Summary:

Proposed Rule—Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses

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Xcenda

Proposed Rule Highlights

On November 26, the Centers for Medicare & Medicaid Services (CMS) released a proposed rule outlining proposed changes to the Medicare Advantage (MA) and Part D programs. The rule is expected to be published in the *Federal Register* on November 30, 2018.

In the proposed rule, CMS is seeking to:

- Provide plan "flexibility" to manage protected classes by: 1) allowing broader use of prior authorization; 2) allowing plans to exclude a drug if a new formulation does not provide a unique route of administration; and 3) allowing plans to exclude a drug if it has cost increases above a certain threshold. It is estimated to save $1.85 million for the federal government and $692 million for beneficiaries.
- Update Part D e-prescribing standards by requiring plans to implement electronic real-time benefit tools (RTBTs) that integrate with provider systems.
- Communicate negotiated drug-pricing information and lower-cost alternatives in the Part D plan's Explanation of Benefits (EOB).
- Introduce new requirements for when MA plans may apply utilization management (UM), including step therapy, for Medicare Part B drugs. CMS estimates that beneficiaries will save up to $17 million over the next 10 years in out-of-pocket (OOP) costs, and the federal government will save up to $425 million.
- Redefine negotiated price as the baseline or lowest possible payment to the pharmacy. This may start as early as 2020, and beneficiaries would save up to $9.2 billion over 10 years from reduced cost-sharing (although they would have slightly higher premiums). The proposal would cost the federal government up to $16.6 billion. Manufacturers would save up to $5.8 billion over 10 years.

Comments are due by January 25, 2019.

Contents

Providing Plan Flexibility to Manage Protected Classes

- Plans are currently required to include all Part D drugs in the classes of clinical concern ("protected classes"). These classes include anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection.
- Drugs in these classes are not allowed to be excluded unless the Secretary of the Department of Health and Human Services (HHS) goes through formal rulemaking.
- CMS is proposing exceptions to the requirement that all drugs in a protected class be included on formulary:
    - Allowing additional use of prior authorization and step therapy
    - Allowing plan sponsors to exclude drugs if the manufacturer introduces a new formulation with the same active ingredient or the drug does not provide a unique route of administration
    - Allowing plans to exclude single-source drugs or biologics that have certain price increases above a threshold
- CMS believes these changes would allow plans additional negotiating leverage and a better ability to manage costs. The agency feels that the protected classes were created during a time period when dual-eligibles were transitioning to Medicare Part D and were unfamiliar with UM.
- The agency says that this "open coverage" increases costs due to overutilization and increased drug prices, stating that it can also harm the beneficiary and require medical treatment that might not have been necessary. CMS also states that the discounts and rebates are less because manufacturers do not compete for formulary placement.

Broader Use of Prior Authorization

- CMS believes that the current inability of plans to use prior authorization in the protected classes limits a plan's ability to determine medical necessity and/or medically accepted indication (or if it should be covered under Medicare Parts A or B).
- One example is the use of immunosuppressant drugs to treat rheumatoid arthritis. CMS believes that this falls outside of the protected classes and that plans should be able to do UM to determine this.
- CMS proposes to expand the use of prior authorization and step therapy for new starts and existing therapies if clinically supported. CMS is looking for feedback on whether it should be new starts only.
- CMS also proposes allowing indications-based formulary design and UM for protected classes beginning as early as 2020.
- CMS cites the "working" coverage and appeals process as grounds for moving forward.

New Formulations

- CMS is seeking to revise the "substantially all" requirement in the protected classes that had allowed the following exceptions:
    - Multiple-source drugs of identical molecular structure
    - Extended-release products if immediate-release formulation is on formulary
    - Products that have the same active ingredient or moiety
    - Dosage forms that do not provide a unique form of administration

- CMS proposes to permit Part D plans to exclude a drug if a manufacturer introduces a new formulation with the same active ingredient that does not provide a unique route of administration—even if that becomes the only formulation available.
- CMS would also include to this change the potential for interchangeable biologic products.

Pricing Threshold for Protected Class Drug Formulary Exclusions

- CMS analysis has shown that price trends for branded drugs in protected classes are higher than those for drugs in non-protected classes.
- CMS proposes that, beginning in 2020, Part D plans could exclude any single-source drug or biologic that has a wholesale acquisition cost (WAC) increase, relative to the price in a baseline month or year, beyond the rate of inflation.
    - The proposed rate of inflation is the Consumer Price Index for all Urban Consumers (CPI-U), although CMS is looking for feedback on this.
    - The baseline would be September 1, 2018 or the first day of the first full quarter after the launch date for new products after September 1, 2018.
    - CMS is seeking input on whether this policy should extend beyond single-source drugs and biological products.
    - The policy, as proposed, could apply to all National Drug Codes (NDCs) assigned to the single-source product (all strengths, dosage forms, notes of administration).
    - If a drug's WAC increases faster than the corresponding CPI-U in the applicable period, a plan sponsor could exclude the drug from its formulary for the contract year associated with that applicable period. The plan would need to submit evidence of this criterion.
- Plan sponsors would be responsible for monitoring price increases and determining CPI-U increases. CMS is also considering an approach where it issues a list of drugs that can be excluded based on this policy.
- Plans can choose to exclude a drug but are not required to exclude a drug based on this proposed policy. Manufacturers may negotiate rebates for formulary placement.
- CMS is considering whether to apply this policy to all of a manufacturer's drugs in a protected class even if only 1 drug fails the policy threshold.

Solicitation of Comments for Special Considerations

- CMS begins this section by applauding itself for how well it protects beneficiaries currently.
- The agency says it wants to minimize interruptions in existing therapy and minimize increases in Medicare spending.
- CMS is looking for feedback on special transition considerations or special patient population considerations.

Prohibition Against Gag Clauses in Pharmacy Contracts

- In October, Congress enacted the "Know the Lowest Price Act of 2018"; this prohibits Part D plan sponsors from restricting pharmacies from informing enrollees of the availability of prescription drugs at a cash price that is below what the enrollee would be charged for the same drug as part of the plan benefit design.
- This law becomes effective January 1, 2020.
- CMS is incorporating this requirement in Part D regulations.

E-Prescribing (eRx) and the Part D Prescription Drug Program: Updating Part D E-Prescribing Standards

- CMS currently requires providers and dispensers to use the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard, Implementation Guide Version 10.6 to communicate the prescription or prescription-related information for certain transactions. Beginning January 1, 2020, CMS is proposing a switch to NCPDP SCRIPT standard, Implementation Guide Version 2017071.
- Medicare Part D plan sponsors and prescribers currently convey electronic formulary and benefits information among themselves using one of 2 different approved versions of the NCPDP Formulary and Benefits (F&B) Standard Implementation Guides.
- CMS views SCRIPT and F&B standards as critical components of the Part D program; this year, 66% of Part D prescriptions have been using the NCPDP SCRIPT standard, and all Part D plans implement electronic F&B using one of the adopted standards.
- However, F&B has limitations given some prescribers rely on them during the eRx process and some do not. Also, F&B is a batch transaction (not real-time) and provides information on a contract level (not patient-specific).
- CMS is proposing an RTBT requirement for Part D sponsors that would serve as a supplement to the existing SCRIPT and F&B electronic standards.

Proposed Adoption of a Real-Time Benefit Tool

- CMS proposes that, beginning January 1, 2020, a Part D sponsor would be required to select or develop at least 1 RTBT to be used with the patient's consent.
- The data would show a complete picture of a beneficiary's prescription benefit information that could include OOP costs for a given patient at a given point in time.
- The RTBT would integrate with prescribers' eRx and electronic medical records systems and provide patient-specific coverage information that would include:
    - OOP patient cost and any formulary alternatives, including any UM requirements (and indications-based restrictions) for each specific alternative presented
    - Each drug's full negotiated price (preferred, but not required by CMS)
- CMS believes this will not only help lower OOP costs but also result in increased medication adherence.
- While there is no RTBT standard to ensure interoperability, CMS notes that it is aware of efforts underway to develop them, hopefully in the near future, and seeks input on standardization efforts that may meet its needs.
- CMS realizes the resources required to implement this policy change, so it is looking for feedback regarding the impact of the proposed effective date on the industry and other interested stakeholders. The agency is also seeking comments from plans and providers on the proposed policy, including overall interoperability and the impact on medical record systems.

Part D Explanation of Benefits

- For each of their enrollees, Part D sponsors are required to provide a written EOB and, when the prescription drug benefits are provided, a notice of the benefits in relation to the initial coverage limit and the OOP threshold for the current year.
- CMS proposes to require plan sponsors to include:
    - Information about negotiated price changes, including the cumulative percentage change in the negotiated price since the first day of the current benefit year for each prescription drug claim; and
    - Lower-cost therapeutic alternatives (meaning drugs with lower cost-sharing or lower negotiated prices) that 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, CMS would like (but does not plan to require) the Part D plans to include relevant beneficiary-specific information, such as diagnosis, the indication for the prescription, or complete step therapy or exception requests, when providing formulary therapeutic alternatives that have lower cost-sharing.
- CMS seeks comments on these proposed changes to the Part D EOB, including impact on the beneficiary.

Medicare Advantage and Step Therapy for Part B Drugs

Introduction

- In a memo released August 7, 2018, CMS announced that, under certain conditions beginning in contract year 2019, MA plans may use UM tools such as step therapy for Part B drugs.
- CMS proposes requirements under which MA plans may apply step therapy as a UM tool for Part B drugs.
- CMS is soliciting comments concerning the impact that allowing step therapy for Part B drugs would have on MA plans and enrollees.

Safeguards for Beneficiaries

- The proposed rule would impose a number of safeguards to 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 time frames applicable in Part D for coverage determinations.
    - Enrollees can request an organization determination if they believe 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.

Step Therapy Disclosures

- 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.
- CMS proposes to include a requirement for plans to establish policies and procedures to educate and inform healthcare providers and enrollees concerning its step therapy policies.
- CMS notes that preferred provider organization (PPO) plans must provide reimbursement for all plan-covered medically necessary services received from non-contracted providers without prior authorization or step therapy requirements.
    - CMS solicits comments whether the final rule should include a specific regulatory provision clarifying this issue.

Pharmacy and Therapeutics (P&T) Committee Involvement

- CMS proposes to require plans to use a P&T committee to review and approve step therapy programs.
    - CMS believes this is necessary to ensure medically appropriate implementation of step therapy for Part B drugs.
- CMS proposes that an MA organization must establish or utilize an existing P&T committee before implementing a step therapy program.
- CMS solicits comments on the following proposals:
    - MA plans with step therapy programs would be required to have P&T committees
    - Whether the requirement for this MA P&T committee should be expanded to all MA plans that have any UM policy (such as prior authorization or dosage limits) applicable to Part B drugs
    - If there are other options to meet the policy goal of ensuring that step therapy programs are medically appropriate underlying the P&T committee proposal

Application of Step Therapy

- CMS proposes that step therapy would not be permitted to disrupt enrollees' ongoing Part B drug therapies.
- CMS proposes 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 taking a Part B medication.
- MA plans would be able to ensure that an enrollee who is newly diagnosed with a particular condition would begin treatment with a biosimilar or generic medication before progressing to a more costly drug therapy if the initial treatment is ineffective or if there are adverse effects.
- CMS proposes to permit MA plans to require an enrollee to try and fail an off-label medically accepted indication (that is, an indication supported by 1 or more citations in the statutory compendia) before providing access to a drug for a Food and Drug Administration (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.

- CMS proposes 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 under Part D by MA plans that also offer prescription drug coverage (MA-PD plans) to ensure that step therapy programs are not, intentionally or unintentionally, barriers to services that must be covered by the MA plan.
- In addition to requiring 1 Part B drug be used before a different Part B drug, 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 UM 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.
    - Therefore, CMS would allow MA-PD plans, starting in 2020, to require step therapy of Part B drugs before Part D drugs for the protected classes. These particular step therapy requirements would be subject to CMS review and approval.
- CMS proposes that requests for Part B drugs, including Part B drugs subject to step therapy, be processed under the same adjudication time frames as used in the Part D drug program.

Coverage Determination and Reconsideration Requests for Part B Drugs

- For expedited organization determination requests for a Part B drug, CMS proposes 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.
- For consistency with the time frame for standard Part D coverage determinations, CMS proposes 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.
- CMS proposes 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.
- CMS proposes 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.

Pharmacy Price Concessions in the Negotiated Price

- CMS is exploring redefining the negotiated price of a covered Part D drug as the baseline or lowest possible payment to the pharmacy so that price concessions made by the pharmacy (not by pharmaceutical manufacturers) can be included in the list price at the point of sale (POS).
- CMS did not officially propose a new rule or guidance but is considering starting this policy as early as the 2020 plan year.

Background (Premiums and Plan Revenues, Cost-Shifting, and Transparency and Competition)

- CMS notes that Part D plan sponsors have been incredibly successful at garnering pharmacy price concessions from network pharmacies, growing by an astounding 45,000% from 2010 to 2017. This growth in price concessions by pharmacies is largely driven by performance-based payment arrangements.
    - These payments have typically been excluded from the definition of negotiated price because the adjustments typically occur after the POS.
    - Sponsors have generally used the payments to reduce premiums but have not applied them at the POS to help reduce beneficiary OOP costs.
- CMS notes that, in recent years, less than 1% of Part D plans have passed through any price concessions to beneficiaries at the POS, and the amount passed through is less than 1% of the total price concessions those plans receive.
- CMS released a Request for Information in November 2017 seeking to gain stakeholder input on applying all price concessions to the price at the POS.
- In exploring this change, CMS anticipates it would redefine negotiated price to include all pharmacy price concessions received by the plan sponsor and to reflect the lowest possible reimbursement for a network pharmacy for a particular drug.
- CMS provides detailed background on the impact of not applying price concessions at the POS but as direct and indirect remuneration (DIR), including:
    - Lower plan premiums and higher plan revenues
        - When price concessions are applied to the end of the coverage year and not to the list price, the main result is a lower plan premium. The average Part D basic beneficiary premium grew at an average rate of only about 1% 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.
        - However, if the DIR received by the plan is above what it projects, it contributes primarily to plan profits. This has been the trend.
    - Cost-shifting to beneficiaries and the government
        - While beneficiaries facing a coinsurance are primarily affected, CMS notes that Part D policy requires any copayment to be actuarially equivalent to the coinsurance required under the defined standard benefit design.
        - If list prices are higher at the POS, so is cost-sharing.
        - Higher OOP costs can result in access and adherence challenges, further resulting in poorer health outcomes.
    - Reduction in consumer and government knowledge about the true costs of prescription drugs
        - It is difficult for beneficiaries to anticipate the price at the POS.
        - Because plans treat these concessions differently, it is hard for beneficiaries to have a complete picture of plan efficiency (premiums vs POS).

Considered Regulatory Changes to the Definition of Negotiated Price

- In 2014, CMS had amended the definition of negotiated price to include all pharmacy price concessions except those that could not be reasonably determined at that time. This was supposed to be a narrow subset of concessions.
- CMS is considering redefining "negotiated price" as "the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug" through the sponsor and/or intermediary contract. Therefore, the negotiated price would:
    - Be defined as a singular term rather than plural to clearly demonstrate "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"
    - Include all pharmacy price concessions and any dispensing fees
    - Exclude additional contingent amounts, such as incentive fees, if these amounts increase prices
    - Be lowered potentially by manufacturer rebates and other DIR
- **All Pharmacy Price Concessions**
    - CMS would potentially define negotiated price as the price reflected from all pharmacy price concessions, even if price concessions are contingent upon performance by the pharmacy.
- **Lowest Price Reimbursement**
    - CMS is exploring requiring the negotiated price to reflect the lowest possible reimbursement that a Part D sponsor pays a network pharmacy.
        - This price would include all price concessions—including dispensing fees—but exclude any additional contingent amounts that could increase prices over the lowest reimbursement level, such as incentive fees.
        - Under a performance-based arrangement, the POS price must "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 paid an amount above the lowest possible amount (ie, receives a bonus payment), the difference between the negotiated price reported to CMS and the final payment to the pharmacy must be reported as negative DIR.
    - CMS believes these changes would help sponsors better determine which payments fall under the current exception.
- **Additional Considerations**
    - To implement the policy, CMS would likely utilize existing reporting mechanisms to ensure sponsors are appropriately applying price concessions to the negotiated price at the POS.
    - CMS may utilize:
        - Estimated rebates at the POS field on the prescription drug event (PDE) record to also collect the amount of POS pharmacy price concessions
        - Fields in the Summary Detailed DIR Reports to collect final pharmacy price concession data at the plan and NDC levels
    - CMS is also exploring requiring sponsors to include pharmacy price concessions in the negotiated price in the coverage gap, for purposes of quantifying manufacturer discounts.
    - CMS is seeking comments on potentially allowing sponsors to apply less than all (eg, 95%) pharmacy price concessions.
    - CMS is also seeking comments on developing a standard set of metrics from which plans and pharmacies would base their contractual agreements.

Pharmacy Administrative Service Fees

- CMS reiterates that any pharmacy administrative fees paid by a pharmacy to a sponsor and/or intermediary be included in the administrative costs of the Part D plan bid.
- However, if a sponsor deducts these costs from payments made to pharmacies for purchases of Part D drugs, these costs are then considered price concessions.

Defining Price Concession

- CMS is exploring broadly defining "price concession" to avoid confusion around terminology.
    - Specifically, the definition would 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."