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July 23, 2021

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
U.S. Department of Labor
200 Constitution Avenue, NW
Room N–5653
Washington, DC 20210

BY ELECTRONIC DELIVERY

RE: Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs; 86 FR 32814; CMS–9905–NC

To Whom It May Concern:

The National Association of Specialty Pharmacy (NASP) is writing to provide comments in response to the *Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs* issued by the Office of Personnel Management; Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; and Centers for Medicare and Medicaid Services, Department of Health and Human Services. NASP represents the entire spectrum of the specialty pharmacy industry, including the nation's leading specialty pharmacies and practicing pharmacists; small and mid-size pharmacy benefit managers (PBMs); pharmaceutical and biotechnology manufacturers of specialty drugs; group purchasing organizations; wholesalers and distributors; integrated delivery systems and health plans; and technology and data management companies. NASP is the unified voice of specialty pharmacy in the United States.

NASP supports efforts to increase the transparency of data and information as a means to promote market competition and reduce health care costs. Perhaps nowhere is this transparency more important than in the prescription distribution channel, particularly related to the fees and remuneration paid and collected by health plans and their pharmacy benefit managers (PBMs).

Pharmacy Direct and Indirect Remuneration

NASP appreciates the improved understanding by the Centers for Medicare and Medicaid Services (CMS) of the financial transactions by health plans and the detrimental impact some, particularly post- point-of-sale, pharmacy Direct and Indirect Remuneration (DIR) fees are currently having on Medicare beneficiaries and the Part D program.

Retroactive pharmacy DIR fees are collected by plans and their PBMs from pharmacies months after a medication has been dispensed to a beneficiary. These fees are collected in the absence of

any transparency, and for many specialty pharmacies have grown to be in the multi-millions per year, resulting in reimbursement far below acquisition cost with consequences to pharmacy operations and beneficiary access to medications. As CMS recognized in 2018[1], these retroactive fees result in higher out-of-pocket costs for beneficiaries, significantly increasing their cost sharing obligation under Medicare Part D. Most recently, as part of its budget justification to Congress, CMS reported that the "data show that pharmacy price concessions, net of all pharmacy incentive payments, grew more than 91,500 percent between 2010 and 2019."[2]

In the proposed Medicare Part D rule issued in 2018, CMS proposed eliminating retroactive pharmacy DIR fees by amending the definition of negotiated price to include all pharmacy price concessions at the point of sale.[3] Under the proposal, plan sponsors would have to reflect the lowest reimbursement a network pharmacy could receive from a Part D sponsor, detailing all data requirements necessary. NASP requests that CMS revisit and work to advance the 2018 regulation and the associated data collection terms proposed. Such an effort is essential to addressing long overdue transparency concerns regarding the transaction for acquired drugs under Medicare Part D, ensuring a fair and competitive market for in-network pharmacies, and reducing drug costs for beneficiaries. NASP submitted extensive comments on the proposed 2018 regulation, for CMS's consideration.

Pharmacy Performance Measures – Data Request

NASP has long advocated for CMS to directly engage in oversight of the performance measures being used by plans and PBMs to evaluate specialty pharmacies. Health plans/PBMs have been recouping increased sums from network pharmacies after the point-of-sale for "poor performance" at a rate far greater than those paid to network pharmacies for "high performance." Since PBMs began to utilize their own select metrics that do not undergo a certification process overseen by CMS, specialty pharmacies have found themselves unfairly subjected to measures that are largely unrelated to the drugs the pharmacies dispense, conditions they treat, or the services they provide. For example, specialty pharmacies that dispense medication and provide patient care services for conditions like cystic fibrosis, hemophilia, or multiple sclerosis encounter DIR-related pharmacy performance scores associated with conditions like diabetes and cardiovascular disease applied against them with the purpose of reducing their reimbursement in the form of claw back fees.

CMS has previously relayed that the variation in the treatment of price concessions by the plan sponsors may have a negative effect on the competitive balance under Medicare Part D, resulting in unnecessary spending by Medicare and its beneficiaries.[4] Specialty pharmacies have found themselves in a no-win situation, being disproportionately affected by so-called performance measure cuts they have no ability to affect. Non-transparent and often excessive

[1] Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses. 83 Federal Register 62152 (November 30, 2018).
[2] Centers for Medicare & Medicaid Services. Department of Health and Human Services Fiscal Year 2022, CMS Justification for Estimates for Appropriations Committees. https://www.cms.gov/files/document/fy2022-cms-congressional-justification-estimates-appropriations-committees.pdf.
[3] Id.
[4] Id.

pharmacy price concessions in the form of claw backs that occur well after the point-of-sale limit a specialty pharmacy's ability to remain in-network. Less market competition ultimately results in higher costs to the Medicare program and restricted patient access for beneficiaries, especially specialty patients with complex medication needs that often require the care management provided by specialty pharmacies.

On January 19, 2021, CMS issued a final rule[5] to require Part D plans to report to CMS the pharmacy performance measures they utilize along with details for how they are applied to pharmacies beginning January 1, 2022. The effort to collect the measures used by plans and to make the information transparent and available is a solid first step toward development of a standardized pharmacy performance metric system. NASP would like to encourage CMS to work with the stakeholder community as this process unfolds to ensure information is appropriately collected and is comprehensive of the plan-based performance measures collected. As part of its data collection effort, it will be important for CMS to understand how measures are established (i.e., criteria and evaluation process involved); how they are applied by pharmacy type and how such a decision is determined; and the mechanisms used to evaluate and calculate pharmacy performance through use of each measure. NASP encourages CMS to issue a proposed regulation to receive stakeholder feedback on the specific data that should be collected and the process for assessing this data as part of the Medicare Part D Reporting Requirements.

Defining the Term "Pharmacy" and Considerations for Specialty Pharmacy

In the RFI, the agencies ask for feedback on what considerations the Departments and OPM should take into account in defining the term "pharmacy," specifically asking if there are different considerations for retail pharmacies versus mail order or specialty pharmacies. NASP has long advocated that the Department of Health define specialty pharmacy. NASP believes that defining specialty pharmacy is essential to protecting pharmacy market competition within plan networks and is likewise essential to ensuring the fair evaluation of pharmacy performance under Medicare Part D and more broadly to ensure measures fairly assess the work specialty pharmacies perform specific to the drugs they dispense.

Specialty pharmacies provide medications for people with serious health conditions that require complex therapies and often complex drug handling and ongoing proactive patient management beyond dispensing of the medication. These conditions include cancer, hepatitis C, rheumatoid arthritis, HIV/AIDS, multiple sclerosis, cystic fibrosis, organ transplantation, and hemophilia and other bleeding disorders. Specialty pharmacies can be independent, hospital-based, home infusion-based, or operate within a larger pharmacy chain.

Any effort to define specialty pharmacy by HHS should specifically and simply focus on quality and third-party independent accreditation. NASP defines a specialty pharmacy as a state-licensed pharmacy that receives accreditation as a specialty pharmacy from one nationally-recognized independent third-party accreditation organization. Accreditation demonstrates a

[5] Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All- Inclusive Care for the Elderly. 86 Federal Register 5864 (January 19, 2021).

commitment to quality, safety, accountability and adoption of nationally recognized standards of practice. Independent third-party accreditation also is essential in establishing rigorous performance standards for specialty pharmacies where the focus is on patient-centered care to those with chronic illness and complex medical conditions that require highly specialized, comprehensive drug therapies with unique storage and handling requirements.

Conclusion

We thank CMS for consideration of NASP's comments and urge the agency to consider future rulemaking efforts that address the areas discussed. NASP will continue to work with the Departments to support increased transparency and market competition for specialty pharmacy within the pharmaceutical channel. If we can provide additional information, please contact me at sarquette@naspnet.org, (703) 842-0122 or NASP's Washington Representative Julie Allen at julie.allen@powerslaw.com, 202-494-4115.

Respectfully submitted,

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