consistent with current policy, to allow Part D sponsors to apply PA and ST requirements for protected class Part D drugs, except antiretrovirals, for new starts only to confirm intended use is for a protected class indication, ensure clinically appropriate use, promote utilization of preferred formulary alternatives, or a combination thereof. Under this exception, PA and ST will continue to be prohibited for antiretroviral medications. Any PA or ST requirements implemented under this exception will be subject to CMS review and approval.

Comment: Several commenters expressed support for our existing transition requirements.

Response: We thank the commenters for their support.

Comment: We received comments in support of our suggestions on other tools that could be used to minimize interruptions in existing therapy of protected class Part D drugs for protected class indications during PA processes, for example, wider use of diagnosis codes on prescriptions, ePA during e-prescribing, targeting protected class Part D drugs in Medication Therapy Management (MTM) programs (including mandatory MTM for Part D enrollees in nursing homes on protected class Part D drugs), or, as another example, expanded use of a data-sharing tool to exchange information for enrollees transitioning from one plan to another. Additionally, a commenter urged improvements to electronic health records and claims processing.

Response: We thank the commenters for their support. As discussed previously, CMS is taking steps to provide e-prescribing improvements such as RTBTs, and Part D electronic prior authorization as required by section 6062 of the SUPPORT for Patients and Communities Act (Pub. L. 115–271). CMS could explore the generation of reports through data sharing platforms. Regarding electronic health records and claims processing, we thank the commenter and welcome more input on this suggestion.

Comment: A number of commenters claimed that existing protections do not reliably ensure access to medically appropriate protected class Part D drugs. Some commenters in support of the proposals also encouraged CMS to improve enrollee protections, namely the appeals and exceptions processes. Commenters disputed our claim that our appeals and exceptions processes are mature and have proven workable, asserting that Medicare Part D enrollees afflicted with conditions addressed by protected class drugs continue to have considerable difficulty in navigating Part D, even after the improvements that CMS has recently taken to assist Medicare beneficiaries with selecting a plan and navigating the appeals and grievance processes. Commenters added that this is particularly concerning given that the proposal does not make mention of any additional CMS resources (such as additional staff or appropriations) to ensure that enrollees who need access to drugs within the protected classes are able to obtain their medications in a timely manner. Some commenters suggested that CMS should establish an expedited exceptions process that functions in less than 24 hours. Other commenters added that broader PA and ST should not be implemented without improvements to electronic health records (EHRs) and claims processing.

Response: CMS disagrees with the assertion that existing appeals processes are inadequate to ensure access to needed to medically-appropriate protected class Part D drugs, and commenters provided no evidence to support statements that Part D enrollees with protected class indications have difficulty navigating Part D. To that end, under the exceptions we are finalizing in this rule, the appeals process will work as it does today. If the enrollee's plan will not cover a drug the enrollee needs, or it will cover the drug at a higher cost than they believe they are required to pay, the enrollee or their prescriber can request a coverage determination (for example, a PA or tiering exception) from their plan. If their plan denies their request, they have the right to appeal that decision to obtain a redetermination. Additionally, the requirements at § 423.568 for coverage determinations and § 423.572 for expedited coverage determinations state that the plan must notify the enrollee ''as expeditiously as the enrollee's health condition requires, but no later than [72 or 24 hours, respectively] after receiving the request, or, for an exceptions request, the physician's or other prescriber's

supporting statement.'' That is to say, if an enrollee's health condition requires a response in less than 24 hours, the plan is obligated to provide one. Therefore, our existing appeals requirements already provide for timeframes of less than 24 hours when warranted.

CMS will continue to closely monitor appeals activity through audits and our Complaints Tracking Module (CTM) to ensure enrollees' requests are appropriately evaluated and that Part D sponsors are adhering to regulations. While we have confidence in our appeals process, CMS continues to take steps to improve the Part D Appeals process. Additionally, e-prescribing improvements such as real-time benefit tools (RTBTs) and Part D electronic prior authorization as required by section 6062 of the SUPPORT for Patients and Communities Act (Pub. L. 115–271) could reduce the need for appeals. CMS will take steps to further improve and strengthen the appeals process in response to any issues that arise.

Finally, CMS does not foresee a need to augment its clinical review staff because we already review PA and ST in the protected classes for new starts.

Comment: Some commenters claimed that the existing formulary review and approval process is inadequate to ensure non-discriminatory PA and ST requirements that would limit access to protected class Part D drugs, and the only way to ensure access to drugs in these classes is to maintain the policy as it exists today. Commenters asserted that our outlier analysis is an insufficient tool to provide oversight against potential discriminatory practices, particularly against enrollees who take high-cost drugs in these classes, HIV patients, LIS enrollees, and dually-eligible enrollees (particularly children). Commenters added that an outlier analysis is simply a test to determine if a certain plan is being more discriminatory than other plans but would not identify common discriminatory practices across plans. However, other commenters highlighted industry practices that are not currently allowed in Part D and were concerned that such practices would be allowed in Part D under our proposed modifications to the protected class policies. For example, some commenters expressed concern that we would allow PA for Truvada® which is indicated for prevention of HIV transmission. Other commenters cited commercial plans' requirements to use multi-tablet regimens for HIV, which are known to reduce medication adherence.

Response: We conduct a discrimination review consistent with § 423.272(b)(2) to ensure that plans' formulary designs are not likely to substantially discourage enrollment by certain part D eligible individuals. Our clinical checks are intended to ensure that formularies are robust and do not substantially discourage enrollment by certain beneficiaries. Our outlier analysis is an additional step that allows us to further question why a specific formulary either has additional or fewer UM requirements than most other plans (for example, an outlier because a Part D sponsor has not imposed PA where most other Part D sponsors require PA, or an outlier because a Part D sponsor requires PA when most other Part D sponsors do not). Being an outlier in and of itself does not mean a formulary substantially discourages enrollment (it might be just the opposite), but rather ensures the plan can justify the basis for its additional or fewer UM requirements compared to other plans.

All of our formulary requirements, when taken together, have resulted in CMS' ability, in its twelve-year experience implementing the benefit, to prevent formularies that are likely to substantially discourage enrollment by certain Part D-eligible individuals under plans. This includes protected class Part D drugs, due to our existing allowance of PA and ST for new starts. We do not anticipate that adoption of this policy will change our ability to prevent formularies that are likely to substantially discourage enrollment by certain Part D-eligible individuals under plans now. We are not aware of any industry-wide practices that would result in formularies that are likely to substantially discourage enrollment by certain Part D-eligible individuals under plans that would also meet the totality of our formulary requirements.

Comment: Some commenters expressed frustration that coverage determinations, exceptions, and appeal approvals are usually only granted for the duration of 1 plan year. Other commenters added that immunosuppressant approvals, specifically, should be extended to match the life of the transplanted organ.

Response: Part D benefits operate on a plan year for 1 calendar year. While extended-duration (that is, longer than 1 calendar year) approvals may be possible for Part D enrollees who stay with a plan across multiple plan years, we recognize such approvals present challenges when Part D enrollees switch plans. CMS has instituted the Additional Beneficiary Information Initiatives (ABII) web portal to facilitate data sharing from Medicare Part A claims data relative to Medicare-covered transplants to aid Part D sponsors in making these determinations; plans may request access to ABII to receive this information about their enrollees. If a Part D enrollee switches plans, the transition policy would apply and plans would be required to provide the medication for at least an approved month's supply. As discussed previously, CMS could explore the generation of additional pertinent reports through secure data-sharing platforms.

Comment: Related to the pricing threshold exception, a commenter suggested that enrollees doing well on a therapy should not lose their ability to take that therapy, and enrollees on an existing therapy should be grandfathered such that they do not lose the ability to continue on that therapy. In addition, for enrollees not eligible for grandfathering, Part D sponsors should be required to notify enrollees of their decision to exclude a therapy any time they do so pursuant to this exception.

Response: We appreciate the concerns raised by these commenters and, as noted previously, will not be finalizing this proposal.

We are finalizing the first exception with the modification to allow Part D sponsors to apply PA and ST requirements for protected class Part D drugs, except antiretrovirals, only for new starts to confirm intended use is for a protected class indication, to ensure clinically appropriate use, to promote utilization of preferred formulary alternatives, or a combination thereof, subject to CMS review and approval. PA and ST will continue to be prohibited for antiretroviral medications under this exception. As such, we also allow indication-based formulary design and utilization management for new starts of protected class Part D drugs, which would allow Part D sponsors to exclude the protected class Part D drug from the formulary for non-protected class indications. As is required for all other Part D drug categories or classes, these formulary design and utilization management edits will be subject to CMS review and approval as part of our annual formulary review and approval process, which includes reviews of PA and ST edits that will restrict access, step therapy criteria, PA outliers, and PA criteria. (For an extensive description of our annual formulary checks see section II.A.1. of this final rule.) We also are finalizing a change to permit exclusion of interchangeable biological products. As modified, the exception is a codification of existing policy and does not place additional limits on beneficiary access to medications.

In response to comments, we are not finalizing the proposed exceptions to (1) allow Part D sponsors to exclude a protected class Part D drug from a formulary if it is a new formulation of a single-source drug or biological product with the same active ingredient of moiety that does not provide a unique route of administration, regardless of whether the other formulation is removed from the market; and (2) to permit Part D sponsors to exclude from their formularies any single-source drug or biological product that is a protected class Part D drug whose price increases, relative to the price in a baseline month and year, beyond the rate of inflation.

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

In October 2018, Congress enacted the ''Know the Lowest Price Act of 2018'' (Pub. L. 115–262). The measure, which amends section 1860D–4 of the Act by adding a paragraph (m), prohibits Medicare Part D plan sponsors from restricting their network pharmacies from informing their Part D plan enrollees of the availability of prescription drugs at a cash price that is below what that the enrollee will be charged (either the cost sharing amount or the negotiated price when it is less than the enrollee's cost sharing amount) for the same drug under the enrollee's Part D plan. In effect, the legislation prohibits Part D sponsors from including in their contracts with their network pharmacies ''gag clauses'', a term used within the prescription drug benefit industry that refers to provisions of drug plan pharmacy contracts that restrict the ability of pharmacies to discuss with plan enrollees the availability of prescriptions at a cash price that is less than the amount the enrollee will be charged when obtaining the prescription through their insurance. The measure becomes effective with the plan year starting January 1, 2020.

To make the Part D regulations consistent with the statute governing the Part D program, we proposed to incorporate the new requirement into the Part D regulations. Specifically, we proposed 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 will be charged to obtain the same medication through the enrollee's Part D plan.

Comment: A number of commenters expressed strong support and appreciation for our effort to incorporate into the Part D regulations the provisions of the ''Know the Lowest Price Act'' promptly after enactment of the legislation.

Response: We thank the commenters for their support.

Comment: Several commenters requested that CMS address additional issues related to beneficiaries' opting to purchase their prescriptions outside their Part D plan. Specifically, they suggested that CMS adopt policies to make it easier for plan enrollees to have their cash purchases reported electronically and automatically to their Part D plan sponsors, allowing the payment amounts to be counted toward beneficiaries' TrOOP and benefit deductible accumulations. Commenters also expressed their concern that prescriptions obtained outside the Part D benefit are not subject to plans sponsors' drug utilization review and medication therapy management tools, creating potential health and safety risks for beneficiaries who pay out of pocket for a covered medication. Some of these commenters urged CMS to take steps to ensure beneficiaries are made aware of this particular risk.

Response: We thank the commenters for their perspectives, though their suggestions are outside the scope of this rule. We have previously advised in sub-regulatory guidance (Chapter 5, Section 30.1 of the Medicare Prescription Drug Benefit Manual) that sponsors should accept paper claims for prescriptions their enrollees obtain without using their Part D benefit so that the sponsor can make the appropriate determinations concerning reimbursement, total gross covered drug cost, and TrOOP. Also, in our guidance, we have affirmed that it is in the best interests of beneficiaries to have their claims processed through their Part D sponsor so that concurrent drug utilization review can be performed (Chapter 14, Section 50.4.3 of the Medicare Prescription Drug Benefit Manual). We will continue to evaluate the impact on the Part D program of Part D plan enrollees filling their prescriptions outside their benefit plan and may consider proposing regulatory changes to address identified concerns in the future.

Comment: A commenter noted that the language of the proposed rule did not exactly mirror the language of the underlying statute. Specifically, the statute states that a sponsor may not restrict a pharmacy from informing a beneficiary of a ''lower price the individual would pay for the drug'' if obtained without using insurance while the rule refers to a ''cash price'' that is below the amount that would be charged to obtain the drug through insurance. The commenter states that the term ''cash price'' is not used in the statute and therefore, to promote uniformity in practical application of the requirement throughout the payer and provider industry, it should not be used in the corresponding rule.

Response: We appreciate the comment, though we believe that while a rule must reflect the meaning of its underlying statute, it need not simply re-state the statutory language. The commenter has not indicated how the use of the term ''cash price'' changes the meaning of the statute or could create confusion in its application. We have used the term ''cash price'' in previous Part D guidance addressing the issue of beneficiaries obtaining drugs outside their Part D benefit plans, including manual chapters and the May 2018 memorandum issued by the Administrator advising Part D sponsors that they should not include gag clauses in their pharmacy contracts. The term ''cash price'' is a term understood within the industry to mean a price charged by a pharmacy to customers not using insurance to obtain a prescription drug and its use in the rule promotes clarity in the statement of the new prohibition.

For the reasons sets forth in the proposed rule and our response to the related comments, we are finalizing the proposed regulation at § 423.120(a)(8)(iii) without modification.

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

1. Legislative Background

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) requires the adoption of Part D E-Prescribing (eRx) standards. Prescription Drug Plan (PDP) sponsors and Medicare Advantage (MA) organizations offering Medicare Advantage Prescription Drug Plans (MA–PD) are required to establish electronic prescription drug programs that comply with the e-prescribing standards that are adopted under this authority. There is no requirement that prescribers or dispensers implement eRx. However, prescribers and dispensers who electronically transmit and receive prescription and certain other information for covered drugs prescribed for Medicare Part D eligible

beneficiaries, directly or through an intermediary, are required to comply with any applicable standards that are in effect.

For a further discussion of the statutory basis for this final rule and the statutory requirements at section 1860D–4(e) of the Act, please refer to section I. of the eRx and the Prescription Drug Program February 2005 proposed rule (70 FR 6256).

2. Regulatory History

Part D eRx standards are periodically updated to take new knowledge, technology, and other considerations into account. CMS currently requires providers and dispensers to utilize the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard, Implementation Guide Version 10.6, which was approved November 12, 2008, to provide for the communication of a prescription or prescription-related information for certain named transactions. However, as of January 1, 2020, prescribers and dispensers will be required to use the NCPDP SCRIPT standard, Implementation Guide Version 2017071, which was approved July 28, 2017 to provide for the communication of prescription or prescription-related information between prescribers and dispensers for the old named transactions and a handful of new transactions named at § 423.160(b)(2)(iv). We also currently require (under § 423.160(b)(5)) Medicare Part D plan sponsors and prescribers to convey electronic formulary and benefits information amongst themselves using Version 3 Release 0 (Version 3.0), from April 2012 of the NCPDP Formulary and Benefits Standard Implementation Guides. (For a detailed discussion of the regulatory history of eRx standards see the November 2017 proposed rule (82 FR 56437 and 56438)).

The NCPDP SCRIPT eRx standards (SCRIPT) and the NCPDP Formulary and Benefits standards (F&B) have become critical components of the Part D program. In the 2018 calendar year, over 66 percent of Part D prescriptions were transmitted electronically using the applicable SCRIPT standard, and all Part D plans implemented electronic F&B files using the adopted standard. Prescribers can use electronic F&B transactions during the eRx process. F&B is a batch mode transaction standard by definition, and therefore does not provide real-time information. A batch transaction allows plans to send the information nightly, weekly or even monthly. As plans make routine changes in their formularies, they may or may not be captured on the batch formulary files. In addition, F&B provides information on a contract level, rather than a patient level, and consequently could not provide out-of-pocket costs for a given patient at a given point in time, since costs and applicability of utilization management could vary significantly for individual beneficiaries depending on a variety of factors. For example, a contract may have a prior authorization (PA) requirement on a drug and that requirement would be listed on F&B data. However, if a particular beneficiary has already completed that PA requirement, RTBT would erroneously indicate that PA would be required in order for the plan to pay for the drug as prescribed. Likewise, F&B data could display outdated information about beneficiary-specific out-of-pocket costs based on the applicable phase of the benefit. For example, it would not indicate the out of pocket costs for a particular beneficiary when the deductible has been exhausted.

We proposed a real-time benefit tool (RTBT) to serve as a critical adjunct to the existing SCRIPT and F&B electronic standards. Should prescribers chose to implement electronic prescribing, the existing SCRIPT standard allows them a means to conduct electronic prescribing, while the F&B standard allows a prescriber to see what is on the plan's formulary. However, neither of those standards 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. We proposed RTBT to be layered on top of F&B data to gain a more complete view of the beneficiary's prescription benefit information. It can augment the information available in F&B because, though F&B is useful, it is a batch mode transaction standard by definition and therefore does not provide real-time information.

As described in more detail in the next section, we believe requiring plans to make one or more RTBTs available to prescribers will lead to higher prescriber use of F&B information during the eRx process. To be eligible for selection by a Part D sponsor, we proposed to require that the RTBT be capable of integrating with at least one prescriber's eRx and EMR system(s) the latter of which will hereinafter be referred to as an electronic health record or EHR for consistency with current Departmental terminology) and providing patient-specific coverage information at the point of prescribing to enable the prescriber and patient to collaborate in selecting a medication based on clinical appropriateness, coverage and cost.

We believe that furthering prescription price transparency is critical to lowering overall drug costs and patients' out-of-pocket costs, and anticipate improved medication adherence, as well as support for the MMA objectives of patient safety, quality of care, and efficiencies and cost savings in the delivery of care.

3. Adoption of a Real-Time Benefit Tool

As we explained in the proposed rule (83 FR 62152), the Medicare Part D program allows contracted entities that offer coverage through the program latitude to design plan benefits, provided these benefits comply with all relevant requirements. This flexibility results in variation in Part D plans' benefit design, cost-sharing amounts, utilization management tools (that is, prior authorization, quantity limits, and step therapy), and formularies (that is, covered drugs). We are aware of several Part D prescription drug plans that have begun to offer RTBT inquiry and response capabilities to some physicians to make beneficiary-specific drug coverage and cost data visible to prescribers who wish to use such data at the point-of-prescribing. We have reviewed multiple RTBT software solutions and have found that they are generally designed to provide patient-specific clinically appropriate information on lower-cost alternative therapies through the prescribers' eRx or EHR systems, if available, under the beneficiary's prescription drug benefit plan. However, for those software solutions that are capable of providing such decision support, based on our current experience, we understand that the prescribers will only embrace the technology if the prescriber finds the information to be readily useful. Thus, we stated in the proposed rule that to ensure success, we believe that the Part D sponsor must present prescribers with formulary options that are all clinically appropriate and accurately reflect the costs of their patient's specific formulary and benefit options under their drug benefit plan. In addition, as stated in the proposed rule, those who use plans' current RTBT technology report that prescribers are most likely to use the information available through RTBT transactions if the information is integrated into the eRx workflow and electronic health record (EHR) system. This will allow the prescriber and patient, when appropriate, to choose among clinically acceptable alternatives while weighing coverage and costs. Since eRx is generally performed within the provider's EHR system, integration of the RTBT function within the EHR generally, and the eRx workflow

specifically, appears to be critical for the successful implementation of the technology. However, we recognize that without an industry standard for RTBT, prescribers may be offered multiple technologies, which may overwhelm and create burden for EHR vendors. We also recognized that without a standard, the RTBT tool provided may not be integrated with a prescriber's EHR, thus limiting its utility.

As stated in the proposed rule (83 FR 62152), we are interested in fostering the use of these real-time solutions in the Part D program, given their potential to lower prescription drug spending and minimize beneficiary out-of-pocket costs. Not only can program spending and beneficiary out-of-pocket costs be reduced, but evidence suggests that reducing medication cost also yields benefits in patients' medication adherence. As mentioned in the proposed rule, a 2012 review of studies found that 85 percent of studies demonstrated that increasing patient cost-share for a medication was associated with a significant decrease in medication adherence.[9] This review also revealed that 86 percent of these studies demonstrated that increased medication adherence was associated with improved clinical outcomes. With respect to studies that directly measured the impact of out-of-pocket costs on outcomes, 76 percent found that increased medication out-of-pocket costs was associated with adverse non-medication related outcomes such as additional medical costs, office visits, hospitalizations, and other adverse events. Subsequently published studies continue to reflect similar findings.[10] [11]

Therefore, we proposed that each Part D sponsor be required to implement one or more RTBT capable of integrating with at least one prescriber's eRx and EHR systems to provide complete, accurate, timely, clinically appropriate and patient-specific real-time formulary and benefit information to the prescriber. We also encouraged plans to use RTBTs to promote full drug cost transparency by showing each drug's full negotiated price (as defined in § 423.100), in addition to the beneficiary's out-of-pocket cost information.

We also stated that health care providers using the RTBT should ensure that individuals are aware that information about services or treatment, such as a future prescription, may be disclosed to the plan by the tool, and effectuate the individual's disclosure restriction request by refraining to use the tool in instances in which the patient intends to self-pay in full. We encouraged covered health care providers to discuss with the individual whether the individual desires the prescriber to use the RTBT as doing so will generally eliminate the beneficiary's ability to request disclosure restrictions as the plan will already be in possession of the query data regarding the desire to prescribe something for a specified condition.

We sought comments on our proposal, including the feasibility for plans to meet the proposed January 1, 2020 deadline, and how our proposal may or may not expedite our goal of giving each Part D enrollee and the clinicians who serve them access to meaningful decision support through RTBT. We also sought relevant feedback about RTBT standardization efforts; this includes the planned fulfillment of any milestones that standardization bodies have already met, or are likely to meet in advance of the proposed January 1, 2020 deadline. We noted that we would consider retraction of our rule if we received feedback indicating that it would be contrary to advancing RTBT within Part D, or if a standard has been voted upon by an accredited Standard Setting Organization or there were other indications that a standard would have been available before the proposed 2020 effective date. In such case, we indicated that we would review such standard, and if we find it suitable for the Part D program consider proposal of that standard as a requirement for implementation in our 2021 rulemaking, effective January 1, 2021. We also solicited comments regarding the impact of the proposal on plans and providers, including overall interoperability and the impact on medical record systems. Finally, we solicited comments regarding the impact of the proposed effective date on the industry and other interested stakeholders.

We received approximately 194 comments on this proposal. Following are summaries of the comments we received and responses to these comments.

Comment: Commenters expressed widespread conceptual support for our proposal as a way to accelerate use of electronic Real-time Benefit Tools (RTBT) in the Part D program. These commenters believed that the provision of patient-specific price and coverage transparency at the point of prescribing will enable patients and providers to make more informed decisions about medication therapy.

Response: We thank commenters for their support.

Comment: We received numerous comments relating to the proposed January 1, 2020 implementation date. Although several commenters stated that the 2020 deadline was achievable, the majority of comments expressed concern. Most commenters believed that it would be prudent to delay the implementation date until an industry standard was available with some commenters characterizing the proposed time frame as overly aggressive or unrealistic given the level of effort required to implement RTBT.

Response: These comments have persuaded us that implementing RTBT will take substantial effort and that a 2020 deadline may be too difficult to achieve for those plans that have not yet begun to implement a real time solution. Given the considerable level of effort involved in developing RTBT we are delaying the required implementation date until January 1, 2021. However, given the potential benefits of RTBT, we strongly encourage plans to facilitate earlier use of RTBT when possible and start implementing prior January 1, 2021.

Comment: Many commenters stated that requiring RTBT in absence of an industry standard will impede integration of real-time information into EHRs and eRx systems. Many commenters urged CMS to continue to work with the industry through the National Council for Prescription Drug Programs (NCPDP) to develop a national standard that could meet the Part D program's needs. A few commenters asked CMS to wait a year or two after a standard becomes available in order to give the industry time to implement it. They noted that the cost of integrating multiple RTBT systems into EHRs will be prohibitive and may be passed on to prescribers through fees to the providers. A commenter suggested that CMS require that RTBT be provided to prescribers free of charge.

Response: CMS continues to support interoperability as a way to reduce the burden on health care providers and, as noted in our proposed rule, we would have preferred to consider and name a single industry standard for use in Part D. However as an industry standard is not yet available and we wish to bring the benefits of RTBT to the Part D

[9] Eaddy, M. T., Cook, C. L., O'Day, K., Burch, S. P., & Cantrell, C. R. (2012). How Patient Cost-Sharing Trends Affect Adherence and Outcomes: A Literature Review. Pharmacy and Therapeutics, 37(1), 45–55.

[10] Hershman, D.L., Tsui, J., Meyer, J., et al. (2014). The change from brand-name to generic aromatase inhibitors and hormone therapy adherence for early-stage breast cancer. Journal of the National Cancer Institute. 106(11), dju319.

[11] Chen SY, Shah SN, Lee YC, et al. (2014). Moving branded statins to lowest copay tier improves patient adherence. American Journal of Managed Care. 20, 34–42.

market as soon as feasible, we are finalizing the provision that each plan implement an RTBT of its choosing. Should a suitable RTBT standard emerge sometime in the future, we can consider it for future rulemaking. We also note that prescribers will be unlikely to use RTBT tools that impose a significant financial burden on their practices. We therefore encourage plans to work with those responsible for their real-time solutions to make sure that they present value to prescribers. The Department of Health and Human Services will continue to engage with standards development organizations, such as NCPDP to encourage the development of standards.

Comment: Several commenters cautioned that holding plan sponsors solely accountable for implementation of RTBT places an unfair burden on the plans and will not result in furthering CMS's goals of widespread use of the technology. Other commenters asked if a Part D sponsor would be considered compliant with this provision if their RTBT only integrates with one EHR.

Response: Though we believe that EHR and eRx providers will adopt well-developed RTBT solutions, we recognize that such acceptance is not always in the Part D plan's control. The proposed and final regulatory language make it clear that the Part D plan is responsible for supporting an RTBT capable of integrating with at least one EHR or eRX system, but stops short of placing the responsibility for widespread prescriber adoption on the plan. We are only requiring compatibility with at least one prescriber's eRx or EHR, since CMS realizes that without an industry-adopted standard, it would be operationally unattainable for a plan to support an RTBT capable of integrating with all EHR or eRx systems that prescribers are potentially using. And, although Part D plans can make sure that the RTBT system is capable of integrating with an EHR or eRx system, the decision to integrate the RTBT with specific prescriber-facing systems is out of the plan's control. Since this rule addresses Part D requirements, we can only address the plan's readiness for integration at this point.

Comment: Some commenters sought guidance about what features and information would satisfy the requirement for a RTBT. Commenters suggested that RTBT include information on the drug that the physician intends on prescribing along with formulary alternatives; they asked if RTBT should include drugs' applicable cash price, beneficiary copayment, any drug utilization controls, or side effects of alternative therapies presented. Some commenters believe that presenting negotiated prices to the prescriber would provide value to the RTBT process, while most commenters believe that that information was either not relevant or was considered proprietary information that should not be widely shared. Some commenters believed that RTBT should include information with respect to all available pharmacy and delivery options while others believe that only the prices of alternatives available at member's selected pharmacy should be populated by the RTBT.

Response: Our proposed regulation indicated that the goal of RTBT is to provide decision support to prescribers by presenting them with relevant details about formulary information and alternatives to the drug which the provider intends on prescribing. Although we encourage the inclusion of the negotiated price in RTBT, we are not mandating it at this time as the majority of commenters opposed its inclusion stating that the information was proprietary and overly confusing. Provider groups opposed its inclusion, since it was outside the scope of their responsibility. However, we believe that RTBT must include some minimal data points that will enable a prescriber and patient to make informed medication choices at the point of prescribing. These include benefit information about the drug which the provider intends on prescribing, enrollee cost-sharing information, and comparable information on formulary alternatives (meaning those medications that may have a different copayment or coinsurance amount than the medication about to be prescribed but may have the same therapeutic efficacy). The benefit information should include patient-specific utilization requirements (such as prior authorization or step therapy requirements) that have yet to be satisfied at the time when the prescription is written, and copayment or coinsurance (or negotiated price values if included) at the patient's selected pharmacy.

Comment: Some commenters expressed concerns that the data populated in the RTBT would not be reliable, that the data would be inaccurate or that it would be used for purposes other than to provide decision support to the prescriber. Commenters stated that existing real-time solutions vary in their functionality and reliability. One provider group pointed out that prescribers are already seeing that some of the RTBT systems are not providing useful information. They report that these systems are causing more effort on the part of the prescriber without providing useful decision support. Other providers noted that the quality of the information provided by multiple vendors is variable, and suggested that CMS assess the outcomes of the alternative vendors.

Response: CMS expects that data presented through RTBT will be patient-specific, timely, and accurate. Part D plans must make sure that they comply with these requirements. We are unsure what commercial purposes were of concern to commenters and how they would adversely impact the intended functionality. Should CMS become aware that RTBTs are being used in ways that are contrary to the Part D program goals, we will address the issues as they arise. Further, we believe that Part D plans are in the best position to assess the effectiveness of the RTBT solutions, since they have a financial stake in ensuring that their enrollees have access to the most cost-effective medications. We expect that widespread adoption of RTBT will, over time, facilitate improved functionality and administrative ease of using the tools in clinical practice. However, if such concerns are not mollified, we would expect that EHR vendors would offer feedback to the plans.

Comment: A few commenters suggested that we refer to RTBTs using other terms, such as real-time pharmacy benefit check or real-time pharmacy benefit transaction to more clearly describe our proposal. A commenter requested that we refer to the technology as a benefit check and not a tool.

Response: We understand that some terms may be clearer to certain readers. However, the ubiquity of the term RTBT leads us to believe that it is the correct term to use. In addition, the suggested terms were sufficiently close to our proposed term that we are convinced that RTBT is an accurate description of our regulatory requirement.

Comment: We received a number of comments objecting to our proposal that providers receive explicit patient consent before reviewing RTBT solutions. Commenters explained to us that requiring affirmative consent would result in providers having to modify their workflow and systems to capture such explicit consent. These systematic changes would require at least 18 months to adopt, implement, test, and remedy any issues. Educating providers across the country on this requirement and implementing the system changes would take at least another three months, which calls into question the ability to fulfill this requirement prior to January 1, 2020. Though one commenter

appreciated the proposed level of protection, all other commenters who addressed the issue stated that the proposed requirement would be a serious obstacle to the real-time process. For example, making system changes that normally require at least 18 months to make, within less than 6 months would require the hiring of significant amounts of new staff and put a burden on their systems to implement prior to the January 1, 2020 deadline.

Response: We are committed to ensuring that RTBT implementation happens as smoothly as possible. The RTBT regulation requires that each Part D plan implement one or more real-time benefit tools, but does not specify the circumstances under which a prescriber should use the technology. We expect that prescribers will only use RTBT when the information provided is useful. As the intent of the RTBT is to help the clinician know if a medication will be covered under a patient's prescription benefit coverage, we do not expect that prescribers will use the tool in those rare instances when a patient has expressed a desire to buy the medication outside of the insurance benefit. Yet, given the importance of protecting an individual from unauthorized disclosure of health information, we considered requiring patient consent before the RTBT was being used just to make sure that patients are fully cognizant that RTBT will be used.

However, on further reflection, under the current RTBT scheme, we believe that requiring that patients provide explicit affirmative consent before each use of an RTBT is unnecessary. In most instances, we expect that the choice about what prescription to prescribe will happen when a beneficiary is present, because the current ePrescribing standard requires the beneficiary to choose where the prescription is to be sent. This means they will be aware that their data will likely be transmitted to parties other than the prescriber. Furthermore, beneficiaries have the opportunity to ask their prescribers about what data is being sent over to the pharmacy.

We conducted more detailed research into how RTBTs would function in the Part D context, and we discovered that after the prescriber finishes consulting with the RTBT, they typically transmit the prescription to the pharmacy electronically. If the enrollee decides to private pay at a pharmacy, the pharmacy is required to send a failed claim notice if a beneficiary decides to pay for the prescription out of pocket, rather than all the information about the prescribed medication. This failed claim notice satisfies the § 423.120(c)(3) requirement for pharmacies to submit claims to the Part D sponsors or its intermediary whenever the Part D member ID card is presented or is on file at the pharmacy, which is a requirement without RTBT use. Thus, we encourage providers to discuss with the individual whether the individual desires to self-pay as after the prescriber uses the RTBT the patient will no longer be able to withhold information about the prescription from their plan under 45 CFR 164.522(a)(1)((vi) (allowing the beneficiary to request disclosure restrictions if they pay for their prescription).

After reviewing the comments, we weighed these potential privacy concerns against the potential disruptions to effective adoption of RTBT raised by commenters. Especially since pharmacy benefit information is generally already available to prescribers and pharmacies under typical patient interactions, we believe that RTBT use will fall within the category of health care treatment disclosures making the disclosure of health care data generally permissible without patient authorization. Nonetheless, we encourage prescribers to use RTBT judiciously and must always allow an individual enrolled in a Part D plan to instruct a prescriber not to use the system for any or all prescriptions, and prescribers should heed that instruction.

Comment: Several commenters suggested that CMS work with the Office of the National Coordinator for Health Information Technology (ONC) to develop incentives for integration of RTBT products into EHRs.

Response: CMS thanks the commenters for this suggestion. However, we do not believe that these incentives are required. Based on our research, we believe many EHRs are moving to integrate RTBTs into prescribers' works flows. In addition, since RTBTs are variable in their functionality it would be difficult for ONC to incentivize use of RTBT until an industry standard is implemented and tested.

Comment: A few commenters suggested that the F&B standards are no longer necessary and others asked us to clarify the role that the F&B standard should play in the future.

Response: In our proposed rule we clarified that F&B remains an important component of the Part D electronic prescription standard and plans must continue to support it. However, the future interaction between RTBT and the F&B standards are out of scope of this regulation.

Comment: A commenter requested that long-term care facilities be exempt from having to use a RTBT.

Response: CMS intends this regulatory requirement to apply solely to Part D plans. Although we encourage the use of RTBTs among providers, guidance for providers is outside of the scope of this final rule.

Comment: A few commenters suggested that CMS require Part D plans to develop a patient tool to provide prescription cost information to patients in addition to, or instead of, the prescriber facing tool we proposed.

Response: We appreciate the comments. However, our proposal was for a prescriber facing tool. A patient tool is outside the scope of this rule.

We are finalizing the proposal for each Part D plan to implement an RTBT of its choosing, effective January 1, 2021. We strongly encourage plans to start implementing this provision prior to 2021. We are removing the proposed requirement that covered health care providers obtain explicit beneficiary consent prior to using the RTBT.

D. Part D Explanation of Benefits (§ 423.128)

Section 1860D–4(a)(4)(A) of the Act requires Part D sponsors to furnish to each of their enrollees a written explanation of benefits (EOB) and, when the prescription drug benefits are provided, a notice of the benefits in relation to the initial coverage limit and the out-of-pocket threshold for the current year. We codified this EOB and notice requirement at § 423.128(e) by requiring the Part D EOB to include specific information written in a form easily understandable to enrollees. Part D sponsors must provide enrollees with an EOB no later than the end of the month following any month in which the enrollee utilized their prescription drug benefit.

Information about negotiated price changes for each of the prescription drugs covered for a beneficiary, including information about lower cost therapeutic alternatives, is not required to be in the EOB under the current regulation. Based on comments received, we are finalizing our proposal that sponsors must include negotiated price increases and lower cost therapeutic alternatives in their beneficiaries' Part D EOBs.

The Part D EOB is one of the principal documents that beneficiaries can rely on to understand where they are in the benefit phases and their changing out-of-pocket costs throughout the year. This document is provided to beneficiaries every month for the immediately preceding month that the

Part D benefit is used. As a retroactive monthly report, the EOB is the means by which beneficiaries can monitor their benefit utilization and prescription costs on a regular and frequent basis.

We received approximately 79 comments on this proposal. We have included a summary of the comments and our responses.

Comment: Commenters unanimously supported increasing drug pricing transparency for beneficiaries.

Response: We thank the commenters for their support. Lowering prescription drug costs is of critical and immediate concern to beneficiaries and the Administration.

Comment: Many commenters voiced concern that including drug pricing information on the EOB would be ineffective for the following reasons: (1) Its retroactive nature makes the price information not meaningful or actionable for the beneficiary; (2) its timing during a benefit year makes it not actionable by the beneficiary because of limitations on enrollment changes; (3) the nature of acute prescriptions means the information is not useful for short-term medications; and (4) this information is not discernable without being read with the prescriber. While asserting different reasons, these commenters generally agreed that the drug cost information would not be meaningful, actionable or useful for the beneficiary due to the enumerated circumstances.

Response: Despite the EOB being a retroactive report, the information provided will allow beneficiaries to engage with their prescriber at their next point of care and discuss their choices in medication. This may lead to beneficiaries switching to a lower cost drug. Even if a beneficiary is not able to change plans mid-year based on the EOB information, the information may still be useful to the beneficiary in the situation we just described—to engage with their prescriber about their medication choices within their existing plan. To address the comments concerning acute prescriptions, we note that on the EOB as it is written today an acute prescription filled one time is not carried over on multiple EOBs. However, we believe there is no harm in including a negotiated price increase and a lower cost alternative for an acute prescription claim, when available. This additional information empowers the beneficiary and provides them with a holistic approach when reviewing their Part D benefit. We believe this, in turn, will ultimately spark dialogue between the beneficiary and their prescriber(s) about lower cost therapeutic alternatives in the future. Thus, we conclude that the EOB will empower the beneficiary with information about drug costs that the beneficiary does not currently have. This initiative will support CMS' commitment to promoting drug price transparency in the Medicare Part D program.

Comment: Many commenters suggested that drug pricing information will be more useful if provided through a prospective tool, such as a real-time benefit tool (RTBT) at the time of prescribing, rather than the EOB. They highlighted that beneficiary knowledge would be more accurate with real-time information on which decisions could be made with their prescriber at the point of care.

Response: Implementing a real-time benefit tool for beneficiaries is an effective way to provide beneficiary-specific information about drug costs (for additional discussion about RTBTs, please see the previous section of this final rule). However, the EOB provides a different method of communicating drug pricing information directly to beneficiaries. Both are valuable price transparency tools.

Comment: Multiple commenters were concerned that displaying the percentage change in negotiated price would not be a helpful metric for beneficiaries when evaluating their Part D benefits. The commenters asserted that the negotiated price is not the correct price to display as it may not change throughout the benefit year, or if it does change, it may not impact the cost-sharing for the beneficiary. However, commenters did not provide alternative pricing that would be of greater impact to the beneficiary.

Response: We do not agree and believe providing this information to the beneficiary is valuable. The negotiated price information required to be included in the EOB is the percentage increase in the total cost for each prescription, when there is an increase, since the first claim of the current benefit year for each prescription drug claim in the EOB, which would display under each medication. Currently and under this new requirement, the EOB would still display the price paid by the beneficiary, plan and any other payer. While increases in negotiated prices may or may not be directly proportionate to a change in a beneficiary's cost-sharing for a variety of reasons, we believe that ensuring beneficiary access to information about changes in drug pricing in the context of their specific use of the benefit will allow them to better assess the value they receive from their Part D benefit.

Comment: Multiple commenters pointed out the Part D EOB is meant to be a brief document but is lengthy and complex. As such, these commenters pointed out that including additional details would only make the document longer, thereby paradoxically making a beneficiary less inclined to read the document thoroughly. Therefore, our EOB proposal would defeat the intent of requiring additional information in it. Some commenters also mentioned that the EOB is not the appropriate document to disseminate the pricing information and will inevitably lead to increased beneficiary confusion. Commenters suggested improving the functionality of the Medicare Plan Finder and other beneficiary-facing tools to convey this information.

Response: We find the current structure of the EOB to be well-suited to include additional information on individual prescription drug claims. Other beneficiary materials are delivered on an annual basis, and are geared toward assisting Part D beneficiaries make enrollment decisions whether to remain with their current prescription drug plan or switch to another. By including these negotiated price increases and lower cost alternatives on a monthly basis in EOBs, beneficiaries will be in greater control of their prescription drug benefits and, with their prescribers, will be able to make more informed decisions about their care. Beneficiaries will have documented drug pricing information and will be able to seek assistance from their prescribers, pharmacists, SHIPs, and family members.

Comment: A few commenters believed that the proposed rule did not provide sufficient definition of a lower cost therapeutic alternative.

Response: The lower cost therapeutic alternatives will be determined by the sponsor based on its formulary, not by CMS. As such, any drug may be identified as a lower-cost therapeutic alternative for another drug if a Part D sponsor reasonably determines it to be so. As stated in the preamble of the proposed rule, lower-cost therapeutic alternatives (meaning drugs with lower cost-sharing or lower negotiated prices) will not be limited to therapeutically-equivalent generic drugs if the original prescription fill is for a brand drug.

Comment: A few commenters wrote that the estimated implementation cost with respect to this proposal was understated in the proposed rule. These commenters also provided an estimate of their increased costs, citing that the programming would be more than CMS estimated, and also that these changes would contribute to increasing the length of the EOB document, thereby increasing printing and mailing costs for

plans. Commenters did not provide alternative solutions for including the drug pricing information and/or lower-cost therapeutic alternatives.

Response: We thank the commenters for providing us with their cost estimates. We have revised the estimated cost to implement the EOB updates; however, we still believe that these updates are necessary for adhering to the Administration's goal of drug price transparency and lowering beneficiary out-of-pocket costs. We will work with stakeholders to improve the model EOB to include this information in the most efficient and effective manner for beneficiaries and sponsors.

Comment: Many commenters wrote that amending the Part D EOB to include this information for the upcoming contract year, beginning January 1, 2020, was unreasonable and too burdensome.

Response: We thank the commenters for their concerns, and acknowledge that there will be administrative and programmatic costs to implement these changes. Given the level of effort involved in updating the Part D EOB, we are delaying the implementation date until January 1, 2021. However, given the potential benefits of these changes, we strongly encourage plans to begin implementing this requirement prior to January 1, 2021.

After consideration of comments received, we are finalizing the reassignment of paragraphs (e)(5) and (e)(6) of § 423.128(e) as paragraphs (e)(6) and (e)(7) to add a new paragraph (e)(5) that will require sponsors to include information about negotiated price increases, if any, and lower-cost therapeutic alternatives in the Part D EOBs. Based on comments received, as to information about negotiated drug price increases, we will require that Part D sponsors include the cumulative percentage increase, if any, in the negotiated price since the first claim of the current benefit year for each prescription drug claim in the EOB.

Second, CMS will require that Part D sponsors provide information about drugs that are therapeutic alternatives with lower cost-sharing, from the applicable approved plan formulary for each prescription drug claim, when such therapeutic alternative are available as determined by the plan. Also, the plan may include therapeutic alternatives with the same copayments if the negotiated price is lower.

Part D sponsors will be permitted and encouraged by CMS to take into consideration relevant beneficiary-specific information, such as diagnosis, the indication for the prescription and completed step therapy or exception requests, when providing formulary therapeutic alternatives in the EOB that have lower cost-sharing. For example, if a plan is aware that a beneficiary has already fulfilled step therapy requirements and the beneficiary's physician has attested that the beneficiary is not able to tolerate a formulary alternative, that formulary alternative does not need to be included on the EOB for that beneficiary.

E. Medicare Advantage and Step Therapy for Part B Drugs (§§ 422.136, 422.568, 422.570, 422.572, 422.584, 422.590, 422.618, 422.619, 422.629, 422.631, 422.633)

1. Medicare Advantage and Step Therapy for Part B Drugs: General Requirements

In a HPMS memo released August 7, 2018,[12] CMS announced that under certain conditions beginning in contract year 2019, MA plans may use utilization management tools such as step therapy for Part B drugs; such utilization management tools, including prior authorization, can be used by MA organizations to both prevent overutilization of medically unnecessary health services and control costs. CMS proposed requirements under which MA plans may apply step therapy as a utilization management tool for Part B drugs and affirmed, based on our reinterpretation of the applicable statute, MA plans' authority to implement appropriate utilization management tools, including prior authorization, for managing Part B drugs in a manner to reduce costs for both enrollees and the Medicare program. Under Part B, traditional Medicare generally pays based on a statutory formula—average sales price plus a 6-percent add-on—for drugs and biological products that are not usually self-administered, such as injections and infusions. We stated in the proposed rule how we believe there is minimal negotiation between MA plans and drug manufacturers to reduce the price of these drugs. Prior to the August 7, 2018, HPMS memo and subsequent FAQs, [13] CMS interpreted existing law to prohibit MA plans from using step therapy for Part B drugs because there was a concern that such utilization management tools could have created an unreasonable barrier to coverage of and access to Part B benefits that MA plans must provide under the law. However, as we explained in the proposed rule, CMS recognizes that utilization management tools, such as step therapy, can provide the means for MA plans to better manage and negotiate the costs of providing Part B drugs. Based on this and for the reasons explained in more detail in this final rule, CMS rescinded the prior guidance prohibiting step therapy for Part B drugs and services in MA, and we are finalizing our proposal to allow MA plans to use step therapy for Part B drugs, subject to certain parameters. In the proposed rule, we explained how we believe the flexibility to use step therapy programs for Part B drugs would considerably assist MA plans in negotiating on behalf of enrollees to get better value for Part B drug therapies. Using internal bid data, excluding MA employer group plans, CMS estimates $9 billion in spending by MA plans for Part B drugs furnished during contract year 2018.

As discussed in the proposed rule, we believe that these tools will better enable MA organizations to take steps to ensure that MA plans and MA enrollees pay less overall or per unit for Part B drugs which could result in lower MA capitation payments by the government to MA organizations and lower average sales prices for Part B drugs, on which Medicare FFS payments for such drugs are based, while also maintaining access to medically necessary Medicare-covered drugs and services. These goals—reducing costs across the Medicare program while ensuring access to medically-necessary Medicare-covered benefits—underlie this final rule. We proposed adding a new regulation, at § 422.136, entitled ''Medicare Advantage and Step Therapy for Part B Drugs.''

Sections 1852(c)(1)(G) and (c)(2)(B) of the Act, and the MA regulations at § 422.4(a)(1)(ii) expressly reference a MA plan's application of utilization management tools, like prior authorization and other ''procedures used by the organization to control utilization of services and expenditures.'' This indicates that MA plans are not prohibited by the statute from implementing utilization management tools such as step therapy. In light of this, we proposed to define step therapy in § 422.2 and adopt requirements under which MA plans may apply step therapy as a utilization management tool for Part B drugs. We solicited comments concerning the impact that allowing step therapy for Part B drugs will have on MA plans and enrollees.

We clarified that for contract year 2020 and subsequent years, coupling

[12] 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.*

[13] Available online at: *https://dpapportal.lmi.org/DPAPMailbox/Documents/Part%20B%20Step%20Therapy%20Questions%20FAQs_8-29-18.pdf.*

drug management coordination with rewards and incentives was not part of our proposal. While MA plans may still offer rewards and incentives programs, savings realized from Part B step therapy must be reflected in the plan's bid, as such savings would reduce the revenue necessary for MA plans to provide basic benefits that MA plans must furnish enrollees and supplemental benefits that MA plans may opt to offer. Additional Part C rebate dollars associated with the lower bid, as with all Part C rebate dollars, must be used to provide supplemental benefits and/or lower premiums for the plans' enrollees.

We noted that existing requirements in §§ 422.112(b) and 422.152 for care coordination activities are sufficient to promote positive health outcomes for both drugs and services; we relied on this and did not propose text at § 422.136 that an MA plan must offer a drug management program. We also recognized that we issued the August 7, 2018 memo that announced our reinterpretation of the statute after bids were submitted for the 2019 plan year and therefore expected plans to utilize the drug management program as a means to pass 2019 savings on to enrollees through rewards and incentives. Because we are finalizing this rule prior to the 2020 bid deadline, MA plans must include savings from implementing Part B step therapy in their bids for 2020 and future years, as the savings will affect the revenue necessary to provide benefits (see § 422.254).

We acknowledged in the proposed rule the potential for utilization management tools like step therapy to create administrative burden and process challenges for network providers. We also explained how, in light of that, we expect MA plans to work closely with the provider community and to adopt best practices that streamline requirements and minimize burden. We also encouraged continued development and advancement of electronic prior authorization processes to more efficiently administer this process. We solicited comment whether our proposed regulation text imposing education and information responsibilities in combination with existing regulations on care coordination are sufficient to ensure that MA organizations specifically address step therapy programs for Part B drugs as part of those care coordination responsibilities and if we should finalize a provision in § 422.136 that addresses the administrative burden imposed on network providers by MA plans.

We proposed and this final rule adopts a number of safeguards that ensure enrollees have timely access to all medically necessary Medicare Part B medications. MA plans will be required to administer the existing organization determination and appeals processes under new time frames that are similar to the timeframes applicable in Part D for coverage determinations; enrollees will be able to seek organization determinations in advance—or when the MA (or MA–PD) plan first starts the step therapy protocol for the enrollee—if the enrollee (typically after consultation with their health care provider) believes they need direct access to a Part B drug that will otherwise only be available after trying an alternative drug. We explained that MA plans will adjudicate these organization determinations based on medical necessity criteria. If an enrollee is dissatisfied with the plan's organization determination, the enrollee has the right to appeal. We noted that CMS monitors organization determination and appeals activity through the audit process and regular discussions with the Part C Independent Review Entity (IRE) to ensure enrollee requests are appropriately evaluated and processed within applicable timeframes.

As discussed in the proposed rule, our existing disclosure requirements at § 422.111 would require MA plans that apply step therapy to Part B drugs to disclose that Part B drugs may be subject to step therapy requirements in the plan's Annual Notice of Change (ANOC) (when initially adopted or subsequently changed) and Evidence of Coverage (EOC) documents. In the ANOC, this information must be included under the Changes to Benefits and Costs for Medical Services. In the EOC, this information must be included in the Medical Benefits Chart under ''Medicare Part B prescription drugs.'' Under existing requirements at § 422.202(b), MA plans must establish policies and procedures to educate and fully inform contracted health care providers concerning plan policies on utilization management, which will include the plan's step therapy policies. We proposed to also include a requirement at § 422.136(a)(2) for plans to establish policies and procedures to educate and inform health care providers and enrollees specifically concerning its step therapy policies. We noted in the proposed rule that preferred provider organization plans (PPOs) are required, as part of the definition of a PPO at section 1852(e)(3)(A)(iv)(II) of the Act and under the MA regulation at § 422.4(a)(1)(v)(B), to reimburse or cover benefits provided out of network; while higher cost sharing is permitted, PPOs are prohibited from using prior authorization or preferred item restrictions in connection with out of network coverage. As such, PPOs must provide reimbursement for all plan-covered medically necessary services received from non-contracted providers without prior authorization or step therapy requirements. We solicited comment whether the final rule should include a specific regulatory provision clarifying this issue.

We proposed at § 422.136 (a)(3), that MA plans will be required to use a Pharmacy and Therapeutics (P&T) committee to review and approve step therapy programs (meaning policies and procedures); we explained that this is necessary to ensure medically appropriate implementation of step therapy for Part B drugs. We explained how we believe the burden of this requirement will be limited because MA–PD plans and MA plans would be authorized to use any existing Part D P&T committees established by the MA–PD plan (or an MA–PD plan under the same contract as an MA-only plan) to comply with part 423 requirements for the Part D benefit. The Paperwork Reduction Act listing for P&T committee record keeping is OMB Control Number 0938–0964. We noted that P&T committee decisions are not public information. We proposed, in the introductory text of proposed paragraph (b), that a MA organization must establish or utilize an existing P&T committee prior to implementation of a Part B step therapy program so that the P&T committee reviews Part B step therapy programs. In addition, we noted in the proposed rule how we continued to actively consider expanding the role of MA P&T committees. Therefore, we solicited comments on our proposal that MA plans with Part B step therapy programs will be required to have P&T committees and, in addition, whether the requirement for this MA P&T committee should be expanded to all MA plans that have any utilization management policy (such as prior authorization or dosage limits) applicable to Part B drugs, and whether there are other options that will meet the policy goal of ensuring that Part B step therapy programs are medically appropriate underlying the P&T committee proposal. We proposed to codify P&T committee requirements for MA plans in § 422.136(b).

Our proposal for the P&T committee mirrors the Part D requirements for such committees currently codified at

§ 423.120(b) with regard to membership, scope, and responsibilities. We explained our position that existing Part D P&T requirements at § 423.120(b) are adequate to ensure MA plans implement step therapy for Part B drugs that is medically appropriate. We note that if necessary we may release subregulatory guidance concerning application of the P&T committee requirements in the context of Part B drugs.

We proposed requirements in § 422.136(b) that would be consistent with Part D requirements for a P&T committee. Specifically, we proposed that the majority of members comprising the P&T committee will be required to be practicing physicians or practicing pharmacists. The committee will be required to include at least one practicing physician member and at least one practicing pharmacist; these specific individuals will be required to be independent and free of conflict with the MA organization, the MA plan, and pharmaceutical manufacturers. In addition, the plan will be required to include at least one practicing physician member and one practicing pharmacist who are experts in the care of elderly and disabled persons. We also encourage MA plans to select P&T committee members representing various clinical specialties (for example, geriatrics, behavioral health) to ensure that all conditions are adequately considered in the development of step therapy programs. We proposed provisions for the responsibilities and scope of the P&T Committee at § 422.136(b)(4) through (11) that would mirror the current regulation text applicable to Part D P&T Committees under § 423.120(b)(1)(iv) through (xi), with minor revisions to tailor the proposed MA regulation to the Part B drug step therapy programs offered by MA plans. We reiterated in the proposed rule how our proposal was to substantially align the requirements of a P&T committee reviewing Part B drugs with Part D requirements because the Part D requirements have proved sufficient in ensuring that plans implement medically appropriate step therapy and utilization management protocols in Part D.

CMS proposed, as a beneficiary protection, to limit Part B step therapy requirements to only new starts of Part B drug therapies. CMS explained in the proposed rule that we believe new step therapy requirements should not disrupt ongoing Part B drug therapies for enrollees. In order to ensure that step therapy requirements do not disrupt ongoing Part B drug therapies, we proposed under § 422.136(a)(1), that step therapy may not disrupt enrollees' ongoing Part B drug therapies. Specifically, we proposed that step therapy only be applied to new prescriptions or administrations of Part B drugs for enrollees who are not actively receiving the affected medication; we proposed to require MA plans to use a lookback period of 108 days, in order to be consistent with established Part D policy with respect to transition requirements for new prescriptions, to determine if the enrollee is actively taking a Part B medication. In the proposed rule, we explained how the Part D lookback period was created with clinical and pharmaceutical input and that CMS believed the same criteria were appropriate to use in setting a lookback period for Part B drugs. We proposed that an MA plan would have to use the lookback period when an enrollee elects a new MA plan (regardless of whether previously enrolled in a MA plan, traditional Medicare, or new to Medicare) to determine whether the enrollee has taken the Part B drug (that will otherwise be subject to step therapy) within the past 108 days.

We explained that under our proposal, if the enrollee is actively taking the Part B drug, such enrollee will be exempted from the plan's step therapy requirement concerning that drug. We proposed to allow MA plans flexibility in implementing step therapy for Part B drugs within specific parameters. Specifically, we proposed that MA plans would be able to use a step therapy program to ensure that an enrollee who is newly diagnosed with a particular condition will begin treatment with a cost-effective biological product licensed under section 351(k) of the Public Health Service Act or generic medication before progressing to a more costly drug therapy if the initial treatment is ineffective or if there are adverse effects. We did not propose that § 422.136 specifically address the standard for exemptions or movement within a step therapy program because, as we explained in the proposed rule, we interpret the MA plan's responsibility to provide all medically necessary covered services and items covered under the original Medicare program to mean that ineffectiveness or adverse effects of a treatment required in a step therapy program would be sufficient basis to grant an exemption or move an enrollee to a higher step in the protocol.

Consistent with existing Part D guidelines, we proposed at § 422.136(c) to permit MA plans to require an enrollee to try and fail an off-label medically accepted indication (that is, an indication supported by one or more citations in the statutory compendia) before providing access to a drug for an FDA-approved indication (on-label indication). However, we proposed that using off-label drugs in step therapy will only be permitted in cases where the off-label indication is supported by widely used treatment guidelines or clinical literature that CMS considers best practices. We solicited comments on our proposal to permit MA plans to use off-label drugs in a Part B step therapy program only when such drugs are supported by widely used treatment guidelines or clinical literature that CMS considers to represent best practices.

We also proposed, at § 422.136(d), that a step therapy program must not include as a component of a step therapy protocol or other condition or requirement any drugs not covered by the applicable MA plan as a Part B drug or, in the case of an MA–PD plan, a Part D drug. Specifically, we proposed § 422.136(d) to prohibit an MA organization from using a non-covered drug as a step in the step therapy program (that is, as a condition to coverage). Under our proposal, each step in a step therapy program would have to be another drug covered by the MA plan (another Part B drug) or MA–PD plan (another Part B drug or a Part D drug) to ensure that step therapy programs are not, intentionally or unintentionally, barriers to services that must be covered by the MA plan pursuant to section 1852 of the Act. Therefore, at § 422.136(d), we proposed regulation text to clarify that only Medicare covered Part B drugs (plus for MA–PD plans, Part D drugs) may be used in a step therapy program. We explained in the proposed rule that we intended to permit an MA plan to require one Part B drug be used before a different Part B drug and to permit MA plans that also offer prescription drug coverage (also known as ''MA–PD plans'') to use step therapy to require a Part D drug therapy prior to allowing a Part B drug therapy because the Part D drug will be covered by the plan.

Additionally, we noted in the proposed rule that the combination of our proposal to specify additional exceptions to the formulary requirements for protected class Part D drugs (section II.A.1 of the proposed rule, ''Broader Use of Prior Authorization for Protected Class Part D Drugs'') and our proposal for step therapy for Part B drugs (section II.F. of the proposed rule, ''Medicare Advantage and Step Therapy for Part B Drugs'') would allow MA–PD plans to require use of a Part B drug before a Part D drug as part of a step therapy program. Our

proposal about Part D protected class drugs is being finalized with modifications in this final rule. As noted previously, we are permitting the use of step therapy for protected class Part D drugs (other than antiretrovirals) for enrollees that are not already using the drug for a protected class indication (that is, ''new starts''), and therefore MA–PD plans may, starting in 2020, require step therapy of Part B drugs before Part D drugs for the protected classes as well, consistent with the requirements we are adopting at § 423.120(b)(2)(vi)(C). MA–PD plans that use cross-benefit step therapy programs must ensure that these requirements are clearly outlined in the Part D prior authorization criteria for the affected Part D drugs and are otherwise consistent with Part D requirements. We also stated in the preamble, as is required for all other drug categories or classes in Part D coverage, that Part D step therapy requirements will be subject to CMS review and approval, as part of our annual Part D formulary review and approval process, which includes formulary tier review, and relative to prior authorization and step therapy, restricted access, step therapy criteria, prior authorization outlier, and prior authorization criteria reviews.

We also solicited comments on the following aspects of our proposal:

- The restriction of step therapy to new starts of Part B drugs.
- The new requirement for a P&T committee for MA plans that implement step therapy and the use of that P&T committee.
- The prohibition on using non-covered drugs, and in certain circumstances, off-label drugs, in the step therapy programs.

We thank commenters for helping inform CMS's Medicare Advantage and Step Therapy for Part B drugs policy. We received approximately 153 comments on this proposal; we summarize them and our responses follow:

Comment: Some commenters strongly encouraged CMS to issue operational guidance for allowing step therapy for Part B drugs more quickly following the finalization of the Medicare Advantage and Step Therapy for Part B drugs final rule. These commenters argued that quickly finalizing this rule will allow for better compliance with CMS requirements.

Response: CMS appreciates commenters concerns regarding finalizing this rule and issuing operational guidance in a timely manner. The step therapy regulation we are finalizing here will be effective for plan years and coverage beginning on and after January 1, 2020. We will continue to work with MA stakeholders to ensure that any additional Part B step therapy program guidance, which may follow the rule, is timely, transparent, and geared to producing positive health care outcomes for enrollees.

Comment: Many commenters expressed concern that the step therapy for Part B drugs proposal would lead to negative health outcomes as a result of restricted access to care or delayed care. Commenters also expressed concern that CMS has not demonstrated how it will ensure that plans' step therapy policies are clinically appropriate and do not impede access to needed care. Some commenters urged CMS to study the effectiveness of step therapy on cost savings and its impact on health outcomes before finalizing this policy. A few commenters supported allowing step therapy as a cost effective utilization management tool.

Response: CMS appreciates commenters' feedback regarding the impact of this rule, including those who expressed concern that the Part B step therapy program will lead to negative health outcomes as a result of restricted access to care or delayed care. MA plans must comply with the statutory requirement that they provide enrollees with access to all medically necessary Part A and Part B benefits available in Original Medicare, as provided at section 1852(a)(1) of the Act. This final rule does not change or limit this requirement for MA plans. Accordingly, step therapy or other utilization management policies may not be used as an unreasonable barrier to deny coverage of medically necessary services or as a means to eliminate access to medically necessary Part B covered benefits. CMS has included a number of safeguards to ensure that access to medically necessary Part B services is maintained for MA enrollees who are subject to step therapy for Part B drugs. We note that consistent with MA regulations at 42 CFR 422.206, MA plans may not restrict the ability of a treating physician to advise enrollees about their treatment options. Thus, if a treating physician believes, based on their own medical judgment, that an MA enrollee should not be subject to step therapy for a Part B drug for medical reasons, the health care provider can furnish advice consistent with that and advocate on behalf of the enrollee. The treating physician can request an organizational determination under § 422.566(c) and the MA plan will make a formal determination of medical necessity that if denied, will require that the enrollee be notified of their right to a timely appeal. Pre-service reconsiderations of a plan denial may also be requested by a treating physician under § 422.578.

CMS appreciates commenters' recommendations that more study is needed to ensure that enrollees' health is not compromised. Although we are finalizing the step therapy policies, we will continue to monitor MA plan's use of Part B step therapy policies and will conduct oversight to ensure compliance with these rules. CMS will conduct audits that target pre-service organization determination and appeal cases related to requests for Part B drugs, monitor the Complaints Tracking Module (CTM) for access concerns, and closely monitor the implementation and operation of step therapy programs.

We believe that this final rule also contains adequate protections to ensure that step therapy policies are clinically appropriate and do not impede access to medically necessary care. This final rule will require that P&T committees have a majority of members who are practicing physicians or pharmacists in order to bring adequate clinical experience to the committee. The P&T committee requirements finalized at § 422.136(b)(2) require that P&T committee members must be free of conflict relative to the MA organization, the MA plan, and pharmaceutical manufacturers. Further, pursuant to § 422.136(b)(5), clinical decisions of the P&T committee must be based on the strength of scientific evidence and standards of practice, including assessing research literature and data as appropriate. We believe P&T committee requirements finalized at paragraph (b)(6) will help ensure MA plans' Part B step therapy policies are based on objective decisions that meet the needs of enrollees, by considering whether a Part B drug included in a step therapy program has therapeutic advantages in terms of safety and efficacy, while allowing practicing providers a role in developing and implementing Part B step therapy program guidance. This final rule, at § 422.136(b)(8), requires an annual reevaluation and analysis of the step therapy protocols and procedures. P&T committees must, pursuant to § 422.136(b)(9), document their decisions, which we believe must show how the committee complies with the regulation. These requirements will ensure that P&T committees' decisions with respect to Part B step therapy are conducted in a manner that is documented, evidenced-based, free from conflict of interest, and subject to CMS oversight. Finally, CMS will hold plans' P&T committees accountable by requesting written documentation, as

needed, regarding the development and revision of step therapy programs.

Comment: Some commenters expressed concern that MA plan step therapy policies would focus more on cost (as opposed to clinical appropriateness), interfere in personalized care, and interfere with provider autonomy. A few commenters expressed concern that this proposal would lead to increased administrative burden, which will frustrate physicians and cause them to leave the practice of medicine.

Response: CMS acknowledges the potential for step therapy programs to create administrative burden and process challenges for network providers. We remind readers that MA PPO plans may not impose limits like prior authorization or step therapy on benefits furnished by out-of-network providers. In a previous rulemaking (70 FR 4616 through 4617), CMS interpreted section 1852(e)(3)(A)(iv) of the Act and 42 CFR 422.4(a)(1)(v)(B) as precluding PPO plans from requiring enrollees to obtain as a condition of coverage pre-certification or pre-authorization, or a coverage determination before receiving a covered service out-of-network. The requirement that both local and regional PPO plans cannot require prior authorization as a condition for out-of-network coverage of services is also described in CMS guidance in Chapter 4, § 110.4 of the Medicare Managed Care Manual. We expect MA plans to work closely with providers to adopt best practices that streamline operations and minimize burden. We consider such efforts consistent with the obligation, under § 422.202, of MA plans to establish a mechanism to consult with the physicians who have agreed to provide services under the MA plan offered by the organization, regarding the organization's medical policy, quality improvement programs and medical management procedures. We also encourage continued development and advancement of electronic prior authorization processes to more efficiently administer Part B step therapy programs.

With respect to clinical concerns and interference with provider care, we reiterate that step therapy or other utilization management policies may not be used as unreasonable means to deny coverage of medically necessary services or to eliminate access to medically necessary Part B covered drugs. The requirements in this rule, in combination with current MA program regulations, ensure access to Part B drugs and limit the potential for step therapy policies to interfere with medically necessary care. Specifically, MA plans must ensure access, consistent with the requirements at § 422.100(a) and § 422.101(a) and (b), to all medically necessary Part A and Part B benefits that are available in Original Medicare. Further, we are not changing or eliminating the existing requirements that MA plans must comply with national and local coverage determinations and guidelines. Organizations have been and remain subject to the MA regulations and must comply with national and applicable local coverage determinations. Step therapy protocols cannot be stricter than an NCD or LCD with specified step therapy requirements. Based on how §§ 422.100 and 422.101 will interact with § 422.136, if an NCD or LCD prohibits or establishes step therapy programs in connection with coverage of a Part B drug, the MA plan must comply with the applicable NCD or LCD.

As finalized in § 422.136(a)(1), Part B drug step therapy requirements may not apply to ongoing courses of Part B drug therapies. This limitation is designed to prevent interference with the provision of care to patients who have already started a drug treatment. As noted in the proposed rule, we recognize that negative health outcomes can arise from disruptions in existing treatment regimens and wish to avoid such occurrences.

Further, the MA regulation at § 422.206 prohibits an MA plan from interfering with health care professionals' medical advice to enrollees. Therefore, a provider's statement in support of a pre-service organization or appeal for access to a Part B drug cannot be prohibited by an MA plan. We expect MA plans to give weight to a provider's medical judgment and expertise when making organization determinations and deciding appeals related to access to Part B drugs that are subject to step therapy protocols; we remind MA plans that under §§ 422.566(d) and 422.590(g)(2), all denials of coverage based on medical necessity—which we expect will be the crux of requests by enrollees to avoid step therapy programs—must be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision. We note as well that under this final rule, the adjudication time periods for Medicare Advantage organization determinations are being shortened for cases related to coverage of Part B drugs. The ability for providers and enrollees to receive a pre-service decision regarding coverage on a Part B drug on this shortened timeframe will greatly reduce the potential for delay in access to medically necessary Part B drugs.

Furthermore, MA plans using step therapy must ensure that step therapy programs are clinically appropriate under this rule and existing rules governing the MA program. Pursuant to § 422.202(b)(1), MA organizations must formally consult with contracted physicians when developing utilization management guidelines, so that policies like step therapy are based on reasonable medical evidence or consensus of medical professionals, consider the needs of enrollees, and are reviewed and updated; taken together these standards mean that step therapy programs, like other utilization management policies, are clinically appropriate. As we stated previously, we are requiring that P&T committees must have a majority of members who are participating physicians or pharmacists and they must follow the requirements at § 422.136(b)(5) through (10) in review, evaluation and approval of step therapy policies. We believe this will help ensure that a MA plan's Part B step therapy policies will be clinically driven and that practicing providers, including network providers, will have a voice as practice guidelines are developed and implemented.

Comment: Some commenters stated Part B Step Therapy conflicted with section 1852(a)(1) of the Act. Specifically, these commenters argued that section 1852(a)(1) of the Act which requires MA plans to cover all Part A and Part B benefits (except for specifically excluded benefits like hospice), means that MA plan coverage policies not be more restrictive than Original Medicare and that CMS cannot allow plans to impose additional restrictions to Part B drug coverage. The commenters argued step therapy amounts to a denial of access to Part B benefits.

Response: As referenced in the proposed rule, CMS's reinterpretation of section 1852 of the Act means that MA plans' may implement appropriate utilization management tools, including prior authorization and step therapy, for managing Part B drugs in a manner to reduce costs for both enrollees and the Medicare program while not denying access to medically necessary services. Section 1852(a)(1) of the Act requires MA plans to provide coverage of items and services for which benefits are available under parts A and B of the Medicare statute, except for hospice care and, beginning 2021, excludes organ acquisitions costs for kidney

transplants. Although CMS previously interpreted this as requiring MA coverage of Part A and Part B benefits to be no more restrictive than coverage in Original (FFS) Medicare, the need to control drug costs prompted our review of the authority and CMS changed this interpretation with respect to utilization management programs applied to Part B drugs upon more careful consideration of the statute as a whole. As discussed in the proposed rule, we expect the use of step therapy for Part B drugs to lead to lower costs for the government and Medicare beneficiaries; lowered costs are undoubtedly a means to ensure the continued health of the Medicare program and a reasonable basis for revisiting the statute to evaluate whether there is authority to provide more flexibility to MA plans in connection with utilization management policies.

Section 1852, in imposing the requirement that MA plans furnish or cover Part A and Part B benefits, does not expressly prohibit the use of utilization management. To the contrary, sections 1852(c)(1)(G) and (c)(2)(B) of the Act expressly reference an MA plan's application of utilization management tools, like prior authorization and other ''procedures used by the organization to control utilization of services and expenditures.'' This clearly indicates that MA plans are not expressly prohibited by the statute from implementing utilization management tools such as step therapy. Although some commenters disagreed that step therapy is a utilization management tool, characterizing it instead as a limitation or restriction on coverage, we believe that it is such a tool and that the reasonable limits these protocols place on when a drug is covered are the means of controlling utilization and cost. All Part B drugs must be covered by the MA plan when medically necessary, for example, when a stepped drug is not effective or appropriate for the patient, the patient must be allowed direct access to an alternative Part B drug. We disagree with commenters that characterize these limits as meaning that certain Part B drugs are no longer covered by the MA plan; these limits on coverage do not eliminate coverage, rather they ensure the most cost effective, clinically appropriate treatment is provided. This is consistent with our current interpretation of the requirement in section 1852 of the Act that MA plans must furnish or cover medically necessary Part A and Part B services, excluding hospice and, beginning 2021, excluding kidney acquisition costs.

Further, we do not believe that the statute must list every possible procedure or policy that controls utilization of services or expenditures for the statute to authorize their use. Section 1860D–4(c) of the Act does not expressly refer to step therapy, but because it is an appropriate method for managing drug costs, we have historically permitted Part D plans to use step therapy as a utilization management program authorized by the statute. Section 1852(c)(1)(G) and (c)(2)(B) of the Act contemplates that MA plans will use utilization management policies that are not used in Original Medicare. If the statute permitted only prior authorization, requiring disclosure of ''procedures used by the organization to control utilization of services and expenditures'' would be unnecessary because subsection (c)(1)(G) already requires disclosure of prior authorization policies. Our interpretation gives meaning to both provisions and reasonably interprets the reference to controlling utilization of services and costs as including step therapy policies.

Further, we have explained our reinterpretation consistently. In the August 7, 2018 HPMS memo [14] and subsequent FAQs,[15] CMS recognized that utilization management tools, such as step therapy, can provide the means for MA plans to better manage and negotiate the costs of providing Part B drugs. In the proposed rule, we explained how we do not believe that MA plans subject to our prior guidance and interpretation engaged in negotiation over the cost of Part B drugs. As previously noted using internal bid data, excluding MA employer group plans, CMS estimates $9 billion in spending by MA plans for Part B drugs during contract year 2018. By providing a basis on which MA plans may more effectively negotiate the price they pay for Part B drugs, this reinterpretation of the statute allows for more cost-effective coverage of these drugs. Further, by using policies that promote the use of more cost effective drugs first when such drugs adequately and appropriate treat an enrollee's condition, step therapy programs can result in lower utilization while ensuring consistent beneficial outcomes.

Because the statute contemplates MA plans use of utilization management policies and procedures and because Part B drugs are accessible and covered when medically necessary (such as if other medications that are used first in a step therapy program are not effective), we have concluded that an MA plan may fulfill its obligations to furnish Part B benefits even if a step therapy program is used. As discussed elsewhere in response to comments, new § 422.136 contains beneficiary protections and limits on how step therapy can be used in order to ensure access to medically necessary Part B drugs. CMS reiterates that MA plans must comply with the statutory requirement that they provide enrollees with access to all medically necessary Part A and Part B benefits available in Original Medicare, as provided section 1852(a)(1) of the Act. This final rule does not contravene this statutory requirement for MA plans.

Comment: Several commenters expressed concerns that the proposal did not include adequate oversight from CMS. Several commenters argued that CMS cannot guarantee consistent enforcement and provide enrollees clinically appropriate Part B medication. Some commenters recommended CMS establish procedures, similar to Part D, in which plans are required to submit step therapy policies for CMS review and approval prior to implementation and use. Commenters also recommended that CMS actively monitor plans to ensure that plan policies and procedures are implemented in a manner that does not violate CMS rules. Commenters also suggested CMS closely monitor the extent to which organization determinations and appeals are being sought so that CMS can assess the need for additional patient protections.

Response: Although § 422.136 does not explicitly address monitoring and enforcement, CMS will leverage its existing oversight programs to include targeted monitoring of the Part B step therapy programs implemented by MA plans.

CMS will monitor beneficiary complaints and organization determinations and appeals related to Part B drug step therapy programs. CMS has regularly scheduled meetings with the Part C IRE contractor; during these meetings, CMS and the IRE contractor identify and evaluate systemic problems with coverage decisions that rise to the IRE based on denials at the plan level. When systemic coverage issues are

[14] Available online at: *https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf.*

[15] Available online at: *https://dpapportal.lmi.org/DPAPMailbox/Documents/Part%20B%20Step%20Therapy%20Questions%20FAQs_8-29-18.pdf.*

identified, CMS takes steps with the MA plan, or the industry as a whole, to ensure correction of the problem. CMS will also monitor compliance with organization determination and appeal adjudication timeframes, both existing and those adopted in this final rule, by MA plans. When MA plans are selected for audit, CMS will target sample pre-service organization determination and appeals related to requests for Part B drugs to ensure compliance with § 422.136, particularly the beneficiary protection requirements like the lookback period and the requirements to educate and inform health care providers and enrollees concerning its step therapy policies. CMS will also monitor step therapy related complaints it receives from stakeholders to learn how MA plans are implementing step therapy programs, including whether plan communications explaining the program and involvement of contracted providers, as we have outlined elsewhere in this final rule, are consistent with program requirements. Finally, when CMS identifies concerns about a step therapy program, CMS may request written documentation from the plan's P&T committee under authority in § 422.136(b)(9) and any other related plan information CMS deems necessary, in accordance with § 422.504(f)(2), in order to assess and evaluate the MA plan's step therapy program and ensure compliance with CMS requirements.

We note that CMS interprets its authority to review Part C bids and plan designs as the authority under which we could review MA plans use of Part B drug step therapy programs. However, given all of these oversight means and tools, we believe CMS can effectively monitor MA plan step therapy programs without reviewing all of the coverage policies and procedures an MA plan adopts for step therapy in advance. As discussed elsewhere in the final rule, P&T committees are responsible for reviewing and implementing Part B step therapy programs that are clinically appropriate and are based in scientific evidence and standards of practice. CMS does not review other utilization management practices (that is, prior authorization) for Part B items or services in advance of implementation by an MA plan. We will continue to hold plans accountable for ensuring coverage of medically necessary Medicare covered items and services through CMS's oversight activities.

CMS solicited comment on the rule's restriction to new medication starts only.

Comment: Some commenters requested CMS remove the new start restriction and allow step therapy for all Part B drug therapies. Several commenters requested that CMS increase the lookback period to determine if the enrollee is actively taking a Part B medication from 108 to 365 days to better ensure uninterrupted care. These commenters pointed out that there are many clinical differences in the drugs covered under Part B compared to those covered under Part D and noted that the FDA-approved dosage period for many Part B drugs exceeds 108 days. One commenter highlighted the following drugs (and their dosage periods) specifically:

- Zoledronic acid for osteoporosis is 1 year
- Denosumab for osteoporosis is 6 months
- Hyaluronic acid injections for knee osteoarthritis are 6 months
- Rituximab for rheumatoid arthritis is dosed at two infusions repeated every 4 to 6 months

Given these examples, these commenters and others recommended a 365-day lookback period to better ensure uninterrupted care, noting that a disruption in therapy could result in poorer disease control including relapse of symptoms and other bad outcomes, such as hospitalization and death, depending on the drug and condition. Commenters also reasoned that a 108 day lookback period may not be clinically appropriate for some disease states, as many patients receive less frequent infusions that may not be captured in this short time period.

Response: Although we proposed that MA plans would be required to have a lookback period of 108 days to determine if the enrollee is actively taking a Part B medication, we explained in the proposed rule how the purpose of the look back period was to determine if an enrollee were actively taking a Part B drug. We stated our belief that consistency with the Part D lookback period, which was created with clinical and pharmaceutical input, would be appropriate. As commenters have pointed out that the FDA-approved dosage periods for some Part B drugs exceeds 108 days, we now believe that in order to fully ensure that an MA enrollee is not already taking a Part B drug, a longer lookback period is appropriate and necessary. Therefore, in order to ensure continuity of care, we are finalizing § 422.136(a)(1) with a lookback period of 365 days as recommended by commenters. Based on this information about the dosage periods for Part B drugs, the justification for the 108-day lookback period used for Part D drugs is not applicable to Part B drugs. In Part D, 108 days is a considered sufficient because PDPs are allowed to provide 90-day supplies. The 108 day period allows for some flexibility beyond 90 days (18 days or 20% of 90 days) if the beneficiary does not refill a prescription exactly 90 days after the first fill. This scenario is not applicable to Part B drugs because Part B drugs are not administered based on a 90-day supply and, as the commenters indicated, may have dosage periods of up to a year. As discussed in the proposed rule, CMS believes new step therapy requirements must not disrupt ongoing Part B drug therapies for enrollees. In order to ensure that step therapy requirements do not disrupt ongoing Part B drug therapies, we proposed, and are finalizing at § 422.136(a)(1), that step therapy may not disrupt enrollees' ongoing Part B drug therapies. The regulation, at § 422.136(a)(1), permits MA plans to apply a step therapy program only to new administrations of Part B drugs, using a minimum lookback period. We believe a 365 day look back period will mean that MA plans identify enrollees who may be using a drug with a longer dosage period and thus better ensure uninterrupted care. Therefore, the final regulation text specifies a 365 day lookback period.

Comment: Commenters also stated that new start protections must be allowed for new MA enrollees as well as enrollees who switch MA plans.

Response: We agree that step therapy programs should be limited to new administrations for all enrollees. We proposed that step therapy should not be permitted to disrupt enrollees' ongoing Part B drug therapies and noted in the proposed rule how we intended the restriction to new starts and the use of the look back period to apply to current enrollees and when an enrollee elects a new MA plan. We clarify here that an enrollee's ongoing Part B drug therapy may not be disrupted even when an enrollee switches plans. MA plans must use the lookback period when an enrollee elects a new MA plan (regardless of whether previously enrolled in a MA plan, traditional FFS Medicare, or new to Medicare) to determine whether the enrollee has taken the Part B drug (that will otherwise be subject to step therapy) within the past 365 days. We are finalizing the requirement in § 422.136(a)(1) that step therapy only be applied to new prescriptions or administrations of Part B drugs, using a 365 day lookback period. This limitation must be applied to all enrollees and means step therapy for a Part B drug may be used only for an enrollee who is not receiving the

medication currently or has not previously received the medication within the lookback period. MA plans must therefore take steps to request and review information as necessary to identify whether an enrollee has used the applicable Part B drug during the lookback period.

Comment: Several commenters urged CMS to include in the final rule an exemption or waiver policy for individuals subject to Part B step therapy. Commenters argued that some beneficiaries have conditions that are too sensitive to be subject to the increased restrictions that step therapy would impose. Commenters reasoned that in some cases a patient being required to first ''fail'' on a plan preferred medication or to wait through a delay due to an appeal can to lead to adverse health outcomes, especially if the patient's condition is stable due to the enrollees' use of prescription drugs already selected by the prescribing health provider. Commenters stated that step therapy requirements prevent patients from adhering to their treatment plans and, therefore, are not in their best interests. Commenters also suggested CMS develop a more expansive exemption or waiver policy for individuals that should not be subject to Part B drug step therapy requirements.

Response: We reiterate that plans cannot deny medically necessary care and enrollees and/or providers may request a pre-service organization determination in order to receive plan approval to bypass the step therapy requirement, but we are not adopting specific regulation text to create additional exemptions from step therapy other than the limits we proposed (meaning, the limits regarding new administrations of a Part B drug, use of only covered drugs, and use of off-label indications). We believe that a request for a pre-service determination, particularly in light of the amendments to the deadlines for responding to requests for organization determinations about coverage of Part B drugs, is an adequate safeguard to ensure enrollee access to medically necessary care. In addition, an enrollee may request an expedited organization determination and reconsideration if necessary. We are also requiring that step therapy be limited to new starts with a 365 day look back period so continuing treatments are not affected. CMS limited step therapy to new starts because a disruption in successful MA enrollee therapy could result in poorer disease control, relapse of symptoms and other bad outcomes including hospitalization and death, depending on the drug and condition.

This final rule includes a number of safeguards that ensure timely access to all medically necessary Part B medications, including the following: (1) Requiring that step therapy only be applied to new prescriptions or administrations of Part B drugs for enrollees who are not actively receiving the affected medication with a lookback period of 365 days to determine if the enrollee is actively or during the lookback period was taking a Part B medication; (2) requiring that MA plans issue organization determinations and decisions on appeals under timeframes similar to those used in the Part D program when the issue is about coverage of a Part B drug; and (3) requiring that plans use a P&T committee to review and approve step therapy programs to ensure medically appropriate implementation of step therapy for Part B drugs.

Comment: Some commenters urged CMS to require that step therapy protocols be aligned with clinical practice guidelines and adhere to recognized standards of care. Other commenters urged CMS to require MA plans to establish processes to evaluate the clinical appropriateness of their step therapy protocols. Some commenters suggested that plan step therapy policies should be supported by evidence-based clinical guidelines and best practices that are based on robust research and publicly available overutilization data.

Response: CMS appreciates commenters' feedback about requiring P&T committees to establish processes to evaluate the step therapy policies developed by MA plans and that these policies be supported by evidence-based clinical guidelines and best practices. We believe that our proposal for P&T committees and the standards they would be required to use in reviewing and approving step therapy programs for Part B drugs are consistent with the commenters' recommendations. CMS is finalizing its proposal at § 423.136(b)(5), that requires P&T committees base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other information as is determines appropriate. This regulation will allow P&T committees discretion to determine the scientific evidence and standards of practice on which their clinical decisions are based, although CMS can monitor this process through review of P&T committee records. CMS is also finalizing regulation text at § 423.135(b)(9) that each P&T committees must document in writing its decisions regarding the development and revision of and utilization management activities and make this document available to CMS upon request. Accordingly, CMS may monitor compliance with (and, as necessary take enforcement and/or compliance action regarding) the P&T committee requirements in § 422.136(b) through requesting written documentation regarding Part B step therapy programs and evaluating whether clinical decisions and criteria are evidence-based and appropriate in terms of safety and efficacy. We may also release subregulatory guidance concerning the application of the P&T committee requirements in the context of Part B drugs.

Comment: A few commenters requested that CMS carefully consider the development of further guidance on how step therapy should align with existing care coordination programs.

Response: We evaluated existing requirements in §§ 422.112 and 422.152 that require care coordination activities and determined that changes to these rules are not needed to include care coordination activities related to Part B step therapy. We may consider further requirements in the future, as needed, and note that CMS is not finalizing a requirement in § 422.136 that an MA plan must offer a drug management care coordination program in conjunction with Part B step therapy. We believe full disclosure to enrollees regarding a plan's Part B step therapy program and good communication between providers and enrollees undergoing step therapy are important features of care coordination. We expect this disclosure to include informing enrollees of their appeal rights and confirming whether enrollees have used the stepped medication within the last year. While all of the care coordination requirements are important, we emphasize that plans should ensure that treating providers consider beneficiary input into the provider's proposed treatment plan, as described at 42 CFR 422.112(a)(6)(iii). We also expect MA plans to ensure that providers closely monitor patients undergoing step therapy to ensure that the prescribed medication is meeting clinical expectations.

Comment: Some commenters expressed concern that the additional education and information responsibilities in this proposal are insufficient and do not adequately inform enrollees and providers of plan step therapy policies. These commenters encouraged CMS to provide greater transparency to enrollees and

providers of step therapy policies by requiring that plans disclose the name of each Part B drug subject to step therapy in the annual notice of changes (ANOC) and explanation of benefits (EOC).

Response: With regard to the comments on the sufficiency of our proposal regarding education and information provided to providers and enrollees, CMS believes transparency and informed beneficiaries and providers are critical to a well-coordinated and efficient utilization management program. We are finalizing the requirement that MA plans establish policies and procedures to educate and inform health care providers and enrollees concerning step therapy policies at § 422.136(a)(2). In addition, we note that existing disclosure requirements in § 422.111 will apply to step therapy programs. We are still considering how to apply and interpret the requirements in § 422.111 regarding the ANOC and EOC to step therapy programs in light of the new requirement we are finalizing here at § 422.136(a)(2), that MA plans establish policies and procedures to educate and inform providers and enrollees about step therapy programs. Subregulatory guidance will be provided §§ 422.111 and 422.136(a)(2) and CMS intends to seek comment in its development of such guidance about whether step therapy requirements should be displayed in a drug-specific manner in the ANOC/EOC documents provided to beneficiaries.

Comment: Some commenters expressed concern that the requirements under this proposal are burdensome and not necessary to administer a drug benefit.

Response: CMS appreciates commenters concerns regarding the administrative burden imposed on network providers by MA plans. CMS encourages MA plans to work closely with providers to adopt best practices that streamline operations and minimize burden. We also encourage continued development and advancement of electronic prior authorization processes to more efficiently administer Part B step therapy programs and potentially minimize burden on health care providers. CMS believes that Part B step therapy programs can reduce medical costs by replacing more expensive drugs with less costly drugs when it is medically appropriate to do so.

Comment: Several commenters expressed concern about the disclosure requirements and argued that beneficiaries should receive more detailed information about drugs subject to Part B step therapy. Commenters suggested that beneficiaries should be able to review step therapy protocols and medications subject to step therapy prior to enrolling in the plan. Commenters recommended increased transparency of plan step therapy requirements, including having plans explain why step therapy is required for a specific medication, how the process works, and what recourse the beneficiary has to appeal. Furthermore, several commenters urged CMS to prohibit mid-year additions to step therapy programs or mid-year implementation of step therapy, noting that such restrictions should only be established in advance of a plan year so that beneficiaries will have access to all plan information prior to making enrollment decisions.

Response: As previously discussed, CMS believes transparency and informed beneficiaries and providers are critical to a well-coordinated and efficient utilization management program. The regulation at § 422.111 requires that MA plans disclose information covered by the plan, including applicable conditions and limitations, premiums, cost-sharing, and any other conditions associated with receipt or use of benefits in the plan's ANOC (when initially adopted or subsequently changed) and EOC documents, which are provided annually to plan enrollees. In the past, we interpreted the regulation to mean that plans must identify that covered services may be subject to utilization management tools, like prior authorization. In light of the comments regarding transparency and the need for enrollees to have detailed information about step therapy programs, we are considering whether § 422.111 should be interpreted to require more detailed disclosure, particularly as we are finalizing a requirement at § 422.136(a)(2) that MA plans establish policies and procedures to educate and inform providers and enrollees about step therapy programs. We intend to seek comment through sub-regulatory guidance as to whether step therapy requirements should be displayed in a drug-specific manner in the ANOC/EOC documents and how MA plans should be required to display this information so that enrollee elections can be made based on all necessary information.

With respect to mid-year changes to implementation of step therapy programs, we note that under § 422.111(d)(3), MA plans must inform all enrollees at least 30 days before the intended effective date of changes in plan rules. Utilization management tools like prior authorization and step therapy are plan rules within the scope of this provision so MA plans must inform enrollees of changes to rules described in the ANOC/EOC consistent with § 422.111(d).

Comment: Some commenters supported the use of P&T committees as an effective mechanism to ensure that step therapy and other utilization policies are clinically appropriate. Other commenters noted that MA plans utilize a Medical Policy committee, which reviews and evaluates drugs covered under the medical, rather than the pharmacy benefit. The commenters suggested CMS should allow MA plans to utilize these committees to develop and review plan step therapy policies instead of a P&T committee, which reviews and approves the Part D drug benefit.

Response: CMS appreciates commenters who shared both opposition and support of the P&T committee requirement. CMS will require MA plans that elect to use Part B step therapy programs to have a P&T committee review and approve such step therapy programs. This regulation affirms our reinterpretation of section 1852 of the Act, and the MA regulations governing benefit coverage and utilization management policies (for example, § 422.4(a)(1)(ii)) to allow MA plans to use utilization management tools such as step therapy for Part B drugs to prevent overutilization of medically unnecessary health services and control costs, subject to limitations finalized in § 422.136. We are finalizing the paragraph (b) provisions requiring use of P&T committees, but are limiting the P&T committee responsibilities to review and approval of Part B step therapy programs only. Our proposed regulation text in paragraphs (b)(6), (b)(7), and (b)(9) referred to utilization management policies and programs and proposed paragraph (b)(10) referred to ''clinical prior authorization criteria;'' we are not finalizing these references, but are limiting the regulation text to step therapy programs. The final rule does not require P&T committee review and approval of Part B utilization management policy other than step therapy programs; MA plans are permitted to use P&T committees more broadly to review and approve other utilization management programs and protocols, but are not required to by § 422.136 as finalized here. Limiting P&T committee responsibilities to step therapy programs is in line with our proposal. As explained in the proposed rule, § 422.136 is specific to step therapy programs applicable to Part B drugs, our reinterpretation permitting such programs, and the appropriate limits on MA plans using such

programs. Our proposal was not explicitly to impose new limits on existing utilization management programs. Although we solicited comments, we did not receive any comments recommending that P&T committee requirements be extended to other programs.

We believe the P&T committee requirements being finalized in this rule are necessary to ensure medically appropriate implementation of step therapy for Part B drugs. P&T committees will promote safe, effective, and cost-effective Part B drug therapy by reviewing and approving the policies and procedures for step therapy. CMS is not adopting any requirements for use of Medical Policy committees because, as discussed in the proposed rule, we believe it is appropriate to substantially align the requirements of a P&T committee reviewing Part B drugs with Part D requirements for administrative efficiency between Part C and Part D programs. P&T committee membership and regulatory requirements are specifically designed to ensure that adequate standards and considerations be used in reviewing step therapy programs for drugs. A medical policy committee's scope would not necessarily be limited to Part B drug review and, therefore, impose unnecessary burden to MA plans. Additionally, Part D requirements for P&T committees have proven sufficient in ensuring that plans implement medically appropriate step therapy and utilization management protocols in Part D.

Comment: Some commenters expressed concern about CMS's requirements regarding the sufficiency of the P&T committee's composition. These commenters believe MA plans should require, rather than encourage, P&T committees to include more specialists, nurse practitioners, and beneficiary representation.

Response: CMS appreciates commenters concerns regarding P&T committee composition. In response to commenters' suggestions that P&T committee composition include more specialists, practitioners, and beneficiary representation, CMS notes that this final rule requires P&T committees include a majority of members who are practicing physicians or pharmacists. Although P&T committees must include a majority of members who are physicians and pharmacists, plans have the discretion to include specialists, nurse practitioners, and beneficiaries as members. We do not believe that adopting different or revised composition requirements will necessarily further our goals for the use of the P&T committee while they could impose additional burden on MA plans, which would not be able to immediately implement use of an existing P&T committee established for the Part D program, if additional members must be added to the committee. As noted in the proposed rule, we believe that using the same rules as apply in the Part D program are appropriate because of the demonstrated success in that context.

Comment: A few commenters expressed concern that this proposal would lead to higher out-of-pocket (OOP) costs for beneficiaries. Some expressed concern that allowing plans to step a Part D drug before a Part B drug would lead to increased OOP costs for beneficiaries due to the differences in cost sharing rules between Part B and Part D drugs. A few commenters urged CMS to allow plans to cross-manage Part B and Part D drugs to enable plans to better manage Part B and Part D drug costs.

Response: CMS acknowledges that in some narrow instances beneficiaries may be financially disadvantaged and experience higher cost sharing if for example, a Part B step therapy program uses a Part D drug as a step to the Part B drug for an enrollee who had reached their MA plans maximum out-of-pocket limit (MOOP). MA enrollee out-of-pocket costs for Part D drugs are not included in the MOOP limit imposed on enrollee out of pocket costs under §§ 422.100(f) and 422.101(d), but enrollee costs for Part B drugs are; therefore, an enrollee who has reached the catastrophic limit would not have any cost sharing charged for a Part B drug, but would have to pay cost sharing for a Part D drug. However, we believe the majority of MA enrollees will realize reduced cost sharing as a result of the step therapy policy finalized in this rule because the enrollees will be directed to a clinically appropriate and more cost effective drug treatment. We expect that the implementation of step therapy will result in lower plan bids, because the cost of furnishing Part A and Part B benefits will be lower. If a plan reduces its bid relative to the benchmark, the plan should be able to charge a lower premium or provide supplemental benefits at a lower (or potentially no) premium.

Comment: Some commenters recommended that CMS permit plans to provide a two-tiered Part B preferred drug list with differential cost-sharing and requested that CMS use its authority through the Annual Rate Notice and Call Letter to permit MA plans to establish non-preferred Part B drug cost sharing greater than 20 percent.

Response: We thank commenters for their suggestions. We note that CMS does not have the authority to make such changes through the annual Call Letter. Section 3202 of the Affordable Care Act amended section 1852 of the Act to establish new standards for MA plans' cost sharing. Specifically, section 1852(a)(1)(B) of the Act was amended by the addition of new clause (iii) that limits cost sharing under MA plans so that it cannot exceed the cost sharing imposed under Original Medicare for specific services identified in new clause (iv). New section 1852(a)(1)(B)(iv) of the Act lists the three service categories for which cost sharing in MA plans may not exceed that required in Original Medicare (chemotherapy administration services, renal dialysis services, skilled nursing care) and section 1852(a)(1)(B)(iv)(IV) of the Act specifies that this limit on cost sharing also applies to such other services that the Secretary determines appropriate. CMS must use rulemaking to identify additional services to which this provision would apply to limit how much cost sharing is charged to an MA enrollee.

As stated in the CY 2012 Call Letter, MA plans and 1876 Cost Plans may not charge enrollees higher cost sharing than is charged under Original Medicare for chemotherapy administration including chemotherapy drugs and radiation therapy integral to the treatment regimen, skilled nursing care, and renal dialysis services (§§ 417.454(e) and 422.100(j)). In addition, in order to ensure that cost sharing is consistent with both §§ 422.254(b)(4) and 422.100(f)(2) and (6), CMS evaluates actuarial equivalent cost sharing limits separately for all Part B drugs. Therefore, the 20 percent limit applies to both Part B drugs-Chemo and Part B Drugs-Other.

Comment: Some commenters also suggested CMS allow plans' utilization management protocols to supersede national coverage determinations (NCDs) and local coverage determinations (LCDs). Specifically, it was suggested that CMS provide guidance that grants plans flexibility in implementing step therapy on Part B drugs with LCDs or NCDs. We also received a comment that encouraged CMS to review NCDs and revise those policies that impose barriers on the utilization of biosimilars.

Response: MA organizations have been and remain subject to § 422.101(b), which requires compliance with national and in some cases, local, coverage determinations. Part B step

therapy protocols for a given drug cannot be stricter than the step therapy provisions specified in an NCD or LCD. For example, if the NCD or LCD has specified Part B step therapy requirements for that particular drug, then the Part B step therapy protocols of an MA plan cannot be stricter than those protocols. We would further note that when NCDs or LCDs do not preclude MA step therapy, we believe that Part B step therapy can be an effective utilization management tool. Where an LCD or NCD addressing coverage of a Part B drug does not address or include a step therapy protocol, this regulation will permit the MA plan to adopt a step therapy for that Part B drug. As we have discussed elsewhere in this final rule, one significant policy goal in allowing Part B step therapy is to enable MA plans to reduce unnecessary drug spending and, in turn, reduce costs for beneficiaries and the Medicare program. MA plans must provide coverage of all Part A and Part B benefits, therefore, MA plans must provide coverage of all Part B drugs. If an NCD specifies that a biosimilar is not covered under Part B, it cannot be used under the Part B drug step therapy program.

Comment: Some commenters requested CMS clarify whether all of the projected savings resulting from step therapy may be incorporated in the bid amount, instead of offering incentives only to those enrollees subject to step therapy who completed specified care management activities, beginning in 2020.

Response: Effective January 1, 2020, MA plans must incorporate anticipated savings in the plan's bid amount; therefore, coupling step therapy with rewards and incentives will not be a requirement in 2020 or future years for MA plans (as it is in 2019) that use a step therapy program for one or more Part B drugs. Pursuant to § 422.254(b), MA bids for the basic benefit are required to reflect the revenue requirements for an MA plan to cover all Part A and Part B benefits; when use of a step therapy program means that the MA plan projects lower utilization or lower pricing (such as due to pricing negotiation with drug manufacturers), that will necessarily result in lower revenue needs to provide the Part B drugs that are subject to the step therapy program. CMS reminds plans that additional Part C rebate dollars associated with the lower bid, as with all Part C rebate dollars, must be used to provide supplemental benefits and/or lower premiums for the plans' enrollees.

We explained in the proposed rule how preferred provider organization plans (PPOs), because of the requirement in § 422.4(a)(1)(v)(B) to reimburse or cover benefits provided out of network without use of restrictions on coverage, would not be able to impose prior authorization or step therapy requirements on out-of-network provision of Part B drugs. We solicited comment on whether the final rule should include a specific regulatory provision clarifying whether preferred provider organization plans (PPOs) can apply step therapy out of network.

Comment: Some commenters requested that CMS allow PPOs to apply step therapy out of network.

Response: We clarify that PPOs are required, as part of the definition of a PPO at section 1852(e)(3)(A)(iv)(II) of the Act and under the MA regulations at § 422.4(a)(1)(v)(B), to reimburse or cover benefits provided out of network; while higher cost sharing is permitted, PPOs are prohibited from using prior authorization or preferred items restrictions in connection with out of network coverage. (70 FR 4616 through 4617). As such, PPOs must provide reimbursement for all plan-covered medically necessary services received from non-contracted providers without prior authorization or step therapy requirements. Therefore, PPO plans may only use step therapy or prior authorization when a Part B drug is provided by an in-network provider.

Comment: Some commenters requested that all step therapy policy, including CMS operational guidance, be subject to advance public notice and an opportunity to provide comment.

Response: CMS thanks commenters for the suggestion and will consider soliciting comment on draft operational guidance related to § 422.136 and its requirements for Part B step therapy in the future. However, we do not believe that we are required to do so. Because of timing factors, as well as other policy considerations, we may release guidance without first soliciting comment.

Comment: Some commenters urged CMS to evaluate and revise existing subregulatory guidance and update relevant Medicare manual chapters to maximize the time plans have to design and implement step therapy programs and incorporate them in their bid applications for CY 2020.

Response: CMS will continue to evaluate and update Part B and Part D subregulatory guidance to ensure accuracy and consistency with new regulations. CMS appreciates that plans need to prepare bid submission and will work to provide additional Part B subregulatory guidance in a timely manner. This final rule provides significant discussion of § 422.136 and the requirements for Part B step therapy. Additional guidance before the bid deadline for CY2020 may not be possible.

Comment: Some commenters supported the proposal to permit MA plans to use off-label drugs in a step therapy program only when such drugs are supported by widely used treatment guidelines or clinical literature that CMS considers to represent best practices. Some commenters requested that CMS clarify what it considers to be ''best practices'' or ''widely used treatment and clinical literature'' in this regard. Others expressed caution that the use of off-label drugs as proposed could limit further investment in developing therapies and could provide disincentives to seeking FDA approval of additional indications. Some commenters expressed concern that the proposed regulation text does not explicitly require that an off-label use meet the definition of a medically accepted indication. Commenters also expressed concern that reliance upon compendia standards as the criteria for off-label coverage is insufficient to determine clinical appropriateness and could undermine the FDA and its role to review and approve investigational uses of approved drugs. Other commenters recommended CMS prohibit step therapy through an off-label medicine, particularly if there is an on-label medicine available.

Response: We thank commenters for their feedback. In order to ensure the medically appropriate use of off-label drugs, CMS's finalized rule prohibits an MA plan from including in step therapy protocols a drug supported only by an off-label indication unless the off-label indication is supported by widely used treatment guidelines or clinical literature. For example, an example of widely used treatment guidelines that would be relevant for Part B drugs would be the National Cancer Center Network (NCCN), which has separate guidelines for different types of cancer, as well as a compendium for cancer drugs.

Comment: A commenter asked whether the policies in our proposed rule allow a MA plan to require the use of a Part D protected class drug prior to the use of a Part B drug (that is., as a step to a Part B drug on a Part B step therapy program). The commenter also asked how the Part B step therapy program would impact enrollees' access to Part D protected class drugs.

Response: This final rule, at § 422.136(d), provides that only Medicare covered Part B drugs (and, for MA–PD plans, also Part D drugs) may be

used in a step therapy program for a Part B drug. A Part B step therapy program used by an MA plan must not include as a step or other component of the program any drugs not covered by the MA plan as a Part B drug, or, in the case of an MA–PD plan, a Part D drug. In addition to requiring one Part B drug be used before a different Part B drug, MA plans that also offer prescription drug coverage (MA–PD plans) may use step therapy to require a Part B drug or a Part D drug therapy, including a protected class Part D drug, prior to allowing a Part B drug therapy because the Part D drug will also be covered by the plan. MA–PD plans may also apply step therapy to require a Part B drug therapy prior to allowing a Part D drug therapy, including, for new starts only, a protected class Part D drug (other than an antiretroviral), as part of a Part D step therapy program or utilization management program; however, MA–PD plans must ensure that these requirements are clearly outlined in the Part D prior authorization criteria for the affected Part D drugs and are otherwise consistent with Part D requirements, including the requirements for the use of prior authorization and step therapy for protected class Part D drugs that we are finalizing elsewhere in this rule.

As discussed previously, after careful consideration of all comments received, and for the reasons set forth in the final rule and in our responses to the related comments, we are adopting a new regulation at § 422.136, substantially as proposed but with some modifications. Specifically, we are making the following changes from the proposal:

- In the proposed regulation text § 422.136(a) (1), we are finalizing a lookback period of 365 days instead of 108 days.'' Thus, § 422.136(a) (1) reads as follows: ''Apply step therapy only to new administrations of Part B drugs, using at least a 365 day lookback period.''
- In the introductory text in § 422.136(b), we are correcting a typographic error in the proposed regulation text to use ''an existing Part D P&T committee'' in place of ''an existing Part D P&T committees.''

We are also amending the P&T committee requirements at § 422.136(b) to clarify that P&T committee responsibilities apply to review and approval of Part B drug step therapy programs, and do not extend to all utilization management policies for Part B items or services. Therefore, we are making the following modifications:

- In the regulation text § 422.136(b)(6), we are replacing ''a utilization management programs, such as'' with ''program''. Thus, we are finalizing § 422.136(b)(6) to read as follows: ''Consider whether the inclusion of a particular Part B drug in a step therapy program has any therapeutic advantages in terms of safety and efficacy.''
- In the regulation text § 422.136(b)(7), we are not finalizing the language ''utilization management processes, including drug utilization review, quantity limits, generic substitution, and therapeutic interchange'' and are finalizing language that refers to step therapy. Thus, we are finalizing § 422.136(b)(7) as follows: ''Review policies that guide exceptions and other step therapy processes.''
- In the regulation text § 422.136(b)(9), we are not finalizing ''and'' and ''utilization management.'' Thus, we are finalizing § 422.136(b)(9), to read as follows: ''Document in writing its decisions regarding the development and revision of step therapy activities and make this documentation available to CMS upon request.''
- In the regulation text § 422.136(b)(10), we are removing ''clinical prior authorization criteria'' and ''protocols and quantity limit restrictions.'' Thus we are revising § 422.136(b)(10), to read as follows: ''Review and approve all step therapy criteria applied to each covered Part B drug.''

2. Medicare Advantage and Step Therapy for Part B Drugs: Adjudication Timeframes

We proposed to amend a number of regulations related to the timeframe for an MA plan to make expedited and standard organization determinations and reconsiderations regarding coverage of Part B drugs. We also received comments on our proposal that requests for Part B drugs, including Part B drugs subject to step therapy, be processed under the same adjudication timeframes as used in the Part D drug program. As we stated in the proposed rule, we believe the clinical circumstances that typically accompany requests for Part B drugs warrant application to coverage decisions regarding Part B drugs of the shorter adjudication timeframes that apply in Part D. In keeping with this rationale, we did not propose to permit MA plans to extend adjudication timeframes for organization determinations and appeals related to Part B drug requests. We explained that our proposal to change the adjudication timeframes applies through the Part C IRE level of review. We did not propose to change how Part C appeals, whether for Part A, Part B or supplemental benefits, are processed by the Office of Medicare Hearings and Appeals (OMHA) and the Medicare Appeals Council (Council) which is housed within the Departmental Appeals Board (DAB).

Specifically, we proposed the following amendments regarding the organization determination and appeal procedures for Part B drugs:

- Add adjudication timeframes at §§ 422.568, 422.572(a), and 422.590(c) and (e)(2) for, respectively, standard organization determinations, expedited organization determinations, standard reconsiderations, and expedited reconsiderations related to coverage of Part B drugs that are the same as the timeframes for these appeal stages for Part D drugs under §§ 423.568, 423.572, and 423.590.
- Add references to determinations regarding Part B drugs to §§ 422.568(d) and (e)(4), 422.584(d), 422. 618(a) and (b), and 422.619(a), (b) and (c).
- Specify in §§ 422.568(b)(2), 422.572(a), and 422.590(c) and (e)(2) that the rules related to extending the adjudication timeframe related to requests for medical services and items (at §§ 422.568(b)(1)(i), 422.572(b) and redesignated § 422.590(f)) do not apply to the timeframes for resolving standard organization determinations, expedited organization determinations, standard reconsiderations, and expedited reconsiderations for Part B drugs.
- Make conforming changes that reference the applicable proposed timeframes and deadlines for determinations regarding Part B drugs and update cross-references in §§ 422.570(d)(1), 422.584(d)(1), and 422.618(a).
- Add a reference to an ''item'' to regulation text to clarify that the scope covers services and items at §§ 422.568(b), (d), and (e); 422.572(a) and (b), 422.590(a), (e), and (f); and 422.619(a) and (b).
- Redesignate existing regulatory paragraphs at § 422.568(b)(1) and (2) to § 422.568(b)(1)(i) and (ii), at § 422.590(c)–(f) to § 422.590(d)–(f), and at § 422.619(c)(2) to § 422.619(c)(3), without substantive change.

We explained in the proposed rule our intent to balance goals of cost savings and efficiencies with enrollee access, enhanced quality of care, and due process protections. We also solicited comments on our proposals related to organization determination and appeals timelines and processes that will be applicable to Part B drugs. Specifically, we solicited comments on our proposal to not permit MA organizations to extend the proposed timeframes for requests for Part B drugs and whether we overlooked an appeal

procedure or timeframe that should also be addressed in order to meet our goal of aligning organization determinations and appeals related to Part B drugs with the procedures and timeframes currently applicable to coverage determinations and appeals for Part D drugs under part 423. For more detail about the proposal, we direct readers to the proposed rule, 83 FR 62171 through 62174.

We explained in our proposal that, in a separate proposed rule, CMS–4185–P, entitled ''Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021'' and appeared in the **Federal Register** on November 1, 2018 (83 FR 54982), we proposed integrated grievance and appeal provisions for certain D–SNPs with aligned enrollment with Medicaid managed care plans. We also solicited comment on whether the proposed timeframes for organization determinations and appeals of coverage of Part B drugs should be incorporated into the integrated appeals procedures for certain D–SNPs.

We received 13 comments on our proposal related to organization determination and appeals timeframes for Part B drug requests:

Comment: Several commenters expressed support for the proposal to mirror Part D adjudication timeframes for Part B drug requests. Commenters stated that they appreciate CMS' efforts to clarify the appeals process and to establish greater consistency in how Part B and Part D drug requests are adjudicated. In expressing support for the adjudication timeframes for Part B drugs, one commenter stated that delays in treatment can have devastating health implications and noted that requiring plans to meet the Part D timeframe of 72 hours for standard organization determinations and 24 hours for expedited organization determinations will help ensure that these adverse outcomes are avoided.

Response: We thank the commenters for their support for this proposal. CMS believes that applying Part D adjudication timeframes to requests for Part B drugs establishes greater clarity and consistency in the coverage determination and appeals processes across the two programs. We believe the approach of applying shorter adjudication timeframes affords the most protection for beneficiaries. In addition, utilizing the timeframes that already exist in the Part D program minimizes changes to program operations for many plans since MA–PD plans are already familiar with and use the Part D timeframes.

Comment: Several commenters supported the proposed changes to the adjudication timeframes, but expressed concern that these beneficiary safeguards may not be strong enough to counter the negative effects of the proposed use of step therapy and utilization management tools. These commenters believe use of utilization management tools undermine patient access to clinically necessary and critical drugs, treatments, and therapies.

Response: We thank the commenters for sharing these concerns. CMS believes that mirroring the Part B adjudication timeframes with those shorter timeframes in Part D provides the best protection for enrollees who need a Part B drug. In all cases, the MA organization must notify the enrollee, and the physician or other prescriber involved, of its decision as expeditiously as the enrollee's health condition requires, but no later than the applicable adjudication timeframe. As we stated in the proposed rule, the rules on disclosure of utilization management requirements and individualized medical necessity determinations, coupled with the right to request an organization determination, ensure that an enrollee is informed about applicable step therapy requirements and has an opportunity for an individualized medical necessity determination related to a Part B drug step therapy requirement. Further, an MA organization has the discretion to establish an evaluation process for the appropriateness of enforcing its step therapy protocols on an enrollee when the enrollee's healthcare provider's assessment of medical necessity for the Part B drug indicates that the lower or earlier steps in the step therapy protocol are not clinically appropriate for that enrollee; this final rule does not prohibit MA organizations from working with their network providers to develop processes that eliminate the necessity for an enrollee to file a request for an organization determination in such cases. However, to the extent an MA organization develops an evaluation process for the appropriateness of enforcing its Part B step therapy protocols as described previously, the MA organization must ensure that the right of the enrollee to request an organization determination is not circumvented by such a process and that organization determination requests are processed in accordance with the requirements in Part 422, Subpart M.

Comment: Some commenters stated that they do not believe the appeals process is adequately responsive to patients with urgent treatment needs as it can be burdensome and slow for patients and their providers attempting to obtain drugs that are not on formulary. Other commenters noted concern about the complexity of the MA appeals process and how the process may be difficult for some beneficiaries to navigate. One commenter stated that the Part D appeals process is too deeply flawed to serve as a model for adopting changes to the MA appeals process for the purpose of providing protections to enrollees affected by plans' use of step therapy programs for Part B drugs. Another commenter stressed that, unlike Part D drugs, Part B drugs are almost exclusively administered to the sickest patients and require a patient to go to their doctor to receive treatment. This commenter indicated that it is critical that any request for direct access to a Part B drug that would otherwise only be available after trying an alternative drug be addressed as promptly as possible, and suggested that MA plans be required to make all decisions about Part B drugs within a 24-hour timeframe rather than a 72 hour timeframe as proposed.

Response: We thank commenters for their concerns and suggestions. We believe that application of shorter adjudication timeframes to requests for Part B drugs compared to the adjudication deadlines for other MA-covered services affords the best protection to enrollees who have an urgent need for the requested drug. As finalized in this rule, the MA organization must notify the enrollee, and the physician or other prescriber involved, of its decision regarding coverage of a Part B drug as expeditiously as the enrollee's health condition requires, but no later than 24 hours for expedited organization determination requests and 72 hours for standard organization determination requests for a Part B drug. We believe this medical exigency standard, coupled with the shorter timeframes, constitute meaningful beneficiary protections for those with urgent treatment needs. We believe that applying the same adjudication timeframes to all drug requests will increase consistency in the Part C and Part D coverage decision processes.

We disagree with the comment that every Part B drug request be adjudicated in a 24-hour period. We believe it is important to provide some flexibility in how MA plans allocate resources so that truly urgent requests are given the requisite level of consideration. As

noted in the proposed rule, we believe applying the 72-hour timeframe to standard Part B drug requests affords appropriate protection for enrollees and we reiterate that, in all cases, the plan must notify the enrollee of its decision as expeditiously as the enrollee's health condition requires. In other words, the plan must notify an enrollee of a decision even more quickly in a case where there is a medical need to do so and we expect plans to triage requests in a manner that ensures that this medical exigency standard is satisfied. In addition, under existing rules, an enrollee or a physician may request that an MA organization expedite an organization determination if an enrollee is waiting to receive a drug. For a request made by an enrollee, the MA organization must provide an expedited decision if it determines that applying the standard timeframe could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function. For a request made or supported by a physician, the MA organization must provide an expedited decision if the physician indicates that applying the standard timeframe could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

Comment: One commenter stated that they believed that the current review time for Part B drugs is appropriate and allows for adequate physician coordination of services and drugs concurrently, and that expediting the Part B determinations would pose no advantage. In a similar vein, another commenter was opposed to the proposed changes to the adjudication timeframes and noted a preference to keep timeframes for Part B and Part D distinct and separate to maintain consistency with current processes; this commenter also indicated that restricting the ability to extend the timeframes would severely constrain their capacity to obtain the necessary and appropriate information to make informed determinations, exacerbating denial rates and adding costs to plans through increased administrative burdens.

Response: We thank the commenters for sharing their perspectives, but believe that the clinical circumstances that typically accompany requests for Part B drugs warrant application of the shorter adjudication timeframes that apply in Part D. As stated in the proposed rule, applying the shorter Part D adjudication timeframes to requests for Part B drugs establishes greater clarity and consistency in the coverage determination and appeals processes across the two programs and affords appropriate protections for enrollees requesting Part B drugs, including those subject to step therapy or other utilization management requirements. In keeping with the rationale that the clinical circumstances that typically accompany requests for Part B drugs warrant application of shorter adjudication timeframes, this final rule does not permit extension of the adjudication timeframes for Part B drug requests, as is allowed for other Part B organization determinations and appeals. With respect to the comment on increased administrative burdens, we believe utilizing the timeframes that already exist in the Part D program will minimize administrative burdens and changes to program operations for many plans since MA–PD plans are already familiar with and use the Part D timeframes.

We did not receive comments specific to our solicitation regarding whether to finalize different 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. As explained below, we are finalizing provisions to require applicable integrated plans to use the same Part B organization determination and appeals timeframes set forth in this rule. CMS finalized integrated appeals procedures for certain D–SNPs with aligned enrollment with Medicaid managed care plans in the final rule CMS–4185–F, Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021. This final rule appeared in the April 16, 2019 **Federal Register** (84 FR 15680). A significant part of the rationale for finalizing certain timeframes for the unified appeals processes for certain applicable integrated plans in that final rule was to provide consistency with existing timeframes in MA appeals procedures. In order to ensure that D–SNPs using the integrated appeals procedures operate consistently with other MA plans and provide protection of shorter timeframes for decisions regarding coverage of Part B drugs, we are finalizing here regulation text to require applicable integrated plans to use the same Part B organization determination and appeals timeframes finalized in this rule. Specifically, we are finalizing here the following amendments to the noted regulations:

- In § 422.629(a), text to require applicable integrated plans to use the Part B drug rules;
- In § 422.631(a), text to specify the applicability of Part B drug rules to integrated organization determinations; and
- In § 422.633(f), text to specify the applicability of Part B drug reconsideration timelines to the integrated reconsideration process.

We note that § 422.634(d) requires that when an applicable integrated plan completely reverses its integrated organization determination involving a Part B drug, the applicable integrated plan authorize or furnish the Part B drug within 72 hours. Because the 72-hour timeframe established in § 422.634(d) applies to all integrated reconsiderations involving benefit, including Part B drugs, that were not furnished while an appeal was pending, we do not believe that any amendment or revision is appropriate to make it consistent with the amendment finalized here at § 422.618(a)(3). Therefore, we are not amending § 422.634(d).

Based on the comments we received on the proposal that requests for Part B drugs be processed under the same adjudication timeframes as used in the Part D drug program and for the reasons provided in the proposed rule and our responses to comments, we are finalizing without substantive modification the following proposed changes to the regulatory provisions at Part 422, Subpart M:

- Add adjudication timeframes at §§ 422.568, 422.572(a), and 422.590(c) and (e)(2) for, respectively, standard organization determinations, expedited organization determinations, standard reconsiderations, and expedited reconsiderations related to coverage of Part B drugs.
- Specify in §§ 422.568(b)(2), 422.572(a), and 422.590(c) and (e)(2) that the rules related to extending the adjudication timeframe for requests for medical services and items (at §§ 422.568(b)(1)(i) and 422.572(b), and at redesignated § 422.590(f), respectively) do not apply to the timeframes for resolving standard and expedited organization determinations and reconsiderations for Part B drugs.
- Make conforming changes that reference the applicable proposed timeframes and deadlines for determinations regarding Part B drugs and update cross-references in §§ 422.570(d)(1), 422.584(d)(1), and 422.618(a).
- Add a reference to an ''item'' to regulation text to clarify that the scope covers services and items at

§§ 422.568(b), (d), and (e); 422.572(a) and (b), 422.590(a), (e), and (f); and 422.619(a) and (b).

- Add references to determinations regarding Part B drugs to §§ 422.568(d) and (e)(4), 422.584(d), 422. 618(a) and (b), and 422.619(a), (b) and (c).

- Redesignate existing regulatory paragraphs at § 422.568(b)(1) and (2) to § 422.568(b)(1)(i) and (ii), at § 422.590(c)–(f) to § 422.590(d)–(f), and at § 422.619(c)(2) to § 422.619(c)(3), without substantive change.

We are finalizing § 422.572(b)(1) with a slight modification to clarify that the rule for extending the timeframe for an MA plan to make its decision only applies if an extension to the timeframe is otherwise permitted; this clarification is necessary because we are finalizing, at § 422.572(a)(2), regulation text to prohibit the extension of the 24 hour timeframe for an MA plan to decide an expedited organization determination regarding coverage of a Part B drug. In addition, we are amending §§ 422.629, 422.631(a) and 422.633(f) to adopt the same timeframes for decisions related to coverage of Part B drugs made by integrated applicable plans.

Finally, as we previously noted, CMS will incorporate the shorter adjudication timeframes for Part B drug requests into the deadlines specified in the Part C IRE's contract per § 422.592(b).

F. Pharmacy Price Concessions in the Negotiated Price (§ 423.100)

In the proposed rule, we sought comment on a potential policy approach for requiring that all pharmacy price concessions be applied to drug prices at the point of sale under Part D. We received over 4,000 comments on this potential policy approach. We thank the commenters for their detailed responses. We will carefully review all input received from stakeholders on this issue as we continue our efforts to meaningfully address rising prescription drug costs for seniors.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a ''collection of information'' requirement is submitted to the Office of Management and Budget (OMB) for review and approval. For the purposes of the PRA and this section of the preamble, collection of information is defined under 5 CFR 1320.3 of the PRA's implementing regulations. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In our November 30, 2018 (83 FR 62152) rule, we solicited public comment on our proposed information collection requirements, burden, and assumptions. As discussed in section III.B.4. of this final rule, we received comments related to our EOB burden estimates and revised our estimates as a result of those comments. We have also revised our business operations specialist-related cost estimates based on internal review (see sections III.A and III.B.5.).

A. Wage Data

To derive average costs we used data from the U.S. Bureau of Labor Statistics' (BLS's) May 2017 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/2017/may/oes_nat.htm*). In this regard, Table 2 presents the mean hourly wage, the upward adjustment to wages to account for the cost of benefits and overhead (calculated at 100 percent of salary), and the resulting adjusted hourly wage.

TABLE 2—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr.)	Benefits and overhead ($/hr.)	Adjusted hourly wage ($/hr.)
Business Operation Specialist	13–1199	$36.42	$36.42	$72.84
Pharmacist	29–1051	58.52	58.52	117.04
Software Developers and Programmers	15–1130	49.27	49.27	98.54

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. We believe that doubling the hourly wage to estimate the total cost is a reasonably accurate estimation method.

As previously mentioned, we have corrected the occupation code for business operations specialists from 13–0000 to 13–1199. The correction adds $1.88/hr. (mean) to our proposed business operations specialist-specific cost estimates and $3.76/hr. (adjusted). The cost under section III.B.5. of this final rule is affected by this change.

We are not making any changes to our Pharmacist (BLS occupation code 29–1051 at $117.04/hr.) or Software Developers and Programmers (BLS occupation code 15–1130 at $98.54/hr.) respondent types.

B. Information Collection Requirements (ICRs)

1. ICRs Regarding the Provision of Plan Flexibility To Manage Protected Classes (§ 423.120(b)(2)(vi)(C))

As described in section II.A. of this rule, the new paragraph at § 423.120(b)(2)(vi)(C) implements the authority granted to CMS by section 1860D–4(b)(3)(G) of the Act to establish exceptions that permit a Part D sponsor to exclude from its formulary (or to otherwise limit access to such a drug, including through prior authorization or utilization management) a particular Part D drug that is otherwise required to be included in the formulary. For the exception that addresses the use of prior authorization and step therapy for protected class drugs, the burden consists of the time and effort for Part D sponsors to submit their formularies to CMS under the active (or currently approved) annual submission process. The aforementioned provisions are active under OMB control number 0938–0763 (CMS–R–262) and will not impose any new or revised information collection requirements or burden.

Consequently, the provisions are not subject to the PRA.

We received no comments on our proposed information collection requirements, burden estimates, and assumptions associated with these exceptions and are finalizing them for the PA and ST exception without modification. We are not finalizing the proposed pricing threshold exception, or the proposed collection of information requirements associated with that exception.

2. ICRs Regarding the Prohibition Against Gag Clauses in Pharmacy Contracts (§ 423.120(a)(8)(iii))

This final rule codifies a ban on contract provisions that prohibit network pharmacies from informing Part D enrollees about instances where the pharmacy has a cash price for a prescribed drug that is lower than the out-of-pocket cost that would be charged to the enrollee. Since the codification will not change any existing practice and the provisions do not have any information collection implications, the provisions are not subject to the PRA. We received no comments on this assumption. As a result, we are finalizing this provision as proposed.

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

We proposed that each Part D plan sponsor adopt one or more Real Time Benefit Tools (RTBTs) that are capable of integrating with at least one e-prescribing (eRx) and electronic medical record (EMR) system(s) (the latter of which will hereinafter be referred to as an electronic health record or EHR for consistency with current Departmental terminology) for use in Part D eRx transactions beginning on or before January 1, 2020. As discussed earlier in this preamble, we understand that some PBMs and a few prescription drug plans have already begun to use RTBT tools capable of meeting the specifications listed in our preamble discussion, which includes providing beneficiary-specific drug coverage and out-of-pocket cost information at the point-of-prescribing.

After giving a high-level description of the impact of this provision (83 FR 62185 through 621877), we solicited comment on the burden for implementing this provision since we had advanced the provision with unclear costs and impacts (83 FR 62185 through 62187).

While we received a few comments relative to the collection of information requirements as initially proposed, the input was not sufficient to help us reliably quantify the burden associated with the RTBT provisions. Consequently, we continue to maintain our inability to reliably score the RTBT burden as it pertains to the PRA. In this regard we are in the process of publishing stand-alone 60- and 30-day **Federal Register** notices that will be subject to the regular non-rule PRA process. Because of the uncertainty, the purpose would be to revisit the burden issues, solicit public comment, quantify the burden, and obtain OMB approval. The RTBT requirements and burden will be submitted to OMB for approval under control number 0938–0763 (CMS–R–262). Subject to renewal, it was last approved on November 28, 2018, and remains active.

A summary of the public comments and our responses are as follows:

Comment: Some commenters stated that a growing number of plans are already using RTBT due to the savings gained from enrollees switching to cheaper drugs as a result of information provided by the RTBT.

Response: We are pleased to see that the industry is moving in this direction and appreciate the feedback confirming that our understanding was correct.

Comment: Commenters provided various estimates of the prevalence of RTBT. The range was 70 percent to 90 percent of current plans are using RTBT or could easily transition to the technology with relative ease.

Response: We thank commenters for their responses, but point out that the range in estimate makes it difficult to estimate the total plan burden for RTBT use. Additionally, prior to publication of the proposed rule, one stakeholder suggested that only 30 percent were using RTBT. This range, 30 percent to 90 percent, which includes conversations prior to publication of the NPRM as well as comments on the NPRM received during the public comment period is one part of our justification for why no impact is provided.

Comment: Several commenters and without dissenting commenters commented that existing third party software was sufficient to meet the needs of RTBT.

Response: We thank these commenters for pointing this out. Based on this comment, we are dropping our estimate of software burden since we do not expect plans to develop their own software.

We are not quantitatively scoring this provision for the following reasons: (i) As just indicated the estimates of how many plans are using RTBT is 30 percent to 90 percent, implying that between 10 percent to 70 percent will need to implement RTBT. (ii) Based on the previously presented comments, we are not assuming any plans will develop their own software. (iii–iv) Based on internal CMS data there are 1.4 billion PDEs per year. Based on conversations with industry, for large volume, the cost of transactions for RTBT would be $0.01 per transaction. (iii) However, we have no basis to ascertain how many of the 1.4 billion PDE will have RTBT applied to them. (iv) Similarly, we have no way of estimating the volume of transactions for each type of drug. Consequently, we have no reliable way of quantifying impact.

4. ICRs Regarding Part D Explanation of Benefits (§ 423.128)

The requirements and burden related to the explanation of benefits (EOB) will be submitted to OMB for approval under control number 0938–0964 (CMS–10141). Subject to renewal, the control number is currently set to expire on November 30, 2021. It was last approved on November 28, 2018, and remains active.

In accordance with § 423.128(e)(5) of this rule, sponsors will be required to include the cumulative percentage change in the negotiated price since the first day of the current benefit year for each prescription drug claim in the EOB. Sponsors will also be required to include information about drugs that are therapeutic alternatives with lower cost-sharing. The intent is to provide enrollees with greater transparency with respect to drug prices, leading to lower costs. Since plans use formularies, they already have the negotiated drug price and the lower cost alternatives in an existing information system. The cost of this provision consists of: Programming systems to calculate and connect information to the Part D EOB production, and the cost of paper, toner, and postage.

In the proposed rule, we assumed it would take 4 hours per contract at $98.54/hr. for a software programmer to link alternative prices to the EOB Model. However, commenters pointed out that there might be numerous systems to update. As a result, we are revising our 4 hour estimate to 160 hours. The change now estimates it will take two software programmers 8 hours (16 hours total) to revise 10 systems at the same hourly wage.

In the proposed rule we considered separate work for each contract. Upon internal review we now believe it is more appropriate to estimate burden by each parent organization since it is typically more efficient for major system

changes to be performed once at the parent organizational level with the contracts of that parent organization sharing the updated system.

Based on bid information and trends we expect 295 Part D Sponsors and PDP parent organizations for 2020. In aggregate, our revised one-time burden estimate for updating systems is 47,200 hours (160 hr per response × 295 responses) at a cost of $4,651,088 (47,200 hr × $98.54/hr) or $15,766 per respondent ($4,651,088/295 sponsors and organizations). Over the course of OMB's anticipated 3-year approval period, we estimate an annual burden of 15,733 hours (47,200 hr/3 years) at a cost of $1,550,363 ($4,651,088/3 years). We are annualizing the one-time labor estimate since we do not anticipate any additional burden after the 3-year approval period expires.

As discussed, commenters pointed out that there would be an added ongoing burden since EOBs would contain additional information about alternatives possibly requiring more printed pages per EOB. Based on internal bid information and projection we expect 47.6 million Part D enrollees in 2020. For our estimates of paper, toner, and postage we are adopting the same estimates that we used on April 16, 2018 (83 FR 16440) for our CY 2019 MA (Part C)/Prescription Drug Benefit (Part D) final rule (CMS–4182–F, RIN 0938–AT08) found on page 16695. However, we are revising the postage rate to the updated 2019 bulk mailing rates. Although our regulations allow electronic submission of Part D EOBs upon request, informal communication from stakeholders indicates small usage. We are therefore assuming mailings to all enrollees. Since we do not require first class postage for Part D EOBs, we are assuming that Part D sponsors will use the least expensive option, namely, the use of bulk mailing rates. We also assume that the added information about alternatives is not started on a separate page as that could be costly; accordingly we assume the current Part D EOB on average ends mid-page and that adding 1–2 pages would on average add 1.5 pages of print requiring at most 1 page of paper (since the other half page of print would go on an already printed page). Furthermore, we assume that the Part D EOB is double-sided. In some cases the extra 1.5 pages may fit on the last printed page and on its other side not necessitating more paper. Bulk mailing rates vary by vendor; an informal survey on the web suggests $0.19 for 2019 rates for 50 pounds (envelope weight is normally considered negligible when citing these rates). Other assumptions are possible but the main drivers of our added cost are paper and toner as opposed to postage. The following breaks down those costs:

- Paper costs $0.005 per sheet ($2.50 for a ream of paper with 500 sheets).
- Toner costs $0.005 per sheet ($50 for a toner cartridge lasting 10,000 sheets).
- Postage costs are $0.000038 per page since—

++ A sheet of paper weights 0.16 ounces (5 pounds/500 sheets × 16 ounces/pound).

++ Commercial bulk postage rates for 2019 are $0.19 for 200 pieces (50 pounds).

++ There are 16 ounces in one pound.

++ Postage cost per page is therefore $0.000038 ([$0.19 × 0.16 ounces per page]/[50 pounds × 16 ounces/pound]).

Thus, the total cost per page is $0.010038 ($0.005 for paper + $0.005 for toner + $0.000038 for postage). Finally, we note that Part D EOBs are sent out once per month to each enrollee summarizing drug transactions for the previous month. Thus we estimate an annual cost of $5,733,706 (47.6 million enrollees × 12 months × 1 page × $0.010038 per page). We believe that after appropriate programming (as discussed previously) the 47.6 million mailings will be performed automatically and will not require extra staff time.

Combining the estimates for system updates and mailing we obtain an annual estimated cost of $7,284,069 ($1,550,363 for updating systems + $5,733,706 for paper, printing, and mailing)

A summary of the public comments and our response follow:

Comment: Commenters disagreed with our burden analysis. They pointed out that multiple systems would have to be updated and disagreed with our estimates regarding template creation. Finally, one sponsor provided a $4.5 million estimate for set-up costs and a $6 million dollar estimate for mailing.

Response: We thank the commenters for this insight. Based on these comments, we revised our estimated time for sponsors to update their systems. Also, we note that our revised estimate assumes Part D sponsors will update their systems to obtain information for the template. Finally, our estimates for initial costs are $4.7 million for system updates $5.7 million for mailing costs. Our estimates, which were independently developed, are very close to the proposed impacts provided by the commenter.

5. ICRs Regarding 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)

The requirements and burden related to the establishment and use of a P&T Committee will be submitted to OMB for approval under control number 0938–0964 (CMS–10141). Subject to renewal, the control number is currently set to expire on November 30, 2021. It was last approved on November 28, 2018, and remains active.

This rule provides protections to help ensure that beneficiaries maintain access to medically necessary Part B drugs while permitting MA plans to implement step therapy protocols that support stronger price negotiation and cost and utilization controls. In order to implement a step therapy program for one or more Part B drugs, this rule requires that an MA plan establish and use a P&T Committee to review and approve step therapy programs used in connection with Part B drugs. The P&T Committee requirements are similar to the requirements applicable to Part D plans under § 423.120(b). This rule allows MA–PD plans to use the Part D P&T Committee to satisfy the new requirements related to MA plans and Part B drugs. For MA plans that do not cover Part D benefits already, they may use the Part D P&T Committee of an MA–P&D plan under the same contract. Under § 422.4(c), every MA contract must have at least one plan offering Part D. Because of the small amount of work needed annually, we believe it is reasonable to assume that no new committees will be formed and that the added work will be performed by the existing P&T Committees.

The finalized § 422.136(b)(4) and (9) requires that the P&T Committee ''clearly articulate and document processes,'' We estimate it would take 1 hour at $72.84/hr. for a P&T Committee business specialist to perform certain tasks and review and retain documentation and information. This 1 hour estimate reflects half of the Part D P&T Committee burden (or 2 hours) that is currently approved by OMB under control number 0938–0964 (CMS–10141). We are estimating 1 hour since the MA P&T committee work for Part B step therapy programs is significantly less than the Part D P&T committee work; more specifically; per Section 30.1 of Chapter 6 of the Prescription Drug Benefit Manual,[16] the Part D P&T committee work has seven tasks, two of which, namely, formulary management

[16] *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf.*

and formulary exceptions, do not apply to the mandatory MA P&T committee work. The MA P&T committee work, under finalized § 422.136, is limited to review and approval of step therapy programs for Part B drugs (and not other types of utilization management programs). We lack quantitative data on the amount of work attributed to each of the seven tasks of the Part D P&T committee work. Therefore, we assumed a 50 percent reduction in the amount of work since two of the seven Part D P&T committee tasks are not required under Part B. In aggregate, we estimate an annual burden of 634 hours (1 hr. × [697 plans − 63 Prescription Drug plans which do not offer Part B]) at a cost of $46,181 (634 hr. × $72.84/hr.).

We received no comments on our proposed requirements and burden analysis and are finalizing this provision without modification.

We are also finalizing, without modification, our proposed beneficiary protection measure related to shorter adjudication timeframes for organization determinations and reconsiderations for requests for Part B drugs. Under this final rule, the adjudication timeframes applicable to requests for Part B drugs will, as proposed, be shorter than the timeframes that apply to requests for other covered medical items and services. At the time of the proposed rule's publication date (November 30, 2018) we did not finalize the necessary revisions to our Notice of Denial of Medical Coverage form and instructions (approved by OMB under control number 0938–0892; CMS–10003). Therefore, we did not set out such burden or solicit comment. Since that time, however, we have published a stand-alone 60-day **Federal Register** notice (April 10, 2019; 84 FR 14383) that sets out the revised form and form instructions. In compliance with the standard PRA process, we will also be publishing a stand-alone 30-day **Federal Register** notice (when ready). Please note that the revised form and instructions have no impact on this rule's burden estimates. Instead, the revision would include the Part B drug adjudication timeframes within the form and update the CFR citations within the instructions.

C. Summary of Information Collection Requirements and Burden

TABLE 3—ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulatory reference	Provision brief title	Control No. (CMS ID No.)	Respondents	Total responses	Hours per respondent	Total hours	Labor cost ($/hr)	Total annual cost ($)
§ 423.128	Part D Explanation of Benefits (Updating Systems).	0938–0964 (CMS–10141)	295	295	160	15,733	$98.54	$1,550,363
§ 423.128	Part D Explanation of Benefits (Extra mailings) *.	0938–0964 (CMS–10141)	295	571,200,000	n/a	n/a	n/a	*5,733,706
§§ 422.136, 422.568, 422.570, 422.572, 422.584, 422.590, 422.618, and 422.619.	Part B Step Therapy (use of PT Committee).	0938–0964 (CMS–10141)	634	634	1	634	72.84	46,181
Total			634	571,200,929	Varies	16,367	Varies	7,330,250

*Non-labor requirements and costs.

IV. Regulatory Impact Analysis

A. Statement of Need

This final rule supports Medicare health and drug plans' negotiation for lower drug prices and reduce out-of-pocket costs for Part C and D enrollees. Although satisfaction with the MA and Part D programs remains high, these proposals are responsive to input we received from stakeholders while administering the programs, as well as through our requests for comment.

HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (May 16, 2018, 83 FR 22692) sought to find out more information about lowering drug pricing using these four strategies: Improved competition, better negotiation, incentives for lower list prices, and lowering out-of-pocket costs. We proposed a number of provisions that implement these four strategies in an attempt to lower out-of-pocket costs with a particular focus on strengthening negotiation for Part D plans and increasing competition in the market for prescription drugs. We proposed to offer more tools to MA and Part D plans that negotiate with drug companies on behalf of beneficiaries, so these plans are equipped with similar negotiation capabilities as group health plans and issuers have in the commercial market. We sought to drive robust competition among health plans and pharmacies, so consumers can shop based on quality and value. These provisions align with the Administration's focus on the interests and needs of beneficiaries, providers, MA plans, and Part D sponsors.

B. Overall Impact

We examined the impact of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act (the Act), section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

The RFA, as amended, requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions.

This final rule affects MA plans and Part D sponsors (NAICS category 524114) with a minimum threshold for small business size of $38.5 million (*http://www.sba.gov/content/small-business-size-standards*). This final rule additionally affects hospitals (NAICS subsector 622) and a variety of provider categories, including physicians, specialists, and laboratories (subsector 621).

To clarify the flow of payments between these entities and the federal government, note that MA organizations submit bids (that is, proposed plan designs and projections of the revenue

needed to provide those benefits, divided into three categories—basic benefits, supplemental benefits, and Part D drug benefits) in June 2019 for operation in contract year 2020. These bids project payments to hospitals, providers, and staff as well as the cost of administration and profits. These bids in turn determine the payments from the Medicare Trust Fund to the MA organizations that pay providers and other stakeholders for their provision of covered benefits to enrollees. Consequently, our analysis will focus on MA organizations.

There are various types of Medicare health plans, including MA plans, Part D sponsors, demonstrations, section 1876 cost plans, prescription drug plans (PDPs), and Program of All-Inclusive Care for the Elderly (PACE) plans. Forty-three percent of all Medicare health plan organizations are not-for-profit, and 31 percent of all MA plans and Part D sponsors are not-for-profit. (These figures were determined by examining records from the most recent year for which we have complete data, 2016.)

There are varieties of ways to assess whether MA organizations meet the $38.5 million threshold for small businesses. The assessment can be done by examining net worth, net income, cash flow from operations, and projected claims as indicated in their bids. Using projected monetary requirements and projected enrollment for 2018 from submitted bids, 32 percent of the MA organizations fell below the $38.5 million threshold for small businesses. Additionally, an analysis of 2016 data—the most recent year for which we have actual data on MA organization net worth—shows that 32 percent of all MA organizations fall below the minimum threshold for small businesses.

If a final rule may have a significant impact on a substantial number of small entities, the final rule must discuss steps taken, including alternatives, to minimize burden on small entities. While a significant number (more than 5 percent) of not-for-profit organizations and small businesses are affected by this final rule, the impact is not significant. To assess impact, we use the data in Table 11C, which show that the raw (not discounted) net effect of this final rule over 10 years is $73.19 million. Comparing this number to the total monetary amounts projected to be needed just for 2020, based on plan submitted bids, we find that the impact of this final rule is significantly below the 3 to 5 percent threshold for significant impact. Had we compared the 2020 impact of the final rule to projected 2020 monetary need, the impact will be still less.

Consequently, the Secretary has determined that this final rule will not have a significant economic impact on a substantial number of small entities, and we have met the requirements of the RFA. In addition, section 1102(b) of the Act requires us to prepare a regulatory analysis for any final rule under title XVIII, title XIX, or Part B of Title XI of the Act that may have significant impact on the operations of a substantial number of small rural hospitals. We are not preparing an analysis for section 1102(b) of the Act because the Secretary certifies that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of UMRA also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2019, that threshold is approximately $154 million. This final rule is not anticipated to have an effect on state, local, or tribal governments, in the aggregate, or on the private sector of $150 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this final rule does not impose any substantial costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

If regulations impose administrative costs on reviewers, such as the time needed to read and interpret this final rule, then we should estimate the cost associated with regulatory review. There are currently 750 MA contracts (which also includes PDPs), 50 State Medicaid Agencies, and 200 Medicaid Managed Care Organizations (1,000 reviewers total). We assume each entity will have one designated staff member who will review the entire rule. Other assumptions are possible and will be reviewed after the calculations.

Using the wage information from the Bureau of Labor Statistics (BLS) for medical and health service managers (code 11–9111), we estimate that the cost of reviewing this rule is $107.38 per hour, including an upward adjustment to wages to account for overhead and benefits. (*http://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it will take approximately 7.6 hours for each person to review this final rule. For each entity that reviews the rule, the estimated cost is therefore, $816 (7.6 hours * $107.38). Therefore, we estimate that the total cost of reviewing this regulation is $816,000 ($816 * 1000 reviewers).

Note that this analysis assumed one reader per contract. Some alternatives include assuming one reader per parent entity or assuming (major) pharmacy benefit managers (PBMs) will read this rule. Using parent organizations instead of contracts will reduce the number of reviewers to approximately 500 (assuming approximately 250 parent organizations), and this will cut the total cost of reviewing in half. However, we believe it is likely that reviewing will be performed by contract. The argument for this is that a parent organization might have local reviewers; even if that parent organization has several contracts that might have a reader for each distinct geographic region, to be on the lookout for effects of provisions specific to that region.

As for PBMs, it is reasonable that only the major PBMs will review this rule. There are 30–50 major PBMs, and this will increase the estimate by 0.3 to 0.5 percent. Reviewing the source of comments on the proposed rule, we find about 300 distinct organizations commenting including health plans, universities and colleges, congressional-related entities, patient-centered associations, medical associations, pharmaceutical companies and manufacturers. Considering the wide source of comments and the wide use of drugs it is very reasonable that the total number of associations reading this is comparable to the number of health plans. This would double our estimate. Using these alternate considerations, we can safely say that the cost of reviewing is between half a million (50 percent * $816,000) and two million (2 * $816,000). Thus, we consider the $1 million a reasonable midpoint figure to estimate review cost.

In accordance with the provisions of Executive Order 12866, this rule was reviewed by the Office of Management and Budget (OMB).

We received no comments on our estimates of impact on small businesses and other items mentioned in the overall impact section.

C. Anticipated Effects

1. Providing Plan Flexibility To Manage Protected Classes (§ 423.120(b)(2)(vi))

In this rule, we are finalizing an exception to the protected class policy to allow Part D sponsors to apply PA and ST requirements for protected class

Part D drugs, except antiretrovirals, only for new starts to confirm intended use is for a protected class indication, and to ensure clinically appropriate use, promote utilization of preferred formulary alternatives, or a combination thereof, subject to CMS review and approval. We also are finalizing a technical change to permit exclusion of interchangeable biological products.

Since under this exception, these utilization management tools (that is, PA and ST for new starts only, except for antiretrovirals) are already permitted today under similar circumstances for the protected classes for new treatment regimens, we do not anticipate any material impacts from the use of these tools for the five classes where it will be allowed. For antiretroviral drugs, we do not believe that utilization management would generate returns for plan sponsors' increased administrative burden, as these drug have narrower indications, clinical criteria, and range of products that curtail inappropriate use. As a result, we estimate no material impact from this provision as well.

Formally recognizing Part D sponsors' utilization management flexibility provides them with negotiating power. Additionally, utilization management will promote substitution when appropriate and reduce wasteful or inappropriate prescriptions. For example, if an antipsychotic drug is prescribed to a beneficiary and the beneficiary does not have a protected class indication that requires such a drug, these additional tools will allow Part D sponsors to better manage utilization of that drug. We did not assume any interactions with Part D sponsors' ability to use indication-based coverage, as no experience on that coverage is currently available.

At this time, we do not anticipate any adverse effects upon enrollee access to drugs in the protected classes. The reasons for this are two-fold. First, we did not propose to change or remove any of the protected classes identified in section 1860D–4(3)(G)(iv) of the Act. Second, in considering whether exceptions to the added protections afforded by the protected class policy are appropriate, we took into account the many other enrollee protections in the Part D program, which are mature and have proven workable. These protections include: Formulary transparency, formulary requirements, reassignment formulary coverage notices, transition supplies and notices, and the expedited exception, coverage determination, and appeals processes.

Comment: Commenters generally agreed with our assessment of the impact of this provision. One commenter questioned why the impact analysis in this final rule sees more generic opportunity in the protected classes than MedPAC.

Response: While MedPAC has cited that the overall level of generic use in the antidepressant, antipsychotic, and anticonvulsant categories was similar to the overall generic use within Part D, our analysis of the drug level data using internal CMS files, on which MedPAC has not specifically commented, indicated that there was significant brand usage with the potential to shift to generic drugs under new utilization management practices. Comparing class-level generic use against overall generic use can also be misleading, as the availability of generics differs widely from class to class and over time.

Comment: Several commenters suggested that the estimated savings from these proposals were too limited to justify modifications to the protected classes policy.

Response: We disagree. While we are not finalizing modifications to the existing policy (but codifying existing policy), we continue to believe that it is possible that certain Part D sponsors may be able to use additional flexibility to improve their negotiating position and/or the effectiveness of their utilization management actions, thereby producing savings that we will not be able to quantify until after the policy takes effect. Additionally, we believe it is incumbent upon us to be a good steward of taxpayer dollars, no matter how modest the savings.

Comment: Some commenters encouraged us to consider manufacturer rebates across other Federal programs, including Medicaid, the VA and the 340B Drug Pricing Program (340B) before implementing our exceptions.

Response: While we appreciate the commenters' concerns, we are unable to quantify savings to the Part D program taking other Federal programs into account. Additionally, specific to 340B, with the exception of claims split-billed through AIDS Drug Assistance Programs (ADAPs), CMS does not collect information on which claims were processed under 340B.

Comment: A number of commenters expressed concern that PA and ST policies can lead to patients' not filling their prescriptions or underutilizing medications, which leads to non-adherence. Commenters expressed concern that non-adherence, in turn, can lead to interruptions in therapy across the six classes, and in the case of HIV, would endanger public health because it is a communicable disease which can rapidly mutate and become resistant to therapy.

Response: CMS acknowledges that PA and ST could potentially cause the issues cited when they are not implemented properly. However, we believe that based upon our more than 12 years of experience with the Part D program, including our existing policy, which allows for PA and ST for new starts of protected class Part D drugs (except antiretrovirals), and the unique protections we have in place, which are more robust than in other comparable programs, demonstrate that such concerns have been mitigated in Part D. For example, in the categories and classes of drugs not covered by the protected class policy, that is, all other Part D drug categories and classes, where wide use of PA and ST have been allowed since the beginning of the Part D program, subject to our other formulary requirements, we have no evidence to suggest that Part D enrollees routinely experience interruptions in therapy as a result of PA and ST requirements. Moreover, CMS is advancing improvements in price transparency, interoperability, and e-prescribing improvements, such as a real-time benefit tool (RTBTs) and Part D electronic prior authorization as required by section 6062 of the SUPPORT for Patients and Communities Act (Pub. L. 115–271), that could help mitigate the kinds of administrative burdens sometimes associated with PA and ST that commenters claim could lead to underutilization. As such, we did not account for any decreases in utilization in our estimate.

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

This provision proposed to codify existing practice and therefore is expected to produce neither savings nor cost.

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

This provision proposed that each Part D plan sponsor adopt one or more Real Time Benefit Tool (RTBT) tools that are capable of integrating with at least one e-prescribing (eRx) and electronic health record (EHR) systems (the latter of which will hereinafter be referred to as an electronic health record or EHR for consistency with current Departmental terminology) for use in Part D E-Prescribing (eRx) transactions beginning on or before January 1, 2020. As discussed earlier in this preamble, we understand that some PBMs and a few prescription drug plans have already begun to use RTBT tools capable of meeting the specifications listed in

our preamble discussion, which includes providing beneficiary-specific drug coverage and out-of-pocket cost information at the point-of-prescribing. CMS sought to accelerate the use of such real time solutions in the Part D program so as to realize their potential to improve adherence, lower prescription drug costs, and minimize beneficiary out-of-pocket cost sharing. These tools have the capability to inform prescribers when lower-cost alternative therapies are available under the beneficiary's prescription drug benefit. We are interested in fostering the use of these real-time solutions in the Part D program, given their potential to lower prescription drug spending and minimize beneficiary out-of-pocket costs. Not only can program spending and beneficiary out-of-pocket costs be reduced, but (as discussed above) evidence suggests that reducing medication cost also yields benefits in patients' medication adherence.

We first give a high-level description of impact. The major savings of this provision will be use of RTBT to encourage prescribing of lower tier cost sharing drugs. This will result in a dollar savings to the Medicare Trust Fund. However, because of both lack of data and complexity of data, we are qualitatively scoring this provision and are therefore scoring this provision as a qualitative savings. In the NPRM we solicited comments from stakeholders on certain data. In response to our solicitation, the following assumptions and complications were pointed out:

- Current usage: Commenters confirmed our belief that some plans are already using RTBT. Commenter estimates ranged from 70 percent to 90 percent. Informal conversations with plans prior to publication of the NPRM provided an estimate of 30 percent. This combined wide range, 30 percent to 90 percent, shows both that RTBT is being adopted, that there is uncertainty on the extent of adoption.
- Cost if this Provision is Finalized:

Software costs: Commenters seem to reject the idea that any plans would create their own RTBT software. They believe that the existing opportunities from intermediaries was sufficient to satisfy new regulatory requirements. As a result of these comments, we are withdrawing in the Final Rule the estimates made in the NPRM on software costs.

Developing substitution logic. Many commenters cautioned that development of the logic to determine which formulary alternatives should be presented to a prescriber in a given situation will impose new burdens on plans. While IT programming can be leveraged across plans variable formularies require that each plan develop its own individual logic about which alternative drugs are available for use in RTBT scenarios. Plans must decide how many potential formulary substitutions should be presented to prescribers and must ensure that the prescriber is not overly burdened with choices.

Lower tier cost sharing substitution: CMS believes the primary source of RTBT savings to arise from the ability of providers to prescribe lower tier cost sharing drugs. While there are also savings from substitutions of generics for brands, many of these substitutions already are currently already being done by pharmacy benefit administrators. The commenters generally agreed with this assessment.

- Implementation date and Standardization:

We received numerous comments relating to the proposed January 1, 2020 implementation date. Although several commenters stated that the 2020 deadline was achievable, the majority of comments expressed concern. Most commenters, believe that it would be prudent to delay the implementation date until an industry standard was available with some commenters characterizing the proposed time frame as overly aggressive or unrealistic given the level of effort required to implement RTBT.

We understand that implementing RTBT requires time and resources for those plans that have not yet begun to implement a real time solution As a result, we are delaying the implementation date until January 1, 2021. However, given the potential benefits of RTBT, we strongly encourage plans to start implementing this requirement prior to January 1, 2021.

- Cost to providers: Some commenters were concerned about the cost of implementing multiple RTBT systems within EHRs. However, other commenters made it clear that plans who have implemented RTBT make the technology available to prescribers at no cost. Some commenters cautioned that RTBT may add time to a medical office visit but did not specify the potential cost impact of the additional time involved. Others commenters stated that while RTBT may add time to a medical office visit, it may provide enhanced benefits in terms of patient adherence to medication therapies which may save time in the long run. These divergent views left us unable to gain a definitive picture whether providers are negatively affected by the finalized provision. As a result, we lack data with which to reliably estimate and include provider costs in our analysis of the impact of this proposal.

CMS further notes that most plans are already making sure that prescribers are not bearing the cost of implementing RTBT tools. Indeed RTBT systems are being implemented by some plans because of the resulting cost savings.

- Savings vs Cost: Nearly all commenters were very enthusiastic about the concept of the proposed provision. They largely believed that any implementation costs incurred would be offset by costs savings. One commenter who has been using RTBT for about a year and noted that when presented with a lower cost, clinically appropriate alternatives, enrollees are receiving a lower cost medication 45 percent of the time, and saving an average of $130 per fill in out of pocket costs compared to the drug originally requested. CMS is unable to confirm these savings but these reported results suggest that RTBT can be instrumental in reducing drug costs. We recognize that it may take plans time to develop an RTBT infrastructure such as developing formulary alternatives and relationships with RTBT vendors.

We are finalizing the proposal for each Part D plan to support an RTBT of its choosing, effective January 1, 2021. We are removing the proposed requirement that covered health care providers get explicit beneficiary consent prior to using the RTBT.

We point out that any savings arising from this provision if finalized would be classified as a transfer since there is (at least as a primary impact) no reduction in consumption of goods (prescription drugs) but rather a transfer of expense from one drug to another. However, this transfer (between manufacturers of drugs) would result in reduced dollar spending by Part D Sponsors and enrollees and would result in reduced spending by the Medicare Trust Fund.

4. Part D Explanation of Benefits (§ 423.128)

In section III. of this final rule, we have detailed the cost to Part D sponsors to update their EOB templates. Additionally, CMS Central Office staff will have to develop the model language to be used by the Part D sponsors.

Significant effort goes into developing a model, including developing instructions and obtaining clearance. Therefore, we estimate that it would take two GS–13-Step 5 employees a month, each working a half a day, or 160 hours (2 employees * 4 hours a day * 5 days a week * 4 weeks) to develop the templates. It would additionally take a supervisory GS–15 staff, 5 hours to give approval.

Wages for 2018 for CMS staff may be obtained from the OPM website at *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2018/DCB_h.pdf.* We estimate a total burden of $17,583 (160 hours * $52.66/hr for GS–13, Step 5 staff * 2 ((for an upward adjustment to wages to account for overhead and benefits)).) + 5 hours * $73.20/hr for GS–15, Step 5 staff * 2 (for an upward adjustment to wages to account for overhead and benefits)).

As estimated in the Collection of Information Section of this Final Rule, the Part D EOB incurs a first year cost of $4.65 million for updating systems and ongoing costs in all years, including the first, of $5.73 million for additional mailings. Thus the total first year cost is $10.40 million (4.65+5.73+0.18 (the $17,583 cost for CMS staff to create a template)) and cost in subsequent years is $5.73 million.

5. Medicare Advantage and Step Therapy for Part B Drugs (§§ 422.136, 422.568, 422.570, 422.572, 422.584, 422.590, 422.618, 422.619, 422.629, 422.633 and 422.634)

Step therapy is a type of utilization management (for example, prior authorization) for drugs that begin medication for a medical condition with the most preferred drug therapy and progress to other therapies only if necessary, promoting more cost effective therapies, potentially better clinical decisions, and lower costs for treatment. The lower costs of treatment primarily benefit MA enrollees and plans and are transferred to the government as savings.

A further source of savings is negotiations. If an MA plan offers all Part B drugs, then it typically will purchase drugs at market price. If the MA plan is allowed to use step therapy, then when there is more than one drug that has the same effect on a medical condition but the drugs differ significantly in price, drug manufacturers in their negotiations with MA plans, have an incentive to lower the cost of their drug so that their drug is selected by the MA plan as the first drug in the plan's step therapy protocol.

However, it is difficult to numerically estimate the savings from increased negotiations because, unlike other impact events, negotiations vary. Furthermore, we do not have access to negotiation data as this is proprietary information between MA plans and manufacturers and is not submitted in the MA bid. For these two reasons (lack of data and volatility) we are leaving the negotiation of increased savings as a qualitative, rather than a quantitative event. We believe that the potential savings from negotiations is significant, but have no way of quantifying the effect.

We note that although we are not estimating the savings from front-end negotiations, we do estimate the savings from back-end negotiations, more specifically, from the rebates manufacturers give plans with favorable drug management practices. Such rebates also occur on the Part D side and we have the data to estimate their effect. This is done in this section of this final rule when discussing the impact on the Medicare Trust Fund and beneficiary cost sharing due to step therapy.

Although CMS believes that step therapy can promote more cost effective therapies, potentially better clinical decisions, and lower costs for treatment for the reasons earlier discussed, we acknowledge that there are various studies suggesting that step therapy may be costly either economically or health-wise. There are two primary reasons for this.[17]

- Discontinuation: Several studies show that there is the potential for enrollees to become discouraged when step therapy is used. This is called discontinuation. Discontinuation means a portion of members with a claim rejection at the point of service go on to not have claims in that class of medications. In other words, an unwanted effect of step therapy is ''giving up'' and not seeking medical treatment. There are several studies of discontinuation.[18] Consequently, when discussing step therapy, it is important to address possible unwanted side effects such as discontinuation.
- Effects of delay: The idea of step therapy is that if the initial drug ''fails first'' then a provider will prescribe the drug they had originally wanted to prescribe. However, when the initially given drug does not work, this creates a delay in the patient receiving the necessary drug and consequently the delay may cause both a worsening of conditions and increased medical costs. Several studies on Part B drugs show this. For example, a study comparing spending in Georgia's Medicaid program found that while there were savings in the cost of medications when step therapy was used, the program spent more money on outpatient services because less-effective medications often led to higher health costs later.[19] Similar studies have been done on— legislation to protect people from certain harms of step therapy.[20] However, the MA program has many beneficiary protections and a robust appeals process to ensure that beneficiaries have access to the medications and health services they need. For example, we expect providers and enrollees who are concerned about the adverse effects of delay or that a drug on the initial step may not be the best or proper course of treatment, to seek pre-service organization determinations that permit use of the ultimate Part B drug and to appeal any denials by the MA plan. Since plan appeal rates are monitored by CMS, this creates a strong incentive for plans to use step therapy wisely and not exacerbating illness.

Summary: Step therapy can result in both savings and costs. While at the time of initiation of the step therapy there is initial savings arising from reduced drug costs, this savings may end up costing in the long run because of worsening conditions arising from the delay in receiving the proper drug resulting in increased medical costs. However, we believe the MA beneficiary protections and appeals process coupled with periodic CMS review and monitoring of MA plans is robust enough to ameliorate or eliminate the possible adverse effects of step therapy.

In addition to the complications in estimating the health savings from step therapy, some step therapy savings arise from negotiations, which are difficult to quantify. We can however, estimate the effect on the Medicare Trust Fund and on enrollee cost sharing.

The estimate of the impact on the Medicare Trust Fund includes the—(1) backend negotiations, rebates from manufacturers to plans; (2) use of less

[17] Article 1: Patrick P Gleason, PharmD, FCCP, BCPS, ''Assessing Step Therapy Programs: A step in the right direction,'' Journal of Managed Care Pharmacy, 13(3), 2007. Article 2: Adams AS, Zhang F, LeCates RF, et al. Prior authorization for antidepressants in Medicaid: Effects among disabled dual enrollees. Arch Intern Med. 2009; 169(8):750–756. Article 3: Zhang Y, Adams AS, Ross-Degnan D, Zhang F, Soumerai SB. Effects of prior authorization on medication discontinuation among Medicaid beneficiaries with bipolar disorder. Psychiatr Serv. 2009; 60(4):520–527.

[18] S. Shoemaker, R. Subramanian, D. Mauch, (Abt Associates). ''Effect of 6 Managed Care Pharmacy Tools: A Review of the Literature,'' Journal of Managed Care Pharmacy, Supplement, July 2010, Vol 16(6a), page s7.

[19] Retrospective assessment of Medicaid step therapy prior authorization antipsychotic medications. Clin Ther. 2008; 30(8):1524–39; discussion 1506–7. doi: 10.1016/j.clinthera.2008.08.009.

[20] Iowa passed a rule restricting the use of Step Therapy in Medicaid after patients encountered medical complications such as stomach ulcers and increased pain in cases where past efforts to find more cost-effective drugs or to try lower priced drugs were not considered by the plans. See *https://www.thegazette.com/subject/news/health/iowa-bill-would-allow-exemptions-from-fail-first-insurance-drug-practices-20170318.* In the absence of safeguards, such as requiring consideration of what works for patients, a grandfathering policy on existing therapies is advisable.

expensive biological products approved under section 351(k) of the Public Health Service Act (for example, biosimilars); and, (3) the choice of less expensive drugs with therapeutically equivalent effect. However, we do not discuss other quantitative effects of step therapy. The articles cited previously lay out many pros and cons of step therapy as well as the need for more studies to ascertain the true impact of step therapy.

CMS acknowledges that step therapy is a widely accepted tool for utilization management. Sixty percent of commercial insurers were using step therapy in 2010; in 2014, 75 percent of large employers offered enrollees plans with step therapy. Furthermore, the concerns expressed in this RIA section are not unique to Federal insurance programs such as Medicare Parts C and D. Eighteen states have enacted laws on the use of step therapy.[21] These laws vary widely and typically provide protections to beneficiaries against the misuse of step therapy.

TABLE 4—ESTIMATED SAVINGS TO MEDICARE TRUST FUND AND BENEFICARIES FROM STEP THERAPY

Year	Enrollment (thousands)	Part B Rx allowed pmpm with growth by medical inflation	Number of months per year	Adjustment for plans for proposed step therapy (%)	Assumed rebate percentage	Backing out of Part B premium (%)	Savings to medicare trust funds	Cost sharing percentage	Adjustment for enrollees for proposed step therapy (%)	Savings to beneficiaries
	(A)	(B)	(C)	(D)	(E)	(F)	(G) ($ millions)	(H)	(I)	(J) ($ millions)
							(G) = (A) * (B) * (C) * (D) * (E) * (F)			(J) = (A) * (B) * (C) * (H) * (I)
2020	23,181	$58.72	12	1.6	66	86	$145	13	0.2	$5
2021	24,062	60.21	12	1.6	66	86	154	13	0.2	5
2022	24,972	61.73	12	1.6	66	86	164	13	0.2	5
2023	25,858	63.30	12	1.6	66	86	174	13	0.2	6
2024	26,708	64.90	12	1.6	66	86	185	13	0.2	6
2025	27,549	66.55	12	1.6	66	86	195	13	0.2	6
2026	28,375	68.23	12	1.6	67	85	207	13	0.2	7
2027	29,161	69.96	12	1.6	67	85	218	13	0.2	7
2028	29,913	71.74	12	1.6	67	85	229	13	0.2	7
2029	30,590	73.55	12	1.6	67	85	240	13	0.2	8

The provision at § 422.136 will allow MA plans to use this utilization management tool for Part B drugs subject to some limits in the regulation. MA plans may explore the most effective ways to use step therapy to achieve savings while also ensuring access to medically necessary treatment options.

In the remainder of this section we estimate the impact on the Medicare Trust Fund and enrollee cost sharing, and explain the calculations which are summarized in Table 4.

We obtained projected MA enrollment from the 2018 Medicare Trust Fund report. This is presented in Column (A) of Table 4.

- 2016 is the most recent year for which we have Part B drug spending and utilization from the CMS data systems. Column (B) presents the average amount that MA enrollees pay per month on Part B drugs. This amount is trended (from 2016) to reflect medical inflation (5.2 percent a year) with ordinary inflation (2.6 percent) carved out. The inflation factors are obtained from the Medicare Trust Fund report. The product of MA enrollment and average Part B spending per month provides the aggregate MA Part B spending per month.
- The Part B spending per month is multiplied by 12 (Column (C)) to obtain the aggregate spending on Part B drugs annually.
- We estimate that, because of this step therapy provision, plans will save 1.6 percent (Column (D)) on the aggregate annual cost of Part B drugs. There are several points about this 1.6 percent. First, it represents the effect of the proposed provision (proposed § 422.136) in this final rule. As discussed earlier in this rule's preamble, an HPMS memo was issued by CMS in August 2018 rescinding an earlier memo prohibiting step therapy.[22] However, because this memo was published in late 2018, we do not have enough data to analyze the impact to 2019 claims at this point, so our estimate of 1.6 percent is based on prior experience. The 1.6 percent savings is independent, and not impacted, by the provisions in the August 2018 HPMS memo; rather, the 1.6 percent savings represents the estimated effects of the finalized provision versus a baseline (zero percent savings) which does not include the proposed provision nor the effects of the HPMS memo.

This finalized proposal surpasses the HPMS memo for periods beginning January 1, 2020 and it is the effects of this provision that the 1.6 percent captures. The 1.6 percent represents three factors contributing to savings from Step Therapy:

- Drugs for which there will be a less expensive biological product approved under section 351(k) of the Public Health Service Act in 2020, such as Remicade or Herceptin.
- Pairs of drugs which are clinically comparable but differ significantly in price. For example, Avastin®, Eylea®, and Lucentis® for the treatment of macular degeneration.
- Drugs for which the manufacturer gives a rebate to MA plans with favorable management patterns. This happens in drugs with sufficient competition, particularly in the treatment of rheumatoid arthritis. Using our experience on manufacturers providing rebates on Part D drugs, we are able to estimate the savings effects of similar rebates on Part B drugs. As mentioned previously, this corresponds to a savings in step-therapy from back-end negotiations.
- The multiplication of enrollment, average Part B cost per member per month, number of months per year and 1.6 percent represents the total dollar savings from this provision.
- We use this total dollar savings to estimate separately savings to the Medicare Trust Fund and savings to enrollees in cost sharing.
- To obtain savings to the Medicare Trust Fund we multiply the aggregate savings from step therapy by the average rebate percentage and the average backing out of part B premium representing the expected percentage reduction to Part B premium arising from savings. These percentages are found in Columns (E) and (F). The numbers in these columns are obtained by trending our experience with plan

[21] *https://www.aad.org/advocacy/state-policy/step-therapy-legislation.*

[22] Available online at: *https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf.*

submitted bids over the next 10 years. Column (G), the product of all previous columns, represents the dollar savings to the Medicare Trust Fund.

• To obtain savings to beneficiaries, we used the 2019 projected bid data submitted by MA plans to CMS in June 2018. These data show that on average 13 cents of every dollar paying for Part B drugs goes to cost sharing. We obtained this number by dividing the cost sharing for Part B drugs by the total cost of Part B drugs. This percentage is found in Column (H).

• We next have to adjust the savings due to step therapy. Recall that Column (D) indicates that step therapy will save 1.6 percent, the 1.6 percent arising from three factors listed previously. Of those three factors, enrollees do not benefit from manufacturer rebates. To illustrate this, consider a $20 drug for which the beneficiary pays a 20 percent copay ($4). At the end of the year, manufacturers and pharmacists give a rebate to plans that have used their products. Let us suppose (for purposes of illustration) that the rebate is $3. Theoretically the enrollee should get 60 cents of this $3 (20 percent copay * $3). However, the enrollee does not get a portion of the rebate. We estimate that 1.6 percent savings has a 1.4 percent component from manufacturer rebates and a 0.2 percent rebate from the other factors listed previously. It follows that for the enrollee, the savings from step therapy are 0.2 percent, not 1.6 percent. This is listed in Column (I).

• To obtain aggregate annual beneficiary savings we multiply MA enrollment (Column (A)), average cost of prescription drugs per month (Column (B)), number of months per year (Column (C)) and the 0.2 percent, the savings to enrollees from this step therapy provision (Column (I)). This gives the total dollar savings, of which enrollees pay 13 percent (Column (H)). The result is presented in Column (J).

The results of our calculations are summarized for 2020–2029 in Columns (G) and (J) of Table 4. The savings to enrollees are between $5 and $8 million; the savings to the Medicare Trust Fund are between $145 and $240 million.

These projected dollar savings to the Medicare Trust Fund are classified as transfers because the money on brand drugs would instead be spent on generic drugs. While brand drugs are more expensive, the primary driver of this expense is the research and development (R&D) that went into them, and for drugs that are already on the market R&D has already been done and would not change. In other words, although this regulatory provision would reduce the return on drug development because enrollees who are expected to purchase the brand and thus pay for the initial R&D would instead purchase generics, this reduced return would be experienced after the initial R&D has been completed; consequently, any immediate reduction in R&D services would not impact the availability of new drugs until later. There would also be no reduction in production of drugs, since generic manufacturers rather than brand manufacturers would produce the drugs consumed by enrollees. However, the cost to the enrollee and the Medicare Trust Fund would be significantly less because the enrollee and Medicare Trust Fund would no longer pay for the initial R&D. In conclusion, this provision would not reduce activities of production but rather transfers the performance of those services from brand manufacturers to generic manufacturers; however, as a consequence, the enrollees and Medicare Trust Fund would experience reduced dollars spent.

The allowance of step therapy for Part B drugs in MA could result in a higher appeal rate. We estimate the aggregate increase in cost in 2016 due to expected increased appeals as $0.8 million. Details are presented in Table 5. The following narrative explains this table.

TABLE 5—ESTIMATED INCREASE IN APPEALS ALL LEVELS DUE TO STEP THERAPY

	Total number of appeals in 2016	Estimated number of appeals involving step therapy (1)	Hours per appeal (2)	Hourly wages of physicians (3)	Total cost (1) × (2) × (3)
Reconsiderations	328,857	3913	0.8	$203.26	$636,350
IRE	58,023	690	0.8	203.26	112,277
Administrative Law Judge (ALJ)	3,481	41	0.8	203.26	6,737
Estimated Cost for 2016					755,363

Data for appeals are reported by MA plans. It typically takes 2 years for CMS to validate these data. Hence the latest year for which we have complete data is 2016. Appeals can happen at various levels. The first level is reconsiderations where an appeal is made for a plan to reconsider a decision. If this is denied, the case goes on to the IRE (a CMS contractor) to be reviewed. If this is also denied, the case can be appealed to an administrative law judge (ALJ) if the amount in controversy is met.

For 2016, there were 328,857 and 58,023 reconsiderations and IRE cases respectively in the MA program. We estimate that in general 6 percent of cases reaching the IRE go on to an ALJ.

Based on data pulled from the Medicare Appeals System for part D appeals, 1.19 percent of plan level appeals involving step therapy were denied. We use this as a proxy for the percent of cases involving part B drugs subject to step therapy that we expect to be appealed since we have no other basis. We believe it is reasonable to consider Part D appeals data related to cases that involve drugs subject to step therapy in developing these estimates. We also use the 1.19 percent as a proxy for the percent of reconsiderations and ALJ cases that involve step therapy. We acknowledge that percentages might be different at different appeal levels but the 1.19 percent is the only proportion we have.

Having derived the expected number of appeals involving step therapy we note that section 1852(g)(2) of the Act requires a reconsideration by a MA plan to deny coverage on the basis of medical necessity to be reviewed by a physician with the appropriate expertise; CMS has adopted two MA regulations (§§ 422.566(d) and 422.590(g)(2)) that implement this requirement for denials based on medical necessity determinations. We believe it is reasonable to assume that a decision to

deny coverage for a drug subject to step therapy will typically involve a medical determination whether the drug would be ineffective or cause adverse effects for the enrollee. A decision on a drug subject to step therapy is also likely to involve evaluation of a healthcare provider's assessment of medical necessity for the Part B drug; for example, the health care provider may indicate that the lower or earlier steps in the step therapy protocol are not clinically appropriate for that enrollee (such as in cases of allergy or a prior unsuccessful use of the preferred drug). Therefore, this estimate accounts for physician review of reconsiderations. Based on the BLS website at *https://www.bls.gov/oes/current/oes_nat.htm,* the mean hourly wage of physicians is $203.26. Our contractor experience with appeals suggests that the average time to process an appeal is 48 minutes, or, 0.8 hour.

Multiplying the number of appeals * 0.8 hour per appeal * $203.26 cost per hour we arrive at total cost for each appeal level. Adding these together we obtain the $0.8 million estimate, based on 2016 data.

Factors that enter into appeal rates include enrollment rates and changes in plan benefit packages. Appeal rates change from year to year. One major factor in appeal rates is enrollment. If enrollment increases by 10 or 20 percent then it is very reasonable that the number of appeals will approximately increase by that amount.

Thus to obtain estimates of cost for 2018 we will multiply the $0.8 million by the ratio of enrollment in 2018 to 2016. Similarly to obtain estimates for 2020 to 2024 we multiply by ratios of enrollment.

The ratio of 2018 to 2016 is 1.1585 based on enrollment figures from the CMS website. Projected enrollment for 2020 through 2029 may be obtained from Table IV.C1 in the 2018 Trustee report. Using these numbers we obtain the estimated cost of increased appeals for 2020 through 2029, presented in Table 6, as $1.0–$1.3 million.

TABLE 6—EXPECTED INCREASE IN APPEAL COSTS DUE TO STEP THERAPY

Year	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
Cost of appeals (in millions)	1.0	1.0	1.0	1.1	1.1	1.1	1.2	1.2	1.2	1.3

We received no comments on impact estimates of the proposed rule.

D. Expected Benefits

Any relevant expected benefits for enrollees, stakeholders, and the government have been fully discussed in section II. of this final rule.

E. Alternatives Considered

1. Providing Plan Flexibility To Manage Protected Classes (§ 423.120(b)(2)(vi))

Previous proposals to address the protected classes were aimed at changing both the protected classes and exceptions to the requirement that formularies include all drugs in the protected class. However, we remain concerned that previous criteria, as established either by statute under the MIPPA authority, or by CMS under the Patient Protection and Affordable Care Act authority, did not strike the appropriate balance among enrollee access, quality assurance, cost-containment, and patient welfare that we were striving to achieve. Consequently, we elected not to propose any changes to the drug categories or classes that are the protected classes. As a result, the critical policy decision was how broadly or narrowly to establish exceptions to the requirement that all protected class drugs be included on the formulary. Overly broad exceptions might inappropriately limit the products within the protected classes, thereby creating access issues for Part D enrollees. Only narrow exceptions afford enrollee protections such as adequate access and improved quality assurance while also providing an incentive for manufacturers to aggressively rebate their products for formulary placement in an operationally feasible manner for Part D sponsors.

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

We proposed to require that each Part D plan select a real time benefit tool (RTBT) of its choosing by January 1, 2020. We had considered delaying regulatory action around real time requirements until the industry has developed a real time standard that could be used by all Part D plans. However, we believe that the benefits that would come with a real time standard in the form of cost transparency are substantial and should not be further delayed. We also considered requiring that plans use the optional fields in the NCPDP Formulary and Benefit standards (F&B) to provide much of the cost data that we believe would be important for prescribers to know. However, by definition, the F&B standards are batch standards so that the information provided is, by definition, not contemporaneous and are not specific to each beneficiary. For these reasons we opted in favor of proposing RTBT rather than proposing to require that plans use enhanced F&B standards.

3. Medicare Advantage and Step Therapy for Part B Drugs (§§ 422.136, 422.568, 422.570, 422.572, 422.584, 422.590, 422.618, 422.619, 422.629, 422.633 and 422.634)

We finalized proposed requirements under which MA plans may apply step therapy as a utilization management tool for Part B drugs. We finalized our proposal to confirm authority for MA plans to implement appropriate utilization management and prior authorization tools for managing Part B drugs and proposed parameters on using step therapy to ensure it is implemented in a manner to reduce costs for both enrollees and the Medicare program. Our finalized policy includes specific parameters for how step therapy may be implemented for Part B drugs, including requiring review and approval from a P&T Committee that meets specific standards and permitting step therapy only for new administrations of the drug (subject to at least a 365 day lookback period). We also finalized our proposal to require new appeal timeframes and deadlines for MA plans to adjudicate and respond to requests concerning Part B drug coverage. An additional alternative considered during development of the proposed regulation was allowing step therapy for ongoing prescriptions or administrations of Part B drugs for enrollees who are actively receiving the affected medication at the time the step therapy program is adopted as well as for new administrations of a Part B drug. However, allowing MA plans to implement step therapy on ongoing prescriptions and administrations of Part B drugs would require the development of a transition process for affected enrollees and might result in negative health outcomes as on-going treatment would be disrupted. We lack a basis to quantify the impact of these expected negative health outcomes.

Furthermore, the estimated costs of developing a transition process, including providing enrollees with appropriate notice regarding their transition process and providing a temporary supply of affected drugs likely outweighs any savings. Moreover, we recognized the health significance of many Part B drug regimens (for example, cancer treatments) and are working to ensure enrollees will not encounter unnecessary barriers to medically necessary drugs or have disruptions in care. Therefore, under the finalized regulations at § 422.136(a)(1), step therapy programs are not permitted to disrupt enrollees' ongoing Part B drug therapies as our finalized regulations require that step therapy only be applied to new prescriptions or administrations of Part B drugs for enrollees who are not actively receiving the affected medication. More specifically, MA plans must have a look back period of 365 days instead of the proposed 108 days, to determine if the enrollee is actively taking a Part B drug and, thus, not subject to step therapy for that Part B drug. Further, when an enrollee elects a new plan, the plan would still be required to determine whether the enrollee has taken the Part B drug (that would otherwise be subject to step therapy) within the past 365 days. If the enrollee is actively taking the Part B drug, such enrollee would be exempted from the plan's step therapy requirement concerning that drug.

F. Accounting Statement and Table

The following table summarizes costs, savings, and transfers by provision.

As required by OMB Circular A–4 (available at *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/*), in Table 7, we have prepared an accounting statement showing the savings and transfers associated with the provisions of this final rule for contract years 2020 through 2029. Table 7 is based on Table 8 which lists savings, costs, and transfers by provision.

TABLE 7—ACCOUNTING STATEMENT—CLASSIFICATIONS OF ESTIMATED SAVINGS, COSTS, AND TRANSFERS NEGATIVE NUMBERS INDICATE SAVINGS

From calendar years 2020 to 2029 [$ in millions]	Savings			Whom is spending or transferring
	Discount Rate		Period Covered	
	7%	3%		
Net Annualized Monetized Cost	7.46	7.38	CYs 2020–2029	MA Organizations, Part D Sponsors, Contractors for the Federal Government.
Annualized Monetized Savings			CYs 2020–2029	
Annualized Monetized Cost.	7.46	7.38	CYs 2020–2029	MA Organizations, Part D Sponsors, Beneficiaries.
Annualized Transfers	(191.23)	(194.63)	CYs 2020–2029	Federal government, MA organizations and Part D Sponsors, Beneficiaries.

The following Table 8 summarizes savings, costs, and transfers by provision and formed a basis for the accounting table. For reasons of space, Table 8 is broken into Table 8A (2020 through 2023), Table 8B (2024 through 2027) and Table 8C (2028 through 2029). In these tables savings are indicated as negative numbers in columns marked savings while costs are indicated as positive numbers in columns marked costs. Transfers result in reduced dollar spending by enrollees and the government and are indicated by negative numbers. All numbers are in millions. The row ''aggregate total by year'' gives the total of costs and savings for that year but does not include transfers. Table 8 forms the basis for Table 7 and for the calculation to the infinite horizon discounted to 2016, mentioned in the conclusion.

TABLE 8A—AGGREGATE SAVINGS, COSTS, AND TRANSFERS IN MILLIONS BY PROVISION AND YEAR

	2020 Savings	2020 Cost	2020 Transfers	2021 Savings	2021 Cost	2021 Transfers	2022 Savings	2022 Cost	2022 Transfers	2023 Savings	2023 Cost	2023 Transfers
Total Savings												
Total Costs		11.40			6.73			6.73			6.83	
Aggregate Total		11.40			6.73			6.73			6.83	
Total Transfers			(150.00)			(159.00)			(169.00)			(180.00)
Protected Classes, Government												
Protected Classes, Enrollees												
Gag Clauses												
E-Prescribing												
Part D EOB		10.40			5.73			5.73			5.73	
Step Therapy, Government			(145.00)			(154.00)			(164.00)			(174.00)
Step Therapy, Enrollees			(5.00)			(5.00)			(5.00)			(6.00)
Step Therapy Appeals		1.00			1.00			1.00			1.10	

TABLE 8B—AGGREGATE SAVINGS, COSTS, AND TRANSFERS IN MILLIONS BY PROVISION AND YEAR

	2024 Savings	2024 Cost	2024 Transfers	2025 Savings	2025 Cost	2025 Transfers	2026 Savings	2026 Cost	2026 Transfers	2027 Savings	2027 Cost	2027 Transfers
Total Savings												
Total Costs		6.83			6.83			6.93			6.93	

TABLE 8B—AGGREGATE SAVINGS, COSTS, AND TRANSFERS IN MILLIONS BY PROVISION AND YEAR—Continued

	2024 Savings	2024 Cost	2024 Transfers	2025 Savings	2025 Cost	2025 Transfers	2026 Savings	2026 Cost	2026 Transfers	2027 Savings	2027 Cost	2027 Transfers
Aggregate Total		6.83			6.83			6.93			6.93	
Total Transfers			(191.00)			(201.00)			(214.00)			(225.00)
Protected Classes, Government												
Protected Classes, Enrollees												
Gag Clauses												
E-Prescribing												
Part D EOB		5.73			5.73			5.73			5.73	
Step Therapy, Government			(185.00)			(195.00)			(207.00)			(218.00)
Step Therapy, Enrollees			(6.00)			(6.00)			(7.00)			(7.00)
Step Therapy Appeals		1.10			1.10			1.20			1.20	

TABLE 8C—AGGREGATE SAVINGS, COSTS, AND TRANSFERS IN MILLION BY PROVISION AND YEAR

	2028 Savings	2028 Cost	2028 Transfers	2029 Savings	2029 Cost	2029 Transfers	Raw 10 year totals
Total Savings							
Total Costs		6.93			7.03		73.19
Aggregate Total		6.93			7.03		73.19
Total Transfers			(236.00)			(248.00)	(1,973.00)
Protected Classes, Government							
Protected Classes, Enrollees							
Gag Clauses							
E-Prescribing							
Part D EOB		5.73			5.73		61.99
Step Therapy, Government			(229.00)			(240.00)	(1,911.00)
Step Therapy, Enrollees			(7.00)			(8.00)	(62.00)
Step Therapy Appeals		1.20			1.30		11.20

G. Conclusion

As indicated in the ''Aggregate Total'' row of Table 8, we estimate that this final rule generates for each year in 2021 through 2029, net costs of approximately $7 million, with a first year cost of approximately $11.4 million. These annual costs primarily reflect mailing and programming costs arising from descriptions of alternatives in the Part D EOB as well as increased appeals arising from the Step Therapy provision. This final rule has no provisions which save.

Although other impacts in this rule are classified as transfers as discussed in each provision, the aggregate effect of these transfers reduce dollar spending by MA enrollees and the Medicare Trust Fund:

- Enrollees: Enrollees are estimated to reduce their spending on cost sharing by $62 million over 10 years from reduced cost sharing from Step Therapy.
- Government: The Medicare Trust Fund in aggregate reduces their dollar spending by $1.91 billion over 10 years from the Step Therapy provisions.

H. Reducing Regulation and Controlling Regulatory Costs

In line with Executive Order 13771, in Table 9, we estimate present and annualized values of costs and cost savings over an infinite time horizon. Costs are indicated by positive numbers. Based on these costs, this Final Rule would be considered a regulatory action under Executive Order 13771. As shown, this final rule generates level annual costs of $5.9 million over an infinite horizon in 2016 dollars discounted at 7 percent.

TABLE 9—E.O. 13771 SUMMARY TABLE

[In 2016 dollars over a perpetual time horizon]

Item	Primary (7%)	Primary (3%)
Present Value of Costs	84.4	217.2
Present Value of Cost Savings	0.0	0.0
Present Value of Net Costs	84.4	217.2
Annualized Cost	5.9	6.5
Annualized Cost Savings	0.0	0.0
Annualized Net Costs	5.9	6.5

List of Subjects

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 1. The authority citation for part 422 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 422.2 is amended by adding a definition for ''Step therapy'' in alphabetical order to read as follows:

§ 422.2 Definitions.

* * * * *

Step therapy means 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.

■ 3. Section 422.136 is added to subpart C to read as follows:

§ 422.136 Medicare Advantage (MA) and step therapy for Part B drugs.

(a) *General.* If an MA plan implements a step therapy program to control the utilization of Part B-covered drugs, the MA organization must—

(1) Apply step therapy only to new administrations of Part B drugs, using at least a 365 day lookback period;

(2) Establish policies and procedures to educate and inform health care providers and enrollees concerning its step therapy policies.

(3) Prior to implementation of a step therapy program, ensure that the step therapy program has been reviewed and approved by the MA organization's pharmacy and therapeutic (P&T) committee.

(b) *Step therapy and pharmacy and therapeutic committee requirements.* An MA plan must establish a P&T committee prior to implementing any step therapy program. An MA plan must use a P&T committee to review and approve step therapy programs used in connection with Part B drugs. To meet this requirement, a MA–PD plan may utilize an existing Part D P&T committee established for purposes of administration of the Part D benefit under part 423 of this chapter and an MA plan may utilize an existing Part D P&T committee established by an MA–PD plan operated under the same contract as the MA plan. The P&T committee must—

(1) Include a majority of members who are practicing physicians or practicing pharmacists.

(2) Include at least one practicing physician and at least one practicing pharmacist who are independent and free of conflict relative to—

(i) The MA organization and MA plan; and

(ii) Pharmaceutical manufacturers.

(3) Include at least one practicing physician and one practicing pharmacist who are experts regarding care of elderly or disabled individuals.

(4) Clearly articulate and document processes to determine that the requirements under paragraphs (b)(1) through (3) of this section have been met, including the determination by an objective party of whether disclosed financial interests are conflicts of interest and the management of any recusals due to such conflicts.

(5) Base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other such information as it determines appropriate.

(6) Consider whether the inclusion of a particular Part B drug in a step therapy program has any therapeutic advantages in terms of safety and efficacy.

(7) Review policies that guide exceptions and other step therapy processes.

(8) Evaluate and analyze treatment protocols and procedures related to the plan's step therapy policies at least annually consistent with written policy guidelines and other CMS instructions.

(9) Document in writing its decisions regarding the development and revision of step therapy activities and make this documentation available to CMS upon request.

(10) Review and approve all step therapy criteria applied to each covered Part B drug.

(11) Meet other requirements consistent with written policy guidelines and other CMS instructions.

(c) *Off-label drug requirement.* An MA plan may include a drug supported only by an off-label indication in step therapy protocols only if the off-label indication is supported by widely used treatment guidelines or clinical literature that CMS considers to represent best practices.

(d) *Non-covered drugs.* A step therapy program must not include as a component of a step therapy protocol or other condition or requirement any drugs not covered by the applicable MA plan as a Part B drug or, in the case of an MA–PD plan, a Part D drug.

■ 4. Section 422.568 is amended by revising paragraphs (b), (d), (e) introductory text, and (e)(4)(i) to read as follows:

§ 422.568 Standard timeframes and notice requirements for organization determinations.

* * * * *

(b) *Timeframes*—(1) *Requests for service or item.* Except as provided in paragraph (b)(1)(i) of this section, when a party has made a request for a service or an item, the MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after the date the organization receives the request for a standard organization determination.

(i) *Extensions; requests for service or item.* The MA organization may extend the timeframe by up to 14 calendar days if—

(A) The enrollee requests the extension;

(B) The extension is justified and in the enrollee's interest due to the need for additional medical evidence from a noncontract provider that may change an MA organization's decision to deny an item or service; or

(C) The extension is justified due to extraordinary, exigent, or other non-routine circumstances and is in the enrollee's interest.

(ii) *Notice of extension.* When the MA organization extends the timeframe, it must notify the enrollee in writing of the reasons for the delay, and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension. The MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(2) *Requests for a Part B drug.* An MA organization must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request. This 72-hour period may not be extended under the provisions in paragraph (b)(1)(i) of this section.

* * * * *

(d) *Written notice for MA organization denials.* The MA organization must give the enrollee a written notice if—

(1) An MA organization decides to deny a service or an item, Part B drug, or payment in whole or in part, or reduce or prematurely discontinue the level of care for a previously authorized ongoing course of treatment.

(2) An enrollee requests an MA organization to provide an explanation of a practitioner's denial of an item, service or Part B drug, in whole or in part.

(e) *Form and content of the MA organization notice.* The notice of any denial under paragraph (d) of this section must—

* * * * *

(4)(i) For service, item, and Part B drug denials, describe both the standard and expedited reconsideration processes, including the enrollee's right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeal process; and

* * * * *

■ 5. Section 422.570 is amended by revising paragraph (d)(1) to read as follows:

§ 422.570 Expediting certain organization determinations.

* * * * *

(d) * * *

(1) Automatically transfer a request to the standard timeframe and make the determination within the 72-hour or 14-

day timeframe, as applicable, established in § 422.568 for a standard determination. The timeframe begins when the MA organization receives the request for expedited determination.

* * * * *

■ 6. Section 422.572 is amended by revising paragraphs (a), the heading to paragraph (b), and (b)(1) to read as follows:

§ 422.572 Timeframes and notice requirements for expedited organization determinations.

(a) *Timeframes*—(1) *Requests for service or item.* Except as provided in paragraph (b) of this section, an MA organization that approves a request for expedited determination must make its determination and notify the enrollee (and the physician involved, as appropriate) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request.

(2) *Requests for a Part B drug.* An MA organization that approves a request for expedited determination must make its determination and notify the enrollee (and the physician or prescriber involved, as appropriate) of its decision as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the request. This 24-hour period may not be extended under the provisions in paragraph (b) of this section.

(b) *Extensions; requests for service or item.* (1) When timeframe may be extended. The MA organization may extend the 72-hour deadline for expedited organization determinations for requests for services or items by up to 14 calendar days if—

(i) The enrollee requests the extension;

(ii) The extension is justified and in the enrollee's interest due to the need for additional medical evidence from a noncontract provider that may change an MA organization's decision to deny an item or service; or

(iii) The extension is justified due to extraordinary, exigent, or other nonroutine circumstances and is in the enrollee's interest.

* * * * *

■ 7. Section 422.584 is amended by revising paragraph (d)(1) to read as follows:

§ 422.584 Expediting certain reconsiderations.

* * * * *

(d) * * *

(1) Automatically transfer a request to the standard timeframe and make the determination within the 30 calendar day or 7 calendar day, as applicable, timeframe established in § 422.590(a) and (c). The timeframe begins the day the MA organization receives the request for expedited reconsideration.

* * * * *

■ 8. Section 422.590 is revised to read as follows:

§ 422.590 Timeframes and responsibility for reconsiderations.

(a) *Standard reconsideration: Requests for service or item.* (1) Except as provided in paragraph (f) of this section, if the MA organization makes a reconsidered determination that is completely favorable to the enrollee, the MA organization must issue the determination (and effectuate it in accordance with § 422.618(a)) as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a standard reconsideration.

(2) If the MA organization makes a reconsidered determination that affirms, in whole or in part, its adverse organization determination, it must prepare a written explanation and send the case file to the independent entity contracted by CMS as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days from the date it receives the request for a standard reconsideration (or no later than the expiration of an extension described in paragraph (a)(1) of this section). The organization must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(b) *Standard reconsideration: Requests for payment.* (1) If the MA organization makes a reconsidered determination that is completely favorable to the enrollee, the MA organization must issue its reconsidered determination to the enrollee (and effectuate it in accordance with § 422.618(a)(1)) no later than 60 calendar days from the date it receives the request for a standard reconsideration.

(2) If the MA organization affirms, in whole or in part, its adverse organization determination, it must prepare a written explanation and send the case file to the independent entity contracted by CMS no later than 60 calendar days from the date it receives the request for a standard reconsideration. The organization must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(c) *Standard reconsideration: Requests for a Part B drug.* (1) If the MA organization makes a reconsidered determination that is completely favorable to the enrollee, the MA organization must issue the determination (and effectuate it in accordance with § 422.618(a)(3)) as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for a standard reconsideration. This 7 calendar-day period may not be extended under the provisions in paragraph (f) of this section.

(2) If the MA organization makes a reconsidered determination that affirms, in whole or in part, its adverse organization determination, it must prepare a written explanation and send the case file to the independent entity contracted with CMS no later than 7 calendar days from the date it receives the request for a standard reconsideration. The organization must make reasonable and diligent efforts to assist in gathering and forwarding the information to the independent entity.

(d) *Effect of failure to meet timeframe for standard reconsideration.* If the MA organization fails to provide the enrollee with a reconsidered determination within the timeframes specified in paragraph (a), (b), or (c) of this section, this failure constitutes an affirmation of its adverse organization determination, and the MA organization must submit the file to the independent entity in the same manner as described under paragraphs (a)(2), (b)(2), and (c)(2) of this section.

(e) *Expedited reconsideration*—(1) *Timeframe for services or items.* Except as provided in paragraph (f) of this section, an MA organization that approves a request for expedited reconsideration must complete its reconsideration and give the enrollee (and the physician involved, as appropriate) notice of its decision as expeditiously as the enrollee's health condition requires but no later than 72 hours after receiving the request.

(2) *Timeframe for Part B drugs.* An MA organization that approves a request for expedited reconsideration must complete its reconsideration and give the enrollee (and the physician or other prescriber involved, as appropriate) notice of its decision as expeditiously as the enrollee's health condition requires but no later than 72 hours after receiving the request. This 72-hour period may not be extended under the provisions in paragraph (f) of this section.

(3) *Confirmation of oral notice.* If the MA organization first notifies an enrollee of a completely favorable expedited reconsideration orally, it

must mail written confirmation to the enrollee within 3 calendar days.

(4) *How the MA organization must request information from noncontract providers.* If the MA organization must receive medical information from noncontract providers, the MA organization must request the necessary information from the noncontract provider within 24 hours of the initial request for an expedited reconsideration. Noncontract providers must make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the MA organization in meeting the required timeframe. Regardless of whether the MA organization must request information from noncontract providers, the MA organization is responsible for meeting the timeframe and notice requirements.

(5) *Affirmation of an adverse expedited organization determination.* If, as a result of its reconsideration, the MA organization affirms, in whole or in part, its adverse expedited organization determination, the MA organization must submit a written explanation and the case file to the independent entity contracted by CMS as expeditiously as the enrollee's health condition requires, but not later than within 24 hours of its affirmation. The organization must make reasonable and diligent efforts to assist in gathering and forwarding information to the independent entity.

(f) *Extensions; requests for service or item.* (1) As described in paragraphs (f)(1)(i) through (iii) of this section, the MA organization may extend the standard or expedited reconsideration deadline for services by up to 14 calendar days if—

(i) The enrollee requests the extension; or

(ii) The extension is justified and in the enrollee's interest due to the need for additional medical evidence from a noncontract provider that may change an MA organization's decision to deny an item or service; or

(iii) The extension is justified due to extraordinary, exigent or other non-routine circumstances and is in the enrollee's interest.

(2) When the MA organization extends the deadline, it must notify the enrollee in writing of the reasons for the delay and inform the enrollee of the right to file an expedited grievance if he or she disagrees with the MA organization's decision to grant an extension. The MA organization must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than upon expiration of the extension.

(g) *Failure to meet timeframe for expedited reconsideration.* If the MA organization fails to provide the enrollee with the results of its reconsideration within the timeframe described in paragraph (e)(1) or (2) of this section, as applicable, this failure constitutes an adverse reconsidered determination, and the MA organization must submit the file to the independent entity within 24 hours of expiration of the timeframe set forth in paragraph (e)(1) or (2) of this section.

(h) *Who must reconsider an adverse organization determination.* (1) A person or persons who were not involved in making the organization determination must conduct the reconsideration.

(2) When the issue is the MA organization's denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the reconsidered determination must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. The physician making the reconsidered determination need not, in all cases, be of the same specialty or subspecialty as the treating physician.

■ 9. Section 422.618 is amended by revising paragraph (a) and adding paragraph (b)(3) to read as follows:

§ 422.618 How an MA organization must effectuate standard reconsidered determinations or decisions.

(a) *Reversals by the MA organization*—(1) *Requests for service.* If, on reconsideration of a request for service, the MA organization completely reverses its organization determination, the organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires, but no later than 30 calendar days after the date the MA organization receives the request for reconsideration (or no later than upon expiration of an extension described in § 422.590(f)).

(2) *Requests for payment.* If, on reconsideration of a request for payment, the MA organization completely reverses its organization determination, the organization must pay for the service no later than 60 calendar days after the date the MA organization receives the request for reconsideration.

(3) *Requests for a Part B drug.* If, on reconsideration of a request for a Part B drug, the MA organization completely reverses its organization determination, the MA organization must authorize or provide the Part B drug under dispute as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days after the date the MA organization receives the request for reconsideration.

(b) * * *

(3) *Requests for a Part B drug.* If, on reconsideration of a request for a Part B drug, the MA organization's determination is reversed in whole or in part by the independent outside entity, the MA organization must authorize or provide the Part B drug under dispute within 72 hours from the date it receives notice reversing the determination. The MA organization must inform the independent outside entity that the organization has effectuated the decision.

* * * * *

■ 10. Section 422.619 is amended by—

■ a. Revising paragraphs (a) and (b);

■ b. Redesignating paragraph (c)(2) as paragraph (c)(3); and

■ c. Adding a new paragraph (c)(2).

The revisions and addition read as follows:

§ 422.619 How an MA organization must effectuate expedited reconsidered determinations.

(a) *Reversals by the MA organization*—(1) *Requests for service or item.* If, on reconsideration of an expedited request for service, the MA organization completely reverses its organization determination, the MA organization must authorize or provide the service or item under dispute as expeditiously as the enrollee's health condition requires, but no later than 72 hours after the date the MA organization receives the request for reconsideration (or no later than upon expiration of an extension described in § 422.590(f)).

(2) *Requests for a Part B drug.* If, on reconsideration of a request for a Part B drug, the MA organization completely reverses its organization determination, the MA organization must authorize or provide the Part B drug under dispute as expeditiously as the enrollee's health condition requires, but no later than 72 hours after the date the MA organization receives the request for reconsideration.

(b) *Reversals by the independent outside entity*—(1) *Requests for service or item.* If the MA organization's determination is reversed in whole or in part by the independent outside entity, the MA organization must authorize or provide the service under dispute as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination. The MA organization must inform the independent outside entity that the

organization has effectuated the decision.

(2) *Requests for a Part B drug.* If, on reconsideration of a request for a Part B drug, the MA organization's determination is reversed in whole or in part by the independent outside entity, the MA organization must authorize or provide the Part B drug under dispute as expeditiously as the enrollee's health condition requires but no later than 24 hours from the date it receives notice reversing the determination. The MA organization must inform the outside entity that the organization has effectuated the decision.

(c) * * *

(2) *Reversals of decisions related to Part B drugs.* If the independent outside entity's determination is reversed in whole or in part by an ALJ/attorney adjudicator or at a higher level of appeal, the MA organization must authorize or provide the Part B drug under dispute as expeditiously as the enrollee's health condition requires but no later than 24 hours from the date it receives notice reversing the determination. The MA organization must inform the outside entity that the organization has effectuated the decision.

* * * * *

■ 11. Effective January 1, 2021, § 422.629 is amended by revising paragraph (a) to read as follows:

§ 422.629 General requirements for applicable integrated plans.

(a) *Scope.* The provisions in this section and in §§ 422.630 through 422.634 set forth requirements for unified appeals and grievance processes with which applicable integrated plans must comply. Beginning January 1, 2021, these provisions apply to an applicable integrated plan in lieu of §§ 422.564, 422.566(c) and (d), and 422.568 through 422.590, and 422.618(a) and §§ 438.404 through 438.424 of this chapter; provisions governing Part B drugs in §§ 422.568(b)(2), 422.570(d)(2), 422.572(a)(2), 422.584(d)(1), 422.590(c), and 422.590(e)(2) apply to an applicable integrated plan.

* * * * *

■ 12. Effective January 1, 2021, § 422.631 is amended by revising paragraph (a) to read as follows:

§ 422.631 Integrated organization determinations.

(a) *General rule.* An applicable integrated plan must adopt and implement a process for enrollees to request that the plan make an integrated organization determination. The process for requesting that the applicable integrated plan make an integrated organization determination must be the same for all covered benefits. Timeframes and notice requirements for integrated organization determinations for Part B drugs are governed by the provisions for Part B drugs in §§ 422.568(b)(2), 422.570(d)(2), and 422.572(a)(2).

* * * * *

■ 13. Effective January 1, 2021, § 422.633 is amended by revising paragraph (f) introductory text to read as follows:

§ 422.633 Integrated reconsideration.

* * * * *

(f) *Resolution and notification.* The applicable integrated plan must make integrated reconsidered determinations as expeditiously as the enrollee's health condition requires but no later than the timeframes established in this section. Integrated reconsidered determinations regarding Part B drugs must comply with the timelines governing Part B drugs established in §§ 422.584(d)(1) and 422.590(c) and (e)(2).

* * * * *

PART 423—MEDICARE PROGRAM; MEDICARE PRESCRIPTION DRUG PROGRAM

■ 14. The authority citation for part 423 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1395w–101 through 1395w–152, and 1395hh.

■ 15. Section 423.120 is amended—

■ a. In paragraph (a)(8)(i) by removing ''and'' from the end;

■ b. In paragraph (a)(8)(ii) by removing the ''.'' and adding in its place ''; and'';

■ c. Adding new paragraph (a)(8)(iii);

■ d. Revising paragraph (b)(2)(vi)(A);

■ e. Redesignating paragraph (b)(2)(vi)(C) as (b)(2)(vi)(D); and

■ f. Adding new paragraphs (b)(2)(vi)(C).

The additions and revisions read as follows:

§ 423.120 Access to covered Part D drugs.

(a) * * *

(8) * * *

(iii) 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.

* * * * *

(b) * * *

(2) * * *

(vi) * * *

(A) Drug or biological products that are rated as either of the following:

(*1*) Therapeutically equivalent (under the Food and Drug Administration's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' also known as the Orange Book).

(*2*) Interchangeable (under the Food and Drug Administration's most recent publication of the Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations).

* * * * *

(C) Subject to CMS review and approval, for enrollees that are not on existing therapy on the protected class Part D drug, and except for antiretroviral medications, prior authorization and step therapy requirements to confirm intended use is for a protected class indication, to ensure clinically appropriate use, to promote utilization of preferred formulary alternatives, or a combination thereof.

* * * * *

■ 16. Effective January 1, 2021, § 423.128 is amended by—

■ a. Redesignating paragraphs (e)(5) and (6) as paragraphs (e)(6) and (7); and

■ b. Adding a new paragraph (e)(5).

The addition reads as follows:

§ 423.128 Dissemination of Part D plan information.

* * * * *

(e) * * *

(5) For each prescription drug claim, must include the cumulative percentage increase (if any) in the negotiated price since the first claim of the current benefit year and therapeutic alternatives with lower cost-sharing, when available as determined by the plan, from the applicable approved plan formulary.

* * * * *

■ 17. Effective January 1, 2021, § 423.160 is amended by adding paragraph (b)(7) to read as follows:

§ 423.160 Standards for electronic prescribing.

* * * * *

(b) * * *

(7) *Real time benefit tools.* No later than January 1, 2021, implement one or more electronic real-time benefit tools (RTBT) that are capable of integrating with at least one prescriber's e-Prescribing (eRx) system or electronic health record (EHR) to provide complete, accurate, timely, clinically appropriate, patient-specific formulary and benefit information to the prescriber in real time for assessing coverage under

the Part D plan. Such information must include enrollee cost-sharing information, clinically appropriate formulary alternatives, when available, and the formulary status of each drug presented including any utilization management requirements applicable to each alternative drug.

* * * * *

Dated: April 25, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: May 8, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2019–10521 Filed 5–16–19; 4:15 pm]

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