NATIONAL ASSOCIATION OF
SPECIALTY PHARMACY
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BY ELECTRONIC DELIVERY

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Re: Proposed Medicare Part D DIR Reporting Requirements for 2016

Dear Director Johnson:

The National Association of Specialty Pharmacy (NASP) appreciates this opportunity to submit comments to the Centers for Medicare & Medicaid Services' (CMS') Proposed Medicare Part D DIR Reporting Requirements for 2016 (Proposed Guidance). NASP is a non-profit trade organization representing a wide range of stakeholders in the specialty pharmacy industry. With over 100 corporate members and 1,200 individual members, NASP is the unified voice of specialty pharmacy. Our members include the nation's leading independent specialty pharmacies, integrated delivery systems and health plans, pharmaceutical and biotechnology manufacturers, Group Purchasing Organizations (GPOs), patient groups, wholesalers/distributors and practicing pharmacists.

Our leaders constantly refine the practice of specialty pharmacy with a single focus on the patients we serve to ensure better outcomes while reducing overall healthcare costs. With this guiding principle, NASP is the leading education resource for specialty pharmacists. The association provides an online education center with over 30 continuing pharmacy education programs, hosts an annual meeting that offers education sessions and continuing education credits, and operates a certification program for specialty pharmacists.

NASP represents an industry that focuses on providing quality patient care first with an added emphasis on outcomes and patient choice. NASP believes that it shares these common goals with CMS and looks forward to partnering with the agency to ensure that all Medicare beneficiaries receive high quality cost effective care from their specialty pharmacy. In furtherance of these shared goals, NASP submits the following comments related to CMS' Proposed Guidance that urges the agency to collect DIR fee data by pharmacy type, further clarify the term "reasonably determined at the point-of-sale,"

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and use its current authority to drive greater transparency into the PBM business model.

I. NASP Commends CMS' Efforts to Verify the Accuracy of the Data Reported

In the Proposed Guidance, CMS requires PDP sponsors to report price concessions received from pharmacies and incentive payments paid to pharmacies separately in new data fields DIR #8 and DIR #9. CMS states that it is making this modification in order for the agency to collect data that is more representative and reflective of how pharmacy payment arrangements are actually structured. NASP supports these efforts as greater transparency and granularity will help the agency further realize and understand the current specialty pharmacy market. NASP further encourages CMS to break out by pharmacy type, retail versus specialty, the collection of DIR fees especially since certain projections estimate that by 2021 the pharmacy industry's revenues will be about 572 billion dollars and that specialty drugs will account for 42 percent of those dollars[1]. By doing this, CMS will learn that very rarely, if ever, does a specialty pharmacy receive any incentive payments; rather, only price concessions. With this greater understanding, NASP believes that CMS can then take the necessary steps to correct this imbalance and require PBMs to create meaningful quality measures that focus on the care provided by specialty pharmacies as the only foundation for the collection of DIR fees. NASP believes that the agency has the statutory authority to require these types of quality measures of the health sponsor.[2] As such, NASP urges the agency to continue to seek greater clarity and understanding of the financial relationships between specialty pharmacies and PBMs.

II. CMS Should Further Clarify the Term "Reasonably Determined at the Point-of-Sale"

Effective January 1, 2016, Part D sponsors are required to include in the negotiated price all price concessions from and additional contingent payments to network pharmacies except those that cannot be reasonably determined at the point-of-sale.[3] The Proposed Guidance further clarifies that "if a sponsor or its PBM pays a pharmacy a specified amount for a prescription event but recoups some of the payment

[1] http://www.drugchannels.net/2017/04/our-exclusive-2021-outlook-for.html
[2] The Social Security Act (SSA) Section 1860D-11(d)(2)(A) states that the "Secretary has the authority to negotiate the terms and conditions of the proposed bid submitted and other terms and conditions of a proposed plan." Since DIR reporting is part of a plan's complete bid, it seems to reason that the Secretary can require plan sponsors to submit DIR data by pharmacy type and oversee the types of quality programs implemented by plan sponsors.
[3] 42 C.F.R. § 423.100.

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after the event, if, for instance the pharmacy has failed to meet performance standards set under a performance based payment arrangement, the amount recouped by the sponsor or its PBM must be reported as positive DIR."[4] NASP believes that the intent of this statement by the agency is to further clarify what can reasonably be determined at the point-of-sale. In other words, the agency seems to believe, that because the recoupment occurs "after the event" it must NOT be able to be reasonably determined at the point of sale.

NASP appreciates the agency's attempt at clarity but believes that the Proposed Guidance does not go far enough as there are plenty of "after the event" recoupments that systemically occur which the PBM knows are going to occur. Therefore, these events can be more than reasonably determined at the point-of-sale and should be included in negotiated price and not as positive DIR. NASP points to the agency's own statements as support for the belief that certain "after the event" adjudications should be included in the negotiated price and not as positive DIR. The agency states that "examples of adjustments to be reported as DIR include any reconciliation amount that accounts for differences between the contracted rate and the higher adjudicated rate received by the pharmacy at the point-of-sale and contingent incentive fees related to, for instance generic dispensing rates, audit performance/error rates, refill rates, preferred dispensing rates, and/or other audit performance metrics, including qualitative measures."[5] These are a wide range of examples and as the agency knows do not apply to every type of pharmacy, especially specialty pharmacies. Yet, many specialty pharmacies "pay" a DIR fee for failing to meet measures that are unattainable and are not meant for their patient population. In fact, NASP briefly surveyed its membership to gain a better sense of how much of the DIR fees paid could have been reasonable determined at the point-of-sale. The numbers are compelling. At a minimum, at least 95 percent of all DIR fees paid by the majority of NASP members could easily been determined at the point- of-sale. This percentage easily scales up to billion dollars in DIR fees that PBMs will collect in 2017 that NASP believes should be accounted for as part of negotiated price and not DIR.

PBMs know based on historical use, patient mix and dispensing patterns that specialty pharmacies will fail many if not all of the current quality measures that are being applied to them at the point-of-sale. These "adjustments" should not be adjustments for purposes of accounting for DIR fees; rather, they should be included in negotiated price. CMS should further clarify that those "adjustments" that occur post point-of-sale that the PBM knows will not be attained by the specialty pharmacy SHOULD be included in the negotiated price calculation, rather than DIR.

[4] Proposed Guidance, DIR #8-Amounts Receives from Pharmacies.
[5] Id.

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NASP therefore urges the agency to reign in the accounting abuses of the PBMs and require them to count the recoupments from specialty pharmacies as negotiated price and not DIR fees when the PBM knows that the specialty pharmacy cannot attain a certain metric, quality measure, and/or generic dispensing rate.

III. CMS Should Collect DIR Fees by Pharmacy Type

CMS recently observed a growing disparity between gross Part D drug costs, calculated based on costs of drugs at the point of sale, and net Part D drug costs, which account for all DIR.[6] This disparity is occurring because of the growth of the post adjudication fees that some PBMs are collecting from specialty pharmacies, typically months after claims are submitted and reimbursed. As mentioned above, these fees are being collected under the guise of "performance-based" fees, which are based on wholly inapplicable performance or quality metrics on drugs, events and/or services that do NOT occur at the specialty pharmacy. NASP is troubled that CMS' Proposed Guidance does not require the plan sponsor to further break out those DIR fees that are collected from a retail pharmacy versus those that are collected from a specialty pharmacy. Plan sponsors are well aware of the type of pharmacies in its network via its own credentialing or contracting policies and procedures. Therefore, NASP does not believe that it is unreasonable for the plan sponsor to submit to CMS DIR fees paid and DIR fees collected by the retail and specialty pharmacy sectors. This simple requirement will give CMS much greater insight into how pharmacy arrangements are actually structured, the types of, and nature of the fees and monies that are exchanged between retail/specialty pharmacies and the plan sponsors.

IV. NASP Member's Trend Data Is Consistent with the Agency's Findings Related to the Exponential Growth of DIR Fees

As mentioned above, CMS has observed a notable growth in DIR fees collected and reported by Part D sponsors because Part D sponsors and PBMs are "engaging to a greater extent in arrangements that feature compensation after the point-of-sale, and the value of such compensation is also generally increasing."[7] NASP's members are witnessing this DIR trend first hand with dramatic impact on patient support programs. Each year since 2015, both the DIR percentages and the scope of the claims that DIR fees are applied to have grown from just a few percentage points on Medicare claims to upwards of close to double digit percentage points on Medicare and Medicaid, claims.

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[6] Medicare Part D—Direct and Indirect Remuneration, CMS (January 19, 2019), available at: https://www.cms.gov/newsroom/mediareleasedatabase/fact-sheets/2017-fact-sheet-items/2017-01-19-2.html.
[7] Id.

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NASP urges the agency to ask why PBMs and plan sponsors are increasingly using a percentage based DIR pricing structure versus a simple, low adjudicated price. The overall Part D Program has not changed since inception such that the only rational conclusion is that the PBMs see more economic benefit by using percentages. It is clear to NASP that PBMs are using percentage based DIR fees to keep more of the economics of the Medicare Part D program, which tragically comes at the expense of Medicare beneficiaries and the overall Part D Program in terms of greater costs and fewer choices.[8]

Without CMS' intervention to stop the abuse of DIR fees, NASP knows that this trend will continue to the point where only the PBM owned specialty pharmacies can participate in the Medicare Part D program because only a subsidiary is be to afford to pay its parent company the DIR fee.

V. Conclusion

NASP greatly appreciates the opportunity to comment on CMS' Proposed Guidance and looks forward to continuing to work with the agency to ensure that Medicare beneficiaries have access to critical specialty drugs and the specialty pharmacy of their choosing. Please contact me at (703) 842-0122 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Sincerely,

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[8] Id.