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# CMS Proposes to Lower Drug Prices and Reduce Out-of-pocket Drug Spending With Respect to Medicare Coverage

## Introduction

On Friday, November 30, 2018, the US Centers for Medicare & Medicaid Services (CMS) issued a proposed rule (Proposed Rule) to revise Medicare Part D (Part D) and Medicare Advantage (MA) regulations to promote health plan negotiation of lower drug prices and to reduce out-of-pocket spending for enrollees.[1] As further discussed below, the Proposed Rule contains four areas of reform focusing on: (1) Plan Flexibility for Coverage of Protected Class Drugs; (2) Real-Time Coverage and Cost Information for Prescribers; (3) Step Therapy by MA Plans for Part B Drugs; and (4) Drug Price Adjustment at Point-of-Sale based on Pharmacy Price Concessions.

## Details of the Proposed Rule

### Plan Flexibility for Coverage of Protected Class Drugs

The Social Security Act requires Part D plan sponsors to include in their Part D formularies drugs in classes and categories of clinical concern identified by CMS.[2] These drugs, known as "protected class" drugs, include the following: (1) antidepressants, (2) antipsychotics, (3) anticonvulsants, (4) immunosuppressants for treatment of transplant rejection, (5) antiretrovirals and (6) antineoplastics, except in limited circumstances.[3] Under current regulations, enrollees have open access to protected class drugs except in limited circumstances.[4]

Based on concerns that open access to protected class drugs encourages overutilization, prevents Part D plan sponsors from monitoring appropriate use and limits the ability of Part D plan sponsors to negotiate rebates for protected class drugs, CMS issued the proposed rule to allow Part D plan sponsors to do the following:

- Implement prior authorization, step therapy and retrospective review for protected class drugs to ensure appropriate use and to take into consideration formulary alternatives, subject to CMS oversight
- Exclude a protected class drug from a formulary if the drug is a new formulation of an existing single-source drug or biologic without a unique route of administration, regardless of whether the older formulation remains on the market
- Exclude a single-source protected class drug or biologic from a formulary if the wholesale acquisition cost (WAC) has increased beyond an inflationary threshold over a specified period, with the rate of inflation calculated against the Consumer Price Index for all Urban Consumers (CPI–U)[5]

If these reforms are adopted, health plans will have greater ability to control utilization of protected class drugs and greater negotiating power with pharmaceutical manufacturers. Providers will have less discretion to prescribe protected class drugs for off-label use or in lieu of less expensive formulary alternatives. Consumers will not be able to use protected class drugs that their physicians have prescribed unless approved by their Part D plan sponsors. Pharmaceutical manufacturers will likely object to these reforms because those prescribed treatments may be denied by health plans.

### Real-Time Coverage and Cost Information for Prescribers

The Proposed Rule proposes to require that Part D plans implement an electronic real-time benefit tool (RTBT) that would integrate with prescribers' e-Prescribing (eRx) and electronic medical record (EMR) systems, which would make drug coverage and cost information visible to prescribers at the point-of-prescribing. CMS hopes this reform will increase drug price transparency, lower drug costs and patient's out-of-pocket expenses, improve medication adherence and promote patient safety and quality of care, in relation to Part D drugs.

To implement this reform, Part D plans would incur costs to implement the RTBT and, together with pharmaceutical manufacturers, may raise concerns about the difficulty in providing accurate real-time information. Providers will also likely incur costs to integrate the RTBT with their eRx and EMR systems, but could benefit from the additional information. Patients would also benefit to the extent providers implement the new systems and actually share drug coverage and cost information with consumers at the point-of-prescribing.

### Step Therapy by MA Plans for Part B Drugs

Under Part B, traditional Medicare generally pays based on a statutory formula – average sales price plus a 6% add-on – for Part B drugs and biologics.[6] As to Part B drugs, CMS believes there is minimal negotiation between MA plans and drug manufacturers to reduce the price of these drugs. As a result, CMS proposes to allow MA plans to use step therapy[7] for Part B drugs in order to assist MA plans in negotiating to get better value for Part B drugs. While step therapy will be allowed, CMS believes consumers will be protected with regulatory safeguards, such as organizational determination and appeals processes, review of step therapy programs by Pharmacy and Therapeutics committees and prohibitions on step therapy that disrupt ongoing treatments.

1 Proposed Rule, *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses*, 83 Fed. Reg. 62152, et seq. (November 30, 2018).

2 42 U.S.C. § 1395-w-104(b)(3)(G)(ii).

3 *Id.*

4 83 Fed. Reg. at 62154 ("Section [42 C.F.R.] 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.").

5 Notably, these three exceptions only apply to the protected class coverage rules and do not supersede the formulary requirements in 42 C.F.R. § 423.120(b)(2), including the requirement to have an adequate formulary.

6 Part B Drugs are drugs that are normally administered at a physician's office or under a physician's supervision and are dispensed by a physician or facility rather than by a pharmacy.

7 Step therapy is a practice whereby health plans require members to use the most cost-effective drugs to treat health conditions, but which provide coverage for more costly and risky therapies if needed to treat a condition.

If step therapy for Part B drugs was allowed, MA plans would benefit from their ability to control utilization and treatment, whereas consumers would lose open access to Part B drugs that are prescribed by physicians to treat specific conditions. Pharmaceutical manufacturers and physicians will likely object to this reform on grounds that prescribed treatments effective at treating specific conditions may be denied by health plans.

**Drug Price Adjustment at Point-of-Sale based on Pharmacy Price Concessions**

Under current law, the "negotiated price" of Part D drugs, which determine out-of-pocket costs for the consumer at the point-of-sale, includes all pharmacy adjustments except for contingent amounts that cannot "reasonably be determined" at the point-of-sale.[8] As a result, negotiated prices do not reflect performance-based pharmacy price concessions that lower the drug price after the sale (post-sale concessions). When post-sale concessions are paid to Part D plans, rather than reflected in the point-of-sale drug price, beneficiaries pay greater out-of-pocket expenses at the point-of-sale, which are unlikely to be offset by premium reductions that may result from the concession.

The Proposed Rule would amend the definition of "negotiated prices" to include all pharmacy adjustments, including post-sale adjustments, by requiring adjustment for the lowest amount a pharmacy could receive for a Part D drug under its contract with the Part D plan (that is, the amount the pharmacy would receive net of the maximum adjustment that could result from any contingent pharmacy payment arrangement and before any additional contingent payment amounts, such as incentive fees). This reform would better align point-of-sale drug pricing with the actual drug cost, allowing consumers to make more rational purchasing decisions and reducing consumers' out-of-pocket spending.

While consumers will benefit from this reform, health plans and drug manufacturers may object because of the uncertainty of contingent adjustments. Pharmacies may object because the net result of this reform will reduce payments to the pharmacy. On the other hand, the reduced amounts paid to the pharmacy may be realized, in part, by the health plans that, like the consumer, may pay less for Part D drugs.

## Next Steps

In connection with the Proposed Rule, CMS has requested that comments be submitted no later than 5 p.m. on January 25, 2019, and has specifically requested comments on the following subjects:

- Real world experience with respect to the ability of Part D plans to negotiate rebates for protected class drugs
- Tools necessary to minimize treatment interruptions that may result from step therapy or prior authorization
- Considerations related to increased utilization that may result secondarily to adverse events from limitations on therapies
- As to single-source drugs and biologics excluded based on price increases, whether an alternative pricing threshold to CPI-U should be considered, and whether an increase in price other than the drug's WAC should be used
- Feedback as to feasibility of implementing reforms by a proposed January 1, 2020 deadline

For more information about the Proposed Rule, including how it might affect market participants, and the opportunities to shape the development of administration policy and agency action, please contact one of the lawyers listed.

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8 42 C.F.R. § 423.100 (definition of "negotiated prices").