

CMS Releases Medicare Advantage and Part D Drug Pricing Proposed Rule for Contract Year 2020

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On November 26, 2018, the Centers for Medicare & Medicaid Services (“CMS”) issued a proposed rule titled “Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses” (“Proposed Rule”).¹

The agency has proposed five changes to amend Medicare Advantage (“MA”) and Medicare Prescription Drug Benefit (“Part D”) regulations to support health and drug plans’ negotiation for lower drug prices and to reduce out-of-pocket costs for MA and Part D enrollees. This Client Alert summarizes the major provisions of the Proposed Rule.

The Proposed Rule also includes regulations addressing the recently enacted “Know the Lowest Price Act,” which was signed into law by President Trump in October and which creates a prohibition against pharmacy gag clauses.

CMS is requesting that the public submit comments on the Proposed Rule, which must be received by CMS no later than 5 p.m. EST on January 25, 2019. This Client Alert sets forth and highlights the specific issues with which CMS has solicited comments.

I. Providing Plan Flexibility to Manage Protected Classes

The Trump administration has stated on multiple occasions, including in its May 2018 *Blueprint*, its intention to provide Medicare Part D more tools to negotiate lower prices for drugs in “protected classes” that are available in the private sector.² The Part D “protected class” policy requires Part D sponsors to include, with limited exceptions, all drugs in six

¹ 83 Fed. Reg. 62,152 (Nov. 30, 2018).

² Alex Azar & Seema Verma, *Proposed Changes to Lower Drug Prices in Medicare Advantage and Part D*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Nov. 26, 2018), <https://www.cms.gov/blog/proposed-changes-lower-drug-prices-medicare-advantage-and-part-d>. See also, U.S. DEP’T OF HEALTH & HUMAN SERVS., AMERICAN PATIENTS FIRST (May 2018), available at <https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf> (outlining the Trump administration’s ideas to decrease health care costs).

categories or classes (antidepressants, antipsychotics, anticonvulsants, immunosuppressants for treatment of transplant rejection, antiretrovirals, and antineoplastics) in their formularies. Due to its belief that the current policy makes it difficult for Part D sponsors to negotiate for lower costs and rebates, CMS is proposing three new exceptions to the protected class policy:

1. *Implementation of Broader Use of Prior Authorization and Step Therapy*

This proposed exception would allow Part D sponsors to use prior authorization and step therapy for protected class drugs without regard to whether the therapy is new or existing. In the preamble, CMS expresses concerns that the current limits of such drug utilization management (“UM”) techniques leads to overutilization of protected class drugs among Part D enrollees, including protected class drugs used for medically-accepted indications (e.g., FDA approved uses) that are not protected class indications. Under the Proposed Rule, prior authorization requirements would be allowed for any protected class drug to confirm that it is being used for a protected class indication, ensure clinically appropriate use, and promote utilization of preferred formulary alternatives. Such utilization management tools would continue to be subject to CMS review and approval, and CMS states it would not support onerous prior authorization criteria.

COMMENTS NEEDED

CMS is seeking comments on whether the exception regarding the broader use of prior authorization and step therapy should be limited to new starts only.

2. *Exclusion of New Formulations of Existing Single-Source Drugs or Biological Products in a Protected Class from a Formulary Regardless of Whether the Older Formulation Remains on the Market*

If finalized, Part D sponsors would be permitted to exclude from their formularies a new formulation of a protected class drug that does not provide a unique route of administration regardless of whether the older formulation remains on the market. CMS is seeking this change to ensure that manufacturers cannot force Part D sponsors to add new products to their formularies by withdrawing from the market older formulations of a drug or biological product when introducing a new, more expensive formulation.

3. *Exclusion of a Protected Class Drug from a Formulary if a Drug Price Increases Beyond a Certain Threshold Over a Specified Look-Back Period*

Citing support that protected class drug prices have increased more than other, non-protected drug classes between 2012 and 2017, CMS is proposing to permit Part D sponsors to exclude a protected class drug if the drug’s price increased, relative to the price in a baseline month and year, beyond the rate of inflation. The exception would be effective for plan years starting on or after January 1, 2020. The rate of inflation is to be calculated using the Consumer Price Index for all Urban Consumers (“CPI-U”). This

exception would apply if between the baseline date and any point in the “applicable period”³ a drug’s wholesale acquisition cost (“WAC”) increased more than the cumulative increase in CPI-U over the same period. To decrease opportunities for price gaming, and so that any price increases planned prior to the release of the Proposed Rule would not be incorporated and result in a higher baseline, CMS proposes September 1, 2018, as the baseline date for all drugs on the market as of that date. For drugs that enter the market after September 1, 2018, the baseline date would be the first full quarter after the launch date.

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 a formulary that excludes the protected class drugs with price increases above the inflation rate. Just because a protected class drug can be excluded from the formulary under this Proposed Rule does not mean exclusion must occur—manufacturers and sponsors can instead negotiate rebate arrangements for formulary placement. Drugs excluded through this exception would be excluded only for the contract year. Part D sponsors wishing to exclude the drug for subsequent years must continue to monitor whether the WAC of the drug increased faster than the inflation rate for the next contract year’s applicable period.

Key Takeaway: Part D sponsors and their pharmacy benefit managers (“PBMs”) will appreciate the additional flexibility and leverage to negotiate prices and rebates afforded by the proposed exceptions. However, drug manufacturer and patient groups have been quick to criticize the proposal on the basis that it may allow Part D sponsors to discriminate against certain categories of “high cost” beneficiaries.⁴ In 2014, CMS faced similar criticism from such stakeholders when it proposed more aggressive regulations to remove the protected status of three drug classes. After facing mounting resistance and significant comments, CMS did not include the proposal in the final rule. It remains to be seen whether CMS’s more moderate proposal to provide Part D sponsors more flexibility to manage protected class drugs, without eliminating any classes, will limit the magnitude of opposition.

³ CMS proposes to add definitions for “applicable period”—for contract year 2020, the applicable period will be September 1, 2018, through February 28, 2019, and for contract year 2021 and subsequent years, the applicable period will be 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. To provide additional clarity, a timeline is included in Table 1 of the proposed regulations.

⁴ See, e.g., *BIO Statement on Proposed Changes to Medicare Advantage and Part D Plans*, Biotechnology Innovation Org. (Nov. 26, 2018), <https://www.bio.org/press-release/bio-statement-proposed-changes-medicare-advantage-and-part-d-plans> (discussing the Proposed Rule’s negative impact on seniors’ access to drugs); *CMS Proposal Effectively Unprotects Six Protected Classes*, CMTY. ONCOLOGY ALL. (Nov. 27, 2018), <https://www.communityoncology.org/coa-cms-proposal-effectively-unprotects-six-protected-classes/> (describing the Proposed Rule as “a potential nightmare for vulnerable patients with cancer”); *NFK Concerned about Proposed Changes to Medicare Part D*, NAT’L KIDNEY FOUND. (Nov. 26, 2018), <https://www.kidney.org/news/nkf-concerned-about-proposed-changes-to-medicare-part-d> (expressing concern that the proposed changes would make it more difficult for transplant recipients to access needed drugs).

COMMENTS NEEDED

CMS seeks comments on the following:

- whether an alternative pricing threshold to CPI-U should be considered;
- whether an increase in price other than the drug's WAC (such as negotiated price or some other standard) should be used to determine whether the protected class drug could be excluded from the Part D formulary;
- whether the protected class drug exception's policy should apply only to single-source drugs and biological products or whether a broader mix of drugs should be eligible for formulary exclusion in accordance with the proposed exception policy;
- the merits of the proposal to have Part D sponsors operationalize the protected class drug exception policy by monitoring changes in WAC and CPI-U or if there is a more effective approach;
- whether an increase in WAC beyond CPI-U for any national drug code ("NDC") assigned to a particular brand of drug or single-source generic drug should be grounds for allowing a sponsor to exclude all NDCs assigned to that drug from the formulary;
- whether WAC as of some date other than September 1, 2018, should be used as the baseline WAC for drugs on the market before September 1, 2018;
- whether to propose that a Part D sponsor could exclude a protected class drug from its formulary for any future contract year once its WAC increased more rapidly than the cumulative increase in inflation;
- whether to propose a price threshold exception to all drugs in the protected classes of a given manufacturer if any one of those drugs' WAC, when compared to baseline WAC, increases beyond the cumulative rate of inflation;
- the impact of this policy proposal on Part D enrollees;
- whether there are additional considerations that would be necessary to minimize interruptions in existing therapy of protected class drugs for protected class drug indications during prior authorization processes;
- whether there are additional considerations that would be necessary to minimize increases in overall Medicare spending from increased utilization of services secondary to adverse events from interruptions in therapy, and why current requirements are inadequate or could be improved; and
- what specific patient populations, individual patient characteristics, specific protected class drugs, or individual protected drug classes would require additional special transition processes or other protections and how such populations can be consistently identified.

II. E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards

Beginning contract year 2020, CMS proposes to require Part D sponsors to implement a real-time benefit tool (“RTBT”) in order to make beneficiary-specific drug coverage, formulary options, and cost data visible to prescribers who wish to use such data at the point of prescribing. Through the RTBT, CMS aims to foster price transparency to aid in lowering overall drug costs and patient out-of-pocket costs and to improve medication adherence.

In the preamble to the Proposed Rule, CMS recognizes that while there is no current industry standard for RTBTs, technologies exist that can interface with electronic medical record (“EMR”) systems to allow for this function. CMS notes that PBMs and a few plans have successfully implemented RTBTs for a small subsection of enrollment. The Proposed Rule would require Part D sponsors to select or develop an RTBT that would be capable of integrating with at least one prescriber’s EMR and e-prescribing system. The RTBT would need to show how the prescription claim would be adjudicated given the information submitted and the claims history of the patient, including the patient’s cost-sharing information, additional formulary alternatives, and relevant indications that could impact coverage. In the preamble, CMS states that it is also encouraging plans to promote full drug cost transparency by showing each drug’s full “negotiated price” (as defined in Part D regulations), although this is not a requirement in the Proposed Rule.

To the extent prescribers and dispensers implement e-prescribing, CMS requires that they comply with applicable standards in effect. Currently, e-prescribing standards include the NCPDP SCRIPT e-prescribing standard for transactions (“SCRIPT”), and the NCPDC Formulary and Benefits (“F&B”) standard. The RTBT would function alongside the existing SCRIPT and F&B standards. CMS found the existing F&B standard inadequate to provide this RTBT function because the existing F&B standard lacks beneficiary-specific formulary information and solely provides batch-only functionality (as opposed to real-time).

Key Takeaway: Since there is no current standard for RTBT implementation and operability across the various Part D sponsors and EMR systems, the development of an RTBT may impose implementation challenges to Part D sponsors (and their PBMs). On the other hand, the proposed requirement presents a significant opportunity for health technology vendors in the EMR and eRx space that have developed or are in a position to develop this tool. How RTBTs will influence the selection of therapies by patients and prescribers in a broader market remains to be seen.

COMMENTS NEEDED

CMS seeks comment on the RTBT proposal as well as the following:

- standards that are currently under development that may be suitable to meet the needs of this RTBT function;
- the feasibility for plans, and the impact on industry and other stakeholders, of the proposed January 1, 2020, deadline;
- how this proposal may, or may not, expedite CMS's goal of giving access to meaningful decision support through RTBT to beneficiaries and their clinicians;
- RTBT standardization efforts, including efforts by standardization bodies;
- whether this proposal would be contrary to advancing RTBT within Part D; and
- the impact of this proposal on plans and providers regarding overall interoperability and the impact to medical record systems.

III. Medicare Advantage and Step Therapy for Part B Drugs

MA plans were early adopters of UM techniques, such as prior authorization, medication formularies, and step therapy, to manage health care benefit costs by assessing the appropriateness of clinical interventions using evidence-based criteria or guidelines. Currently, UM is not permitted for Part B drugs under traditional Medicare. On August 7, 2018, CMS reversed this position and recognized that under certain conditions, MA plans may implement step therapy for Part B drugs beginning in contract year 2019.⁵ This acknowledged step therapy as an officially sanctioned UM technique for both Medicare and the private MA programs.

The Proposed Rule would codify this change in policy to expand MA plans' existing authority to implement appropriate utilization management and prior authorization programs for the management of Part B drugs while creating requirements that plans must follow in order to do so. This change provides a platform to mandate utilization of lower-cost pharmaceutical interventions prior to resorting to drugs on the high-cost tiers. The change is intended to enable MA plans and enrollees to pay less for drugs while maintaining patient access to necessary treatment. Perhaps signaling a recognition of clinical efficacy over promotion, the changes further permit MA plans to *require* an

⁵ CTRS. FOR MEDICARE & MEDICAID SERVS., *Medicare Advantage Prior Authorization and Step Therapy for Part B Drugs* (Aug. 7, 2018), <https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-prior-authorization-and-step-therapy-part-b-drugs>.

enrollee to try and fail off-label medically-accepted indications before providing access to a drug for an FDA-approved indication (i.e., to institute a “fail first” requirement).

The Proposed Rule would add a new regulation at 42 C.F.R. § 422.136 titled “Medicare Advantage and Step Therapy for Part B Drugs.” The changes would allow MA plans to offer beneficiaries the most cost-effective Part B drug before progressing to other, more costly options.

Anticipating critics, CMS denies in the Proposed Rule that this change would restrict access to necessary medications, indicating that the Proposed Rule is “embedded with strong patient protections” that will ensure quality treatment is not sacrificed. These protections include the disclosure of step therapy in benefits offerings, an appeals process, response timelines, and continuity of care.

1. Disclosure Requirements

MA plans would be required to disclose that Part B drugs may be subject to step therapy requirements in a plan’s Annual Notice of Change (“ANOC”) to Benefits and Costs for Medical Services and Evidence of Coverage (“EOC”) Medicare Part B prescription drug documents. Under existing requirements, MA plans must establish policies and procedures to fully inform contracted health care providers of UM methodology. CMS proposes that these MA policies and procedures include specific disclosures related to step therapy policies. MA plans must also explain coverage rules, practice guidelines, payment policies, and procedures allowing for individual medical necessity determinations.

2. Determination and Appeals Processes

The Proposed Rule requires MA plans to administer a determination and appeals process if they choose to implement step therapy for Part B drugs. Enrollees can request a determination if they believe that they need direct access to a covered Part B drug without first trying the cost-effective biosimilar. Such determination may be standard or expedited due to the medical condition of the enrollee. MA plans would review this determination based upon medical necessity criteria. If dissatisfied with this initial determination, the enrollee can appeal.

Additional protections include a committee review and approval of step therapy programs as well as shorter timeframes for adjudication requests (no later than 24 hours for expedited determinations and 72 hours for standard determination requests). Also, step therapy would only be permitted for new prescriptions or administrations of Part B drugs for enrollees not actively receiving the affected medication.

Key Takeaway: CMS indicates that the primary aim of permitting MA plans to implement step therapy for Part B drugs is to increase MA plans’ negotiating power with pharmaceutical companies. It is likely that manufacturers will face stronger competition for favorable formulary placement and heightened pressure to discount more expensive

drugs. By reducing overall pharmacy spend, patients and providers may receive the added benefit of access to new clinical interventions as insurers move to meet the medical loss ratio spend requirements. However, it is also likely that patients will encounter additional process hurdles and delays; even if access is not denied, it may be hampered.

COMMENTS NEEDED

CMS is seeking comments concerning:

- the impact that allowing step therapy for Part B drugs would have on MA plans and enrollees;
- the proposal that MA plans with step therapy programs would be required to have Pharmacy and Therapeutics (“P&T”) committees;
- the use of off-label drugs in the step therapy programs; and
- the organization’s determination and appeals timelines and processes that would be applicable to Part B drugs.

IV. Pharmacy Price Concessions to Drug Prices at the Point of Sale

In the Proposed Rule, CMS considers adopting a new definition of “negotiated price” to include all pharmacy price concessions received by the plan sponsor for a Part D drug.

This proposal follows from a prior request for information issued by CMS in November of 2017 (“RFI”), which was addressed in a prior Epstein Becker Green *Health Care & Life Sciences Client Alert*.⁶ Pharmacy price concessions, which are negotiated between pharmacies and Part D sponsors or their PBMs, are often tied to the pharmacy’s performance on various defined measures. Currently, the definition of “negotiated price” includes all price concessions except those that cannot reasonably be determined at the point of sale. CMS notes that generally such pharmacy performance adjustments are not included in the drug’s price at the point of sale because these adjustments typically occur after the point of sale, such that they are reported to CMS as direct and indirect remuneration (“DIR”) at the end of the coverage year. The definition of “negotiated price” is used to calculate the beneficiary’s cost-share as well as the reimbursement amount paid to the dispensing provider of the Part D drug. In turn, this negotiated price determines plan, beneficiary, manufacturer, and government liability during the course of a given year, subject to final reconciliation.

⁶ Constance Wilkinson, et al., *Comment Deadline Approaches for CMS’s Proposed Changes to Medicare Advantage and Part D Programs for CY 2019 – Part 1: Negotiated Prices for Drugs*, EPSTEIN BECKER & GREEN (Jan. 3, 2018), <https://www.ebglaw.com/news/comment-deadline-approaches-for-cmss-proposed-changes-to-medicare-advantage-and-part-d-programs-for-cy-2019-part-1-negotiated-prices-for-drugs/>.

CMS highlighted several policy concerns related to pharmacy price concessions being counted as DIR:

- Including more pharmacy price concessions as DIR instead of at the point of sale creates a profit incentive for Part D plan sponsors to have higher negotiated prices along with higher DIR.
- The growth in pharmacy price concessions creates difficulty for consumers to understand the beneficiary share of the drug's price they pay versus what the plan pays (this is important because reflecting pharmacy price concessions as end-of-year DIR rather than including in the negotiated price may serve to shift costs to the beneficiary).
- When Part D sponsors recognize pharmacy price concessions as DIR rather than include them in negotiated prices, they may be able to reduce their plan bids to achieve lower plan premiums in an effort to gain a competitive advantage based on technical differences in how costs are reported.
- This scenario may also create competitive concerns by discouraging independent pharmacies from participating in plan networks.

1. *"Negotiated Price" Definition*

CMS is proposing to redefine "negotiated price" to mean the lowest amount that a pharmacy could receive as reimbursement for a Part D drug. CMS proposes to remove from the definition the exception for amounts that cannot be "reasonably determined at the point of sale." The agency also proposes to require that all contingent incentive payments be excluded from "negotiated price." CMS believes that the new definition would address the above issues by providing more meaningful price transparency, allowing consistent application of pharmacy payment concessions by Part D sponsors and preventing cost-shifting to beneficiaries and taxpayers.

2. *Lowest Possible Reimbursement Requirement*

CMS proposes to require the negotiated price to reflect the lowest possible reimbursement that a pharmacy could receive from a specific Part D sponsor, thereby capturing all pharmacy price concessions at the point of sale in a consistent manner across sponsors. Regarding performance-based contingent payment arrangements between a pharmacy and a sponsor, CMS proposes to mandate that reported point of sale price reflect the final payment to the pharmacy as if the pharmacy were to receive the lowest possible performance score (i.e., the scenario where the sponsor recoups the maximum amount from the pharmacy for poor performance). If the pharmacy ultimately does not receive the lowest performance score possible, CMS proposes to require that a negative DIR amount be reported, which reflects the difference between the "negotiated price" and the final payment received by the pharmacy, to "true up" the DIR reported to the actual amount. Upon review of comments submitted to the RFI, CMS notes that

pharmacies rarely receive an incentive payment above the original reimbursement rate for the drug claim.

3. *Other Related Issues*

CMS proposes to utilize existing reporting mechanisms (i.e., prescription drug event records and DIR reports) when implementing this proposal to ensure proper application of the pharmacy price concessions at the point of sale. CMS is considering whether to require sponsors to include pharmacy price concessions in the negotiated price for beneficiaries in the coverage gap, for the purpose of determining manufacturer coverage gap discount liability. CMS is considering an option to develop a standard set of metrics on which plans and pharmacies would base their contractual agreements. CMS is considering creating a definition of “price concession,” which would be broadly defined, to include all forms of discounts, direct or indirect subsidies, or rebates.

COMMENTS NEEDED

CMS seeks comments on the following aspects of the proposal regarding pharmacy price concessions:

- whether CMS should move forward with this proposal, effective for contract year 2020;
- alternate approaches to requiring sponsors to include pharmacy price concessions in the negotiated price in the coverage gap;
- alternatives to the lowest possible reimbursement approach that would require Part D sponsors to apply less than 100 percent of pharmacy price concessions at the point of sale; and
- whether plan/pharmacy metrics could be designed to provide pharmacies with more predictability in their reimbursement while maintaining a plan’s ability to negotiate terms, and which agency or organization would be the most appropriate to develop such standards.

Key Takeaway: Notably in the Proposed Rule, CMS did not address the topic of passing along a percentage of manufacturer rebates at the point of sale, as discussed in CMS’s November 2017 RFI. Because Part D plan sponsors receive the vast majority of price concessions from manufacturers, rather than pharmacies, the reform is unlikely to produce dramatic cost savings at the pharmacy point of sale. Nevertheless, it would have a significant impact on contractual relations between Part D plan sponsors, PBMs, and network pharmacies. In anticipation of the finalization of this regulation, Part D sponsors will need to prepare to make adjustments in how they report negotiated prices and pharmacy price concessions. The method of calculating the lowest possible

reimbursement to implement this new proposed definition of “negotiated price” appears to set a default calculation baseline but may not comport with current industry practice.

V. Part D Explanation of Benefits

Currently, Part D sponsors are required to furnish each of their enrollees with a written explanation of benefits (“EOB”). When drugs are provided, Part D sponsors are required to provide enrollees with a notice of benefits in relation to the initial coverage limit and out-of-pocket threshold for the current year. Neither the EOB nor the notice of benefits requires the inclusion of information about negotiated drug price changes or lower-cost alternatives. The Trump administration’s May 2018 *Blueprint* solicited feedback on improving the usefulness of the Part D EOB statement by including information about drug price changes and lower-cost alternatives. Citing the supportive comments received, CMS proposes to require the inclusion of negotiated drug pricing information and lower-cost alternatives in the Part D EOB in order to provide enrollees with greater transparency and thereby encourage lower costs. In addition, CMS believes this proposed change would better educate beneficiaries on drug prices and empower them to make more informed decisions when choosing a prescription drug.

CMS proposes to require Part D sponsors to include a cumulative percentage change in the negotiated drug price since the first day of the current benefit year for each prescription drug claim in the EOB. CMS solicits feedback on operationalizing this in the EOB to best serve beneficiaries, which could include information such as the percent change in the negotiated price since the close of open enrollment in addition to the percent change in price since the first day of the benefit year.

CMS also proposes to require Part D sponsors to provide information about drugs that are therapeutic alternatives with lower cost sharing, when available, as determined by the applicable approved plan formulary for each prescription drug claim. CMS encourages, but does not require, sponsors to provide relevant beneficiary-specific information.

COMMENTS NEEDED

CMS seeks comments on the proposed changes to Part D EOB, including the impact on the beneficiary.

Key Takeaway: In the absence of beneficiary-specific information, there would appear to be a high likelihood of confusion regarding whether alternatives are appropriate for that particular patient, which may increase the burden on providers or plans to field these questions.

VI. Prohibition Against Pharmacy Gag Clauses

On October 10, 2018, President Trump signed into law the Know the Lowest Price Act, which prohibits “gag order” clauses in contracts between pharmacies and PBMs that are

designed to bar pharmacists from disclosing to Medicare beneficiaries at the pharmacy point of sale whether or not a drug's cash price would be lower than the beneficiary's cost-sharing burden under his or her prescription drug plan.⁷ The new law, which will go into effect on January 1, 2020, follows upon the Trump administration's previously announced plan to ban gag order clauses in its May 2018 *Blueprint*.

The Proposed Rule includes new regulations that will implement the recently enacted law's pharmacy "gag order" prohibition under Medicare Part D. Specifically, the Proposed Rule would amend the pharmacy contracting requirements at Section 423.120(a)(8) by adding language that a Part D sponsor may not prohibit a pharmacy from, or penalize a pharmacy for, informing Part D plan beneficiaries of a lower cash price available at that pharmacy for a prescription medication that a beneficiary would pay more out-of-pocket for if purchased through the Part D plan. CMS acknowledges that it would simply be codifying existing practice with this proposed change. Accordingly, the new regulatory language is not expected to produce savings or costs.

Key Takeaway: The new federal prohibition on pharmacy gag clauses, which CMS proposes to implement through regulation, has been embraced by pharmacy interests and will help ensure and promote transparency between pharmacists and beneficiaries under the Medicare program.⁸ Nevertheless, the practical impact of the reform may be moderated by the fact that many PBMs no longer incorporate these clauses in their pharmacy contracts, largely due to existing laws in several states that prohibit the practice.

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⁷ GOVTRACK, S. 2553: *Know the Lowest Price Act of 2018* (Oct. 10, 2018), <https://www.govtrack.us/congress/bills/115/s2553/summary>.

⁸ See Lynn Snyder, et al., *New Federal Laws Banning "Gag Clauses" in the Pharmacy*, HEALTH L. ADVISOR (Oct. 19, 2018), <https://www.healthlawadvisor.com/2018/10/19/new-federal-laws-banning-gag-clauses-in-the-pharmacy/> (explaining the implications of the Know the Lowest Price Act).

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