NCPA Analysis of Medicare Part D Pharmacy DIR Fee Reform Policy Proposal and Other Policies Impacting Community Pharmacies in the CMS Proposed Rule, *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses*

On Nov. 30, 2018, the Centers for Medicare and Medicaid Services published the proposed rule, *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses, CMS-4180-P.*[1] The proposed rule features critical policy changes to the application of pharmacy price concessions, also known as direct and indirect remuneration fees. The National Community Pharmacists Association's aggressive advocacy on this matter, including meetings with high-ranking government officials and grassroots lobbying by NCPA members, is reflected in CMS' proposal.

The following is NCPA's analysis of key aspects of the proposal regarding pharmacy DIR fees, as well as a summary of other changes in the proposed rule that impact community pharmacies.

What are the main points of the proposal?

• Implement a definition of "negotiated price" to include all pharmacy price concessions.

The current definition of negotiated price would be amended to require plan sponsors to reflect the lowest possible reimbursement that a network pharmacy could receive from a Part D sponsor for a covered Part D drug. Requiring the lowest possible reimbursement would move the negotiated price closer to a pharmacy's actual reimbursement, which is "closer to the actual cost of the drug for the Part D sponsor."[2] This change would effectively eliminate *retroactive* pharmacy DIR fees.

To achieve this, CMS proposes the following language to amend the definition of "negotiated price:"

> 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

[1] 83 Fed. Reg. 231, 62152 (published Nov. 30, 2018).
[2] *Id.* at 62178.

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(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.[3]

• Exclude from the "negotiated price" definition any contingent price concessions that could flow to a pharmacy.

CMS notes that incentive payments to pharmacies currently are "quite rare," while penalties assessed against pharmacies are abundant.[4] By excluding additional contingent price concessions like incentive payments from the negotiated price, CMS seeks to encourage plan sponsors to actually motivate pharmacies with after-the-fact incentive payments not included in a pharmacy's lowest reimbursement.[5] CMS states that this proposal would not require pharmacies to be paid a certain way, but would require a standardized reporting to CMS of drug prices at the point of sale.[6]

• Allow plan sponsors to elect to pass-through non-pharmacy price concessions (i.e., manufacturer rebates) to point of sale.

CMS only addresses pharmacy price concessions, a subset of overall DIR, in this proposal. Plan sponsors could still choose whether to include manufacturer rebates, etc., in the negotiated price and thus include them at the point of sale.

Technically speaking, how will CMS ensure that all pharmacy price concessions will be included in the negotiated price?

Part D sponsors/pharmacy benefit managers would load revised drug pricing tables reflecting the lowest possible reimbursement into their claims processing systems, which interface with contract pharmacies. CMS notes that the estimated rebates at the point-of-sale field on the PDE record can be used to collect the amount of point-of-sale pharmacy price concessions. Further, CMS states that the fields on the Summary and Detailed DIR Reports can be used to collect final pharmacy price concession data at the plan and NDC levels.[7]

How did CMS reach the conclusions found in the proposal?

CMS cites a number of reasons for this proposal, including many NCPA-endorsed arguments regarding transparency and competition. CMS states that due to the significant growth in pharmacy price concessions in recent years, it has been difficult for consumers to know what they will be

[3] *Id.* at 62179.

[4] *Id.* at 62178. While payments to pharmacies is rare, the utilization of incentive fees accounts for a large portion of total pharmacy price concessions in Medicare Part D. CMS states, "[t]he 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." *Id.* at 62174.

[5] *Id.* at 62178.

[6] *Id.*

[7] *Id.* at 62179.

paying for their prescription drugs when searching for a plan on Medicare Plan Finder.[8] CMS also notes that the different applications of pharmacy price concessions across varying plans allows certain plans to utilize a technical difference in reporting pharmacy DIR to gain a competitive advantage over another plan sponsor.[9]

Finally, CMS highlights that "the one-sided nature of the pharmacy payment arrangements that currently exists also creates competition concerns by discouraging independent pharmacies from participating in a plan's network and thereby increasing market share from the sponsors' or PBMs' own pharmacies." CMS states that when these kinds of arrangements harm independent pharmacies, market competition is not achieved.[10]

CMS' overall goals for this proposal are: 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.

What other policy changes related to pharmacy DIR fees are being considered under the proposal?

• Define "price concessions."

Currently, the term "price concessions" is not defined in statute or in regulation. CMS proposes a definition of "price concessions" to be broad enough to include "all forms of discounts and DIR" that serve to reduce the costs incurred under Part D plans.
The proposed language reads:

> *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.*[11]

• Develop a standard set of metrics for contingent amounts.

The proposal requests feedback on whether contingent metrics, including quality and performance metrics, could be designed to provide pharmacies with more predictability.[12] NCPA continues to initiate conversations with CMS officials regarding the type of quality and performance metrics that could appropriately measure community pharmacies.

• Reaffirm the inclusion of administrative service fees in a sponsor's bid.

CMS highlights that some plan sponsors and PBMs charge fees to network participating pharmacies that are classified as "administrative," "technical," or "service" fees. CMS notes that some plans and

[8] *Id.* at 62177.
[9] *Id.*
[10] *Id.* at 62176.
[11] *Id.* at 62180.
[12] *Id.* at 62195.

PBMs charging these fees do not consider the fees to be price concessions and thus, do not report these fees in the sponsor's Part D bid. CMS' proposal restates that when pharmacy administrative fees are taken in the form of deduction from payments to pharmacies, they are an offset of the sponsor's or PBM's operating costs and thus, these administrative fees should be accounted for in the administrative costs of a plan's Part D bid. CMS concludes that "the regulations governing the Part D program require that price concessions be fully disclosed."[13]

If this proposal is finalized, when would the changes go into effect?

This proposal contemplates an effective date as early as contract year 2020.[14] CMS is accepting comments on the proposed rule until Jan. 25, 2019.

What will be the economic impact of this proposal?

The following table from the proposed rule outlines the total economic impact this proposal is projected to incur to the government, beneficiaries, plan sponsors, and manufacturers.

Provision	Description	Impact
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.

What else is included in this proposed rule that impacts community pharmacies?

• <u>Updates Part D e-prescribing standards.</u>

The proposal would require plan sponsors to implement an electronic real-time benefit tool 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

[13] *Id.* at 62180.
[14] *Id.* at 62175.

consider that information at the point of prescribing. The proposal, if finalized, would go into effect by January 1, 2020.

Community pharmacists should be aware of this change because it is an additional step for practioners to have complete, accurate, timely, and clinically appropriate patient-specific real-time formulary and benefit information.

• Allows plan to manage protected classes in Part D.

CMS proposes three exceptions to the requirement that sponsors include on their formularies all drugs in the current six protected classes. First, the proposal would allow plans/PBMs to utilize prior authorizations and step therapy for the drugs in the protected classes. Second, a protected class drug would be excluded from a formulary if the drug represents only a new formation of an existing single-source drug or biologic. Finally, a protected class drug would be excluded from a formulary if the price of the drug increased beyond a certain threshold over a specified look-back period.

Community pharmacists should be aware of this proposal because the patients who receive drugs from these six protected classes will be impacted and may have questions about new coverage at the pharmacy counter. Additionally, community pharmacists may see an uptick in prior authorizations and step therapy for these drugs.

• Includes step therapy for Part B drugs.

CMS proposes requirements under which Medicare Advantage plans may apply step therapy as a utilization management tool for Part B drugs. This August, CMS provided guidance to the industry allowing MA plans via their PBMs to utilize step therapy for Part B drugs. This proposal is a codification of that guidance. Community pharmacists should be aware of this as it may impact the volume of step therapy processes seen at the pharmacy counter.

• Codifies gag clause prohibition.

CMS codifies into Part D regulations the statutory prohibition of gag clauses in the Medicare program. Specifically, CMS amends 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.

For more information on the prohibition of gag clauses, see NCPA's Pharmacist Fact Sheet.[15]

• Updates Part D explanation of benefits templates.

CMS proposes to update Medicare beneficiaries' explanation of benefits 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.

[15] NCPA, *Prohibition of Gag Clauses: Pharmacist Fact Sheet*, *available a*t http://www.ncpa.co/pdf/qAM/pharmacist-fact-sheet-prohibition-gag-clauses.pdf.