DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 422 and 423

[CMS–4180–P]

RIN 0938–AT92

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: Proposed rule.

SUMMARY: This proposed rule would amend 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.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 25, 2019.

ADDRESSES: In commenting, please refer to file code CMS–4180–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4180–P, P.O. Box 8013, Baltimore, MD 21244–8013. Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4180–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Christian Bauer, (410) 786–6043, Part D Issues. Marty Abeln, (410) 786–1032, Jelani Murrain, (410) 786–2274, or Brandy Alston, (410) 786–1218, Part C Issues.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that website to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Executive Summary and Background

A. Purpose

The primary purposes of this proposed rule are to: Make revisions to the Medicare Advantage (MA) program (Part C) 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 enrollees. This regulation would 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 beneficiaries at the pharmacy and other sites of care.

B. Summary of the Major Provisions

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

Current Part D policy requires sponsors to include on their formularies all drugs in six categories or classes: (1) Antidepressants; (2) antipsychotics; (3) anticonvulsants; (4) immunosuppressants for treatment of transplant rejection; (5) antiretrovirals; and (6) antineoplastics; except in limited circumstances. This regulatory provision proposes 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 drugs, including to determine use for protected class indications; (2) exclude a protected class drug from a formulary if the drug represents only a new formulation of an existing single-source drug or biological product, regardless of whether the older formulation remains on the market; and (3) exclude a protected class drug from a formulary if the price of the drug increased beyond a certain threshold over a specified look-back period.

The first proposed exception would allow Part D sponsors to use PA and ST for protected class drugs, including to determine use for protected class indications, without distinguishing between new starts and existing therapies, as is currently allowed for all other drug categories and classes. We would also allow indication-based formulary design and utilization management for protected class drugs. This would be consistent with our July 25, 2018 Health Plan Management System (HPMS) memorandum titled, ''Indication-Based Utilization Management.'' It would also be consistent with our August 29, 2018 HPMS memorandum titled, ''Indication-Based Formulary Design Beginning in Contract Year (CY) 2020,'' and we are proposing to codify this policy for protected class drugs. This would also allow Part D sponsors to exclude the protected class drug from the formulary for non-protected class indications. As is required for all other drug categories and classes, these formulary design and utilization management edits would be subject to CMS review and approval as part of our annual formulary review and approval process, which includes reviews of prior authorization and step therapy edits that would restrict access, step therapy criteria, prior authorization outliers, and prior authorization criteria. (For an extensive description of our annual formulary checks see the January 2014 proposed rule (79 FR 1939).)

The second proposed exception would permit Part D plans to exclude from the formulary protected class drugs that are a new formulation of a protected class Part D drug, even if the older formulation is removed from the market. That is, Part D plans would be permitted to exclude from their formularies a protected class 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.

The third proposed exception is to permit Part D sponsors to exclude from the formulary any protected class drug whose price increases, relative to the price in a baseline month and year, beyond the rate of inflation. The rate of inflation would be calculated based on

the Consumer Price Index for all Urban Consumers (CPI–U).

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

This rule proposes to require that Part D plan sponsors implement an electronic real-time benefit tool (RTBT) capable of integrating with prescribers' e-Prescribing (eRx) and electronic medical record (EMR) systems under section 1860D–4(e)(2)(D) of the Act. We believe that requiring Part D plan sponsors' implementation of electronic access to real-time benefits (RTB) information would be appropriate given the timing requirements at section 1860D–4(e)(2)(D) of the Act, and would improve the cost-effectiveness of the Part D benefit. RTBTs 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 we believe that there currently are no industry-wide electronic standards for RTBTs, we are proposing that each Part D plan implement at least one RTBT of its choosing that is capable of integrating with prescribers' e-Rx and EMR systems to provide prescribers who service its beneficiaries 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, 2020.

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 rule proposes requirements under which MA plans may apply step therapy as a utilization management tool for Part B drugs. In this proposed rule, we reaffirm MA plans' existing authority to implement appropriate utilization management and prior authorization programs 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 would enhance the ability of MA plans to negotiate Part B drug costs and ensure that taxpayers and MA enrollees face lower per unit costs or pay less overall for Part B drugs while maintaining medically necessary access to Medicare-covered services and drugs. Additionally, and in order to make sure enrollees maintain access to all medically necessary Part B covered drugs, we propose to modify Part C adjudication time periods for organization determinations and appeals involving Part B drugs.

4. Pharmacy Price Concessions to Drug Prices at the Point of Sale (§ 423.100)

The ''negotiated prices'' of drugs, as the term is currently defined in § 423.100, must include all pharmacy payment adjustments except those contingent amounts that cannot ''reasonably be determined'' at the point-of-sale. As a result of this exception, negotiated prices typically do not reflect any performance-based pharmacy price concessions that lower the price a sponsor ultimately pays for a drug, based on the rationale that these amounts are contingent upon performance measured over a period that extends beyond the point of sale and thus cannot reasonably be determined at the point of sale.

In this proposed rule, we are considering for a future year, which could be as soon as 2020, eliminating this exception for contingent pharmacy price concessions. We are considering deleting the existing definition of ''negotiated prices'' at § 423.100 and adopting a new definition for the term ''negotiated price'' at § 423.100, which would mean the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug under its contract with the Part D plan sponsor or the sponsor's intermediary (that is, the amount the pharmacy would receive net of the maximum negative adjustment that could result from any contingent pharmacy payment arrangement and before any additional contingent payment amounts, such as incentive fees). To implement the change we are considering to the definition of negotiated price at the point of sale, Part D sponsors and their PBMs would load revised drug pricing tables reflecting the lowest possible reimbursement into their claims processing systems that interface with contracted pharmacies.

We are also considering adding a definition of ''price concession'' at § 423.100. While ''price concession'' is a term important to the adjudication of the Part D program, it has not yet been defined in the Part D statute, Part D regulations, or sub-regulatory guidance. We are considering defining price concession in a broad manner to include all forms of discounts and direct or indirect subsidies or rebates that serve to reduce the costs incurred under Part D plans by Part D sponsors.

C. Summary of Costs and Benefits

Provision	Description	Impact
Providing Plan Flexibility to Manage Protected Classes (§ 423.120(b)(2)(vi)).	We propose to allow the following exceptions related to protected class drugs: (1) Allow broader use of prior authorization and step therapy for protected class drugs, including to determine use for protected class indications; (2) allow plans to exclude a protected class drug from the formulary if the drug is a new formulation that does not provide a unique route of administration; and (3) allow plans to exclude a protected class drug from the formulary if the drug had a price increase beyond a certain threshold.	The estimated savings to the Trust Fund are $141–$180.5 million in 2020–2024, increasing to $195–$240 million in 2025–2029. The governments saves $1.85 billion. Enrollees save $692 million in cost sharing.
E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards (§ 423.160).	We propose to require each Part D plan Sponsors' implementation of one or more RTBT of its choosing that are capable of integrating with providers' e-Rx and EMR systems and delivering complete, accurate, timely and clinically appropriate patient-specific real-time F&B information beginning on or before 01/01/2020.	The scoring of this provision is complex. While there is potential for savings to the Trust Fund arising from substitution of lower cost-sharing tier drugs, we have no way of quantifying this. Also, we are uncertain at this point of the cost to industry to implement this provision. The implementation would most likely involve plans building their own software or use of 3rd party vendors. Both these options are very expensive and might outweigh the savings.
Part D Explanation of Benefits (§ 423.128) ...	We propose to require the inclusion of negotiated drug pricing information and lower cost alternatives in the Part D Explanation of Benefits. The intent of the proposal is to provide enrollees with greater transparency, thereby encouraging lower costs.	There is an estimated cost of $0.2 million in the first year of implementation.

Provision	Description	Impact
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 propose 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 $7 million for 2020–2024 and are between $7 and $10 million for 2025–2029. The savings to the Trust Fund are between $145 and $185 million for 2020–2024 and between $195 and $240 million for 2025–2029. 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. These estimates reflect use of step therapy for which CMS announced authority for MA organizations beginning 2019; that is, estimates reflect impact on the Medicare Trust Fund if plans start using step therapy in 2020.
Pharmacy Price Concessions in the Negotiated Price (§ 423.100).	We are considering for a future plan year, which may be as early as 2020, to redefine negotiated price as the baseline, or lowest possible, payment to a pharmacy.	If this policy were adopted for 2020 or a future year, there would be an impact on beneficiaries, the government, and manufacturers. Beneficiaries would save $7.1 to $9.2 billion over 10 years (2020 to 2029), resulting from reduced cost-sharing, offset by slightly higher premiums. However, the provision would be estimated to cost the government $13.6 to $16.6 billion over that span. Manufacturers would also save, about $4.9 to $5.8 billion from 2020 to 2029. Part D sponsors would incur a first year cost of $0.1 million in additional administrative activities related to submission of PDE data.

D. Background

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) created a new ''Part C'' in the Medicare statute (sections 1851 through 1859 of the Social Security Act (the Act)) which established what is now known as the Medicare Advantage (MA) program. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), enacted on December 8, 2003, added a new ''Part D'' to the Medicare statute (sections 1860D–1 through 42 of the Act) entitled the Medicare Prescription Drug Benefit Program (PDP), and made significant changes to the existing Part C program, which it renamed the Medicare Advantage (MA) Program. The MMA directed that important aspects of the Part D program be similar to, and coordinated with, law for the MA program. Generally, the provisions enacted in the MMA took effect January 1, 2006. The final rules implementing the MMA for the MA and Part D prescription drug programs appeared in the January 28, 2005 **Federal Register** (70 FR 4588 through 4741 and 70 FR 4194 through 4585, respectively).

Since the inception of both Parts C and D, we have periodically revised our regulations to improve the CMS customer experience through our knowledge obtained through experience with both programs. For instance, in the April 2018 final rule (83 FR 16440), we revised certain delivery and disclosure requirements to be consistent with changing technologies and beneficiary access to on-line information and to revise the marketing and communication standards applicable to MA organizations and Part D Sponsors to focus our mandatory review of marketing materials more effectively.

Through our experience implementing the Part C and D programs and through the research conducted in developing the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (May 16, 2018, 83 FR 22692), we have identified several proposed regulatory changes that would lower the cost of medications and reduce out-of-pocket costs for enrollees in the Part D program. These changes would 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.

II. Provisions of the Proposed Regulations

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 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 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 and 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 prior authorization or utilization management) a particular 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 exclude from their formulary therapeutically equivalent drugs, apply utilization management edits for safety, and exclude other drugs that CMS specifies through a medical and scientific process which also permits public notice and comment.

We are not proposing to change or remove any of the protected classes identified in section 1860D–4(b)(3)(G)(iv) of the Act. Instead, we are proposing 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 prior authorization and utilization management. We propose to revise § 423.120(b)(2)(vi) to permit Part D sponsors to implement prior authorization and step therapy requirements for protected class drugs for broader purposes than allowed currently. We also propose to permit Part D sponsors to exclude specific protected class drugs from their formularies if they are a singlesource

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. We believe these exceptions would strengthen the Part D program by allowing Part D sponsors to better manage protected class drugs to help ensure their safe and appropriate use, limit the protected class requirement to the intended protected class indications, and provide Part D sponsors with additional tools to negotiate as competitive a price as possible in order to provide drug pricing relief for Medicare Part D enrollees, while maintaining beneficiary access to protected class drugs when used for protected class indications. Specifically, we are proposing three exceptions that would allow Part D sponsors to: (1) Implement broader use of prior authorization and step therapy for protected class drugs, including to determine use for protected class indications; (2) exclude a protected class drug from a formulary if the drug is a new formulation of an existing single-source drug or biological product, regardless of whether the older formulation remains on the market; and (3) exclude a protected class drug from a formulary if the price of the drug increased beyond a certain threshold over a specified look back period. However, we note that these exceptions would apply only to the requirement that the drug be included on the formulary because it is a protected class drug. In other words, an exception from the protected class policy would not supersede our other formulary requirements in § 423.120(b)(2).

1. Background

a. History of the Protected Class Policy

Section 1860D–11(e)(2)(D)(i) of the Act requires that in order to approve a plan, we must not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain Part D-eligible individuals. We refer to this as our ''non-discrimination'' policy. Under this authority, in 2005 before the start of the Part D program, we directed Part D sponsors through guidance to include on their formularies all or substantially all drugs in six categories or classes: (1) Antidepressants; (2) antipsychotics; (3) anticonvulsants; (4) immunosuppressants for treatment of transplant rejection; (5) antiretrovirals; and (6) antineoplastics.

This guidance helped to ensure a smooth transition of the approximately 6 million Medicare-Medicaid dually-eligible enrollees who were converting from Medicaid drug coverage to Medicare drug coverage at the start of the Part D program (79 FR 1937). Under the circumstances existing at the time of implementation of the Part D benefit, any formularies that did not have all or substantially all drugs in these categories or classes potentially would have been discriminatory for the dually-eligible population, because state Medicaid program formularies were generally open at the time compared to the Part D formularies that we were anticipating Part D sponsors to adopt prior to the beginning of the Part D program. Thus, it stood to reason that dually-eligible enrollees and many of their providers were largely unaccustomed to drug utilization management techniques. That is, for the most part they had little experience dealing with the rejection of a drug claim at the point-of-sale because the drug was either not on formulary, or another drug needed to be tried first, or because more information was required to determine whether the drug could be covered under the plan. Moreover, because the majority of the dually-eligible enrollees did not make a decision to elect their new plan but were instead auto-enrolled into a Part D plan, these individuals may not have understood or known whether their current medications would continue to be covered under their new Medicare Part D plan. Because the Part D program would be administered by private plans with extensive experience managing prescription drug costs through tighter formularies and a variety of utilization management techniques, we anticipated the need for a learning curve to avoid delays associated with navigating new plan prescription drug benefit processes beginning January 1, 2006 that might put at risk the enrollees who needed access to drugs in these particular categories or classes. Therefore, we established our policy for coverage of the six drug classes of clinical concern.

However, the circumstances that existed when this policy was originally implemented have changed dramatically in the nearly 12 years the program has been in operation. In addition to advances in e-prescribing, which can also provide streamlined e-prior authorization processes, CMS, Part D sponsors, providers, our partners that assist enrollees with making enrollment choices, and particularly dually-eligible enrollees and their advocates have had a great deal of experience working with Part D plans since 2005. Additionally, under § 423.120(b)(3), each Part D sponsor must provide for an appropriate transition process for Part D drugs that are not on its formulary. (For a detailed explanation of our transition requirements, see section 30.4 of Chapter 6 of the Medicare Prescription Drug Benefit Manual, available at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf.* We also finalized changes to the days' supply required by the Part D transition process in our April 2018 final rule (83 FR 16601). Other enrollee protections include our formulary requirements, formulary transparency, reassignment formulary coverage notices, and the expedited exception, coverage determination, and appeal processes.

After the Part D provisions of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) were enacted in 2003, the Medicare Improvements for Patients and Providers Act (MIPPA) was enacted in 2008 and established specific criteria that should be used to identify drug categories or classes of Part D drugs of clinical concern for which all Part D drugs therein shall be included on Part D sponsor formularies. While we worked to identify them, the Patient Protection and Affordable Care Act was enacted in 2010 and superseded the MIPPA provisions. Section 3307 of the Patient Protection and Affordable Care Act amended section 1860D–4(b)(3)(G) of the Act to specify that the existing drug categories or classes of clinical concern would remain so until such time as the Secretary established new criteria to identify drug categories or classes of clinical concern under section 1860D–4(b)(3)(G) of the Act through notice and comment rulemaking.

Our next applicable notice and comment rulemaking was the January 2014 proposed rule titled ''Medicare Program; Contract year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs'' (79 FR 1917) (hereinafter referred to as the January 2014 proposed rule). For purposes of the remainder of this Background section, we are summarizing the January 2014 proposed rule but are including detail when it is directly relevant to our current proposal.

In the January 2014 proposed rule (79 FR 1936), we proposed to interpret the Patient Protection and Affordable Care Act authority at section 1860D–4(b)(3)(G)(i) of the Act to limit protected classes to those for which access to all

drugs in the drug category or class is necessary: (1) In less time than the timeline for expedited exception, coverage determination, and appeals processes provide; and (2) when more specific formulary requirements would not suffice. This proposal would have specified that antidepressants, antipsychotics, and immunosuppressants for the treatment of transplant rejection were no longer protected classes. In response to comments, we did not finalize this proposal.

b. CMS Concerns With the Protected Class Policy and Proposals

The protected class policy, inclusive of its current limitations on prior authorization, is unique to the Medicare Part D program and does not appear elsewhere in other Federal programs, such as the Veteran's Health Administration (VA), TRICARE, the Federal Employees Health Benefits Program (FEHBP), the 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 and classes 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 or lack of safety edits) and increased drug prices due to lack of competition between manufacturers to achieve inclusion on plan formularies. We have previously detailed concerns that the policy potentially facilitates the overutilization of drugs within the protected classes. By limiting the ability of Part D sponsors to implement utilization management tools (for example, prior authorization or step therapy 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. Not only can this increase Part D costs, but inappropriate use can also lead to adverse effects that can harm the beneficiary and require medical treatment that would otherwise not have been necessary. We believe the profitability of products not subject to normal price negotiations as the result of protected class status is a strong incentive for the promotion of overutilization, particularly off-label overutilization, of some of these drugs.

Additionally, an open coverage policy substantially limits Part D sponsors' ability to negotiate price concessions in exchange for formulary placement of drugs in these categories or classes. Since the beginning of the Part D program we have heard from stakeholders that this policy—frequently referred to as the ''protected classes'' policy—significantly reduces any leverage the sponsor has in price negotiations and results in higher Part D costs. A report by the OIG in March 2011 documented similar assertions from selected Part D sponsors, including assertions that ''they received either no or minimal rebates for the drugs in these six classes,'' that ''there is little incentive for drug manufacturers to offer rebates for these six classes of drugs because they do not need to compete for formulary placement,'' and that '' 'if [a rebate] is provided, it's probably at a lower percentage than [the rebate for the drugs] that had some competition.' '' (HHS Office of Inspector General, ''Concerns with Rebates in the Medicare Part D Program'', March 2011, OEI–02–08–00050) (For a detailed explanation of these concerns, see the January 2014 proposed rule, 79 FR 1937.) We solicit comments on these concerns. Specifically, we ask commenters to provide evidence and research indicating that these concerns are warranted given real world experience.

Second, as a means to negotiate additional rebates, Part D sponsors can, in theory, subject enrollees to higher cost sharing by placing protected class drugs on non-preferred tiers (for example, non-preferred brand or non-preferred generic) or the ''specialty tier.'' However, Part D sponsors can only utilize the ''specialty tier'' if the cost of the drug exceeds the specialty tier threshold of $670 per month. Moreover, the 11.7 million dually-eligible enrollees whom the policy was originally intended to protect are shielded from the cost sharing usually applied to drugs on the non-preferred and specialty tiers because they receive a low-income cost-sharing subsidy. Thus, while a 2013 Avalere study found that Part D sponsors place anticonvulsants on higher tiers than do commercial plans, the data do not support the same conclusion for the five remaining protected classes. (Brantley, Kelly, Wingfield, Jacqueline, and Washington, Bonnie, Avalere, ''An Analysis of Access to Anticonvulsants in Medicare Part D and Commercial Health Insurance Plans,'' June 2013, *http://avalere.com/research/docs/Anticonvulsants_in_Part_D_and_Commercial_Health_Insurance.pdf*.) Finally, this option is not ideal because Part D sponsors typically apply rebates to reduce premiums, and therefore higher manufacturer rebates are not applied to reduce enrollee cost-sharing.

Indeed, many expert studies continue to demonstrate the role that the protected class policy plays in higher drug prices for protected class drugs in general. A 2008 study conducted by the actuarial and consulting firm Milliman found that the six protected drug classes disproportionately accounted for between 16.8 percent and 33.2 percent of total drug spend among sponsors surveyed (Kipp RA, Ko C). (See ''Potential cost impacts resulting from CMS guidance on 'Special Protections for Six Protected Drug Classifications' and Section 176 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275)'' available at: *http://amcp.org/WorkArea/DownloadAsset.aspx?id=9279*). Milliman reported that the Part D program administrators (Part D sponsors and PBMs) commented that the protected status of these drug classes limited Part D sponsors' ability to effectively negotiate lower costs with manufacturers since it is known that these drugs must be included on the formulary. The Milliman report estimated that affected drug costs were on average 10 percent higher than they would be in the absence of the protected class policy and that this represented $511 million per year in excess costs to beneficiaries and the Part D program. We note that numerous brand drug patents expired since this report was published, which might reduce cost projections. Another 2008 study from the National Bureau of Economic Research (NBER) suggested that while Medicare Part D led to a substantial decline in average pharmaceutical prices, Medicare-intensive drugs in protected classes did not experience price declines as did their counterparts not in protected classes and may have actually experienced price increases (Duggan M, Morton FS. 2010. ''The Effect of Medicare Part D on Pharmaceutical Prices and Utilization,'' American Economic Review, American Economic Association, volume 100(1), pages 590–607). Part D sponsors can still negotiate with manufacturers for preferred or non-preferred tier placement of protected class drugs, but CMS does not have any information on the justification for the relative magnitude of these rebates. However, it can reasonably be anticipated that such rebates would vary widely for individual manufacturers and sponsors, and anecdotal evidence would suggest the leverage these options provide sponsors may be minimal when compared to leverage available in connection with an initial decision regarding formulary inclusion, especially since tier placement has no impact on statutory LIS cost sharing

levels. Consequently, we would predict future savings for both beneficiaries and the Part D program from both increased price competition as newly approved drugs come onto the market and more immediate savings if plans were able to remove some currently covered agents from their formularies. Another recent study by Milliman, prepared on behalf of America's Health Insurance Plans (AHIP), found that brand drugs in the protected classes had the lowest proportion of drugs with rebates and the lowest rebates as a percentage of gross drug cost for those drugs receiving rebates. Out of 124 protected class brand drugs, 16 drugs (13 percent) received rebates, compared to 36 percent of brand drugs overall. Protected class brand drugs without rebates accounted for $16.3 billion in gross drug spending compared to $6.0 billion for protected class drugs with rebates. Of protected class brand drugs that received rebates, the average rebate as a percentage of gross drug cost was 14 percent, whereas non-protected brand drugs with direct competition had average rebates of 39 percent. (Milliman, ''Prescription Drug Rebates and Part D Drug Costs: Analysis of historical Medicare Part D drug prices and manufacturer rebates.'' July 2018. *https://www.ahip.org/wp-content/uploads/2018/07/AHIP-Part-D-Rebates-20180716.pdf.*) Additionally, although we are not able to speak to the actual rebate values provided by Milliman, CMS internal analyses of rebate data reported by Part D sponsors generally support Milliman's conclusion that Part D sponsors obtain substantially smaller rebates for protected class drugs than they do for non-protected class drugs.

In contrast to the numerous studies we reviewed that support the assertion that the limited negotiation ability Part D sponsors have for protected class drugs results in higher prices for such drugs, we identified at least one report, published by The Pew Charitable Trusts, that suggested that given the current high rates of generic use within the protected classes, there may be limited potential for savings from changes to the protected class policy, and that rebates on protected-class drugs are consistent with other brand-name drugs. (The Pew Charitable Trusts. ''Policy Proposal: Revising Medicare's Protected Classes Policy.'' March 7, 2018. *https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2018/03/policy-proposal-revising-medicares-protected-classes-policy.*) We disagree with these suggestions. First, as mentioned earlier in the preamble, CMS's 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 drugs than they do for non-protected class drugs. Second, the Pew study itself notes ''the possibility that plans could obtain higher-than-average rebates for these products if they had a greater ability to exclude them from coverage.''

We conclude that despite some formulary flexibility and ability to use drug utilization techniques for protected class 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 are not proposing to eliminate any of the protected classes, we now propose to use the authority under section 1860D–4(b)(3)(G) of the Act to propose revisions to § 423.120(b)(2)(vi). Specifically, we propose to permit Part D sponsors to implement prior authorization and step therapy requirements on protected class drugs for broader purposes than allowed currently and to exclude specific protected class drugs from their formularies based upon price increases or if they are a new formulation of a single-source drug or biological product with the same active ingredient or moiety that does not provide a unique route of administration, regardless of whether the older formulation is removed from the market. By ''single-source drug or biological product,'' we mean a covered Part D drug that is either produced or distributed under a new drug application (NDA) under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) or is an authorized generic as defined in section 505(t)(3) of the FDCA, or a biological product licensed under section 351 of the Public Health Service Act. We believe these exceptions would strengthen the Part D program by allowing Part D sponsors to better manage the protected class drugs to help ensure their safe and appropriate use, limit the protected class requirements to the intended protected class indications, and provide Part D sponsors with additional tools to negotiate as competitive a price as possible in order to provide drug pricing relief to Medicare Part D enrollees. Specifically, we are proposing three exceptions that would allow Part D sponsors to: (1) Implement broader use of prior authorization and step therapy for protected class drugs, including to determine use for protected class indications; (2) exclude a protected class drug from a formulary if the drug is a new formulation of an existing single-source drug or biological product, regardless of whether the older formulation remains on the market; and (3) exclude a protected class drug from a formulary if the price of the drug increased beyond a certain threshold over a specified look back period. However, we note that these exceptions would apply only to the requirement that the drug be included on the formulary because it is a protected class drug. In other words, an exception from the protected class policy would not supersede our other formulary requirements in § 423.120(b)(2).

2. Broader Use of Prior Authorization for Protected Class 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 prior authorization or utilization management, a particular Part D drug that is otherwise required to be on the formulary because it is in a protected class. Moreover, this authority applies without regard to whether an enrollee is initiating therapy (new starts) or is currently taking a drug (existing therapy).

As explained earlier, although Part D sponsors can employ some drug utilization management techniques within the protected classes, their ability to do so is not comparable with the commercial market. We find this concerning because prior authorization, as a standard feature of larger, industry-wide utilization management programs, is an important tool to identify clinically inappropriate therapy and control costs within the Part D program. For example, coverage under Part D is not available for drugs that are not medically necessary or used for a medically-accepted indication, or for drugs covered under Medicare Parts A or B as prescribed and dispensed or administered. Therefore, existing limits on Part D coverage permit prior authorization as a tool to determine whether a drug is a Part D drug being used for a medically-accepted indication, as defined in section 1860D–2(e)(4) of the Act, or to verify a drug is medically necessary or is not covered under Medicare Parts A or B as prescribed and dispensed or administered, as specified under sections 1860D–2(e)(3)(A) and 1860D–2(e)(2)(B) of the Act. As another example, as previously discussed in this preamble, we have concerns regarding the overutilization of protected class drugs, and in particular, antipsychotic drugs, among Medicare Part D enrollees. (For a detailed explanation of these

concerns, see the January 2014 proposed rule, 79 FR 1938). Additionally, a number of protected class drugs have medically-accepted indications for non-protected class uses. CMS considers a medically-accepted indication consistent with the description of the drug category or class of the protected class to be a ''protected class indication.'' The protected class indications for anticonvulsants, antidepressants and antipsychotics, antiretrovirals, and antineoplastics in the Part D program would be seizure disorders, mental disorders, HIV/AIDS, and cancer, respectively. Because the statute at section 1860D–4(b)(3)(G)(iv) of the Act specifies ''immunosuppressants for treatment of transplant rejection,'' the protected class indication for immunosuppressants in the Part D program would be treatment of transplant rejection only.

For example, antineoplastic and immunosuppressant drugs are also used for medically-accepted indications (that is, a use that is approved by the Food and Drug Administration (FDA) or is supported by one or more citations included or approved for inclusion in specified compendia) that are not protected class indications, such as rheumatological disorders. Thus, unless a Part D sponsor can use prior authorization 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 rheumatological disorders that would be clinically appropriate. Under this proposed policy, prior authorization requirements would be allowed for any protected class drug with more than one medically-accepted indication to determine that it is being used for a protected class indication, regardless of its status as a new start or existing therapy. This would strengthen an important tool Part D sponsors use to ensure clinically appropriate therapy (for example, to ensure use for a medically appropriate indication or medical necessity, or to implement step therapy or quantity limits), differentiate between protected and non-protected indications, and appropriate management of costs.

This proposal would expand the use of prior authorization within the protected classes to be consistent with what is currently permitted for non-protected classes given that (1) section 1860D–4(b)(3)(G)(i)(II) of the Act authorizes us to allow Part D sponsors to limit access to protected class drugs through prior authorization and utilization management for both new starts and existing therapy; (2) our expedited exception, coverage determination, and appeals processes are mature and have proven workable; and (3) Part D sponsors need additional tools to control costs of protected class drugs. Unlike our proposal in the January 2014 proposed rule, this expansion would preserve the six protected classes. Specifically, we propose to allow Part D sponsors to use prior authorization as is currently allowed for all other drug categories and classes, including to implement step therapy for protected class drugs or to determine use for protected class indications or both, without distinguishing between new starts or existing therapies, consistent with section 30.2.2 of Chapter 6 of the Medicare Prescription Drug Benefit Manual. We would also allow indication-based formulary design and utilization management for protected class drugs. This would be consistent with our July 25, 2018 Health Plan Management System (HPMS) memorandum titled, ''Indication-Based Utilization Management,'' in which we clarified that Part D sponsors can use indication-based utilization management for non-protected class drugs. (While the HPMS memo allows indication-based utilization management for non-protected class drugs starting in 2019, indication-based utilization management for protected class drugs would not be permitted until 2020, if this proposal is finalized.) It would also be consistent with our August 29, 2018 HPMS memorandum titled, ''Indication-Based Formulary Design Beginning in Contract Year 2020,'' which we are proposing to codify for protected class drugs later in this rule. While we are proposing to permit prior authorization for protected class drugs for both new starts and existing therapy, we would not approve onerous prior authorization criteria that are not clinically supported. As is required for all other drug categories and classes, these utilization management edits would be subject to our review and approval, as part of our annual 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. (For an extensive description of our annual formulary checks see the January 2014 proposed rule (79 FR 1939)). Also, we seek comment on whether this exception should be limited to new starts only.

We propose to codify this proposal by redesignating current § 423.120(b)(2)(vi)(C) as § 423.120(b)(2)(vi)(F), and adding an exception at new § 423.120(b)(2)(vi)(C) for prior authorization and step therapy requirements that are implemented to confirm that the 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.

It has been brought to our attention that some Part D sponsors have assumed that, because all protected class drugs have to be on the formulary, that there is no need for retrospective drug utilization review, as described in section 10.6.1 of Chapter 6 of the Medicare Prescription Drug Benefit Manual (available at *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf*). We would like to clarify that this is not, and has never been, the case, nor does this proposal obviate the requirement that Part D sponsors conduct retrospective drug utilization review on protected class drugs. Further, this exception does not preclude a Part D sponsor from taking appropriate action should they determine that, upon retrospective drug utilization review, protected class drugs were not prescribed for a particular individual for a medically-accepted indication or may have been fraudulent.

Additionally, we note that the August 2018 HPMS memorandum entitled, ''Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage'' and section II.F. of this proposed rule, entitled ''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. If both proposals in section II.A.2. of this proposed rule (this proposal, Broader Use of Prior Authorization for Protected Class Drugs) and section II.F. of this proposed rule are finalized, the result would be to allow MA–PD plans, starting in 2020, to require step therapy of Part B drugs before Part D drugs for the protected classes as well. Again, as is required for all other drug categories and classes, these step therapy requirements would be subject to our review and approval as part of our annual 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.

3. New Formulations

Before the start of the Part D program, we directed Part D sponsors to include on their formularies all or substantially all drugs in the six protected classes. ''Substantially all'' in this context meant that all drugs and unique dosage forms in these categories were expected to be included on Part D sponsor formularies, with the following exceptions:

- Multiple-source drugs of the identical molecular structure.
- Extended-release products when the immediate-release product is included.
- Products that have the same active ingredient or moiety.[1]
- Dosage forms that do not provide a unique route of administration (for example, tablets and capsules versus tablets and transdermals).

However, we codified in our June 2010 final rule (75 FR 32858) an exception at § 423.120(b)(2)(vi)(A) for drug products that are rated as therapeutically equivalent (under the FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' also known as the Orange Book).

Since that time, one manufacturer introduced a more expensive extended-release version of a drug to the market while also withdrawing from the market the predecessor immediate-release version when no generic was available. We are concerned that such a scenario could arise with a protected class drug that might leave Part D sponsors with no option but to add the new, more expensive product to their formularies and could result in increased costs for Part D enrollees and the Part D program. To prevent such behavior from occurring within the protected classes, we propose to permit Part D sponsors to exclude from their formularies a protected class single-source drug or biological product for which the manufacturer introduces a new formulation with the same active ingredient or moiety that does not provide a unique route of administration.

First, we would revise § 423.120(b)(2)(vi)(A) to reflect the forthcoming introduction of interchangeable biological products to the market. Specifically, we propose to amend § 423.120(b)(2)(vi)(A) to specify drug or biological products that are rated as—(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); 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 propose to add a new exception at new paragraph § 423.120(b)(2)(vi)(D) that would 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.

Part D plans are not required to include a new formulation of a drug on their formularies when the older formulation is still available. This policy would still apply. In other words, the purpose of this proposed exception is to specify that even if a new formulation of a single-source drug or biological product in the protected class becomes the only formulation available, Part D sponsors could 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 and approval process.

4. Pricing Threshold for Protected Class Drug Formulary Exclusions

As noted earlier, over the course of the Part D benefit, a number of Part D sponsors and pharmacy benefit managers (PBMs) have asked CMS to address their limited ability to negotiate manufacturer rebates and achieve appreciable savings relative to drugs within the protected classes. 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 at all for such drugs from 2016 to 2017. Accordingly, in developing exceptions to the protected class policy to obtain better pricing for drugs in these classes, CMS considered whether protected class drugs with price increases over a certain threshold during a particular look-back period should be required to be on all Part D formularies.

We propose, 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 drug whose price increases, relative to the price in a baseline month and year, beyond the rate of inflation. The rate of inflation would be calculated using the Consumer Price Index for all Urban Consumers (CPI–U). Specifically, we propose to add an exception at § 423.120(b)(2)(vi)(E) to specify that a part D sponsor can exclude from its formulary protected class single-source drug or biological products subject to our other formulary requirements in § 423.120(b)(2), that the Part D sponsor identifies, for which wholesale acquisition cost between the baseline date and any point in the applicable period has increased more than the cumulative increase in the CPI–U over the same period. The baseline date would be—(1) September 1, 2018 for drugs on the market as of September 1, 2018; or (2) the first day of the first full quarter after the launch date for drugs that enter the market after September 1, 2018. We also propose to add to § 423.100 a definition for the ''applicable period'' that would mean with respect to exceptions in accordance with § 423.120(b)(2)(vi)(E)—

- For contract year 2020, September 1, 2018 through February 28, 2019; or
- For contract year 2021 and subsequent years, September 1 of the third year prior to the contract year in which the exception would apply, through August 31 of the second year prior to the contract year in which the exception would apply.

[1] The FDA, at 21 CFR 314.3 defines an active moiety to be ''the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.'' Such term could be used to describe different salts of the same drug, for example, metoprolol tartrate versus metoprolol succinate. Additionally, such term could be used to describe a given drug with two versions of itself that are identical in chemical structure, but are mirror images of each other, having left and right-handed versions, like a pair of gloves, and where one of those images (or ''gloves''), exerts stronger pharmacological activity than the other and could be isolated to achieve a greater clinical effect, for example, citalopram versus escitalopram, or omeprazole versus esomeprazole. In these two examples, citalopram and omeprazole contain equal mixtures of both the right and left-handed versions of the drug, whereas escitalopram and esomeprazole represent isolates of only the left-handed versions.

First, we seek comment on whether an alternative pricing threshold to the CPI–U should be considered for this exception. The CPI–U is a measure of the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services. We proposed this pricing threshold for a variety of reasons. First, provided by the U.S. Department of Labor, Bureau of Labor Statistics, the CPI–U is a widely used and publicly available indicator of price inflation. There are also several examples of the CPI–U being used as an indicator of inflation in the administration of the Medicare and Medicaid programs. For example, the CPI–U is used as an integral part of the computation of the unit rebate amounts for innovator drugs in the Medicaid Drug Rebate Program. (The amount of rebate due for each unit of an innovator drug is based on statutory formulas of the greater of 23.1 percent of the Average Manufacturer Price (AMP) per unit or the difference between the AMP and the best price per unit and adjusted by the CPI–U based on launch date and current quarter AMP.) Moreover, several income and asset limits used to determine some aspects of Medicare eligibility are currently indexed to the CPI–U. Eligibility for Part D Low-Income Subsidies (LIS) depends on an applicant's assets falling below certain thresholds that are updated annually by the change in the CPI–U, and cost-sharing amounts paid by Part D LIS beneficiaries for Part D drugs are indexed to the CPI–U. The annual adjustment to the Part D catastrophic coverage threshold is also partially linked to the CPI–U. However, there are price indices that are more specific to health care inflation; there is a CPI specific to prescription drugs (CPI–PD), as well as a CPI specific to medical care more broadly (CPI–M). CMS would be open to considering one of these alternative measures for inflation, although these indices are not, to our knowledge, currently used in CMS programs as an indicator of inflation. While the fact that prices increase more quickly for protected class drugs may or may not have a greater impact on the CPI–PD, we note that one concern CMS considered with using the CPI–PD for this policy is that it would be ''self-fulfilling''—that is, the CPI–PD would just measure the existing increase in drug prices, which we believe is unsustainable and would defeat the purpose of this proposed exception. We solicit comment as to whether one of these more specific indices should serve as the pricing threshold for this policy as opposed to the more general CPI–U. For more information on the price indices referenced here, see the website for the Bureau of Labor Statistics at *https://www.bls.gov/cpi/*.

Next, we are soliciting comment on whether an increase in a price other than the drug's WAC, such as the negotiated price, or some other pricing standard (for example, the Average Wholesale Price (AWP) or the National Average Drug Acquisition Cost (NADAC)), should be used to determine whether the protected class drug could be excluded from a Part D formulary. We are proposing to use WAC as the pricing standard because it is a widely available, published list price, and thus verifiable by CMS. WAC is also widely used across the pharmacy supply chain, and commonly forms the basis of acquisition costs and pharmacy reimbursement (negotiated price). For more information on historical drug pricing trends, see National Health Expenditures information at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html*.

We also recognize that using the WAC (or any other public pricing standard) is mostly applicable to single-source drugs and biological products, given that payers typically use proprietary maximum allowable cost (MAC)—based pricing methodologies to pay for multisource generic drugs. Because MAC-based pricing methodologies are not generally public and transparent, we do not have a publicly available, reliable way to validate increases in MAC prices for generic drugs. Also, payers already pay a ''maximum'' cost for generic drugs, which makes changes in public list prices less relevant. Moreover, MAC price is the same for all generics related to the reference product, regardless of the list price. Per our discussion earlier in this preamble, we consider ''single-source drugs and biological products'' to be Part D drugs that are—(1) approved under a new drug application under section 505(b) of the FDCA; (2) an authorized generic drug as defined in section 505(t)(3) of the FDCA; or (3) in the case of a biological product, licensed under section 351 of the Public Health Service Act. We believe that limiting this exception policy to single-source drug and biological products is appropriate given the current lack of incentive to reduce prices as a result of the generally limited competition for such drugs. We also solicit comment on whether this exception policy should apply only to single-source drug and biological products, or whether a broader mix of drugs should be eligible for formulary exclusion in accordance with this proposed exception policy.

Further, because different medical conditions can warrant different routes of administration, multiple dosage forms may exist for a particular drug or biological product. Since drugs are available in multiple strengths and dosage forms, with each strength and form having its own, or even multiple, national drug code(s) (NDC), we propose to identify a protected class drug for purposes of this policy as all the NDCs assigned to the single-source drug or biological product name, including NDCs for all strengths, dosage forms, and routes of administration associated with a particular drug. Further, we propose that if the WAC for any NDC assigned to the drug increases faster than inflation (as described previously), that the Part D sponsor can exclude from its formulary all NDCs assigned to that drug. We solicit comment as to whether an increase in WAC beyond CPI–U for any NDC assigned to a particular brand drug or single-source generic drug should be grounds for allowing a sponsor to exclude all NDCs assigned to that drug from the formulary.

Moving into the operational components of the proposal, when determining the proposed baseline for drugs currently on the market, we wanted to select a date prior to the publication of this proposed rule and before the usual price increases that generally take place the first day of the last quarter of the year. That way, opportunities for price gaming would be decreased, and any price increases planned prior to the release of this proposed rule would not be incorporated and result in a higher baseline. For drugs not currently on the market, we believed choosing the WAC as of the beginning of a quarter would aid in operational ease and consistency. We therefore propose that the baseline WAC, which Part D sponsors would use to determine whether a protected class drug's price has increased faster than inflation, would be determined as follows: (1) For a single-source drug or biological product that was first marketed in the United States on or before September 1, 2018, the baseline WAC would be the WAC as of September 1, 2018; (2) for a single-source drug or biological product that is first marketed in the United States after September 1, 2018, the baseline WAC would be the WAC as of the date that is the first day of the first full quarter after the date the single-source drug or biological product was first marketed in the United States. For example, if a protected class drug is first marketed on

July 15, 2019, baseline WAC would be the WAC as of October 1, 2019. We propose that the increase in a drug's WAC would be determined by comparing the baseline WAC to the WAC at any point during the relevant applicable period (which we describe later in this section) for a contract year. We solicit comment on whether the WAC as of some date other than September 1, 2018 should be used as the baseline WAC for drugs that are on the market on or before September 1, 2018.

As previously noted, we propose that the increase in protected class drug's WAC would be compared to the corresponding cumulative increase in the CPI–U for the same period. To make this comparison, we propose that the baseline CPI–U for a protected class drug would be determined as follows: (1) For a single-source protected class drug or biological product that was first marketed in the United States on or before September 1, 2018, the baseline CPI–U would be the September 2018 CPI–U (which will be released in October 2018, but which we refer to as the September 2018 CPI–U in this proposed rule); and (2) for a single-source protected class drug or biological product that is first marketed in the United States after September 1, 2018, the baseline CPI–U would be the CPI–U for month in which the baseline WAC is established for the drug or biological product. To use our previous example, if a protected class drug is first marketed on July 15, 2019, the baseline CPI–U would be the CPI–U for October 2019.

We further propose that in making the comparison of the increase in a protected class drug's WAC to the corresponding increase in the CPI–U, the rate of change of CPI–U must be calculated on a cumulative basis for the same months for which the change in WAC is observed. For example, the change in WAC for a drug between September 1, 2018 and February 19, 2019 would be compared to the corresponding cumulative change in the CPI–U between September 2018 and February 2019. We also want to highlight that in the rare case that a CPI–U may be negative during the applicable period, note if the CPI–U goes down in a year that could lower the cumulative CPI–U for the applicable period.

We propose that in order for a protected class drug to be excluded from the formulary for a given plan year, the comparison of the WAC increase to the cumulative CPI–U increase would need to be measured for an ''applicable period,'' which we propose to define as described in this proposed rule. For contract year 2020, we propose that the applicable period is September 1, 2018 through February 28, 2019. The applicable period for contract years 2021 and thereafter would begin on September 1st, 3 years before the contract year in which the exception would apply, and end August 31st of the second year prior to the contract year in which the exception would apply (see Table 1). We note that the proposed applicable period for contract year 2020 is shorter given that the bids for contract year 2020 are due in June 2020, and in order for this policy to take effect in contract year 2020, a shorter applicable period is necessary to align with the Part D bid cycle, and for beneficiaries to start to benefit from this policy change, if finalized, as quickly as possible.

If a Part D sponsor determines that a protected class drug's WAC has increased faster than the corresponding cumulative increase in the CPI–U within the applicable period, we propose that the Part D sponsor could exclude the protected class drug from its formulary for the contract year associated with that applicable period. To effectuate such an exclusion, the Part D sponsor would be required to submit, along with its formulary submission, information sufficient to demonstrate that the drug or biological product meets the criteria for exclusion that we are proposing. CMS would review the information as part of its formulary review and approval process.

Please see Table 1 for an illustration of how we project the timeline for the implementation of this proposal.

We believe this timeline would allow Part D sponsors to take this policy into account as they negotiate pricing and rebates with manufacturers for the applicable contract year (that is, the contract year in which the exception from protected class status would apply). We understand that Part D sponsors begin negotiations with manufacturers for formulary status in early fall (October/November) of the year preceding the year in which bids are due for the upcoming plan year (that is, for contract year 2021, we believe that plans will begin negotiation with manufacturers in the fall of 2019, in advance of bids for contract year 2021 being due in June 2020). Ending the applicable period at the end of the third quarter annually allows the Part D sponsor to determine which protected class drugs (if any) could be excluded from the formulary in time to negotiate for their formulary inclusion and placement if desired.

We understand that the proposed applicable periods for contract year 2020 and contract year 2021 overlap from September 1, 2018 through February 28, 2019, such that if a manufacturer increases the WAC for a protected class drug during that time at a rate faster than the growth in CPI–U during that time, a Part D sponsor could exclude the drug from its formulary for both contract years 2020 and 2021. Part D sponsors should note that even if the exclusion policy is triggered for both plan years 2020 and 2021, our approval of formularies for each plan year would have to be obtained separately for the applicable formulary submission.

For additional clarity, we provide another example of how the proposed applicable periods would work. For contract year 2022, the applicable period would be September 1, 2019 through August 31, 2020. If during any month in the applicable period, the WAC for a protected class drug increases more than the cumulative change from the baseline CPI–U to the CPI–U at any time during the relevant applicable period, a Part D sponsor could exclude the drug from its formulary for contract year 2022.

TABLE 1—PROPOSED PRICING THRESHOLD POLICY TIMELINE FOR CALENDAR YEARS 2020 THROUGH 2023

Date	Activity(ies)
September 1, 2018	Baseline WAC established for drugs on the market as of 9/1/2018. Applicable period for Contract Year 2020 and Contract Year 2021 begins.
October 2018	Baseline September 2018 CPI–U released.
February 28, 2019	Applicable period for Contract Year 2020 ends.
June 3, 2019	Deadline for submission of Contract Year 2020 Bids, Formularies, Transition Attestations, Prior Authorization/Step Therapy (PA/ST) Attestations, and P&T Attestations due from all sponsors offering Part D including Medicare-Medicaid Plans (11:59 p.m. PDT).
August 31, 2019	Applicable period for Contract Year 2021 ends.
September 1, 2019	Applicable period for Contract Year 2022 begins.

TABLE 1—PROPOSED PRICING THRESHOLD POLICY TIMELINE FOR CALENDAR YEARS 2020 THROUGH 2023—Continued

Date	Activity(ies)
December 31, 2019	Contract Year 2019 ends.
January 1, 2020	Contract Year 2020 Begins. Approved formulary exclusions *begin* for drugs with increased price past the CPI–U in the applicable period for Contract Year 2020.
June 1, 2020	Deadline for submission of Contract Year 2021 Bids, Formularies, Transition Attestations, Prior Authorization/Step Therapy (PA/ST) Attestations, and P&T Attestations due from all sponsors offering Part D including Medicare-Medicaid Plans (11:59 p.m. PDT).
August 31, 2020	Applicable period for Contract Year 2022 ends.
September 1, 2020	Applicable period for Contract Year 2023 begins.
December 31, 2020	Contract Year 2020 ends. Approved formulary exclusions *end* for drugs who increased price past the CPI–U in the applicable period for Contract Year 2020.
January 1, 2021	Contract Year 2021 begins. Approved formulary exclusions *begin* for drugs who increased price past the CPI–U in the applicable period for Contract Year 2021.
June 7, 2021	Deadline for submission of Contract Year 2022 Bids, Formularies, Transition Attestations, Prior Authorization/Step Therapy (PA/ST) Attestations, and P&T Attestations due from all sponsors offering Part D including Medicare-Medicaid Plans (11:59 p.m. PDT).
August 31, 2021	Applicable period for Contract Year 2023 ends.
September 1, 2021	Applicable period for Contract Year 2024 begins.
December 31, 2021	Contract Year 2021 ends. Approved formulary exclusions *end* for drugs who increased price past the CPI–U in the applicable period for Contract Year 2021.
January 1, 2022	Contract Year 2022 begins. Approved formulary exclusions *begin* for drugs who increased price past the CPI–U in the applicable period for Contract Year 2022.
June 6, 2022	Deadline for submission of Contract Year 2023 Bids, Formularies, Transition Attestations, Prior Authorization/Step Therapy (PA/ST) Attestations, and P&T Attestations due from all sponsors offering Part D including Medicare-Medicaid Plans (11:59 p.m. PDT).
August 31, 2022	Applicable period for Contract Year 2024 ends.
September 1, 2022	Applicable period for Contract Year 2025 begins.
December 31, 2022	Contract Year 2022 ends. Approved formulary exclusions *end* for drugs who increased price past the CPI–U in the applicable period for Contract Year 2022.
January 1, 2023	Contract Year 2023 Begins. Approved formulary exclusions *begin* for drugs who increased price past the CPI–U in the applicable period for Contract Year 2023.
June 5, 2023	Deadline for submission of Contract Year 2024 Bids, Formularies, Transition Attestations, Prior Authorization/Step Therapy (PA/ST) Attestations, and P&T Attestations due from all sponsors offering Part D including Medicare-Medicaid Plans (11:59 p.m. PDT).
August 31, 2023	Applicable period for Contract Year 2025 ends.
September 1, 2023	Applicable period for Contract Year 2026 begins.
December 31, 2023	Contract Year 2023 ends. Approved formulary exclusions *end* for drugs who increased price past the CPI–U in the applicable period for Contract Year 2023.

For further clarity on this proposal, we provide an example of how we foresee calculations would take place to monitor changes in price to determine which protected class drugs could be excluded from the formulary on the basis of price increases.

Baseline WAC for Drug Y (as of September 1, 2018) = $100

Baseline CPI–U (for September 2018) = 100.0

February 15, 2019 WAC for Drug Y = $110

February 2019 CPI–U (released in March 2019) = 105.0

The rate of change of the WAC for Drug Y = (February 2019 WAC − Baseline WAC) ÷ 100 = ($110 − $100) ÷ 100 = 0.1 or 10 percent growth

The rate of change of the CPI–U = (February 2019 CPI–U − Baseline CPI–U) ÷ 100 = (105 − 100) ÷ 100 = 0.05 or 5 percent growth)

The WAC for Drug Y grew by 10 percent between September 2018 and February of 2019, whereas the CPI–U only grew by 5 percent cumulatively over the same time period. Therefore, the WAC for Drug Y grew faster than inflation in February 2019, which falls in the proposed applicable periods for both contract year 2020 and 2021. Thus, in this example, a Part D sponsor could exclude Drug Y from its formulary for both contract years 2020 and 2021.

Under our proposal, Part D sponsors would be responsible for monitoring price increases, determining the cumulative CPI–U increases for the corresponding applicable periods, and deciding whether they wish to submit for our approval a formulary that excludes protected class drugs with price increases that exceed the rate of inflation. As an alternative to this approach, we also considered an approach where each year, CMS would produce a list of protected class drugs a Part D sponsor could exclude from its formulary for a specified contract year as a result of the drug's WAC increasing, such that it exceeds the rate of inflation (that is, the CPI–U) as compared to the drug's baseline WAC. However, we declined to propose this approach, because we believe Part D sponsors will be better able to make these determinations more quickly, and we see merit and benefit in providing Part D sponsors with the flexibility to determine whether they would exclude the drug or negotiate with the manufacturer for formulary inclusion and placement. Having sponsors monitor price increases allows them immediate access to the information needed to inform bid submissions, particularly for contract year 2020. We solicit comment on the merits of our proposal to have Part D sponsors operationalize this exception policy by monitoring changes in WAC and CPI–U, or if a more effective approach would be for CMS to monitor these price changes and produce a list of drugs that could be excluded from Part D formularies for a given contract year. If commenters believe that CMS should be providing such a list, we solicit comment as to when that list should be released each year.

As noted previously, we propose that once a drug can be excluded from formularies as a result of a price increase described previously (that is, during any month of the applicable period), that the drug can be excluded

from formulary only for the contract year for which the applicable period applies (that is, a drug is excepted from protected class status in contract year 2020 if the price increases more than the CPI–U for any month in the contract year 2020 applicable period). Therefore, to exclude a protected class drug from its formulary for the next contract year, the Part D sponsor would need to monitor whether the WAC of the drug has increased faster than inflation for the next contract year's applicable period. If the WAC has increased beyond the applicable period CPI–U for the next contract year's applicable period, then it could be excluded from the formulary, but if the WAC has not increased beyond the applicable period CPI–U for the next contract year's applicable period, it could not be excluded from the formulary for that contract year. This would also mean that, for example, if the WAC for a protected class drug in February 2020 exceeded the rate of inflation, as of February 2020, the drug could be excluded from a Part D formulary for contract year 2022 even if the WAC were lowered below the rate of inflation in March 2020.

However, we note that just because a protected class drug *can* be excluded from formulary under this proposed policy, it does not mean that a Part D sponsor *must* exclude the drug from formulary. Rather, we believe that instead, manufacturers and Part D sponsors could negotiate rebate arrangements for formulary placement of these protected class drugs as they do for non-protected-class drugs, and in such an event Part D sponsors could continue to include drugs on formulary even if their WACs exceeded the rate of inflation in the applicable period. We also considered whether to propose that a Part D sponsor could exclude a protected class drug could from its formulary for *any* future contract year once its WAC increased more rapidly than the cumulative increase in inflation. We solicit comment on such a policy approach.

In order to maximize the impact this policy would have on addressing high-cost drugs in protected classes, we also considered whether we should apply this price threshold exception to *all* drugs in the protected classes of a given manufacturer if *any one* of those drugs' WAC, when compared to the baseline WAC, increases beyond the cumulative rate of inflation. For example, if a manufacturer makes three protected class drugs, but the WAC for only one of those drugs increases beyond the CPI–U from its baseline WAC, we contemplated proposing that all three of those drugs could be excluded from the formulary. We solicit comment on this iteration of the proposed exception policy.

To assuage any concerns that the proposed regulatory change would reduce access to protected class drugs, we again note that even if a protected class drug could be excluded from a Part D formulary under this proposed policy, Part D sponsors are not required to do so. Nothing in this proposal would prohibit the Part D sponsor from including the drug on its formulary. Moreover, it is our expectation that this exception policy would benefit the program and beneficiaries by encouraging manufacturers to work with Part D sponsors to ensure formulary inclusion and favorable access (for instance, better cost sharing, more competitive negotiated prices, etc.) for Part D enrollees, rather than a loss of formulary inclusion for drugs in the protected classes. Finally, we note that existing enrollee protections, namely the coverage determination and appeal process, and the Part D formulary requirements as discussed elsewhere in this preamble, provide safeguards to access to all prescription drugs. These safeguards would continue to be available to protect enrollees' access to their medically necessary medications. For instance, our annual formulary review and approval process includes extensive checks to ensure adequate representation of all necessary Part D drug categories or classes for the Medicare population. We remind stakeholders, in particular Part D sponsors, that even if a protected class drug could be excluded from the formulary for a contract year, on the basis of this proposed exception to the protected class requirements, the drug may be required to be included on the formulary for other reasons, for example, if the drug is needed to fulfill other applicable formulary requirements, such as the protected class drug in question is required to be on formulary because it is the only drug available in its category or class. CMS solicits comment on the impact of this policy proposal on Part D enrollees.

5. Solicitation of Comment for Special Considerations

In considering whether exceptions to the added protections afforded by the protected class policy are appropriate, we take other enrollee protections in the Part D program into account. There are five such enrollee protections, and these are formulary transparency, formulary requirements, reassignment formulary coverage notices, transition supplies and notices, and the expedited exception, coverage determination, and appeals processes. (For a detailed discussion of these protections, see the January 2014 proposed rule, 79 FR 1938.) Our formulary review and approval process includes a formulary tier review, and for prior authorization and step therapy, we also conduct restricted access, step therapy criteria, prior authorization outlier, and prior authorization 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/ST criteria submitted to CMS by Part D plans. We note that best practice utilization management practices would not require an enrollee who has been stabilized on an existing therapy of a protected class drug for a protected class indication to change to a different drug in order to progress through step therapy requirements, and we would not expect Part D sponsors to require, nor would CMS be likely to approve, this if our proposed exceptions to the protected class policy were finalized. Moreover, we believe our current approach that ensures at least one drug within the class is offered on a preferred tier and free of prior authorization and step therapy requirements are working well and should be maintained. Currently, Part D formularies frequently have more than one protected class drug at a preferred cost sharing level, especially in classes with significant generic availability, without any prior authorization or step therapy requirement, and we would not expect that this proposal would prompt Part D sponsors to stop including protected class drugs on tiers with preferred cost sharing. (For a detailed discussion of our formulary review processes, see the January 2014 proposed rule, 79 FR 1939.) Finally, our transition policy will continue to require Part D sponsors to provide all new enrollees that are currently taking a protected class drug with an approved month's supply if the Part D sponsor will be utilizing prior authorization to confirm if an enrollee is a taking a protected class drug for a protected class indication. (For a detailed discussion of our transition requirements, see the January 2014 proposed rule, 79 FR 1940, and regulations at § 423.120(b)(3).)

Nonetheless, we wish to make certain that our three proposed exceptions (that is, broader use of prior authorization, new formulations, and pricing thresholds) to the protected class policy would not introduce interruptions for

enrollees on existing therapy of protected class drugs for protected class indications.

We seek comment on whether there are additional considerations that would be necessary to minimize: (1) Interruptions in existing therapy of protected class drugs for protected class indications during prior authorization processes; 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 drugs for which the Part D sponsor has established prior authorization requirements, or as another example, for transitioning some enrollees taking protected class drugs for protected class indications to alternative Part D drugs. If so, we seek comment on why our current requirements and protections are inadequate, or could be improved. In addition, we seek comment on what specific patient population(s), individual patient characteristic(s), specific protected class drugs or individual protected drug classes would require such additional special transition or other protections and how such population(s) can be consistently identified. Finally, we seek comment on other tools that could be used to minimize interruptions in existing therapy of protected class drugs for protected class indications during prior authorization processes, for example, wider use of diagnosis codes on prescriptions, e-PA during e-prescribing, targeting protected class 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.

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 would 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 would 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 propose to incorporate the new requirement into the Part D regulations. Specifically, we propose to amend the set of pharmacy contracting requirements at § 423.120(a)(8) by adding a paragraph (iii) that provides that a Part D sponsor may not prohibit a pharmacy from, nor penalize a pharmacy for, informing a Part D plan enrollee of the availability at that pharmacy of a prescribed medication at a cash price that is below the amount that the enrollee would be charged to obtain the same medication through the enrollee's Part D plan.

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 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 proposed 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. As of January 1, 2020, however, 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 either Version 1, Release 1 (Version 1.0), from October 2005, or Version 3 Release 0 (Version 3.0), from April 2012 of the National Council for Prescription Drug Programs (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. Thus far in 2018, 66 percent of Part D prescriptions were written electronically using the applicable SCRIPT standard, and all Part D plans implement electronic F&B using one of the adopted standards. However, based on industry feedback, we understand that while some prescribers rely on electronic F&B transactions to support prescribers during the eRx process, others do not. For example, vendors of electronic medical records (EMR) systems have stated that some of their clients find F&B data useful, but approximately half of their clients chose not to access F&B data at all. 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/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.

We are proposing to require a real-time benefit tool (RTBT) requirement on Part D sponsors to serve as a critical adjunct to the existing SCRIPT and F&B electronic standards. There is no requirement that prescribers or dispensers implement electronic prescribing but the existing SCRIPT standard allows prescribers means of conducting electronic prescribing, while the F&B standard allows a prescriber to see what is on the plan's formulary, but 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. If finalized, RTBT data would be layered on top of F&B data to gain a complete view of the beneficiary's prescription benefit information. It will 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. Further F&B provides information on a contract level, rather than a patient level, and consequently could not provide information about out-of-pocket costs for a given patient at a given point in time.

As described in more detail in the next section, we believe requiring plans to make one or more RTBT 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 propose to require that the RTBT be capable of integrating with prescribers' eRx and EMR systems 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 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, and supports for the MMA objectives of patient safety, quality of care, and efficiencies and cost savings in the delivery of care if our proposals are finalized.

3. Proposed Adoption of a Real-Time Benefit Tool

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 program 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 EMR 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, 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, 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 medical record (EMR) system. This would allow the prescriber and patient, when appropriate, to choose among clinically acceptable alternatives while weighing costs. Since eRx can generally be performed within the provider's EMR system, integration of the RTBT function within the EMR generally, and the eRx workflow specifically appears to be critical for the successful implementation of the technology. However, we recognize that without a standard for RTBT, prescribers may be offered multiple technologies, which may overwhelm and create burden for EMR vendors. We also recognize that without a standard, the RTBT tool provided may not be integrated with a prescribers' EMR, thus limiting its utility.

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. In a 2012 review of studies investigating how patient out-of-pocket costs affects medication adherence and outcomes, researchers found that 85 percent of studies demonstrated that increasing patient cost-share for a medication was associated with a significant decrease in medication adherence.[2] 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.[3] [4]

Therefore, we are proposing that each Part D sponsor be required to implement a RTBT capable of integrating with prescribers' eRx and EMR systems to provide complete, accurate, timely, clinically appropriate and patient-specific real-time formulary and benefit information to the prescriber. While we recognize that there currently is no industry-established transaction standard for RTBTs for CMS to propose adopting, we believe it is appropriate to require implementation of solutions based on available technologies. There appear to be multiple existing technologies capable of interfacing with multiple EMR systems and providing to prescribers the patient-specific real-time coverage information we have described in this preamble, and, given that, that it would be inappropriate to wait any longer for an industry-wide standard to be developed given current concerns about drug prices. Under this proposed rule Part D plan sponsors would be required to select or develop an RTBT capable of integration with at least one prescriber's EMR and eRx systems; we

[2] 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.

[3] 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.

[4] 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.

encourage EMR and eRx vendors to work with Part D plans to ensure that the information can be requested and viewed in real time by a user of their product at the point of prescribing. In order to meet this proposed requirement, each Part D plan sponsor will be required to implement an RTBT that is capable of integrating with at least one of prescribers' eRx and EMR systems to provide the prescriber with complete, accurate, timely, and clinically appropriate patient-specific real-time formulary and benefit information at the point of eRx. Each system response value would need to show an accurate reflection of how the prescription claim would be adjudicated given the information submitted and the claims history of the patient with that plan, including relevant indications that could impact coverage, at the time the prescriber query is made. Further, the system would be required to present real-time values for the patient's cost-sharing information and additional formulary alternatives. This requirement would include the formulary status of clinically appropriate formulary alternatives, including any utilization management requirements, such as step therapy, quantity limits and prior authorization, and indications-based restrictions, for each specific alternative presented.

We are interested in bringing RTBT's benefits to the Part D program as soon as feasible. In evaluating how quickly plans could choose and implement an RTBT functionality, we note that a number of firms have already developed the technology required to provide the information we describe through some eRx/EMR systems. Pharmacy benefit managers (PBMs) that service the majority of Part D plans, and a few plans themselves, have successfully implemented RTBTs for a small subsection of the plans' enrollment, which were capable of conveying the information described and interfacing with most EMR and eRx products. We believe that should RTBT systems continue to result in reduced drug costs, plans will expand the number of prescribers who have access to RTBT technologies over the next several years, ultimately paving the way for universal RTBT deployment within Part D in contract year 2020. As plans develop their formularies and benefit packages for 2020, we believe that they will be able to include RTBT implementation in the 2020 planning process. Because section 1860D–12(f)(2) of the Act prohibits the implementation of ''significant'' regulatory requirements on a prescription drug plan other than at the beginning of the calendar year, if finalized, we are proposing to implement the RTBT requirement on January 1, 2020.

We also encourage plans to use RTBTs to promote full drug cost transparency by showing each drug's full negotiated price (as defined in 42 CFR 423.100), in addition to the beneficiary's out-of-pocket cost information. Displaying both values would provide prescribers with additional decision support by providing visibility into both their patients' cost-sharing amounts as well as total cost to the Medicare program. Viewing negotiated price at the point of prescribing would be of particular interest when alternative drugs in a plan's formulary have comparable out-of-pocket costs and clinical value; in those cases a prescriber may consider negotiated prices as well, which would be of value to the Medicare program. For this reason we encourage plans to include negotiated price with their RTBT solution, although we are not proposing to make it a requirement at this time.

We believe that beneficiaries will benefit from their prescribers' use of RTBT. However, we would caution that RTBT should not be used by providers to evaluate alternatives for drugs prior to discussing whether the patient intends to self-pay for the prescribed drug. Such practices will preserve the patient's ability to exercise their right under the privacy regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) [5] and modified pursuant to, among other laws, the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009.[6] If requested by the individual, the HIPAA Privacy Rule at 45 CFR 164.522 requires covered entities to agree to a restriction of the disclosure of PHI to a health plan for payment and health care operations when an individual pays for the item or service out-of-pocket in full.

Therefore covered 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. Covered health care providers should discuss with the individual whether the individual desires the prescriber to use the RTBT as doing so would generally eliminate the beneficiary's ability to request disclosure restrictions as the plan would already be in possession of the query data regarding the desire to prescribe something for a specified condition.

We considered building upon the existing F&B standard to provide prescribers with decision support. Under this scenario, we would require that plans use the existing NCDP Formulary and Benefit (F&B) Standard (version 1.0 or 3.0) but modify our requirement for Part D so that plans would be required to populate certain optional fields such as copay tier, dollar copay value, and utilization management criteria for each drug. We considered this option as a solution because it would be built upon an existing transaction standard and allow interface with all EMR systems to deliver the information to the prescriber within the normal workflow. However, we believe that a prescriber tool that relied on the F&B would fail to provide the real-time information currently used by many plans. Many prescribers have chosen not to include F&B information in their EMRs because they view the information presented as unreliable as the data is not specific to the patient's benefit plan. Given the inherent complexities associated with Part D formularies and benefits, we concluded that under this option, the patient information available to the practitioner at the time of prescribing would often lack sufficient and current detail necessary for clinical decision-making, which could lead to confusion for prescribers and patients. For example, we understand that a plan that had a prior authorization in place for a targeted portion of its population conveyed the prior authorization requirement for all patients. The plan's rationale was that they would not know which patient was accessing the F&B data, so the plan chose to include the requirement for all enrollees rather than the reverse which would be to omit the requirement for some of their enrollees. Similarly the F&B standard could convey a step therapy requirement for the population at large, but could not discern whether or not an individual patient had fulfilled the requirement.

However, in spite of these shortcomings, including the inherent lack of beneficiary-specific formulary information or its batch-only

[5] *See* the Administrative Simplification provisions of title II, subtitle F, of the HIPAA (Pub. L. 104–191), which added a new part C to title XI of the Social Security Act (sections 1171–1179 of the Social Security Act, 42 U.S.C. 1320d–1320d–8).

[6] The HITECH Act was enacted as title XIII of division A and title IV of division B of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5).

functionality, we continue to believe that the NCPDP F&B 1.0 and 3.0 continue to provide value to the Part D program, and, as a result, we are not proposing to retire those standards. This value is evidenced by the fact that, as previously noted, many EMRs convey F&B data to their prescribers. Even strong proponents of adopting RTBT state that the standards work best when used with F&B. They state that F&B can provide a general view of the plan's formulary while RTBT aids the prescriber in choosing between the formulary alternatives offered.[7] We also note that where a prescriber has limited formulary choices due to the patient's specific clinical condition, F&B may provide all the information needed. Finally many EMRs use the F&B and RTBT transactions in different places within in the eRx work-flow. Therefore, we believe that both the F&B and RTBT transactions add value to the eRx process and are not interchangeable and should be used in tandem.

Prior to proposing that each Part D plan choose an RTBT tool to support, we sought to identify an industry standard that could be used throughout the Part D program. We prefer industry-wide standards when they are available due to their significance in promoting collaboration and interoperability across industry partners. Unfortunately, we were unable to identify a suitable RTBT standard that has been balloted and approved by an accredited standard setting body to ensure interoperability. However, we are aware that efforts are underway to develop RTBT standards, and are hopeful that they will come to fruition in the near future. We are interested in, and solicit comments on, assessments from knowledgeable parties about whether any of the standards that are currently under development may be suitable to meet our intended purposes described herein. Based on these considerations, we are proposing to amend § 423.160(b) by adding the requirement that all Part D plan sponsors implement one or more RTBT by January 1, 2020 to be used with the patient's consent. This would require that each Part D plan carefully review the drugs that exist on the formulary and determine which, if any, formulary alternatives exist. The plan's RTBT system would integrate with automated prescriber systems (eRx or EMR) to present a list of the formulary alternatives to the prescriber along with any applicable utilization management requirements and patient's cost sharing for each one. This would allow, with the patient's consent, a prescriber to consider both the clinical appropriateness and patient copayment of a drug during the prescribing process. If finalized, this tool could provide complete, accurate, timely and clinically appropriate patient-specific real-time formulary and benefit information that could be capable of integrating with prescriber's eRx and EMR systems. Formulary and Benefits information delivered through the RTBT would be required to include patient-specific adjudication and out-of-pocket cost information, and would be required to provide decision support reflecting clinically appropriate formulary alternatives and utilization management requirements such as step therapy, quantity limits and prior authorization requirements.

We welcome comments on this proposal, including the feasibility for plans to meet the proposed January 1, 2020 deadline. We understand that should this proposal be finalized some Part D plans may need to invest considerable resources in order to execute effective RTBT solutions. At a minimum, each plan will need to scrutinize individual formulary drugs to see whether lower cost alternatives exist, and evaluate how these alternatives can be presented in such a way that will be helpful to clinicians who make prescribing decisions for patients who may have multiple co-morbidities and conditions. We also realize that RTBT can only achieve the desired cost savings if plans can partner with medical records and eRx vendors to support these efforts by transmitting accurate the information to the prescriber in an easily actionable format. We welcome comments on how this 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 seek 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 would consider retraction of this proposed rule if we receive feedback indicating that the rule 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 are other indications that a standard will be available before the 2020 effective date of this proposed provision. In such case, we would review such standard, and if we find it suitable for our program consider proposal of that standard as a requirement for implementation in our 2021 rulemaking, effective January 1, 2021. We are also soliciting comments regarding the impact of this proposal on plans and providers, including overall interoperability and the impact on medical record systems. Finally, we are soliciting comments regarding the impact of the proposed effective date on the industry and other interested stakeholders.

D. Part D Explanation of Benefits (§ 423.128)

Section 1860D–4(a)(1)(A)(4) 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 all of the following information written in a form easily understandable to enrollees:

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

Part D sponsors must provide enrollees with EOB no later than the end of the month following any month in which the enrollee utilized their prescription drug benefit.

Lowering prescription drug costs is of critical and immediate concern to beneficiaries, CMS and the Administration. ''The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs,'' released in May 2018 [8] specifically solicited comment on improving the usefulness of the Part D Explanation of Benefits statement by including information about drug price changes and lower cost alternatives. As expected, many beneficiary advocacy groups submitted supportive comments regarding amending the Part D EOB. Many groups commended the Administration's desire to further

[7] *https://www.pocp.com/hit-drug-price-transparency-opportunities.*

[8] ''The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs,'' HHS (May 2018). Please see: *https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf.*

transparency efforts through improvements in beneficiary education materials, such as the Part D EOB. Requiring sponsors to include additional information about negotiated drug price changes and lower cost therapeutic alternatives in the EOB would help improve cost transparency of Part D prescriptions and mitigate drug price increases in the Part D program.

The items required to be included in the EOB under the current regulation do not include information about negotiated price changes for each of the prescription drugs covered for a beneficiary, nor do they specify including information about lower cost therapeutic alternatives. Because we do not require this information under the regulation as currently written, for contract year 2019 as specified in the July 24, 2018, HPMS Memorandum, ''Model Notice and Policy Updates,'' we added an option for sponsors to use the existing notes field in the EOB for information on drug price increases and more affordable formulary alternatives.[9]

We propose to redesignate paragraphs (e)(5) and (e)(6) of § 423.128(e) as paragraphs (e)(6) and (e)(7) to add a new paragraph (e)(5) to require sponsors to include information about negotiated price changes and lower-cost therapeutic alternatives in the Part D EOBs. First, as to information about negotiated drug price increases, we propose to require that Part D sponsors include the cumulative percentage change in the negotiated price since the 1st day of the current benefit year for each prescription drug claim in the EOB. For example, when a beneficiary fills a prescription under his or her Part D plan in April of the current benefit year that begins on January 1, the cumulative percentage by which the negotiated price has changed since January 1 of that year would display in the EOB. To illustrate, if the negotiated price of the beneficiary's medication was $100 in January, $102 in February, $103.50 in March, and $104 in April, the April EOB would display a 4 percent increase in the drug's negotiated price. Thus, this information would provide drug price trend information for the beneficiary for all their covered Part D drugs. We specifically request stakeholder feedback on operationalizing this in the EOB to best serve beneficiaries which could include, for instance, including information in the EOB on the percent change in negotiated price since the close of open enrollment in addition to the percent change in price since the 1st day of the benefit year.

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

Lower-cost therapeutic alternatives (meaning drugs with lower cost-sharing or lower negotiated prices) would not be limited to therapeutically equivalent generics if the original prescription fill is for a brand drug. It could also include a different drug, not within the same category or class, but one that has a medically-accepted indication to treat the same condition. Additionally, we would not require information about formulary therapeutic alternatives available at lower cost sharing to be beneficiary-specific, and we acknowledge that alternatives may not always be available. However, Part D sponsors would be permitted and encouraged by CMS to include relevant beneficiary-specific information, such as diagnosis, the indication for the prescription and complete step therapy or exception requests, when providing formulary therapeutic alternatives in the EOB that have lower cost-sharing. As with including the negotiated price changes on EOBs, this mechanism would provide even greater transparency for beneficiaries when reviewing their annual out-of-pocket costs for prescriptions.

These two proposed requirements would help improve cost transparency of Part D prescriptions. Updating the Part D EOB requirements as we propose would provide greater information to beneficiaries by displaying the fluctuations in their prescription drug prices, so that they can become more educated concerning their drug costs and about potential lower cost alternative drugs. This in turn should spark dialogue between the Part D beneficiaries and their providers about possible lower cost therapeutic alternatives, and empower them to make more informed decisions when choosing a prescription.

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.

Given the frequency of EOB issuance, the proposed policy would help call beneficiaries' attention to drug prices and more affordable options on an ongoing, regular basis. The current structure of the model EOB is well-suited to include additional information on individual prescription drug claims. Other beneficiary materials are delivered on an annual basis. These documents are geared toward assisting Part D beneficiaries make enrollment decisions whether to remain with their current prescription drug plan or switch to another. By viewing these costs on a monthly basis in EOBs, beneficiaries would be much more up-to-date with regard the impact of drug prices and whether there are less expensive options available. We solicit comment on these proposed changes to the Part D explanation of benefits, including impact on the beneficiary.

F. 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)

In a HPMS memo released August 7, 2018,[10] 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. This rule proposes requirements under which MA plans may apply step therapy as a utilization management tool for Part B drugs. In this proposal, we confirm MA plans' existing 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 believe there is minimal negotiation between MA plans

[9] See Part D Model Materials at: *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Part-D-Model-Marketing-Materials.html.*

[10] Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage (August 2018). Retrieved from *https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf.*

and drug manufacturers to reduce the price of these drugs. Prior to the August 7, 2018 HPMS memo and subsequent FAQs,[11] CMS guidance [12] interpreted existing law to prohibit MA plans from using step therapy for Part B drugs because such a utilization management tool would create an unreasonable barrier to coverage of and access to Part B benefits that MA plans must provide under the law. However, 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. As a result, we are proposing to allow MA plans to use step therapy, which we believe would considerably assist MA plans in negotiating on behalf of enrollees to get better value for Part B drug therapies, which constitute around $12 billion in CY 2016 [13] in spending by MA plans.

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 proposal. In the regulatory text, we propose 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. Therefore, we are proposing requirements under which MA plans may apply step therapy as a utilization management tool for Part B drugs. We are also proposing to define step therapy in § 422.2. We solicit comments concerning the impact that allowing step therapy for Part B drugs would have on MA plans and enrollees. For contract year 2020 and subsequent years, coupling drug management coordination with rewards and incentives remains an option for MA plans to pass back savings to beneficiaries. Anticipated savings not passed on to beneficiaries through rewards and incentives must be reflected in the plan's bid. 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 acknowledge the potential for utilization management tools like step therapy to create administrative burden and process challenges for network providers. 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 encourage continued development and advancement of electronic prior authorization processes to more efficiently administer this process. We note that existing requirements in §§ 422.112(b) and 422.152 already require care coordination activities that are sufficient to promote positive health outcomes for both drugs and services, so we are not proposing text at § 422.136 that an MA plan must offer a drug management program. We solicit 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.

This proposed rule would impose a number of safeguards that ensure enrollees have timely access to all medically necessary Medicare Part B medications. MA plans would be required to administer the existing organization determination and appeals processes under new proposed time frames that are similar to the timeframes applicable in Part D for coverage determinations; enrollees can request an organization determination if they believe that they need direct access to a Part B drug that would otherwise only be available after trying an alternative drug. MA plans would 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. CMS monitors organization determination and appeals activity through the audit process to ensure enrollee requests are appropriately evaluated and processed within applicable timeframes.

Consistent with our existing disclosure requirements at § 422.111, when applying step therapy to Part B drugs, MA plans must 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 would include the plan's step therapy policies. We propose 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 note that preferred provider organization plans (PPOs) are required, as part of the definition of PPO at section 1852(e)(3)(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 items restrictions in connection with out of network coverage. As such, preferred provider organization plans (PPOs) must provide reimbursement for all plan-covered medically necessary services received from non-contracted providers without prior authorization or step therapy requirements. We solicit comment whether the final rule should include a specific regulatory provision clarifying this issue.

Under proposed paragraph (a)(3), MA plans would be required to use a Pharmacy and Therapeutics (P&T) committee to review and approve step

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

[12] Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services. (September 2012). Retrieved from *https://www.asrs.org/content/documents/cms_step_therapy_memo_091712-2.pdf.*

[13] Medicare Part B Drug. CMS Enterprise Portal. Retrieved at *https://portal.cms.gov/wps/portal/unauthportal/unauthmicrostrategyreports link?evt=2048001&src=mstrWeb.2048001&documentID=AEC7511A11E817EF2FBA0080EFC5E3D8&visMode=0&currentViewMedia=1&Server=E48V126P&Project=OIPDA-BI_Prod&Port=0&connmode=8&ru=1&share=1&hiddensections=header,path,dockTop,dockLeft,footer.*

therapy programs (meaning policies and procedures); we believe that this is necessary to ensure medically appropriate implementation of step therapy for Part B drugs. We believe the burden of this requirement would be limited because we are proposing to allow MA–PD plans to utilize any existing Part D P&T committees established by the MA–PD plan to comply with part 423 requirements for the Part D benefit and to allow MA-only plans to use existing P&T committees when there is a Part D or MA–PD plan under the same contract. The Paperwork Reduction Act listing for P&T committee record keeping is OMB Control Number 0938–0964. We note that P&T committee decisions are not public information. The introductory text of proposed paragraph (b) provides that a MA organization must establish or utilize an existing P&T committee prior to implementation of a step therapy program. The P&T committee would review step therapy programs under our proposal. We are actively considering expanding the role of MA P&T committees and are therefore soliciting comments on our proposal that MA plans with step therapy programs would 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 would meet the policy goal of ensuring that step therapy programs are medically appropriate underlying the P&T committee proposal. We propose 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 believe 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.

The proposed requirements in § 422.136(b) are consistent with Part D requirements for a P&T committee. Specifically, we propose that the majority of members comprising the P&T committee would be required to be practicing physicians and/or practicing pharmacists. The committee would be required to include at least one practicing physician member and at least one practicing pharmacist; these specific individuals would be required to be independent and free of conflict with the MA organization, the MA organization's plans, and the pharmaceutical manufacturers. In addition, the plan would 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 are proposing to include provisions for the responsibilities and scope of the P&T Committee at proposed § 422.136(b)(4) through (11) that 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 proposed § 422.136(b) to the Part B drug step therapy programs offered by MA plans. These proposed provisions include requirements applicable to P&T committee membership, to the standards and considerations used in reviewing step therapy programs and to documenting its reviews. We reiterate here that we are proposing to substantially align the requirements of a P&T committee reviewing Part B drugs with Part D requirements because CMS has found that Part D requirements for administrative efficiency between the Part C and Part D programs and because the Part D requirements have proved sufficient in ensuring that plans implement medically appropriate step therapy and utilization management protocols in Part D.

Under § 422.136(a)(1) of the proposed rule, step therapy would not be permitted to disrupt enrollees' ongoing Part B drug therapies. We are proposing 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. MA plans would be required to have a look-back period of 108 days, consistent with Part D policy with respect to transition requirements for new prescriptions, to determine if the enrollee is actively taking a Part B medication. The Part D look back period was created with clinical and pharmaceutical input and CMS believes the same criteria is appropriate for Part B drugs. Further, when an enrollee elects a new MA plan (regardless of whether previously enrolled in a MA plan, traditional Medicare, or new to Medicare), our proposal would require the MA plan to determine whether the enrollee has taken the Part B drug (that would otherwise be subject to step therapy) within the past 108 days. We propose this time period to align with applicable Part D subregulatory guidance on this topic. 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. Under our proposal, we would allow MA plans flexibility in implementing step therapy for Part B drugs within specific parameters. Specifically, MA plans would be able to ensure that an enrollee who is newly diagnosed with a particular condition would begin treatment with a cost-effective biological product approved 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. While proposed § 422.136 does not specifically address the standard for exemptions or movement within a step therapy program, we rely on the MA plan's responsibility to provide all medically necessary covered services and items under the original Medicare program as meaning that cases raising ineffectiveness or adverse effects of treatment as being sufficient basis to grant an exemption or move an enrollee to a higher step in the protocol. However, we propose limits on flexibility in paragraphs (c) and (d).

Consistent with existing Part D guidelines, at § 422.136(c) we are proposing 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). Using off-label drugs in step therapy would 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 are soliciting comments on our proposal to permit MA plans to use off-label drugs only when such drugs are supported by widely used treatment guidelines or clinical literature that CMS considers to represent best practices in a step therapy program.

Additionally, we propose 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). Each step in a step therapy program should be another drug covered under Part B by the MA plan or Part D

by the MA–PD plan 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 clarify that only Medicare covered Part B (and for MA–PD plans, Part D drugs) may be used in a step therapy program. In addition to requiring one Part B drug be used before a different Part B drug, MA plans that also offer prescription drug coverage (also known as ''MA–PD plans'') may use step therapy to require a Part D drug therapy prior to allowing a Part B drug therapy because the Part D drug would 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 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. Additionally, as noted section II.A.2 of this proposed rule (Broader Use of Prior Authorization for Protected Class Drugs), the August 2018 HPMS memorandum entitled, ''Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage'' and section II.F (this proposal, 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. If both proposals II.A.2 and II.F are finalized, the result would be to allow MA–PD plans, starting in 2020, to require step therapy of Part B drugs before Part D drugs for the protected classes as well. Again, as is required for all other drug categories and classes, these particular step therapy requirements would be subject to CMS review and approval, as part of our annual 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.

Section 1852(g)(1) of the Act prescribes that MA organizations must have a procedure for making determinations regarding whether an enrollee is entitled to receive a health service under the MA program and the amount (if any) that the enrollee is required to pay with respect to such service. Such procedures must provide for organization determinations to be made on a timely basis, as required by section 1852(g)(3) of the Act, which prescribes what constitutes timely notice to an enrollee of an expedited organization determination and reconsideration. With respect to expedited organization determinations and reconsiderations, the MA organization must notify the enrollee (and the physician involved, as appropriate) of the decision under time limitations established by the Secretary, but no later than 72 hours from the receipt of the request for the organization determination or reconsideration (or receipt of the information necessary to make the decision) or such longer period as the Secretary may permit in specified cases. For standard reconsiderations, section 1852(g)(2) of the Act states that a reconsideration shall be within a time period specified by the Secretary but shall be made (subject to the expedited provision in section 1852(g)(3)) no later than 60 days after the date the reconsideration request is received.

We are proposing 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, such as in § 423.568(b). While the proposed timeframes for processing organization determinations and appeals for Part B drugs are a departure from the current adjudication timeframes that apply to organization determinations and appeals for medical items and services under the MA program, we believe the clinical circumstances that typically accompany requests for Part B drugs warrant application of the shorter adjudication timeframes that apply in Part D. In keeping with this rationale, we are not proposing that the adjudication timeframes for Part B drugs could be extended, as is allowed for other Part B organization determinations and appeals. This proposed approach not only creates greater consistency in how requests for drugs are handled throughout the initial coverage decision and appeals processes under Part B and Part D, but we believe that adopting the Part D adjudication timeframes for Part B drugs would allow MA–PD plans to better coordinate their drug benefits, specifically in cases where there is uncertainty about coverage under Part B or Part D. These proposed changes would affect the adjudication timeframes through the Part C IRE level of review. We are not proposing 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).

The rules related to organization determinations and appeals under Part 422, subpart M apply to all benefits an enrollee is entitled to receive under an MA plan, including basic benefits as described under § 422.100(c)(1) and mandatory and optional supplemental benefits as described under § 422.102, and the amount, if any, that the enrollee is required to pay for covered benefits. A request for covered medical items or services (including Part B drugs) is currently adjudicated under the timeframes set forth at §§ 422.568, 422.572, and 422.590, with specific requirements related to expediting determinations at §§ 422.570 and 422.584. Requirements for effectuating standard and expedited reconsidered determinations (that is, reversals by the MA organization itself, the independent review entity, or other adjudicator on appeal of an initial denial of coverage), are identified in §§ 422.618 and 422.619.

We are proposing to do all of the following:

- 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 discuss our proposal in more detail later in this section.

Under the regulations at § 422.572(a), an MA organization must notify an enrollee (and the physician involved, as appropriate) of an expedited organization determination as expeditiously as the enrollee's health requires, but no later than 72 hours after receiving the request. For expedited organization determination requests for a Part B drug, we are proposing at new paragraph (a)(2) of § 422.572 that an MA organization must make its determination and notify the enrollee (and the physician or prescriber involved, as appropriate) of its decision no later than 24 hours after receipt of the request. This proposed 24-hour timeframe for expedited organization determinations involving a Part B drug is permissible by statute, as section 1852 (g)(3)(B)(iii) of the Act requires that the enrollee be notified of an expedited decision under time limitations established by the Secretary, but not later than 72 hours from the time the request is received. With respect to pre-service standard organization determinations, the regulations at § 422.568(b) state that the MA organization must notify the enrollee of its decision as expeditiously as the enrollee's health condition requires, but no later than 14 calendar days after the MA organization receives the request for a standard determination. For consistency with the timeframe for standard Part D coverage determinations, we are proposing at § 422.568(b)(2) that, for a request 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 no later than 72 hours after receipt of the request. Section 422.568(b)(1) relates to standard requests for services and sets forth the existing timeframe of 14 calendar days, while proposed new paragraph (b)(2) would establish the 72-hour timeframe for standard organization determination requests for Part B drugs. We are proposing to redesignate existing paragraphs (b)(1) and (b)(2) with respect to extensions and notice of extensions for requests for service to § 422.568(b)(1)(i) and (ii), respectively. We are also proposing corresponding changes to § 422.568(d) and (e)(4) related to notice requirements to specifically reference Part B drug requests, to distinguish these requests from requests for medical services.

In all circumstances, the MA organization must notify the enrollee, and the physician or other prescriber involved, as appropriate of its decision as expeditiously as the enrollee's health condition requires, but no later than the proposed timeframes of 24 hours for expedited organization determination requests and 72 hours for standard organization determination requests for a Part B drug. As noted previously, we believe the nature of drug benefits supports shorter adjudication timeframes so enrollees have timely access to necessary prescription drugs. To that end, we are not proposing to permit MA organizations to extend the proposed timeframes for requests for Part B drugs under current rules at §§ 422.568(b)(1) and 422.572(b), and are proposing specific prohibitions on such extensions for Part B drugs in new text at §§ 422.568(b)(1), 422.572(b), and 422.590(c) and (e). Extending adjudication timeframes is not permitted under the Part D program and we do not believe extensions are warranted in the case of a request for a Part B drug due to the clinical circumstances typically involved in a request for a drug. The overall goal of these proposals is to ensure that MA enrollees have timely access to Part B drugs and to establish more consistency in the adjudication timeframes applicable to requests for Medicare drug benefits. At proposed §§ 422.568(b)(1)(i), 422.572(b), and redesignated § 422.590(f), we are specifying that the rules related to extending the adjudication timeframe relate to requests for medical services and items, but not requests for Part B drugs.

We recognize that there may be circumstances under which an enrollee would not be able to satisfy a Part B drug step therapy requirement due to the enrollee's medical condition and believe these issues can be resolved under the organization determination process. Further, under current regulation at § 422.111, MA organizations must disclose to enrollees the benefits under a plan, including applicable conditions and limitations, premiums and cost-sharing (such as copayments, deductibles, and coinsurance) and any other conditions associated with receipt or use of benefits. Therefore, MA organizations must disclose prior authorization rules and other review requirements (for example, step therapy) that condition or limit coverage and must be met in order to ensure payment for services. In addition, the rules at § 422.112 require MA organizations to have policies and procedures (coverage rules, practice guidelines, payment policies, and utilization management) that allow for individual medical necessity determinations. We believe 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. An MA plan can determine through the organization determination process that a particular enrollee should be exempted from step therapy requirements for reasons of medical necessity; as with other organization determinations under existing regulations, the enrollee would be notified that he/she has been determined eligible for such exemption. Although not required under our proposal, an MA organization may 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 (such as in cases of allergy or a prior unsuccessful use of the preferred drug). MA organizations may work 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. We are not proposing to require such additional policies or processes but we are similarly not prohibiting them.

At § 422.590, we are proposing at redesignated paragraph (e)(2) that if an MA organization approves a request for an expedited reconsideration, it 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. At redesignated paragraph (e)(3), we are proposing to add the term ''orally'' to existing regulation text to clarify that if the MA organization first notifies an enrollee of a completely favorable expedited reconsideration orally, it must also mail written confirmation to the enrollee within 3 calendar days.

With respect to the independent review entity (IRE) level of review, the current contract with the Part C IRE

requires enrollees to be notified of an expedited reconsideration decision no later than 72 hours from the IRE's receipt of the case. This 72-hour timeframe is consistent with the current adjudication timeframe for expedited Part D IRE reconsiderations. If this proposal is finalized, we would modify our contract with the Part C IRE to require that enrollees be notified of a standard reconsideration related to a Part B drug no later than 7 calendar days from receipt of the case.

We are proposing a conforming change to § 422.584(d)(1) to reference the proposed 7-day timeframe for standard Part B drug requests at § 422.590(c). If a MA organization denies a request for expedited reconsideration of a Part B drug, it must automatically transfer the request to the standard timeframe and make the determination within the 7 calendar day timeframe in proposed § 422.590(c). The timeframe begins the day the MA organization receives the request for expedited reconsideration.

We are also proposing conforming changes at § 422.570(d). At paragraph (d), with respect to actions following a denial of a request for an expedited determination, we are proposing to add a reference to the proposed 72-hour timeframe for standard Part B drug requests to existing text that specifies automatic transfer to the 14-calendar day timeframe for standard determinations regarding services. So, if an MA organization denies a request for an expedited determination, it must automatically transfer a request to the standard timeframe and make the determination within the proposed 72-hour timeframe at § 422.568(b)(2) for standard determinations regarding Part B drugs. The timeframe begins when the MA organization receives the request for expedited determination.

As a corollary to the proposed changes to the adjudication timeframes, we are proposing changes to the effectuation timeframes at §§ 422.618 and 422.619. As with the proposals related to the adjudication timeframes, the proposed changes to the effectuation timeframes are intended to ensure that MA organization enrollees receive necessary Part B drugs in a timely manner and are consistent with the Part D timeframes. Specifically, we are proposing a new § 422.618(a)(3) to state that if, on a standard reconsideration of a request for a Part B drug, the MA organization 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. We are also proposing a new § 422.618(b)(3) to state that if, on a standard 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 and, further, that the MA organization must inform the independent outside entity that the organization has effectuated the decision.

We are proposing to add § 422.619(a)(1) and (2) whereby paragraph (a)(1) would include the existing regulation text at § 422.619(a) related to reversals by the MA organization for expedited requests for a service. Proposed paragraph (a)(2) of § 422.619 would account for reversals by the MA organization for expedited reconsideration requests for a Part B drug. We are proposing that paragraph (a)(2) state that if the MA organization reverses its organization determination on an expedited reconsideration request for a Part B drug, 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. At § 422.619, we are proposing to add paragraphs (b)(1) and (2). Proposed § 422.619(b)(1) would include the existing regulation text at § 422.619(b) related to reversals by the independent outside entity for expedited reconsideration requests for a service and proposed § 422.619(b)(2) would account for reversals by the independent outside entity for expedited reconsideration requests for a Part B drug. We are proposing that paragraph (b)(2) state that if, on expedited reconsideration, 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. At § 422.619(c)(2) we are proposing to redesignate paragraph (c)(2) as new paragraph (c)(3) and propose that new paragraph (c)(2) address reversals of decisions related to Part B drugs by other than the MA organization or the independent outside entity. Specifically, we are proposing that paragraph (c)(2) state that if the independent outside entity's expedited 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. Finally, we are proposing a change to § 422.619(a) to update a cross-reference to § 422.590 affected by these proposed changes.

Finally, we are also proposing to add a reference to an ''item'' as it relates to regulatory requirements applicable to medical items and services, rather than just a reference to ''services'' as some of the regulatory text currently reads. At §§ 422.568(b), (d) and (e), 422.572(a) and (b), 422.590(a), (e), and (f), and 422.619(a) and (b) we have revised the language to include a reference to ''items'' to more clearly distinguish requests for medical services and items from requests for Part B drugs and requests for payment, to clarify the regulation text and have it conform to how items and services may be covered benefits.

We solicit comments on these proposals for various requirements, described in this preamble, under which MA plans could apply step therapy as a utilization management tool for Part B drugs in 2020 and subsequent years. Through these proposals to permit use of step therapy for Part B drugs and the application of shorter adjudication timeframes for Part B drug requests, we are seeking to balance the goals of cost savings and efficiencies with enrollee access, enhanced quality of care and due process protections. We are expressly soliciting comment on the following aspects of our proposal and whether there are additional considerations that would further these goals:

- The restriction to new starts.
- 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.
- The organization determination and appeals timelines and processes that would be applicable to Part B drugs, particularly our proposal to not permit MA organizations to extend the

proposed timeframes for requests for Part B drugs and whether we have 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.

Finally, we note that in a recent 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 published 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 are actively considering whether, if those proposed revisions to part 422, subpart M are finalized, these proposed changes in the timeframes applicable to organization determinations and appeals of coverage of Part B drugs should be incorporated into the integrated appeals processes. We solicit comment on that and whether including these specific, shorter timeframes for determinations related to Part B drugs are consistent with the goals and rationale of our proposal for integrated appeals procedures for certain D–SNPs in that proposed rule.

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

1. Introduction

Part D sponsors and their contracted PBMs have been increasingly successful in recent years at negotiating price concessions from network pharmacies. The data Part D sponsors submit to CMS as part of the annual required reporting of direct or indirect remuneration (DIR) show that pharmacy price concessions, net of all pharmacy incentive payments, have grown faster than any other category of DIR received by sponsors and PBMs. This means that pharmacy price concessions now account for a larger share than ever before of reported DIR and thus a larger share of total gross drug costs in the Part D program.

The data show that pharmacy price concessions, net of all pharmacy incentive payments, grew more than 45,000 percent between 2010 and 2017. The data also show that much of this growth occurred after 2012, when the use by Part D sponsors of performance-based payment arrangements with pharmacies became increasingly prevalent. Performance-based pharmacy price concessions, net of all pharmacy incentive payments, increased, on average, nearly 225 percent per year between 2012 and 2017 and now comprise the second largest category of DIR received by sponsors and PBMs, behind only manufacturer rebates.

Such price concessions are negotiated between pharmacies and sponsors or their PBMs, independent of CMS, and are often tied to the pharmacy's performance on various measures defined by the sponsor or its PBM. Under the current definition of ''negotiated prices'' at § 423.100, negotiated prices must include all price concessions from network pharmacies except those that cannot reasonably be determined at the point of sale. However, because these performance adjustments typically occur after the point of sale, they are not included in the price of a drug at the point of sale. We further understand, through comments received from the pharmacy industry in response to our Request for Information on pharmacy price concessions (included in the November 2017 proposed rule (82 FR 56419 through 56428)), that the share of pharmacies' reimbursements that are contingent upon their performance under such arrangements has grown steadily each year. (We discuss the comments received in response to this Request for Information in more detail later in this section.) As a result, sponsors and PBMs have been recouping increasing sums from network pharmacies after the point of sale (pharmacy price concessions) for ''poor performance,'' sums that are far greater than those paid to network pharmacies after the point of sale (pharmacy incentive payments) for ''high performance.''

When pharmacy price concessions are not reflected in the price of a drug at the point of sale, beneficiaries might see lower premiums, but they do not benefit through a reduction in the amount they must pay in cost-sharing, and thus, end up paying a larger share of the actual cost of a drug. Moreover, given the increase in pharmacy price concessions in recent years, when the point-of-sale price of a drug that a Part D sponsor reports on a PDE record as the negotiated price does not include such discount, the negotiated price is rendered less transparent at the individual prescription level and less representative of the actual cost of the drug for the sponsor. Finally, variation in the treatment of these price concessions by Part D sponsors may have a negative effect on the competitive balance under the Medicare Part D program. These issues are discussed in more detail later in this section.

At the time the Part D program was established, we believed, as discussed in the January 2005 final rule (70 FR 4244), that market competition would encourage Part D sponsors to pass through to beneficiaries at the point of sale a high percentage of the price concessions they received, and that establishing a minimum threshold for the price concessions to be applied at the point of sale would only serve to undercut these market forces. However, actual Part D program experience has not matched expectations in this regard. In recent years, less than 1 percent of plans have passed through any price concessions to beneficiaries at the point of sale, and the amount that is passed through is less than 1 percent of the total price concessions those plans receive. Instead, because of the advantages that accrue to sponsors in terms of lower premiums (also an advantage for beneficiaries), the shifting of costs, and increases in plan revenues (given the treatment of price concessions under the Part D payment methodology), sponsors may face distorted incentives as compared to what we anticipated in 2005.

For this reason, as part of the November 2017 proposed rule, we published a ''Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale,'' (82 FR 56419 through 56428). We solicited comment on whether CMS should require that the point-of-sale price for a covered Part D drug must include all price concessions that the Part D sponsor could potentially collect from a network pharmacy for any individual claim for that drug. Of the many timely comments received, the majority were from pharmacies, pharmacy associations, and beneficiary advocacy groups that supported the adoption of such a requirement because it would: (1) Lower beneficiary out-of-pocket costs (especially critical for beneficiaries who utilize high cost drugs); (2) stabilize the operating environment for pharmacies (because of greater transparency and predictability of the minimum reimbursement on a per-claim level, thus allowing more accurate budgeting and improved ability to evaluate proposed contracts from PBMs); and (3) standardize the way in which plan sponsors and their PBMs treat pharmacy price concessions. Some commenters—mostly Part D sponsors

and PBMs—were against such a policy, in particular because it would limit their ability to incentivize quality improvement from pharmacies. We address the issue of incentivizing quality improvement by pharmacies in the discussion of lowest possible reimbursement later in this section.

In this rule we are considering for a future year, which could be as soon as 2020, adopting a new definition of ''negotiated price'' to include all pharmacy price concessions received by the plan sponsor for a covered Part D drug, and to reflect the lowest possible reimbursement a network pharmacy will receive, in total, for a particular drug. As part of the policy being considered, we would first delete the current definition of ''negotiated prices'' (in the plural) and add a definition of ''negotiated price'' (in the singular) to make clear that a negotiated price can be set for each covered Part D drug, and the amount of the pharmacy price concessions may differ on a drug by drug basis. Then, we would implement a definition of ''negotiated price'' that is intended to ensure that the prices available to Part D enrollees at the point of sale are inclusive of all pharmacy price concessions. We believe such an approach would be more reflective of current pharmacy payment arrangements.

2. Background

Section 1860D–2(d)(1) of the Act requires that a Part D sponsor provide beneficiaries with access to negotiated prices for covered Part D drugs. Under the definition of ''negotiated prices'' at § 423.100, the negotiated price is the price paid to the network pharmacy or other network dispensing provider for a covered Part D drug dispensed to a plan enrollee that is reported to CMS at the point of sale by the Part D sponsor. This point-of-sale price is used to calculate beneficiary cost-sharing. More broadly, the negotiated price is the primary basis by which the Part D benefit is adjudicated, as it is used to determine plan, beneficiary, manufacturer (in the coverage gap), and government liability during the course of the payment year, subject to final reconciliation following the end of the coverage year.

Under current law, Part D sponsors can generally choose whether to reflect in the negotiated price the various price concessions they or their intermediaries receive. Specifically, section 1860D–2(d)(1)(B) of the Act requires that negotiated prices ''shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs. . . .'' Currently, Part D sponsors are allowed, but generally not required, to apply rebates and other price concessions at the point of sale to lower the price upon which beneficiary cost-sharing is calculated. The only exception is the requirement under the existing definition of negotiated prices at § 423.100 that negotiated prices must include all price concessions from network pharmacies that can reasonably be determined at the point of sale.

To date, very few pharmacy price concessions have been included in the negotiated price at the point of sale. All pharmacy and other price concessions that are not included in the negotiated price must be reported to CMS as DIR at the end of the coverage year using the form required by CMS for reporting Summary and Detailed DIR (OMB control number 0938–0964). These data on price concessions are used in our calculation of final plan payments, which, under the statute, are required to be based on costs actually incurred by Part D sponsors, net of all applicable DIR.

When price concessions are applied to reduce the negotiated price at the point of sale, some of the concession amount is apportioned to reduce beneficiary cost-sharing. In contrast, when price concessions are applied after the point of sale, as DIR, the majority of the concession amount accrues to the plan, and the remainder accrues to the government. For further discussion on this matter, please see the CMS Fact Sheet from January 19, 2017 ''*Medicare Part D Direct and Indirect Remuneration,*'' found on the CMS website at *https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir.* As described later in this section of this proposed rule, pharmacy price concessions applied as DIR can lower plan premiums and increase plan revenues, result in cost-shifting to beneficiaries and the government, and reduce consumer and government knowledge about the true costs of prescription drugs.

a. Premiums and Plan Revenues

The main benefit to a Part D beneficiary of price concessions applied as DIR at the end of the coverage year (and not to the negotiated price at the point of sale) is a lower plan premium. A sponsor must factor into its plan bid an estimate of the expected DIR for the upcoming payment year. That is, in the bid the sponsor must lower its estimate of plan liability by a share of the projected DIR, which has the effect of reducing the price of coverage under the plan. Under the current Part D benefit design, applying price concessions after the point of sale as DIR reduces plan liability (and thus premiums), more than applying price concessions at the point of sale.

Therefore, to the extent that plan bids reflect accurate DIR estimates, the pharmacy and other price concessions that Part D sponsors and their PBMs negotiate, but do not include in the negotiated price at the point of sale, put downward pressure on plan premiums, as well as the government's subsidies of those premiums. The average Part D basic beneficiary premium grew at an average rate of only about 1 percent per year between 2010 and 2017, and the average premium has declined each year since 2017 due in part to sponsors' projecting in their bids that DIR growth would outpace the growth in projected gross drug costs each year. The average Medicare direct subsidy paid by the government to cover a share of the cost of coverage under a Part D plan has also declined, by an average of 9.4 percent per year between 2010 and 2017, partly for the same reason.

However, any DIR a sponsor receives that is above the projected amount factored into its plan bids contributes primarily to plan profits, not lower premiums. The risk-sharing construct established under the Part D statute at section 1860D–15(e) of the Act allows sponsors to retain as plan profit the majority of all plan revenues above the bid-projected amount. Given that plan bids, and, thus, plan revenues, are based on cost *projections,* the plan's *actual experience* may yield unexpected losses (when bid-based payments to plans—plan revenues— fall short of actual plan costs) or unexpected savings (when plan revenues exceed actual plan costs) for Part D plan sponsors. In order to limit Part D sponsors' exposure to unexpected drug expenses and the government's exposure to overpayments, Medicare shares risk with sponsors on the drug costs covered by their plan bids, using symmetrical risk corridors to cover or recoup a share of unexpected losses or savings.

Under the Part D risk corridors, if a plan's actual drug costs are within +/−5 percent of the drug costs estimated in its bid, the plan assumes all of the losses or savings. If its costs are more than 5 percent above or below its bid, the government assumes a growing share of the losses or savings, and the plan assumes the remainder. Any unexpected losses or savings that a plan assumes affect its final profit margin. Thus, when a plan underestimates the amount of DIR that it will receive, any additional amount of DIR constitutes additional plan revenues. In the event that overall

plan revenues exceed the amount projected in the plan sponsor's bid, the sponsor is permitted to retain most, if not all, of the excess amount. Our analysis of Part D plan payment and cost data indicates that in recent years, DIR amounts that Part D sponsors and their PBMs actually received have consistently exceeded bid-projected amounts, by as much as three percent as a share of gross drug costs.

To capture the relative premium and other advantages that price concessions, including pharmacy price concessions, applied as DIR offer sponsors over lower point-of-sale prices, sponsors sometimes opt for higher negotiated prices in exchange for higher DIR and, in some cases, even prefer a higher net cost drug over a cheaper alternative. This may put upward pressure on Part D program costs and, as explained in this proposed rule, shift costs from the Part D sponsor to beneficiaries who utilize drugs in the form of higher cost-sharing and to the government through higher reinsurance and low-income cost-sharing subsidies.

b. Cost-Shifting

Beneficiary cost-sharing is generally calculated as a percentage of the negotiated price. When pharmacy price concessions and other price concessions are not reflected in the negotiated price at the point of sale (that is, are applied instead as DIR at the end of the coverage year), beneficiary cost-sharing increases, covering a larger share of the actual cost of a drug. Although this is especially true when a Part D drug is subject to coinsurance, it is also true when a drug is subject to a copayment because Part D rules require that the copayment amount be at least actuarially equivalent to the coinsurance required under the defined standard benefit design. For many Part D beneficiaries who utilize drugs and thus incur cost-sharing expenses, this means, on average, higher overall out-of-pocket costs. Higher costs to beneficiaries have occurred even after accounting for the premium savings tied to higher DIR. For the millions of low-income beneficiaries whose out-of-pocket costs are subsidized by Medicare through the low-income cost-sharing subsidy, those higher costs are borne by the government. See the lowest possible reimbursement example later in this section of the rule for a specific example of the effect the change to the definition of negotiated price being considered would have on the determination of beneficiary cost-sharing.

This potential for cost shifting to beneficiaries grows increasingly pronounced as pharmacy price concessions increase as a percentage of gross drug costs and continue to be applied outside of the negotiated price. Numerous research studies suggest that higher cost-sharing can impede beneficiary access to necessary medications, which leads to poorer health outcomes and higher medical care costs for beneficiaries and Medicare. [14] [15] [16] Based upon this research, we believe it is important to weigh the effects of current Part D policies on beneficiaries' access to affordable prescription drugs—higher cost-sharing per prescription versus lower plan premiums.

Finally, beneficiaries progress through the four phases of the Part D benefit as their total gross drug costs and cost-sharing obligations increase. Because both of these values are calculated based on the negotiated prices reported at the point of sale, when pharmacy price concessions are not applied at the point of sale, the higher negotiated prices result in more rapid movement of Part D beneficiaries through the Part D benefit phases. This, in turn, shifts more of the total drug spend into the catastrophic phase, where Medicare liability is highest (80 percent, paid as reinsurance) and plan liability is at its lowest (except with respect to applicable drugs in coverage gap) (15 percent). With such cost-shifting to the government under current rules, Part D sponsors may have weak incentives, and, in some cases no incentive, to lower prices at the point of sale. See the Regulatory Impact Statement in this proposed rule for a discussion of cost impacts to beneficiaries, the government, and plan sponsors.

c. Transparency and Competition

Given the significant growth in pharmacy price concessions in recent years, when such amounts are not reflected in the negotiated price, it has become increasingly difficult for consumers to know at the point of sale what share, or approximate share, they are paying of the costs of their prescription drugs to the plan; nor are negotiated costs reflected on the Medicare Prescription Drug Plan Finder (Plan Finder) tool. Consequently, consumers cannot efficiently minimize both their costs and costs to the taxpayers by seeking and finding the lowest-cost drug or a plan that offers them the lowest-cost drug and pharmacy combinations.

The quality of information available to consumers is even less conducive to producing efficient choices when pharmacy price concessions are treated differently by different Part D sponsors; that is, when they are applied to the point-of-sale price to differing degrees and/or estimated and factored into plan bids with varying degrees of accuracy. First, when some sponsors include pharmacy price concessions in negotiated prices while others treat them as DIR, the concept of negotiated price no longer has a consistent meaning across the Part D program, undermining meaningful price comparisons and efficient choices by consumers. Second, if a sponsor's bid is based on an estimate of net plan liability that is understated because the sponsor has been applying pharmacy price concessions as DIR at the end of the coverage year rather than using them to reduce the negotiated price at the point of sale, it follows that the sponsor may be able to submit a lower bid than a competitor that applies pharmacy price concessions at the point of sale. This lower bid results in a lower plan premium, which could allow the sponsor to capture additional market share. The resulting competitive advantage accruing to one sponsor over another in this scenario stems only from a technical difference in how plan costs are reported to CMS. Therefore, the opportunity for differential treatment of pharmacy price concessions could result in bids that are not comparable and in premiums that are not valid indicators of relative plan efficiency.

Finally, the one-sided nature of the pharmacy payment arrangements that currently exist also creates competition concerns by discouraging independent pharmacies from participating in a plan's network and thereby increasing market share for the sponsors' or PBMs' own pharmacies. Part D is a market-based approach to delivery of prescription drug benefits, and relies on healthy market competition. Thus, adopting policies that promote competition is an important and relevant consideration in protecting Medicare beneficiaries and the Medicare trust fund from unwarranted costs. Market competition is best achieved when a wide variety of pharmacies are able to compete in the market for selective contracting with plan sponsors and PBMs.

[14] Michele Heisler et al., ''The Health Effects of Restricting Prescription Medication Use Because of Cost,'' Medical Care, 626–634 (2004) available at *https://www.ncbi.nlm.nih.gov/pubmed/15213486.*

[15] Peter Bach, ''Limits on Medicare's Ability to Control Rising Spending on Cancer Drugs,'' The New England Journal of Medicine, 360, 626–633 (2009) available at *https://www.nejm.org/doi/full/10.1056/NEJMhpr0807774.*

[16] Sonya Blesser Streeter et al., ''Patient and Plan Characteristics Affecting Abandonment of Oral Oncolytic Prescriptions,'' Journal of Oncology Practice, 7, no. 3S, 46S–51S (2011) available at *http://ascopubs.org/doi/full/10.1200/jop.2011.000316.*

3. Considered Regulatory Changes to the Definition of Negotiated Price (§ 423.100)

As previously discussed, Part D sponsors and PBMs have been recouping increasing sums from network pharmacies after the point of sale in the form of pharmacy price concessions. We addressed concerns about these pharmacy payment adjustments when we established the existing requirements for negotiated price reporting in the May 2014 final rule (79 FR 29844). In that rule, we amended the definition of ''negotiated prices'' at § 423.100 to require Part D sponsors to include in the negotiated price at the point of sale all pharmacy price concessions and incentive payments to pharmacies—with an exception, intended to be narrow, that allowed the exclusion of contingent pharmacy payment adjustments that cannot reasonably be determined at the point of sale (the reasonably determined exception). However, when we formulated these requirements in 2014, the most recent year for which DIR data was available was 2012, and we did not anticipate the growth of performance-based pharmacy payment arrangements that we have observed in subsequent years.

We now understand that the reasonably determined exception we currently allow applies more broadly than we had initially envisioned because of the shift by Part D sponsors and their PBMs towards contingent pharmacy payment arrangements. As suggested by numerous stakeholders in response to CMS's November 2017 Request for Information (82 FR 56419 through 56428), nearly all performance-based pharmacy payment adjustments may be excluded from the negotiated price on the grounds that they cannot reasonably be determined at the point of sale. Specifically, several stakeholders have suggested to us that sponsors apply the reasonably determined exception to all performance-based pharmacy payment adjustments. These stakeholders assert that the amount of these adjustments, by definition, is contingent upon performance measured over a period of time that extends beyond the point of sale and, thus, cannot be known in full at the point of sale. Therefore, performance-based pharmacy payment adjustments cannot ''reasonably be determined'' at the point of sale as they cannot be known in full at the point of sale. These assertions are supported by the information plan sponsors report to CMS as part of the annual DIR reports. As a result, the reasonably determined exception prevents the current policy from having the intended effect on price transparency, consistency (by reducing differential reporting of pharmacy payment adjustments by sponsors), and beneficiary costs.

Given the predominance of the use of performance-contingent pharmacy payment arrangements by plan sponsors, we do not believe that the existing requirement that pharmacy price concessions be included in the negotiated price can be implemented in a manner that achieves the goals previously discussed: Meaningful price transparency, consistent application of all pharmacy payment concessions by all Part D sponsors, and prevention of cost-shifting to beneficiaries and taxpayers. Therefore, to establish a requirement that accomplishes these goals while better reflecting current pharmacy payment arrangements, we are considering adding a definition of the term ''Negotiated price'' at § 423.100 to mean the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug under its contract with the Part D sponsor or the sponsor's intermediary (that is, the amount the pharmacy would receive net of the maximum possible negative adjustment that could result from any contingent pharmacy payment arrangement). First, we are considering deleting the current definition of ''Negotiated prices'' (in the plural) and adding a new definition of ''Negotiated price'' (in the singular) in order to make clear that a negotiated price can be set for each covered Part D drug, and the amount of pharmacy price concessions may differ on a drug–by-drug basis. Next, we are considering the policy that the negotiated price for a covered Part D drug must include all pharmacy price concessions and any dispensing fees, and exclude additional contingent amounts, such as incentive fees, if these amounts increase prices. Finally, we are considering continuing to permit Part D sponsors to elect whether to pass-through non-pharmacy price concessions and other direct or indirect remuneration amounts (for example, manufacturer rebates, legal settlement amounts, and risk-sharing adjustments) to enrollees at the point of sale. These considered provisions are discussed in the following sections.

Requiring that all pharmacy price concessions be included in the negotiated price, as we have described, would lead to more accurate comparability of drug prices, Part D bid pricing, and plan premiums. When negotiated prices reflect relative plan efficiencies, there would not be unfair competitive advantages accruing to one sponsor over another based on a technical difference in how costs are reported. In short, because Part D is a market-based approach to delivering prescription drug benefits, and relies on healthy market competition, we believe the policy being considered could make the Part D market more competitive and efficient.

a. All Pharmacy Price Concessions

We are considering the policy that the new definition of ''Negotiated price'' omit the reasonably determined exception. That is, we would require that all price concessions from network pharmacies, negotiated by Part D sponsors and their contracted PBMs, be reflected in the negotiated price that is made available at the point of sale and reported to CMS on a PDE record, even when such price concessions are contingent upon performance by the pharmacy.

Section 1860D–2(d)(1)(B) of the Act requires that negotiated prices ''shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs . . .'' We have previously interpreted this language to mean that some, but not all, price concessions must be applied to the negotiated price (see, for example, 70 FR 4244 and 74 FR 1511). However, we now believe that our initial interpretation may have been overly definitive with respect to the intended meaning of ''take into account.'' Requiring that all pharmacy price concessions be applied at the point of sale would ensure that negotiated prices ''take into account'' at least some price concessions and, therefore, would be consistent with the plain language of section 1860D–2(d)(1)(B) of the Act.

b. Lowest Possible Reimbursement

To effectively capture all pharmacy price concessions at the point of sale consistently across sponsors, we are considering requiring the negotiated price to reflect the lowest possible reimbursement that a network pharmacy could receive from a particular Part D sponsor for a covered Part D drug. Under this approach, the price reported at the point of sale would need to include all price concessions that could potentially flow from network pharmacies, as well as any dispensing fees, but exclude any additional contingent amounts that could flow to network pharmacies and thus increase prices over the lowest reimbursement level, such as incentive fees. That is, if a performance-based payment arrangement exists between a sponsor and a network pharmacy, the point-of-

sale price of a drug reported to CMS would need to equal the final reimbursement that the network pharmacy would receive for that prescription under the arrangement if the pharmacy's performance score were the lowest possible. If a pharmacy is ultimately paid an amount above the lowest possible contingent incentive reimbursement (such as in situations where a pharmacy's performance under a performance-based arrangement triggers a bonus payment or a smaller penalty than that assessed for the lowest level of performance), the difference between the negotiated price reported to CMS on the PDE record and the final payment to the pharmacy would need to be reported as negative DIR as part of the annual report on DIR following the end of the year. For an illustration of how negotiated prices would be reported under such an approach, see the example provided later in this section.

By requiring that sponsors assume the lowest possible pharmacy performance when reporting the negotiated price, we would be prescribing a standardized way for Part D sponsors to treat the unknown (final pharmacy performance) at the point of sale under a performance-based payment arrangement, which many Part D sponsors and PBMs have identified as the most substantial operational barrier to including such concessions at the point of sale. We believe, based on the overwhelming support received from commenters on our November 2017 Request for Information, that this is the best approach to achieve our goals, as noted previously, of—(1) consistency (standardized reporting of negotiated prices and DIR); (2) preventing cost-shifting to beneficiaries; and (3) price transparency for beneficiaries, the government, and other stakeholders.

Regarding consistency in reporting, we believe that the approach we are considering would be clearer for Part D sponsors to follow than the requirements in place today, which require Part D sponsors to assess which types of pharmacy payment adjustments fall under the reasonably determined exception. We expect this increased clarity would reduce sponsor burden in terms of the resources necessary to ensure compliance in the absence of a clear standard. Finally, we believe that the change we are considering would improve the quality of drug pricing information available across Part D plans and thus improve market competition and cost efficiency under Part D.

Requiring the negotiated price to reflect the lowest possible pharmacy reimbursement, would move the negotiated price closer to the final reimbursement for most network pharmacies under current pharmacy payment arrangements, and thus closer to the actual cost of the drug for the Part D sponsor. We have learned from the DIR data reported to CMS and feedback from numerous stakeholders that pharmacies rarely receive an incentive payment above the original reimbursement rate for a covered claim. We gather that performance under most arrangements dictates only the magnitude of the amount by which the original reimbursement is reduced, and most pharmacies do not achieve performance scores high enough to qualify for a substantial, if any, reduction in penalties.

Finally, we are considering requiring that all contingent incentive payments be excluded from the negotiated price. As noted previously, we understand that such incentive payments are quite rare. Furthermore, even in those instances in which a pharmacy may qualify for such a payment, including the amount of any contingent incentive payments to pharmacies in the negotiated price would make drug prices appear higher at a ''high performing'' pharmacy, which receives an incentive payment, than at a ''poor performing'' pharmacy, which is assessed a penalty, and would also reduce price transparency. This pricing differential could also potentially create a perverse incentive for beneficiaries to choose a lower performing pharmacy for the advantage of a lower price. We believe the approach we are considering would prevent these unintended consequences and thus avoid reducing the competitiveness of high performing pharmacies by increasing the negotiated price charged to the beneficiary at those pharmacies. Additionally, Part D sponsors and their intermediaries have argued in the past that network pharmacies lose motivation to improve performance when all performance-based adjustments are required to be reported up-front. Revising the negotiated price definition as we are considering doing would mitigate this concern by allowing sponsors and their intermediaries to motivate network pharmacies to improve their performance with the promise of future incentive payments that would increase pharmacy reimbursement from the level of the lowest possible reimbursement per claim. Further, we emphasize that the policy being considered would not require pharmacies to be paid in a certain way; rather we would be requiring standardized reporting to CMS of drug prices at the point of sale.

c. Lowest Possible Reimbursement Example

To illustrate how Part D sponsors and their intermediaries would report costs under the approach we are considering, we provide the following example. Suppose that under a performance-based payment arrangement between a Part D sponsor and its network pharmacy, the sponsor will implement one of three scenarios: (1) Recoup 5 percent of its total Part D-related payments to the pharmacy at the end of the contract year for the pharmacy's failure to meet performance standards; (2) recoup no payments for average performance; or (3) provide a bonus equal to 1 percent of total payments to the pharmacy for high performance. For a drug that the sponsor has agreed to pay the pharmacy $100 at the point of sale, the pharmacy's final reimbursement under this arrangement would be: (1) $95 for poor performance; (2) $100 for average performance; or (3) $101 for high performance. Under the current definition of negotiated prices, the reported negotiated price is likely to be $100, given the reasonably determined exception for contingent pharmacy payment adjustments. However, under the approach we are considering here, for all three performance scenarios the negotiated price reported to CMS on the PDE record at the point of sale for this drug would be $95, or the lowest reimbursement possible under the arrangement. Thus, if a plan enrollee were required to pay 25 percent coinsurance for this drug, then the enrollee's costs under all scenarios would be 25 percent of $95, or $23.75, which is less than the $25 the enrollee would pay today (when the negotiated price is likely to be reported as $100). Finally, any difference between the reported negotiated price and the pharmacy's final reimbursement for this drug would be reported as DIR at the end of the coverage year. Under this requirement, the sponsor would report $0 as DIR under the poor performance scenario ($95 minus $95), –$5 as DIR under the average performance scenario ($95 minus $100), and –$6 as DIR under the high performance scenario ($95 minus $101), for every covered claim for this drug purchased at this pharmacy.

d. Additional Considerations

In order to implement the change being considered, we would leverage existing reporting mechanisms to confirm that sponsors are appropriately applying pharmacy price concessions at

the point of sale, as we do with other cost data required to be reported. Specifically, we would likely use the estimated rebates at point of sale field on the PDE record to also collect the amount of point-of-sale pharmacy price concessions. We also would likely use fields on the Summary and Detailed DIR Reports to collect final pharmacy price concession data at the plan and NDC levels. Differences between the amounts applied at the point of sale and amounts actually received, therefore, would become apparent when comparing the data collected through those means at the end of the coverage year. To implement the change being considered to the definition of negotiated price at the point of sale, Part D sponsors and their PBMs would load revised drug pricing tables that reflect the lowest possible reimbursement into their claims processing systems that interface with contracted pharmacies.

Additionally, we note that the negotiated price is also the basis by which manufacturer liability for discounts in the coverage gap is determined. We are considering whether to require sponsors to include pharmacy price concessions in the negotiated price in the coverage gap, for purposes of determining manufacturer coverage gap discounts, as would be required of sponsors in all other phases of the Part D benefit under approach being considered. We request comment on the alternate approaches.

Under section 1860D–14A(g)(6) of the Act, the term ''negotiated price'' has the meaning it was given in § 423.100 as in effect as of the enactment of the Patient Protection and Affordable Care Act, except that it excludes any dispensing fee. This definition is codified in the coverage gap discount program regulations at § 423.2305. Because the statutory definition of negotiated price for purposes of the coverage gap discount program references price concessions that the Part D sponsor has *elected to* pass through at the point of sale, we do not believe it would appropriate to require sponsors to include all price concessions in the negotiated price for purposes of the coverage gap discount program. However, we believe there would be authority under the statute to require sponsors to include all *pharmacy* price concessions in the negotiated price for purposes of the coverage gap discount program because such concessions necessarily affect the amount that the pharmacy receives in total for a particular drug. We also note that pharmacy price concessions account for only a share of all price concessions a sponsor might receive. Thus, even if a plan sponsor is required to include all pharmacy price concessions in the negotiated price at the point of sale, the plan sponsor must still make an election as to how much of the overall price concessions (including manufacturer rebates and other non-pharmacy price concessions) it receives will be passed through at the point of sale. Under this approach, Part D sponsors would be required to include all pharmacy price concessions in the negotiated price during the coverage gap, and the same negotiated price could be used to adjudicate claims during all phases of the Part D benefit.

If we do not require sponsors to include pharmacy price concessions in the negotiated price in the coverage gap, we would need to operationalize different definitions of ''negotiated price'' for the coverage gap versus the non-coverage gap phases of the Part D benefit. Under this alternative approach, during the non-coverage gap phases, claims would be adjudicated using the negotiated price determined as described in the lowest possible reimbursement example above. In contrast, during the coverage gap, plans would have the flexibility to determine how much of the pharmacy price concessions to pass through at the point of sale, and beneficiary, plan, and manufacturer liability in the coverage gap would be calculated using this alternate negotiated price.

We also request comment on a considered alternative to the lowest possible reimbursement approach that would require Part D sponsors to apply less than 100 percent, *e.g.,* 95 percent or more, of pharmacy price concessions at the point of sale. This alternative might grant sponsors additional flexibilities in regards to the application of price concessions, thus potentially limiting the beneficiary premium impact, while still improving price transparency in a meaningful way. We believe that requiring less than 100 percent of pharmacy price concessions be applied at the point of sale would have a proportionately smaller impact on beneficiary, government, and manufacturer costs than the impacts we outline in the Regulatory Impact Statement in this proposed rule for requiring the point-of-sale application of 100 percent of pharmacy price concessions.

In addition, we are considering an option to develop a standard set of metrics from which plans and pharmacies would base their contractual agreements. We request commenter feedback on whether these metrics could be designed to provide pharmacies with more predictability in their reimbursements while maintaining plan's ability to negotiate terms. Additionally, we seek comment on the most appropriate agency or organization to develop these standards, or whether this a matter better left to private negotiations.

Finally, given the many considerations outlined above, we have not concluded, at this time and without the benefit of public comment, that we should move forward with changing the definition of negotiated price for contract year 2020 or otherwise. However, we seek comment on whether we should do so, including whether to adopt in the final rule the approach considered above or a logical outgrowth of it, whether to make such a change for the contract year 2020, and on the contours and contentment of the policy considered and outlined above. If such a change is adopted, we anticipate the regulation text at § 423.100 would read as follows:

Negotiated price means the price for a covered Part D drug that—

(1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the lowest possible reimbursement such network entity will receive, in total, for a particular drug and

(2) Meets all of the following:

(i) Includes all price concessions (as defined at § 423.100) from network pharmacies or other network providers;

(ii) Includes any dispensing fees; and

(iii) Excludes additional contingent amounts, such as incentive fees, if these amounts increase prices.

(3) Is reduced by non-pharmacy price concessions and other direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale.

4. Pharmacy Administrative Service Fees

We are aware that some sponsors and their intermediaries believe certain fees charged to network pharmacies—such as ''network access fees,'' ''administrative fees,'' ''technical fees,'' or ''service fees''—represent valid administrative costs and, thus, do not believe such fees should be treated as price concessions. However, pharmacies and pharmacy organizations report that they do not receive anything of value for such administrative service fees other than the ability to participate in the Part D plan's pharmacy network.

Thus, we are restating the conclusion we provided in the May 2014 final rule (79 FR 29877): When pharmacy administrative service fees take the form

of deductions from payments to pharmacies for Part D drugs dispensed to Part D beneficiaries, they clearly represent charges that offset the sponsor's or its intermediary's operating costs under Part D. We believe that if the sponsor or its intermediary contracting organization wishes to be compensated for these services and have those costs treated as administrative costs, such costs should be accounted for in the administrative costs of the Part D bid. If instead these costs are deducted from payments made to pharmacies for purchases of Part D drugs, such costs are price concessions and must be treated as such in Part D cost reporting. This is the case regardless of whether the deductions are calculated on a per-claim basis or not.

The regulations governing the Part D program require that price concessions be fully disclosed. If not reported at all, these amounts would result in another form of so-called PBM spread in which inflated prices contain a portion of costs that should be treated as administrative costs. That is, even if these costs did represent services rendered by an intermediary organization for the sponsor, then these costs would be administrative service costs, not drug costs, and should be treated as such. Failure to report these costs as administrative costs in the bid would allow a sponsor to misrepresent the actual costs necessary to provide the benefit and thus to submit a lower bid than necessary to reflect its revenue requirements (as required at section 1860D–11(e)(2)(C) of the Act and at § 423.272(b)(1) of the regulations) relative to another sponsor that accurately reports administrative costs consistent with CMS instructions.

5. Defining Price Concession (§ 423.100)

Section 1860D–2(d)(1)(B) of the Act stipulates that the negotiated price shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered Part D drugs. Section 1860D–2(d)(2) of the Act further requires that Part D sponsors disclose to CMS the aggregate negotiated price concessions by manufacturers that are passed through in the form of lower subsidies, lower monthly beneficiary premiums, and lower prices through pharmacies and other dispensers. While ''price concession'' is a term important to the adjudication of the Part D program, it has not yet been defined in the Part D statute or in Part D regulations and subregulatory guidance. Therefore, to avoid confusion among Part D sponsors and other stakeholders of the Part D program resulting from inconsistent terminology, we are considering providing a definition for the term ''price concession'' at § 423.100. We would consider implementing, for 2020 or another future year, a provision that defines price concession in a broad manner, to include all forms of discounts, direct or indirect subsidies, or rebates that serve to reduce the costs incurred under Part D plans by Part D sponsors.

In considering how to define price concession, we believe it is important to define the term in a broadly applicable manner, while maintaining clarity. We believe the approach we are considering would be consistent with the statute, would support consistent accounting by plan sponsors of amounts that are price concessions, and would ensure that certain forms of discounts are not inappropriately excluded from being considered price concessions.

An alternative would be not to define price concession at all. However, this option would not support consistent accounting of amounts that are price concessions among Part D sponsors, which is particularly important in light of the change being considered for the definition of negotiated price.

If such a change is adopted, we anticipate the regulation text at § 423.100 would read as follows:

Price concession means any form of discount, direct or indirect subsidy, or rebate received by the Part D sponsor or its intermediary contracting organization from any source, that serves to decrease the costs incurred under the Part D plan by the Part D sponsor. Examples of price concessions include but are not limited to: Discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, coupons, free or reduced-price services, and goods in kind.

We note that the change we are considering for the definition of price concession would not affect the way in which price concessions must be accounted for by Part D sponsors in calculating costs under a Part D plan. Defining price concessions as we are considering doing also would not require the renegotiation of any contractual arrangements between a sponsor and its contracted entities. Therefore, this definition we are considering for price concession has no impact under the federal requirements for Regulatory Impact Analyses.

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 60-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. 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 this proposed rule, we are soliciting public comment on each of these issues for the following sections of this rule that contain proposed ''collection of information'' requirements as defined under 5 CFR 1320.3 of the PRA's implementing regulations.

A. Wage Data

To derive average costs for the private sector, 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/current/oes_nat.htm*). In this regard, Table 2 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 2—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Business Operation Specialist	13–1000	34.54	34.54	69.08

TABLE 2—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES—Continued

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
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 fringe 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 total cost is a reasonably accurate estimation method.

B. Proposed Information Collection Requirements (ICRs)

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

The requirements and burden related to the proposed justification under § 423.120(b)(2)(vi)(E) will be submitted to OMB for approval under control number 0938–0763 (CMS–R–262).

As described in section III.B. of this rule, the proposed new paragraph at § 423.120(b)(2)(vi) would implement the authority granted to CMS by section 1860D–4(b)(3)(G) of the Act to establish exceptions that would 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 proposed exceptions that expand the use of prior authorization and step therapy for protected class drugs at § 423.120(b)(2)(vi)(C) and the exceptions for protected class drugs that are new formulations at § 423.120(b)(2)(vi)(D), the burden would consist of the time and effort for Part D sponsors to submit their formularies to CMS under the existing annual submission process. The annual submission requirements and burden are currently approved by OMB under control number 0938–0763 (CMS–R–262). The proposed provisions would not impose any new or revised information collection requirements or burden. Consequently, the provisions are not subject to the PRA.

For the proposed exceptions related to § 423.120(b)(2)(vi)(E), for protected class drugs for which a Part D sponsor chooses to exclude from their formulary due to a price increase beyond a certain threshold, Part D sponsors would be required to submit an additional justification to CMS during the annual formulary submission process. The justification must explain why the Part D sponsor is excluding such drug from their formulary. The burden associated with this exception would consist of the time and effort put forth by Part D sponsors to prepare and submit their formularies to CMS along with the justification.

While the annual formulary preparation and submission process and burden are currently approved by OMB without the need for change, we estimate that it would take an average of 10 minutes (0.167 hours) at $117.04/hr for a pharmacist to prepare and submit each justification. Because Part D sponsors already research list prices to inform the existing formulary negotiation process, we only consider the time necessary to prepare and submit the justification to CMS. We estimate that all 218 Part D plan sponsors (32 PDP parent organizations and 186 MA–PD parent organizations, based on plan year 2018 plan participation) would be subject to this requirement. In aggregate, we estimate an annual burden of 36 hours (0.167 hr × 218 sponsors) at a cost of $4,213 (36 hr × $117.04/hr).

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

This proposed change would codify in Part D regulation 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 this would not change any existing practice and the provisions do not have any information collection implications, the provisions are not subject to the PRA.

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

This provision proposes that each Part D plan sponsor adopt one or more Real Time Benefit Tool (RTBT) tools that are capable of integrating with e-prescribing (eRx) and electronic medical record (EMR) systems for use in part D E-Prescribing (eRx) transactions beginning on or before January 1, 2020. We are advancing a provision with unclear costs and impacts to reflect the direction that the industry is moving in, and we want to ensure that protections and guidance are given before it becomes too widespread. Because of a desire to address the high costs of drugs and the potential savings that could be realized through RTBT we do not wish to delay such a proposal. This provision also supports the MMA objectives of patient safety, quality of care, and efficiencies and cost savings in the delivery of care if our proposals are finalized.

Because of our inability to quantitatively score this provision, we are soliciting comments on potential information collection implications.

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

Section 1860D–4(a)(1)(A)(4) of the Act requires that Part D sponsors 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.

In this rule we are proposing to require that sponsors 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 would 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, thereby encouraging lower costs. Since plans use formularies we believe it is reasonable to assume that all plans already have the negotiated drug price

and the lower cost alternatives in an existing system. Nonetheless, we seek comment on the availability and feasibility of this information. If our assumption is correct, the sole cost of this proposal to plans would be placing this information in the Part D EOB model, a model which all impacted plans have and use for their enrollees.

We assume that half a day of programming work (4 hours) per contract at $98.54 an hour is needed to link alternative prices to EOB Model. Therefore, the aggregate first year impact is 2,240 hours (560 Part D contracts * 4 hours per contract) at an aggregate cost of $0.2 million (560 Part D Sponsors and PDPs * 4 hours * $98.54/hr). Since this is a first time impact only, the annualized impact over 3 years is 747 hours (2,240/3) at a cost of $73,609 (747 hours * $98.54/hr).

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)

This rule proposes protections that ensure 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, we are proposing that an MA plan must establish and use a P&T Committee to review and approve step therapy programs used in connection with Part B drugs. The proposed P&T Committee requirements are the same as the requirements applicable to Part D plans under § 423.120(b). We propose to allow MA–PD plans to use the Part D P&T Committee to satisfy the new requirements proposed in this rule 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 another 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 (and estimated in this rule) 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. We estimate it would take 1 hour at $69.08/hr for a P&T Committee business specialist to perform certain tasks and review and retain documentation and information as described in § 422.136(b)(4) and (9). The one hour estimate reflects half the Part D P&T Committee burden (or two hours) that is currently approved by OMB under control number 0938–0964 (CMS–10141). We believe that the added hour is reasonable since the P&T Committee requires significantly less work for Part B than for Part D. In aggregate we estimate an annual burden of 634 hours (1 hour × [697 plans—63 Prescription Drug plans which don't offer Part B]) at a cost of $43,797 (634 hr × $69.08/hr).

Another proposed beneficiary protection measure is related to organization determinations and reconsiderations for Part B drugs. The proposal only changes the adjudication timeframes for an MA plan (including an MA–PD plan). We are not proposing to change any other requirements (for example, notice requirements, content, standards for decision making, etc.). Consequently, the provision is not subject to the PRA.

6. ICRs Regarding Pharmacy Price Concessions in the Negotiated Price (§ 423.100)

We are considering redefining ''negotiated price'' as the baseline, or lowest possible, payment to a pharmacy and adding a definition of ''price concession.'' The definitions being considered would not impose any new or revised information collection requirements or burden on sponsors, pharmacies, or any other stakeholders. Consequently, the provisions would not be subject to the PRA.

C. Summary of Proposed Information Collection Requirements and Burden

TABLE 3—ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulatory reference	Provision brief title	OMB and CMS control Nos.	Item	Respondents	Total responses	Hours per respondent	Total hours	Labor cost ($/hr)	Total annual cost ($)
§§ 423.120(b) and 422.136(b)	Step Therapy Part B	0938–0964 (CMS 10141).	Documentation Requirements.	634	634	1	634	69.08	43,797
§ 423.120(b)(2)(vi)	Plan Flexibility to Manage Protected Classes.	0938–0763 (CMS R 262).	Additional Justification ..	218	218	0.167	36	117.04	4,213
§ 423.128	Part D Explanation of Benefits.	N/A	Part D Explanation of Benefits.	560	560	4	[1]747	98.54	73,609
Subtotal (Private Sector)	.....	.....	.....	*1,412*	.....	*Varies*	*1,417*	*Varies*	*121,619*
Total	.....	.....	.....	1,412	.....	Varies	1,417	Varies	*121,619*

Note: The 747 reflects an annualization of a first year cost over 3 years: 560 * 4/3 − 747.

D. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to the Office of Management and Budget (OMB) for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections previously discussed, please visit CMS's website at: *https://www.cms.gov/Regulations-andGuidance/Legislation/PaperworkReductionActof1995/PRAListing.html,* or call the Reports Clearance Office at (410) 786–1326.

We invite public comments on these proposed information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule and identify the rule (CMS–4180–P) and where applicable: the ICR's CFR citation, CMS ID number, and OMB control number.

See the **DATES** and **ADDRESSES** sections of this proposed rule for further information.

IV. Regulatory Impact Analysis

A. Statement of Need

This rule proposes to support 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 are proposing 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 proposed rule on strengthening negotiation for Part D plans and increasing competition in the market for prescription drugs. We propose 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 seek to drive robust competition among health plans and pharmacies, so consumers can shop based on quality and value. These proposed 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 proposed 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 proposed 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 proposed 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 proposed rule may have a significant impact on a substantial number of small entities, the proposed 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 proposed rule, the impact is not significant. To assess impact, we use the data in Table 14, which show that the raw (not discounted) net effect of this proposed rule over 5 years is $1.2 billion. 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 proposed rule is significantly below the 3 to 5 percent threshold for significant impact. Had we compared the 2020 impact of the proposed rule to projected 2020 monetary need, the impact would be still less.

Consequently, the Secretary has determined that this proposed 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 proposed 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 2018, that threshold is approximately $150 million. This proposed 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 proposed rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this proposed 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 proposed 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 fringe benefits and overhead costs (*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 proposed 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 * 1,000 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 would reduce the number of reviewers to approximately 500 (assuming approximately 250 parent organizations), and this would 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 would review this rule. There are 30–50 major PBMs, and this would increase the estimate by 0.3 to 0.5 percent. Using these alternate estimates, we can safely say that the cost of reviewing is between half a million (50 percent * $816,000) and a million (1.005 percent * $816,000). Thus, we consider the $816,000 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).

C. Anticipated Effects

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

CMS is proposing three exceptions to the protected class policy that would allow Part D sponsors to: (1) Implement broader use of prior authorization and step therapy for protected class drugs, including to determine use for protected class indications; (2) exclude a protected class drug from a formulary if the drug represents only a new formulation of an existing single-source drug or biological product, regardless of whether the older formulation remains on the market; and (3) exclude a protected class single-source drug or biological product from a formulary if the price of the drug increased beyond a certain threshold over a specified look-back period.

Under this proposal, we reviewed the total expenditure, the rebate amounts, expected patent expirations, and the generic availability for all drugs in the six protected classes and determined that the proposal will have meaningful impact on three classes, which are the anticonvulsants, antidepressants, and antipsychotics. For the remaining three classes, antineoplastics, antiretrovirals, and immunosuppressants, the narrower indications and complicating clinical criteria would limit Part D sponsors' ability to do significant management. Due to restrictions on disclosure of rebate data, CMS is not able to release this analysis to the public.

Granting Part D sponsors additional management flexibility provides them with greater negotiating power in determining manufacturer rebate levels. Additionally, utilization management will promote generic 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 diagnosis for a condition 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.

Since manufacturers have been paying relatively high rebates for some drugs, we assume that the rebates would not increase for those drugs whose manufacturers pay for 25 percent or more of their costs. However, there are different market forces behind those drugs whose manufacturers pay lower rebates. Therefore, we assume the rebates will increase by a modest 5 percent for most of those drugs currently with rebates less than 25 percent of their costs. Further, for those drugs with generic versions available, we assume that 5 percent of the brand-name prescriptions will be shifted to generic versions. Since there were no data readily available, we relied upon pharmacy benefit management experience and actuarial judgment to arrive at these 5 percent estimates. Lastly, in the absence of data, and using actuarial judgment, we estimate an overall 0.5 percent of cost reduction due to a reduction in wasteful or inappropriate prescriptions when Part D sponsors implement broader use of prior authorization (for the reasons discussed previously and in section III.B.2. of this proposed rule). We considered studies such as the 2014 NIH study [17] on prior authorization, but based on the focus on a more limited set of drugs, the fact that participants were Medicaid beneficiaries, and the inconclusive nature of the results, we determined it would not be applicable to this provision.

Because the current rebates concentrate on a handful of drugs for which manufacturers already pay relatively high rebates, the further rebate increases are projected to be only about $11 million in 2020. The projected increase in generic substitution affects more than the highly rebated drugs in those three classes (antidepressants, anticonvulsants, and antipsychotics) because most of them have generic competition. Estimated savings to the Medicare Trust Fund for these generic substitutions are $104 million in 2020. The projected savings to the Medicare Trust Fund from reduced overall prescriptions are $77 million in 2020 with 0.5 percent being applied to the total cost adjusted for the projected impact from the generic substitution. Table 4 presents the projected yearly total savings to the Medicare Trust Fund for 2020–2029, carving out the effects of ordinary inflation. The annual savings to the Medicare Trust Fund for 2020–2029 is projected to be $192 to $320 million. The annual savings for Part D enrollees, comprising both lower premiums and lower cost sharing, for 2020–2029 is projected to be $51 to $88 million.

Factors entering into the trend considerations were based on internal CMS data and assumptions on Part D expenditures. We also carved out ordinary inflation of 2.6 percent.

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 are not proposing 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.

Out of an abundance of caution to make certain that our three proposed

[17] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3980661.*

exceptions to the protected class policy would not introduce interruptions for enrollees on existing therapy of protected class drugs for protected class indications, we seek comment on whether there are additional considerations that would be necessary to consider before we would effectuate these exceptions.

TABLE 4—PROJECTED MEDICARE TRUST FUND AND PART D ENROLLEE SAVINGS FOR PROVIDING PLANS FLEXIBILITY TO MANAGE PROTECTED CLASSES

[In millions of dollars]

Year	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
Medicare Trust Fund Savings	141	151	161	170	180	188	199	209	220	232
Part D Enrollee Share of Savings	51	56	59	63	67	70	75	79	84	88

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,[18] and for drugs that are already on the market, R&D has already been done and would not change. In other words, although this proposed 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 be also no immediate reduction in production of drugs, since generic manufacturers would produce the drugs consumed by enrollees rather than brand manufacturers. However, the cost to the enrollee and the Medicare Trust Fund would be significantly less because the enrollee and 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 Trust Fund would experience reduced dollars spent.

We solicit comment on these estimates.

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

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

[18] ''Why do generic medicines cost less than brand name medicines,'' *https://www.fda.gov/drugs/resourcesforyou/consumers/questionsanswers/ucm100100.htm.*

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

This provision proposes that each Part D plan sponsor adopt one or more Real Time Benefit Tool (RTBT) tools that are capable of integrating with e-prescribing (eRx) and electronic medical record (EMR) systems for use in part D E-Prescribing (eRx) transactions beginning on or before January 1, 2020. CMS believes that requiring Part D sponsors to implement real-time benefits (RTB) information may improve the cost effectiveness of the Part D benefit, as required by section 1860D–4(e)(2)(D) of the Act. 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 seeks 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 would be use of RTBT to encourage prescribing of lower tier cost sharing drugs. This would result in a dollar savings to the Medicare Trust Fund. However, we are unable to fully quantify the impact of this provision due to lack of adequate data. Because of lack of data we are not scoring this provision. We however, provide below a list of data items needed and solicit comments on any of these factors.

To illustrate the potential both for costs and savings we present below some estimates on costs below. We hope commenters can help provide us with information so we can have a more concrete estimate at the time of the final rule.

The list of items for which we do not have adequate data are the following:

- *Current usage:* Some plans are already using some form of RTBT. We do not know how many plans are using RTBT nor do we know to what extent the plans that are using the RTBT are meeting the specifications listed in our preamble discussion.
- *Use of intermediaries for software:* There is a wide range of charges from intermediaries for RTBT. Cost is reduced for large volume which might help large plans but hurt small plans. There is industry concern that if a requirement of RTBT is finalized, intermediaries might raise rates because of increased demand. There is also concern that if a requirement is finalized, Part D plans may struggle to use PBM information with another intermediary, therefore further raising costs for software.
- *Software costs:* Although we are not fully cognizant of all requirements for a plan to program its own software for RTBT, several scenarios discussed in more detail below show a high cost, in fact a cost that could offset the savings.
- *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, these substitutions already are done by pharmacies and providers. We solicit comment on this perspective. We are particularly interested in those stakeholders already using some form of RTBT to ascertain where savings comes

from. We have not found a unique definitive answer to this.

• *Cost after implementation:* If any cost would be incurred from some plans having to make changes once NCPDP develops a universal standard.

• *Cost to providers:* We also believe there could be a cost to providers as they may need training on multiple RTBT tools and time would be taken away from clinical work to consult this tool.

• *Number of impacted beneficiaries:* Due to the limited scope of the current implementation efforts, we are unsure of the number of beneficiaries that would be impacted by this change. The number of impacted beneficiaries could be informed by how aggressively the plans trained prescribers, how many EHRs each RTBT integrated with, and knowledge from the beneficiary to ask for such information.

Prior to stating estimates we outline how they are used. We estimate cost at the parent organization level since software available from a parent organization would suffice for all its contracts. Thus each per parent-organization estimate is multiplied by 240 (the number of parent organizations). This figure is based on all parent organizations creating software is used as a factor in scenarios. For example—

• If we assume 50 percent of parent organizations have adequate software (or cheap intermediaries) then our estimate for cost would be 50 percent * 240 (parent organizations) * Cost per parent organization.

• If we assume 25 percent of parent organizations have adequate software or cheap intermediaries) then our estimate for cost would 25 percent * 240 * Cost per parent organization.

In other words the calculation of cost per parent organization is simply a factor that is to be used in computations of impact by scenario.

Rather than include an assumption about how many parent organizations need to program software, we did not calculate the cumulative impact of the potential costs for software implementation across parent organizations. As discussed below, we are seeking comment on how many plans are already doing RTBT (and conversely, how many would incur costs for software implementation).

We now estimate separately the following:

• Savings from RTBT.

• Cost for software implementation per parent organization.

Cost for intermediaries is not estimated since we have no basis and there is concern that rates might go up.

Savings from RTBT: CMS believes that the primary source of savings of RTBT is the prescription of lower-tier cost sharing drugs. There may also be some savings from substitutions of generics for brands but we currently believe that substitutions of generics for brands is adequately addressed by providers themselves and pharmacies. We solicit stakeholder comment on this perspective of savings as well as stakeholder experience.

Any such savings would be classified as a transfer since there is 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 Truest Fund.

Cost of plans writing their own software: We are not aware of all software requirements. Therefore, we estimate a minimum requirement and show that even that is prohibitive. We obtain hourly wages from the BLS website. Minimum daily costs are summarized in Table 5.

TABLE 5—COST TO PRODUCE SOFTWARE IMPLEMENTING RTBT

Occupation code	Occupation title	Mean wages per hour	Fringe benefits and overtime	Wage per person	Number of people	Wage per occupation	Hours per day	Wage per day
29–1051	Pharmacists	$58.52	$58.52	$117.04	2	$234.08	8	$1,873
29–1060	Physicians	101.63	101.63	203.26	2	406.52	8	3,252
15–1133	Software developers system software.	53.74	53.74	107.48	2	214.96	8	1,720
15–1131	Programmers	42.08	42.08	84.16	2	168.32	8	1,347
Total cost per day								8,192

We assume that minimally a plan would need a unit of two software developers, two programmers, two physicians and two pharmacists. The total cost per day for this minimal unit is $8,192. The needs for each of these occupations should be clear: Programmers to write the code and software developers for business requirements. Both physicians and pharmacists would be needed to identify clinically equivalent drugs. The use of ''two'' is simply a minimum number. We again emphasize that this minimal unit is a factor not a statement of actual need. The following examples of impacts of scenarios are illustrative:

• If we assume a year of work we would need $2.1 million (52 weeks * 5 days a week * $8,192 cost per day = $2.1 million).

• If we further assume that four of each occupation is needed we would double this (2 (twice as many staff) * 52 weeks * 5 days a week * $8,192 cost per day) = 2 * $2.1 million = $4.2 million).

• If we assume only 6 months are needed then half would be needed ($1.05 million or $2.1 million/2).

Similarly, maintenance costs could be obtained by multiplying number of days needed for maintenance by daily costs. For example if a week each month is needed, maintenance costs would be $0.7 million ($8192 * 12 months * 5 days). If more or less are needed then the maintenance numbers would go up or down.

• *Transaction costs:* We obtained information from only one stakeholder who advised us of a three cent cost per transaction if the volume of requests exceeds 100,000 per month. Since CMS internal data shows 1.5 billion prescription drug events per year, we estimate a $45 million maximum cost (0.03 cost per transaction * 1.5 billion PDE). It follows that transaction cost can be prohibitive. We solicit comments, particularly from stakeholders already using some form of RTBT on the number of PDE involved as well as their experience with cost per transaction.

We are soliciting input from stakeholders on the following questions in order to inform the impact analysis and to help us develop an estimate of the impacts of this proposal across plans:

• How many plans are already doing RTBT?

• What were the costs?

• Are there further costs in going from a trial run to a full run if that is applicable?

• Are the cost estimates for creating software realistic and consistent with plan experience?
• Are plans using intermediaries to provide this service?
• What are the costs for high volume usage?
• What training is provided to prescribers when RTBT is implemented, and how much does that training cost?
• Are providers actively using the RTBT software? What specific provider patterns of usage of RTBT are relevant to this proposal.
• What will the extra cost be to imposing this requirement and then implementing the NCPDP standard?
• Was there a change in prescribing patterns once RTBT was implemented? Did it lead to reduce spending on drugs?

We are also interested in comments that would help us to understand whether the potential benefits or cost savings associated with this proposal outweigh the potential costs of this proposal.

4. Part D Explanation of Benefits (§ 423.128)

In the Collection of Information portion of this document we have detailed the $0.2 million 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. We therefore 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, five 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 overtime and fringe benefits) + 5 hours * $73.20/hr for GS–15, Step 5 staff * 2 (for overtime and fringe benefits)).

5. 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)

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 a plan offers all drugs, then it typically will purchase drugs at market price. There could be a pair of drugs that have the same effect on a medical condition but differ significantly in price and the plan is allowed to use step therapy. This creates an incentive for drug manufacturers to lower further the cost of the less expensive drug of the drug pair and then incentivize drug manufacturers to negotiate with MA plans so that their drugs become the drug selected by the plan as the first step in a therapy.

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 proposed rule when discussing the impact on the Medicare Trust Fund and beneficiary cost sharing due to step therapy.

Despite the rationale just stated, there are various studies suggesting that step therapy may be costly either economically or health-wise. There are two primary reasons for this.[19]

• *Discontinuation:* Several studies show that enrollees 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. One article cites eight studies, four with data, each showing a discontinuation rate of about 10 percent. There are several studies of discontinuation.[21] While discontinuation produces savings, it does so at the expense of enrollee health, an undesirable consequence. On the other hand, higher drug costs might lead to a reduction in medication adherence. The studies cited do not account for this side-effect and other risk-risk tradeoffs.

• *Effects of delay:* The idea of step therapy is that if the initial drug ''fails first'' then a provider will prescribe the drug they may have originally wanted to prescribe. But then there is a delay in the patient receiving this drug. That delay may cause a worsening of conditions leading to increased medical costs. Several studies 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.[20] Similar studies have been done on—(1) Maine Medicaid residents; [21] and (2) on people with cardiovascular disease.[22] One state enacted legislation to protect people from certain harms of step therapy.[23]

[19] 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.

[20] 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.

[21] Step therapy in Maine's Medicaid program was linked with higher risks of hospitalization. See Soumerai et al., ''Use of atypical antipsychotic drugs for schizophrenia in Maine Medicaid following a policy change''. Health Aff (Millwood). 2008; 27(3): W185–95. DOI: 10.1377/hlthaff.27.3.w185.

[22] The National Center for Biotechnology Information at NIH published a study showing that people with cardiovascular conditions who had restrictive prescription drug access had a statistically significant increase in hospital visits. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2496984/*.

[23] 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-*

Continued

Summary: Step therapy can result in both savings and costs. While at the time of initiation of the step therapy there is initial savings, this savings may end up costing more in the aggregate because of worsening conditions and increased medical costs. Furthermore, some of the savings arises from negotiations which are difficult to quantify. We can 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 effects of—(1) back-end negotiations, rebates from manufacturers to plans; (2) less expensive biological products approved under section 351(k) of the Public Health Service Act (*e.g.,* 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.[24] These laws vary widely and typically provide protections to beneficiaries against the misuse of step therapy.

TABLE 6—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 [1] (in millions)	Cost sharing percentage	Adjustment for enrollees for proposed step therapy (%)	Savings to beneficiaries [2] (in millions)
	(A)	(B)	(C)	(D)	(E)	(F)	(G)	(H)	(I)	(J)
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

[1] (G) = (A) * (B) * (C) * (D) * (E) * (F).
[2] (J) = (A) * (B) * (C) * (H) * (I).

This provision will allow MA plans to use this utilization management tool for Part B drugs and examine 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. We now explain the calculations which are summarized in Table 6.

We obtain projected MA enrollment from the 2018 Medicare Trust Fund report. This is presented in Column (A) of Table 6.

- 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 proposed rule. An HPMS memo was issued by CMS rescinding an earlier memo prohibiting step therapy. This proposal surpasses this memo 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.
- 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

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.

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

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 submitted bids over the next ten 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 6. 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 proposed 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 be also no reduction in production of drugs, since generic manufacturers would produce the drugs consumed by enrollees rather than brand manufacturers. However, the cost to the enrollee and the Medicare Trust Fund would be significantly less because the enrollee and 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 Trust Fund would experience reduced dollars spent.

The allowance of step therapy 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 7. The following narrative explains this table.

TABLE 7—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 plan reported. 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 it goes on to the IRE (a CMS contractor) to be reviewed. If this is also denied it can be appealed to an administrative law judge (ALJ) if the amount in controversy is met.

For 2016, we have 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) 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 a MA regulation (§ 422.566(d)) that implements 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 regarding the enrollee's ability to take the drug required in the step therapy criteria and 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 would multiply the $0.8 million by the ratio of enrollment in 2018 to 2016. Similarly to obtain estimates for 2020–2024 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 2020–2029 may be obtained from Table IV.C1 in the 2018 Trustee report. Using these numbers we obtain the estimated cost of increased appeals for 2020–2029, presented in Table 8, as $1.0–$1.3 million.

TABLE 8—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

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

In this rule, we include an extensive discussion of the consideration of a new definition of ''negotiated price'' that includes all pharmacy price concessions received by the plan sponsor for a covered Part D drug, and reflects the lowest possible reimbursement a network pharmacy will receive, in total, for a particular drug. As we are not proposing to move forward with such a policy for 2020, there is no impact in this regard. As moving forward with the policy is an alternative that is under consideration, we provide and seek comment on the following regulatory impact analysis.

As part of the approach being considered, we would first delete the current definition of ''negotiated prices'' (in the plural) and add a definition of ''negotiated price'' (in the singular) to make clear that a negotiated price can be set for each covered Part D drug, and the amount of the pharmacy price concessions may differ on a drug by drug basis. Then, we would implement a definition of ''negotiated price'' that is intended to ensure that the prices available to Part D enrollees at the point of sale are inclusive of all pharmacy price concessions. We believe such an approach would be more reflective of current pharmacy payment arrangements.

We note Part D sponsors and their contracted PBMs have been increasingly successful in recent years at negotiating price concessions from network pharmacies. Performance-based pharmacy price concessions, net of all pharmacy incentive payments, increased, on average, nearly 225 percent per year between 2012 and 2017 and now comprise the second largest category of DIR received by sponsors and PBMs, behind only manufacturer rebates.

Pharmacy price concessions are negotiated between pharmacies and sponsors or their PBMs, independent of CMS, and are often tied to the pharmacy's performance on various measures defined by the sponsor or its PBM. Under the current definition of ''negotiated prices'' at § 423.100, negotiated prices must include all price concessions from network pharmacies except those that cannot reasonably be determined at the point of sale. However, because these performance adjustments typically occur after the point of sale, they are not included in the price of a drug at the point of sale.

We further understand, through comments received from the pharmacy industry in response to our Request for Information on pharmacy price concessions (included in the November 2017 proposed rule (82 FR 56419 through 56428) and evaluation of the DIR data submitted by Part D sponsors, that the share of pharmacies' reimbursements that are contingent upon their performance under such arrangements has grown steadily each year. As a result, sponsors and PBMs have been recouping increasing sums from network pharmacies after the point of sale (pharmacy price concessions) for ''poor performance,'' sums that, in some instances, are far greater than those paid to network pharmacies after the point of sale (pharmacy incentive payments) for ''high performance.''

When pharmacy price concessions are not reflected in the price of a drug at the point of sale, beneficiaries might see lower premiums, but the following negative effects occur:

- *Beneficiary Cost-Sharing:* Beneficiaries do not benefit from pharmacy price concessions through a reduction in the amount they must pay in cost-sharing, and thus, end up paying a larger share of the actual cost of a drug.
- *Transparency:* When the point-of-sale price of a drug that a Part D sponsor reports on a PDE record as the negotiated price does not include pharmacy price concessions, the negotiated price is rendered less transparent at the individual prescription level and less representative of the actual cost of the drug for the sponsor.
- *Competition:* Variation in the treatment of these price concessions by Part D sponsors may have a negative effect on the competitive balance under the Medicare Part D program.

For this reason, as part of the November 2017 proposed rule, we published a ''Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale,'' (82 FR 56419 through 56428). The majority of commenters, representing pharmacies, pharmacy associations, and beneficiary advocacy groups, supported the adoption of a requirement that pharmacy price

concessions be applied at the point of sale because it would—

- Lower beneficiary out-of-pocket costs (especially critical for beneficiaries who utilize high cost drugs);
- Stabilize the operating environment for pharmacies (because of greater transparency and predictability of the minimum reimbursement on a per-claim level, thus allowing more accurate budgeting and improved ability to evaluate proposed contracts from PBMs); and
- Standardize the way in which plan sponsors and their PBMs treat pharmacy price concessions.

The proposal would have several impacts on a variety of stakeholders:

I. Impacts on prescription drug costs for beneficiaries and manufacturers.

II. One time administrative costs for Part D sponsors.

These impacts are summarized in the following tables and further discussed in narratives. These tables reflect two possible approaches to this concession provision:

- *All-Phase Assumption:* Assume the application of pharmacy price concessions to the point-of-sale occurs at all phases of the Part D Benefit including the gap.
- *Gap-Excluded Assumption:* Assume the application of pharmacy price concessions to the point-of-sale occurs at all phases of the Part D benefit except the when the purchasing enrollee is in the gap.
- Tables 9 and 10 summarize impacts on prescription drug costs for beneficiaries, Part D sponsors and manufacturers, under the all-phase assumption.
- Table 11 summarizes one-time administrative costs for Part D sponsors. This is independent of which approach is taken.

Table 10 summarizes the ten-year impacts we have modeled for requiring that sponsors move all pharmacy price concessions to the point of sale in all phases of the Part D benefit, including the coverage gap. Table 10 reflects ten year raw sums of the figures in Table 9. For example, the second row of Table 10 lists a $14.8 billion savings to beneficiaries. The row header references row (I) in Table 9. The sum of the numbers in row (I) of Table 9, is in fact $14.8 (0.8 + 0. 9 + . . . + 2.3 = 14.8). Throughout this narrative, the quantitative aspects of the discussion may be found in the corresponding labeled rows of Table 10. There are several key assumptions involved in the development of these estimates, particularly the expected growth of pharmacy price concessions in future years. Actual pharmacy price concessions have increased from $229 million in 2013 to $4 billion in 2017. The use of preferred pharmacy networks is now widespread, with over 85% of standalone prescription drug plans using a preferred network in 2017. Because the rate of growth has been volatile in recent years, and because so many plan sponsors have incorporated preferred networks into their plan design, we estimate that the growth rate for pharmacy price concessions will slow in future years. Our best estimate is that the average growth of pharmacy price concessions will be approximately 10% per year going forward. This still represents a significant increase in the price concessions as a percentage of gross drug cost, from 2.6% in 2017 to 3.5% in 2029, and is a reasonable estimate in our judgment. We note that this assumption has a high degree of uncertainty given the changes in price concessions over the past five years. If the actual growth rate emerges differently, it could materially change the results in tables 9, 10, 12, 13, and 14.

Under the policy to require the negotiated price reflect the lowest possible amount the pharmacy could receive for a covered Part D drug, beneficiaries would see lower prices at the point of sale at the pharmacy and on Plan Finder, beginning immediately in the year the policy takes effect. (This is summarized in Table 10 in the row ''beneficiary costs'' which reflects the sum of the rows ''cost sharing'' and ''premiums''; these three rows correspond, as indicated in Table 10, to sums of rows K, I, and J, respectively in Table 9.) Lower point-of-sale prices would result directly in lower cost-sharing for non-low income beneficiaries. For low income beneficiaries, whose out-of-pocket costs are subsidized through Medicare's low-income cost-sharing subsidy, cost-sharing savings resulting from lower point-of-sale prices would accrue to the government. Plan premiums would likely increase as a result of the change to the definition of negotiated prices being considered—if all pharmacy price concessions are required to be passed through to beneficiaries at the point of sale, fewer such concessions could be apportioned to reduce plan liability in the bid, which would have the effect of increasing the cost of coverage under the plan. At the same time, the reduction in cost-sharing obligations for the average beneficiary would be large enough to lower their overall out-of-pocket costs. The increasing cost of coverage under Part D plans as a result of requiring pharmacy price concessions to be applied at the point of sale would likely have a more significant impact on government costs, which would increase overall due to the significant growth in Medicare's direct subsidies of plan premiums and low income premium subsidies.

The increase in direct subsidy and low-income premium subsidy costs for the government are partially offset by decreases in Medicare's reinsurance and low income cost-sharing subsidies. Decreases in Medicare's reinsurance subsidy result when lower negotiated prices slow down the progression of beneficiaries through the Part D benefit and into the catastrophic phase, and when the government's reinsurance payments, which reflect 80 percent of allowable drug costs incurred in the catastrophic phase less a share of the overall price concessions received by the plan sponsor, are based on lower negotiated prices. Similarly, low income cost-sharing subsidies would decrease as beneficiary cost-sharing obligations decline due to the reduction in prices at the point of sale. Finally, the slower progression of beneficiaries through the Part D benefit would also have the effect of reducing manufacturer coverage gap discount payments as fewer beneficiaries would enter the coverage gap phase or progress entirely through it.

TABLE 9—IMPACT (Billions) OF REQUIRING APPLICATION OF PHARMACY PRICE CONCESSIONS AT POINT OF SALE INCLUDES APPLICATION TO COVERAGE GAP

Label	Item/year	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
(A)	Gross Drug Cost (GDCC)	(5.7)	(6.4)	(7.1)	(7.8)	(8.6)	(9.3)	(10.2)	(11.1)	(12.2)	(13.2)
(B)	Drug cost covered by plan (Supplemental and non-Part D) CCP.	(4.1)	(4.5)	(4.9)	(5.4)	(5.8)	(6.2)	(6.8)	(7.4)	(8.0)	(8.6)
(C)	OOP including GAP Discount	(1.6)	(1.9)	(2.1)	(2.4)	(2.7)	(3.0)	(3.4)	(3.8)	(4.2)	(4.6)
(D)	General Premium Subsidy	1.9	2.2	2.4	2.7	3.0	3.2	3.6	3.9	4.3	4.6
(E)	Reinsurance	(0.6)	(0.6)	(0.7)	(0.7)	(0.7)	(0.8)	(0.8)	(0.8)	(0.9)	(0.9)
(F)	LIS Cost-Sharing Subsidy	(0.5)	(0.6)	(0.6)	(0.7)	(0.8)	(0.9)	(1.1)	(1.2)	(1.3)	(1.4)

TABLE 9—IMPACT (Billions) OF REQUIRING APPLICATION OF PHARMACY PRICE CONCESSIONS AT POINT OF SALE INCLUDES APPLICATION TO COVERAGE GAP—Continued

Label	Item/year	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
(G)	LIS Premium Subsidy	0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.2
(H)	Total Government	0.9	1.1	1.2	1.4	1.5	1.7	1.9	2.1	2.3	2.5
(I)	Cost sharing enrollees	(0.8)	(0.9)	(1.1)	(1.2)	(1.4)	(1.5)	(1.7)	(1.9)	(2.1)	(2.3)
(J)	Premiums from Enrollees	0.3	0.4	0.4	0.5	0.5	0.6	0.6	0.7	0.8	0.9
(K)	Total Enrollee Costs	(0.5)	(0.6)	(0.7)	(0.7)	(0.8)	(0.9)	(1.0)	(1.2)	(1.3)	(1.4)
(L)	Total Benefits	1.2	1.4	1.6	1.8	2.1	2.3	2.5	2.8	3.1	3.3
(M)	Gap Discount	(0.4)	(0.4)	(0.4)	(0.5)	(0.5)	(0.6)	(0.6)	(0.7)	(0.8)	(0.8)

TABLE 10—TOTAL IMPACTS FOR 2020 THROUGH 2029 WITH APPLICATION IN COVERAGE GAP

	Total (billions)	Average per member—per year	Percent change
Beneficiary Costs (G6: (K))	($9.2)	($16.52)	(1)
Cost Sharing (G6: (I))	(14.8)	(26.69)	(3)
Premium (G6: (J))	5.6	10.16	2
Government Costs	16.6	29.95	1
Direct Subsidy (G6: (D))	31.8	57.71	14
Reinsurance (G6: (E))	(7.6)	(13.94)	(1)
LI Cost-Sharing Subsidy (G6: (F))	(9.2)	(16.54)	(2)
LI Premium Subsidy (G6: (G))	1.5	2.73	2
Manufacturer Gap Discount (G6: (M))	(5.8)	(10.50)	(3)

One primary purpose or effect of performance-based pharmacy payment arrangements, according to Part D sponsors responding to our Request for Information, is to encourage generic substitutions for brand drugs. For example, a pharmacy may claim that its staff informs patients when a generic alternative is available for their prescription, and that they may have lower costs for the generic version. The pharmacy is willing to structure its payments contingent on meeting a generic dispensing rate through these interventions. Such substitutions, although saving money to enrollees and plan sponsors, are a transfer primarily between the manufacturers of brand drugs and the manufacturers of generic drugs.

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 proposed 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 be also no reduction in production of drugs, since generic manufacturers would produce the drugs consumed by enrollees rather than brand manufacturers. However, the cost to the enrollee and the Medicare Trust Fund would be significantly less because the enrollee and 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 Trust Fund would experience reduced dollars spent.

II. One-Time Administrative Costs for Part D Sponsors

We anticipate that this potential policy change would require Part D sponsors to make certain system changes related to the calculation of the amounts they report in one or two fields in the PDE data collection form. We anticipate that this would cause sponsors to incur one-time administrative costs.

Please note that the impact amounts for this policy are consistent with the feedback received through the Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale in the Medicare Program that was included in the proposed rule, entitled ''Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the Pace Program'' (82 FR 56419).

To estimate the administrative costs associated with submission of PDE data, we consider the following factors: (1) The amount of data that must be submitted; (2) the number of plan sponsors (or sponsors' intermediaries) submitting data; and (3) the time required to complete the data processing and transmission transactions.

PDE Data Submission: The amount of data that must be submitted is a function of the number of prescription drug events per beneficiary and the number of data elements per event (57). Based on 3 years of enrollment data (2014, 2015, and 2016), CMS estimates that an annual average of 38,009,579 Medicare beneficiaries are enrolled in Part D prescription drug plans. The average number of PDEs per year is 1,409,828,464 (based on 2013, 2014, and 2015). To compute the average number of PDEs per beneficiary, we divide the average number of PDEs per year by the average number of beneficiaries enrolled per year. This computation leads to an average of 37 PDEs per beneficiary per year.

Number of Part D Contracts (Respondents): The average number of Part D contracts per year is 779 (based on 2014, 2015, and 2016 data).

Time Required to Process Data: The third factor that contributes to the burden estimate for submitting PDE data depends upon the time and effort necessary to complete data transaction

activities. Since our regulations require Part D sponsors to submit PDE data to CMS that can be linked at the individual level to Part A and Part B data in a form and manner similar to the process provided under § 422.310 (Part C), the data transaction timeframes will be based on risk adjustment (Part C) and prescription drug industry experiences. Moreover, our PDE data submission format will only support electronic formats. The drug industry's estimated average processing time for electronic data submission is 1 hour for 500,000 records. The average number of PDE records per year is 1,409,828,464. Therefore, the estimated total annual processing time for all PDE records is 2,820 hours. The estimated average annual electronic processing time cost per hour is $17.75. The estimated total cost related to PDE processing is therefore $50,055 (2,820 * $17.75). There are on average 38,009,579 beneficiaries enrolled in Part D, which means that the average cost of PDE processing per beneficiary is $0.0013 (that is, $50,055/38,009,579). The average number of Part D beneficiaries enrolled in a Part D contract is 48,793. The average annual cost to respondents for each Part D contract is therefore $63.43 (that is, $0.0013 * 48,793). We believe the additional effort needed to make the system changes necessitated by the amendment to the definition of negotiated prices being considered will cause a one-time increase in the administrative costs related to submission of PDE data. Therefore, we have doubled the cost per hour to $35.50 for contract year 2020. The estimated average cost related to PDE processing for contract year 2020 only is $126.86, which represents a one-time increase of $63.43 per sponsor. We estimate that the amendment to the definition of negotiated prices being considered will cause the administrative costs related to submission of PDE data for all Part D sponsors to be $100,110 for contract year 2020 only, which is an increase of $50,055 over the estimated administrative costs related to submission of PDE data reporting in the absence of the amendment being considered.

The estimated annual administrative costs related to submission of PDE data are shown in Table 11, along with the 1-year cost estimate for contract year 2020.

TABLE 11—ESTIMATED ADMINISTRATIVE COSTS RELATED TO SUBMISSION OF PRESCRIPTION DRUG EVENT (PDE) DATA

		Notes
A. Number of Respondents	779	779 is the annual average number of Part D contracts from 2013, 2014, and 2015.
B. Number of Medicare Beneficiaries Enrolled in Part D per Year.	38,009,579	Average number of Medicare beneficiaries enrolled in Part D.
C. Average Number of Part D Beneficiaries per Contract.	48,793	(B) divided by (A).
D. Average Number of PDEs per Year	1,409,828,464	The average is based on annual average PDEs from 2013 to 2015.
E. Frequency of Response	37 PDEs/per beneficiary per year	Average PDEs per beneficiary per year.
F. Number of Transactions per Hour	500,000	Drug industry's estimated average processing volume per hour.
G. Total Annual Transaction Hours	2,820	(D) divided by (F).
H. Average Electronic Cost per Hour	Annual: $17.75	Based on $17.75 per hour, the risk adjustment estimated average annual electronic processing cost per hour.
	Contract Year 2020: $35.50	Doubled in 2020 to reflect increased effort associated with implementing system changes.
I. Cost of Annual Transaction Hours	Annual: $50,055 Contract Year 2020: $100,110.	(H) multiplied by (G).
J. Average Cost per Part D Beneficiary	Annual: $0.0013 Contract Year 2020: $0.0026.	(I) Divided by (B).
K. Annual Cost to Respondents	Annual: $63.43 Contract Year 2019: $126.86.	(J) multiplied by (C).

The discussion earlier in section C.6 of this regulatory impact analysis assumes cost based on the application of the new definition of ''negotiated price'' being considered to determine the price at the point of sale both outside the coverage gap and in it (that is, during all phases of the Part D benefit). For purposes of comparison, to allow for equal consideration of both options, we also provide a cost analysis of the provision based on the application of the new definition of ''negotiated price'' being considered to determine the price at the point of sale only outside the coverage gap. The 10-year impact is summarized in Table 12, which reflects raw sums of the figures in the corresponding rows in Table 13. The construction of and labels in Tables 12 and 13 are identical to those in Tables 9 and 10; therefore the explanatory narrative provided for Tables 9 and 10 in Section C.6 of this proposed rule, applies to Tables 12 and 13 and need not be repeated here.

TABLE 12—TOTAL IMPACTS FOR 2020 THROUGH 2029 WITHOUT APPLICATION IN COVERAGE GAP

	Total (billions)	Average per member—per year	Percent change (%)
Beneficiary Costs (G8: (K))	($7.1)	($12.80)	(1)
Cost Sharing (G8: (I))	(11.8)	(21.22)	(2)
Premium (G8: (J))	4.7	8.42	2
Government Costs	13.6	24.58	1

TABLE 12—TOTAL IMPACTS FOR 2020 THROUGH 2029 WITHOUT APPLICATION IN COVERAGE GAP—Continued

	Total (billions)	Average per member—per year	Percent change (%)
Direct Subsidy (G8: (D))	25.8	46.72	12
Reinsurance (G8: (E))	(5.7)	(10.55)	(1)
LI Cost-Sharing Subsidy (G8: (F))	(7.7)	(13.85)	(2)
LI Premium Subsidy (G8: (G))	1.3	2.26	2
Manufacturer Gap Discount (G8: (M))	(4.9)	(8.80)	(2)

TABLE 13—IMPACT (BILLIONS) FROM CONCESSIONS

[Assumes no application in coverage gap]

Label	Item/year	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029
(A)	Gross Drug Cost (GDCC)	(4.7)	(5.3)	(5.9)	(6.5)	(7.2)	(7.8)	(8.6)	(9.4)	(10.3)	(11.1)
(B)	Drug cost covered by plan (Supplemental and non-Part D) CCP.	(3.5)	(3.8)	(4.2)	(4.5)	(4.9)	(5.3)	(5.8)	(6.2)	(6.8)	(7.3)
(C)	OOP including GAP Discount	(1.2)	(1.5)	(1.7)	(2.0)	(2.2)	(2.5)	(2.8)	(3.1)	(3.5)	(3.8)
(D)	General Premium Subsidy	1.5	1.8	2.0	2.2	2.4	2.6	2.9	3.2	3.5	3.8
(E)	Reinsurance	(0.5)	(0.5)	(0.5)	(0.5)	(0.6)	(0.6)	(0.6)	(0.6)	(0.6)	(0.7)
(F)	LIS Cost-Sharing Subsidy	(0.4)	(0.4)	(0.5)	(0.6)	(0.7)	(0.8)	(0.9)	(1.0)	(1.1)	(1.2)
(G)	LIS Premium Subsidy	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.2	0.2	0.2
(H)	Total Government	0.7	0.9	1.0	1.1	1.3	1.4	1.5	1.7	1.9	2.1
(I)	Cost sharing enrollees	(0.6)	(0.7)	(0.8)	(0.9)	(1.1)	(1.2)	(1.4)	(1.5)	(1.7)	(1.9)
(J)	Premiums from Enrollees	0.2	0.3	0.3	0.4	0.4	0.5	0.5	0.6	0.7	0.7
(K)	Total Enrollee Costs	(0.3)	(0.4)	(0.5)	(0.6)	(0.6)	(0.7)	(0.8)	(0.9)	(1.0)	(1.1)
(L)	Total Benefits	1.0	1.2	1.3	1.5	1.7	1.9	2.1	2.3	2.6	2.8
(M)	Gap Discount	(0.3)	(0.3)	(0.4)	(0.4)	(0.5)	(0.5)	(0.5)	(0.6)	(0.7)	(0.7)

Moreover, while not accounted for when modeling the impacts in Section C, we believe that requiring pharmacy price concessions to be included in the negotiated price, as we consider, would also lead to prices and Part D bids and premiums being more accurately comparable and reflective of relative plan efficiencies, with no unfair competitive advantage accruing to one sponsor over another based on a technical difference in how costs are reported. We believe this outcome could make the Part D market more competitive and efficient.

D. Expected Benefits

Any relevant expected benefits for enrollees, stakeholders, and the government have been fully discussed in section IV.C. of this proposed 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.

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

We propose 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.

4. 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 rule proposes requirements under which MA plans may apply step therapy as a utilization management tool for Part B drugs. In this proposal, we confirm authority for MA plans to implement appropriate utilization management and prior authorization tools for managing Part B drugs and propose parameters on using step therapy to ensure it is implemented in a manner to reduce costs for both enrollees and the Medicare program. Our proposal includes specific parameters for how step therapy may be implemented for Part B drugs, including requiring approval from P&T Committee that meets specific standards and permitting step therapy only for new administrations of the drug (subject to a 108 look-back period). We also proposed 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. MA plans may be able to provide better oversight for step therapy programs that do not distinguish new prescriptions from enrollees who are actively receiving the affected medication and allowing plans to utilize step therapy for all Part B drugs might result in more cost savings for enrollees and Medicare. However, allowing MA plans to implement step therapy on ongoing prescriptions and administrations would require the development of a transition process for affected enrollees. The estimated costs of developing a transition process, including notification to enrollees with appropriate notice regarding their transition process and providing a temporary supply of affected drugs likely outweighs any savings. Moreover, CMS recognizes the significance of many Part B drug regimens (for example, cancer treatments) and is working to ensure enrollees will not encounter unnecessary barriers to medically necessary drugs or have disruptions in care. Therefore, under § 422.136(a)(1) of the proposed rule, new step therapy programs would not be permitted to disrupt enrollees' ongoing Part B drug therapies. We are proposing 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. MA plans would be required to have a look back period of 108 days, consistent with current policy in Part D, to determine if the enrollee is actively taking a Part B medication. 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 108 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.

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

The critical policy decision was how to adapt the existing negotiated price reporting standards to best account for current pharmacy payment practices and achieve transparency and consistency in how pharmacy price concessions and drug costs are reported and treated. Several alternative approaches were considered.

- The current regulatory structure implements the statute accurately and could have been maintained, but does not account for the performance-contingent pharmacy payment adjustments that dominate today.
- Another option would be to require Part D sponsors to adjust negotiated prices in the current period using pharmacy payment adjustments determined for prior periods, which would not allow for price transparency in the current period and could drive beneficiaries away from high performing pharmacies, for which the negotiated prices would include incentive payments and, thus, be higher than for poor performing pharmacies.
- An additional option we considered was to require Part D sponsors to include in the negotiated price an approximation of the pharmacy payment adjustments that would apply. However, this approach would have no effect on differential reporting among Part D sponsors given that the accuracy of the approximations would likely vary by Part D sponsor, and it would not allow for greater price transparency if the approximations are inaccurate. This option would also drive beneficiaries away from high performing pharmacies for which the negotiated prices would be higher than for poor performing pharmacies.
- Finally, we considered an option to develop a standard set of metrics from which plans and pharmacies would base their contractual agreements. We request commenter feedback on whether these metrics could be designed to provide pharmacies with more predictability in their reimbursements while maintaining plan's ability to negotiate terms. Additionally, we seek comment on the most appropriate agency or organization to develop these standards, or whether this a matter better left to private negotiations.

In summary, the revision to the definition of negotiated price we are considering would create uniform, easily interpreted standards for negotiated price reporting that would support consistent implementation by all Part D sponsors and, thus, impose the least amount of burden on Part D sponsors and their intermediaries.

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 14, we have prepared an accounting statement showing the savings and transfers associated with the provisions of this proposed rule for contract years 2020 through 2029. Table 14 is based on Table G15 which lists savings, costs, and transfers by provision.

TABLE 14—ACCOUNTING STATEMENT—CLASSIFICATIONS OF ESTIMATED SAVINGS, COSTS, AND TRANSFERS

[Negative numbers indicate savings]

From calendar years 2020 to 2024 ($ in millions)	Savings			Whom is spending or transferring
	Discount rate		Period covered	
	7%	3%		
Net Annualized Monetized Savings.	1.13	1.13	CYs 2020–2029	Federal government, MA organizations and Part D Sponsors, Pharmacy Benefit Managers, Pharmacies.
Annualized Monetized Savings.	.....	.....	CYs 2020–2029	Pharmacies.
Annualized Monetized Cost ..	1.13	1.13	CYs 2020–2029	MA Organizations, Part D Sponsors, Contractors for the Federal Government.
Transfers	(437.83)	(445.55)	CYs 2020–2029	Federal government, MA organizations and Part D Sponsors, Pharmacy Benefit Managers, Pharmacies, Beneficiaries.

The following Table 15 summarizes savings, costs, and transfers by provision and formed a basis for the accounting table. For reasons of space, Table 15 is broken into Table 15A (2020 through 2024) and Table 15B (2025 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 may be negative or positive with negative numbers indicating savings to the Medicare Trust Fund and positive numbers indicating costs to the Medicare Trust Fund. 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 15 forms the basis for Table 14 and for the calculation to the infinite horizon discounted to 2016, mentioned in the conclusion.

TABLE 15A—AGGREGATE SAVINGS, COSTS, AND TRANSFERS IN MILLION 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	2024 Savings	2024 Cost	2024 Transfers
Total Savings															
Total Costs		1.20			1.00			1.00			1.10			1.10	
Aggregate Total		1.20			1.00			1.00			1.10			1.10	
Total Transfers			(342.00)			(366.07)			(388.54)			(413.36)			(438.48)
Protected Classes, Government			(141.00)			(151.07)			(160.54)			(170.36)			(180.48)
Protected Classes, Enrollees			(51.00)			(56.00)			(59.00)			(63.00)			(67.00)
Gag Clauses															
E-Prescribing															
Part D EOB		0.20													
Step Therapy, Government			(145.00)			(154.00)			(164.00)			(174.00)			(185.00)
Step Therapy Cost Sharing			(5.00)			(5.00)			(5.00)			(6.00)			(6.00)
Step Therapy Appeals		1.00			1.00			1.00			1.10			1.10	

TABLE 15B—AGGREGATE SAVINGS, COSTS, AND TRANSFERS IN MILLION BY PROVISION AND YEAR

	2025 Savings	2025 Cost	2025 Transfers	2026 Savings	2026 Cost	2026 Transfers	2027 Savings	2027 Cost	2027 Transfers	2028 Savings	2028 Cost	2028 Transfers	2029 Savings	2029 Cost	2029 Transfers	Raw 10 year totals
Total Savings																
Total Costs		1.10			1.20			1.20			1.20			1.30		10.20
Aggregate Total		1.10			1.20			1.20			1.20			1.30		10.20
Total Transfers			(459.22)			(487.89)			(512.89)			(539.88)			(567.77)	(4,516.11)
Protected Classes, Government			(188.22)			(198.89)			(208.89)			(219.88)			(231.77)	(1,851.11)
Protected Classes, Enrollees			(70.00)			(75.00)			(79.00)			(84.00)			(88.00)	(692.00)
Gag Clauses																
E-Prescribing																
Part D EOB																0.20
Step Therapy, Government			(195.00)			(207.00)			(218.00)			(229.00)			(240.00)	(1,911.00)
Step Therapy Cost Sharing			(6.00)			(7.00)			(7.00)			(7.00)			(8.00)	(62.00)
Step Therapy Appeals		1.10			1.20			1.20			1.20			1.30		11.20

G. Conclusion

As indicated in Table 14, we estimate that this proposed rule generates for each year in 2020–2029, net annualized costs of approximately $1.1 million primarily to entities involved with the Part D appeal process, such as Part D sponsors, the appeals contractor, and administrative law judges. The annualized $1.1 million cost primarily reflects increased appeals arising from the Step Therapy provision. There are additional (minor) first year costs in 2020 to (i) contractors for the Federal Government who will respond to requests for claims data, and (ii) to CMS staff for updating templates with the Part D EOB. The aggregate raw cost is $10.2 million from 2020–2029.

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 Medicare Advantage enrollees and the Medicare Trust Fund:

- *Enrollees:* Enrollees are estimated to reduce their spending on cost sharing by $754 million over 10 years ($62 million and $692 million arising from reduced cost sharing from Step Therapy and Protected Classes respectively).
- *Government:* The Medicare Trust Fund in aggregate reduces their dollar spending by $3.8 billion over 10 years (the Trust Fund reduces its dollar spending by $1.85 billion, and $1.91 billion arising from the Protected Class and Step Therapy provisions, respectively).

H. Reducing Regulation and Controlling Regulatory Costs

The Department believes that this proposed rule, if finalized as proposed, is considered a regulatory action under Executive Order 13771. The Department estimates that this rule generates $0.9 million in annualized cost at a 7-percent discount rate, discounted relative to 2016, over a perpetual time horizon. Notably, however, this estimate does not include impacts related to the RTBT proposal. If this proposal were finalized, the related costs or cost savings (on which we seek comment below) would also be considered under Executive Order 13771.

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 proposes to amend 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 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 108 day look-back 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 committees 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 utilization management program, such as step therapy, has any therapeutic advantages in terms of safety and efficacy.

(7) Review policies that guide exceptions and other utilization management processes, including drug utilization review, quantity limits, generic substitution, and therapeutic interchange.

(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 and utilization management activities and make this documentation available to CMS upon request.

(10) Review and approve all clinical prior authorization criteria, step therapy protocols, and quantity limit restrictions 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 a 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 paragraph (a), the paragraph (b) subject heading, and paragraph (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) 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.* 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, of this section, 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.

* * * * *

PART 423—MEDICARE PROGRAM; MEDICARE PRESCRIPTION DRUG PROGRAM

■ 11. 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.

■ 12. Section 423.100 is amended by adding a definition for ''Applicable period'' in alphabetical order to read as follows:

§ 423.100 Definitions.

* * * * *

Applicable period means—

(1) With respect to exceptions in accordance with § 423.120(b)(2)(vi)(E) for contract year 2020, September 1, 2018 through February 28, 2019; or

(2) With respect to exceptions in accordance with § 423.120(b)(2)(vi)(E) for contract year 2021 and subsequent years, September 1 of the third year prior to the contract year in which the exception would apply, through August 31 of the second year prior to the contract year in which the exception would apply.

* * * * *

■ 13. 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 period and adding in its place ''; and'';

■ c. Adding paragraph (a)(8)(iii);

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

■ e. Reassigning paragraph (b)(2)(vi)(C) as (b)(2)(vi)(F); and

■ f. Adding new paragraph (b)(2)(vi)(C) and paragraphs (b)(2)(vi)(D) and (E).

The revision and additions 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) Prior authorization and step therapy requirements 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.

(D) 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.

(E) A single-source drug or biological product, meaning a Part D drug that is approved under a new drug application submitted under section 505(b) of the Federal Food Drug and Cosmetic Act (FDCA); an authorized generic as defined under section 505(t)(3) of the FDCA; or in the case of a biological product, licensed under section 351 of the Public Health Service Act, that a Part D sponsor identifies, for which the wholesale acquisition cost between the baseline date and any point in the applicable period, increased more than the cumulative increase in the consumer price index for all urban consumers over the same period. The baseline date is the following:

(*1*) September 1, 2018 for a drug or biological product that is first marketed in the United States on or before September 1, 2018.

(*2*) The first day of the first full quarter after the date a drug or biological product is first marketed in the United States after September 1, 2018.

* * * * *

■ 14. Section 423.128 is amended by redesignating paragraphs (e)(5) and (6) as paragraphs (e)(6) and (7) and adding a new paragraph (e)(5) to read as follows:

§ 423.128 Dissemination of Part D plan information.

* * * * *

(e) * * *

(5) For each prescription drug claim, include the cumulative percentage change (if any) in the negotiated price since the first day 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.

* * * * *

■ 15. Section 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, 2020, implement one or more electronic real-time benefit tools (RTBT) that are capable of integrating prescribers' e-Prescribing (eRx) and electronic medical record (EMR) systems 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. Patients must specifically consent to use of their protected health information for RTBT.

* * * * *

Dated: November 16, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: November 19, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

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