

**NCPA Summary of Final Rule:  
*Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce  
Out-of-Pocket Expenses*  
May 16, 2019**

**Pharmacy DIR Fees:**

- **Proposed:** Would have amended the negotiated price definition in Part D to assess all pharmacy price concessions, excluding positive contingent amounts, at the point of sale.
- **NCPA Comments:** Supported this change and asked for additional consideration to standardizing pharmacy quality metrics.
- **Final:** CMS did not finalize this proposal despite recognizing that there were over 4,000 comments in support of the proposed change. CMS said, “In the proposed rule, we sought comment on a potential policy approach for requiring that all pharmacy price concessions be applied to drug prices at the point of sale under Part D. We received over 4,000 comments on this potential policy approach. We thank the commenters for their detailed responses. We will carefully review all input received from stakeholders on this issue as we continue our efforts to meaningfully address rising prescription drug costs for seniors.”

**Protected Classes:**

- **Proposed:** Would have created three exceptions to the requirement that sponsors include on their formularies all drugs in the current six protected classes, including to: 1) Allow plans/PBMs to utilize prior authorizations and step therapy for the drugs in the protected classes; 2) Allow protected class drug to be excluded from a formulary if the drug represents only a new formation of an existing single-source drug or biologic; and 3) Allow protected class drugs to be excluded from a formulary if the price of the drug increased beyond a certain threshold over a specified look-back period.
- **NCPA Comments:** Asked to only apply such policy to patients starting a new therapy if Part D sponsors allowed to use prior authorization and step therapy . Alternatively, NCPA requested to exempt long term care facility residents from all enhanced drug utilization management techniques contemplated under this proposal.
- **Final:** CMS did not finalize the latter two proposals regarding the protected classes. CMS only finalized the proposal that would allow plans/PBMs to utilize prior authorizations and step therapy for the drugs in the protected classes but limited the usage of these tools to new start therapies only (an NCPA ask). CMS did not address NCPA’s LTC ask.

**Gag Clauses:**

- **Proposed:** Would codify into Part D regulations the statutory prohibition of gag clauses in the Medicare program. Specifically, CMS proposed to amend the set of pharmacy contracting requirements in the Medicare regulations to state 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.

- **NCPA Comments:** Asked CMS to align the Part D regulation text to the gag clause laws.
- **Final:** CMS finalized the proposal and noted it did not need to mirror the language of the statute and it only needs to reflect the meaning of its underlying statute. Specifically, the CMS said "[t]he term 'cash price' is a term understood within the industry to mean a price charged by a pharmacy to customers not using insurance to obtain a prescription drug and its use in the rule promotes clarity in the statement of the new prohibition."

#### **Real Time Benefit Tool ("RTBT"):**

- **Proposed:** By Jan. 1, 2020, would require plan sponsors to implement an electronic RTBT that would integrate prescribers' e-prescribing and electronic medical records. The goal is to have beneficiary-specific drug coverage and cost information available to prescribers who want to consider that information at the point of prescribing.
- **NCPA Comments:** Requested that CMS provide specific operating rules around a RTBT before implementation in 2020. NCPA asked for a regulatory prohibition that a RTBT cannot be used by prescribers' eRX and EMR systems and by plans to steer patients to pharmacies other than a patient's pharmacy of choice. NCPA also asked for further time beyond the proposed 2020 implementation date.
- **Final:** CMS is delaying the required implementation date until Jan. 1, 2021. Regarding steering, CMS stated "[s]hould CMS become aware that RTBTs are being used in ways that are contrary to the Part D program goals, we will address the issues as they arise. Further, we believe that Part D plans are in the best position to assess the effectiveness of the RTBT solutions, since they have a financial stake in ensuring that their enrollees have access to the most cost-effective medications."

#### **Step Therapy for Part B Drugs:**

- **Proposed:** Would establish requirements under which Medicare Advantage plans may apply step therapy as a utilization management tool for Part B drugs.
- **NCPA Comments:** Requested that CMS should continue to monitor issues with beneficiary access to Part B drugs that are subject to step therapy.
- **Final:** CMS finalized the proposal.

#### **Explanation of Benefits:**

- **Proposed:** Would update Medicare beneficiaries' explanation of benefits ("EOBs") to include the negotiated drug pricing information and lower cost alternatives. The intent of the proposal is to provide enrollees with greater transparency, thereby encouraging lower costs.
- **NCPA Comments:** Supported CMS' proposal to include in the EOBs the information described in the Proposed Rule but caution that this change may not provide the

robust level of information necessary to achieve true drug cost transparency, especially in the absence of beneficiary-specific information.

- **Final:** The proposal was finalized to require the inclusion of negotiated drug pricing information and lower cost alternatives in the Part D EOB beginning on Jan. 1, 2021. With regards to beneficiary-specific information, CMS stated that “Part D sponsors will be permitted and encouraged by CMS to take into consideration relevant beneficiary-specific information, such as diagnosis, the indication for the prescription and completed step therapy or exception requests, when providing formulary therapeutic alternatives in the EOB that have lower cost-sharing. For example, if a plan is aware that a beneficiary has already fulfilled step therapy requirements and the beneficiary’s physician has attested that the beneficiary is not able to tolerate a formulary alternative, that formulary alternative does not need to be included on the EOB for that beneficiary.”