Proposed Medicare Part D Rule Contract Year 2019

Shifting Pharmacy Price Concessions (DIR) to the Point of Sale:

CMS proposed revising the definition of negotiated prices at 423.100 to require all price concessions from pharmacies (DIR Fees) be reflected in the negotiated price that is made available at the point of sale and reported to CMS on a PDE record, even when such concessions are contingent upon performance by the pharmacy.

In order to do this, CMS is considering proposing that the point of sale reimbursement reflect all price concessions or fees from the pharmacy. In addition, this also assumes that any incentive fees or pay for performance would not be reflected at point of sale and would take place after the point of sale (and plan sponsors would report these amounts as negative DIR).

CMS estimates that that change would result in in significant beneficiary savings in cost sharing (at the pharmacy counter) as well an overall savings (taking into account both premium amount and cost sharing amounts) over ten years.

This approach would provide pharmacies with certainty at the point of sale and in addition would provide the groundwork for true pay for performance arrangements that would reward pharmacies for exemplary performance rather than simply imposing less of a financial penalty for positive outcomes.

CMS Consideration of Shifting Manufacturer-Derived DIR or Rebates to Point of Sale:

CMS proposes a number of different ways in which manufacturer rebate amounts (essentially manufacturer derived DIR amounts) could potentially be reflected at the point of sale in order to benefit beneficiaries. CMS in currently considering various approaches—including applying a certain percentage of manufacturer rebates to point of sale or perhaps only on a certain subset of drugs.

Comprehensive Addiction and Recovery Act (CARA) Implementation:

- Updating Part D E-prescribing Standards. Would require the use of the NCPDP SCRIPT Standard Version 2017071 and retirement of the current NCPDP SCRIPT Version 10.6 as the official electronic prescribing standard for transmitting prescriptions and prescription-related information using electronic media for covered Part D drugs for Part D eligible individuals. Effective January 1, 2019.

- Exempted Beneficiaries: CARA Act defines exempted beneficiary as hospice patients, residents of a long-term care facility (in which frequently abused drugs are dispensed for residents through a contract with a single pharmacy or who the Secretary elects to treat as an exempted individual. PROPOSED REGULATION: would also add to the list of exempted beneficiaries those individuals with a cancer diagnosis and

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residents of other types of residential facilities in which drugs are dispensed to residents through a contract with a single pharmacy.

Clarification of "Any Willing Pharmacy":

The proposed rule states CMS' position that just because a retail pharmacy may also engage in other lines of business like compounding or specialty –they must still be offered the standard terms and conditions for participation in Part D networks.

- "We have anecdotal evidence that some Part D plan sponsors have declined to permit willing pharmacies to participate in their network on the grounds that they do not meet the Part D plan sponsor's definition of a pharmacy type for which it has developed standard terms and conditions." (p. 265). "Part D sponsors must not exclude pharmacies from their retail network solely on the basis that they, for example, maintain a traditional business while also specializing in certain drugs or diseases or providing home delivery service by mail to surround areas."

Definition of "Mail-Order Pharmacy":

To date, there is no definition of "mail order" pharmacy for the purposes of Part D. CMS has heard from many pharmacies that provide home delivery services by mail (relative to that pharmacy's overall operation) that Part D plan sponsors then have classified them as mail order pharmacies for network participation and require them to be licensed in all fifty states.

- Therefore—CMS proposes to define "mail order pharmacy" as "a licensed pharmacy that dispenses and delivers extended days' supplies of covered Part D drugs via common carrier at mail order cost sharing." [Under this definition, independent community pharmacies that provide medications to patients through the mail would NOT be considered mail order pharmacies].

- Correspondingly, in order to clarify, CMS also proposes the following definition of "retail pharmacy" to incorporate the key concepts of being open to the public and subject to retail cost-sharing. "any licensed pharmacy that is open to dispense prescription drugs to the walk-in general public from which Part D enrollees could purchase a covered Part D drug at retail cost sharing without being required to receive medical services from a provider or institution affiliated with that pharmacy."

CMS Reaffirmation of Part D Policy on Access to Specialty Drugs and Opposition to PBM-specific specialty credentialing requirements:

In this proposed rule CMS restates their long standing policy that Part D plans cannot restrict access to certain Part D drugs to specialty pharmacies within their Part D network in such a manner that contravenes the convenient access protections of section 1860D-4(b)(1)(C). NCPA has heard from many pharmacies that plan sponsors/PBMs have been attempting to require their own specialty accreditation requirements in addition to nationally recognized accreditation. CMS shares these concerns as well.

- "CMS is concerned that Part D plan sponsors might use their standard pharmacy contracts in a way that inappropriately limits dispensing of specialty drugs to certain pharmacies by requiring accreditation by multiple accrediting organizations or additional Part D plan/PBM specific credentialing criteria for network participation."

- CMS: "We do not support the use of Part D plan sponsor or PBM-specific credentialing criteria, in lieu of, or in addition to accreditation by recognized accrediting organizations (apart from drug specific limited dispensing criteria, i.e., REMS)

Timing and Pharmacy Access to Standard Terms and Conditions for Network Participation:

NCPA member pharmacies have explained to CMS that many times plan sponsors delay sending them the requested terms and conditions for weeks or months or require pharmacies to complete extensive paperwork before they will provide the pharmacy with the information. CMS is concerned that these actions are thwarting the intent of the any willing pharmacy requirement.

- Therefore, CMS proposes to require all Part D plan sponsors to have standard terms and conditions for network participation readily available for requesting pharmacies no later than September 15 of each year for the succeeding benefit year. In addition, Part D sponsors must provide the standard terms and conditions document to a requesting pharmacy within two business days of receipt of the request

LTC Transition Days' Supply:

- CMS is proposing that the transition days' supply in the LTC setting be the same as it is in the outpatient setting