NATIONAL ASSOCIATION OF
SPECIALTY PHARMACY
300 New Jersey Ave., Suite 900
Washington, DC 20001
www.naspnet.org

April 6, 2020

Ms. Seema Verma, MPH
Administrator
U.S. Department of Health and Human Services
Centers for Medicare and Medicaid Services
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

BY ELECTRONIC DELIVERY

RE: CMS-4190-P

Dear Administrator Verma:

The National Association of Specialty Pharmacy (NASP) is pleased for the opportunity to provide comments on the proposed rule for "Medicare and Medicaid Programs; Contract Year 2021 and 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" at 85 Fed. Reg. 9002 et seq; RIN 0938-AT9. NASP shares the administration's goals of lowering out-of-pocket costs for beneficiaries under Medicare Part D, improving the transparency of fees, and ensuring competitive balance under the Medicare Part D program. We want to thank the administration for its ongoing dialogue on issues that affect specialty patients and the pharmacies that serve them, and we look forward to working with you to address these matters going forward.

NASP's members are committed to the practice of specialty pharmacy and to serving specialty patients to ensure better clinical outcomes and responsibly manage overall healthcare costs.

NASP defines a specialty pharmacy as a state-licensed and registered pharmacy that:

- Is accredited by, or in the process of specialty pharmacy accreditation by an independent, third-party accreditor; AND
- Solely or largely provides medications and patient medication management services to patients with serious health conditions requiring treatment with complex medication therapies.

NASP represents the entire spectrum of the specialty pharmacy industry from the nation's leading independent specialty pharmacies and practicing pharmacists to 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. With over 120 corporate members and 1,800 individual members, NASP is the unified voice of specialty pharmacy in the United States.

NASP supports CMS' efforts in the proposed rule to assess and reform a pharmacy performance evaluation system and offer our thoughts and recommendations on how to implement such reforms to specifically address the needs of specialty patients and the pharmacies that serve their needs. NASP remains committed to continuing to work with CMS to advance this important reform. We also offer our comments and recommendations on other sections of the proposed rule, specifically, reforms that would establish a second "preferred" specialty tier under Medicare Part D.

Establishing Pharmacy Performance Measure Reporting Requirements (§ 423.514)

In the proposed rule, CMS outlines a plan to amend the regulatory language at § 423.514(a) to establish a requirement for Part D sponsors to disclose to CMS the measures they use to evaluate pharmacy performance, as established in their network pharmacy agreement. NASP is so pleased to see CMS' interest in taking a significant step forward to oversee the pharmacy performance measure system and understand more about a process that has otherwise been "a black box" for pharmacies, patients, and for the federal government. We support and look forward to working with CMS as it institutes this oversight, while continuing to work with the agency on a longer-term effort that ultimately de-links the pharmacy performance system from the current pharmacy direct and indirect remuneration (DIR) system, which has been significantly abused.

In the 2018 Medicare Part D proposed rule, CMS explained that their data shows pharmacy price concessions grew more than 45,000 percent between 2010 and 2017, with much of that growth occurring after Part D sponsors stood up "performance-based" pharmacy payment arrangements that only served to institute sizeable reductions in pharmacy reimbursement and zero savings for beneficiaries. CMS also correctly highlighted that 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."

PBM-Lead Pharmacy Performance Measures Not Applicable to Specialty Pharmacy

In this proposed rule, CMS states that collecting performance measure information that is used to determine whether a financial reward or penalty is incurred by a pharmacy after the point-of-sale (POS) will enable CMS to better understand the extent to which the measures are applied, whether it be uniformly or specific to pharmacy type. On this important point, NASP can clearly state that for specialty pharmacies, there has almost never been an upside in regard

to the application of such PBM performance metrics. **Since PBMs began to utilize their own select metrics that have not undergone a process overseen by CMS, specialty pharmacies have found themselves unfairly subjected to metrics 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. Rather than evaluating performance, measures have been used in a punitive fashion, with the sole purpose being a reduction in pharmacy reimbursement in the form of DIR claw back fees. There is no information provided to the pharmacies when they are found not to be compliant with measures. Often, specialty pharmacies have no idea what measures they were supposedly evaluated against. There is no appeals process in place to request clarity or reevaluation of performance. **We believe strongly that oversight of the pharmacy performance measures instituted by PBMs/plans will improve transparency for the process, specifically for CMS and pharmacies, and confirm for CMS that many of the measures do not provide appropriate metrics across all types of pharmacies. Oversight will also ensure uniform and consistent administration of the Part D program for all beneficiaries, independent of plan or plan sponsor.**

Evaluating Pharmacy Performance

It is critically important as CMS works to institute a new pharmacy performance measure reporting process that the agency ask the correct questions as it collects information. **The agency must first ensure that it is asking for measures to be reported by pharmacy type. To fairly do this, the agency must acknowledge the different pharmacy business models that exist, including those that remain without a regulatory classification – particularly specialty pharmacy.** Measures used for pharmacy performance evaluation must be tied to the drugs dispensed and disease states being managed by each pharmacy type. CMS must also understand why specific measures were applied against a specific type of pharmacy and how the measures compare to the drugs a pharmacy dispenses and the services it provides. Without adequate information to assess the fairness and applicability of the measures assessed against a pharmacy, CMS will never have adequate data in which to determine if there is truly a pharmacy performance problem that needs to be addressed.

CMS must remember that the current pharmacy DIR process was never meant to be a pharmacy performance or quality program. Under the current construct, when pharmacies meet measures, DIR fees collected by PBMs/plans would be reduced. So, there is no incentive to reward high pharmacy performers. This is only further emphasized by the fact that there are large, vertically integrated players in specialty pharmacy that have zero incentive for rewarding those specialty pharmacies that are in its network.

Pharmacy Performance Information Proposed for Collection and Publication

In the proposed rule, CMS states that once collected, the agency would publish the list of pharmacy performance measures to increase public transparency. CMS further states that quality measures can document a pharmacy's contribution to value-based care and incentivize high quality care. NASP has been an advocate for moving toward a true value-based payment system for pharmacy. We disagree strongly, however, with trying to build such a payment system on the back of the pharmacy price concessions/DIR payment system. For the reasons outlined above, the PBMs/plans that control the current pharmacy performance measure system have no incentive to reward a pharmacy for meeting measures. With the current and significant flaws in the system, measures are being applied to pharmacies – especially specialty pharmacies – that they cannot possibly meet given the types of patients they serve and almost always have nothing to do with the drugs they dispense. For a value-based payment system to work, it must be de-coupled from the current pharmacy DIR process and must be overseen and managed by the Secretary.

We urge CMS not to move forward with the publication of the current pharmacy performance measures being assessed by PBMs/plans or information on pharmacy performance on those measures at this time. CMS must first take the time to understand what measures are being applied, which pharmacies they are being applied to, and whether the application of the measures is appropriate given pharmacy types and the patients they serve. A thorough assessment and clean up of this process is critically important to ensure we do not mislead patients about the performance of their pharmacies.

Information to be Collected by CMS

CMS proposes to collect much information concerning the performance measures being applied for pharmacy evaluation today, including:

- Name of the performance measure;
- Performance calculation methodology;
- Success/failure threshold(s);
- Financial implications of success/failure to achieve threshold(s);
- Pharmacy appeal requirements; and
- Method of payment of collection.

In addition to the data proposed, NASP urges CMS to also require that PBMs/plans report their criteria for applying specific measures against different types of pharmacies. PBMs/plans must be asked to demonstrate that pharmacy performance measures are appropriately applied to pharmacies in a way that ensures pharmacies can be fairly evaluated and scored. We are pleased that CMS acknowledges in the proposed rule that stakeholders would have the opportunity to provide additional feedback on the actual data elements under consideration by the agency as it develops its oversight and reporting system. NASP looks

forward to working with CMS to ensure that the data elements provide the necessary information for CMS to evaluate the pharmacy performance system in place today and work toward necessary oversight and improvements going forward.

Collecting Retrospective Information on Pharmacy Performance

CMS states that the agency may also consider collecting retrospective information on the number of pharmacies by pharmacy type that achieved established success/failure thresholds and average scores or other statistics for each measure. NASP strongly encourages CMS to consider retrospective information, again ensuring that it requires such information be reported by pharmacy type. There must also be a process to allow pharmacies to subsidize this information and address any concerns with how such information is being relayed. We encourage CMS to ensure that such a retrospective review includes insight from the broader pharmacy stakeholder community.

Developing a New Consensus Process for Pharmacy Performance Measures

NASP continues to believe that it is essential that any new process for pharmacy performance measure development be consensus- and stakeholder-driven with appropriate oversight by CMS/HHS. For far too long, the current pharmacy "performance" system has been perverted by PBMs/plans that have no incentive for rewarding high performing pharmacies and utilize the current measure process to significantly increase pharmacy DIR clawback fees. The current process does nothing to support patient care as information is not being assessed in a way to support patient quality. The system needs a complete do-over, and a true pharmacy value-based payment system needs to be established. **CMS should never expect that any voluntary consensus measure development process will ensure Part D sponsors and their PBMs adopt and standardize such measures. A new measure system must be overseen by CMS/HHS and required for participation in the Part D program. Such a new system must also be removed from the current pharmacy DIR construct to truly reward high-performing pharmacies outside of the price concession process.**

NASP is pleased that the industry continues to work together on developing a set of pharmacy performance measures through the Pharmacy Quality Alliance (PQA) as a consensus measure developer. However, we need to ensure that any such consensus developer also has checks and balances against bias in its system. PQA or any measure developer must ensure adequate and appropriate representation for all types of pharmacies when developing relevant measures. For example, while there is significant representation of vertically-integrated specialty pharmacies, there is limited representation of non-vertically integrated specialty pharmacies at the PQA leadership level. This creates concern as we work to be a collaborative partner on the periphery to ensure specialty pharmacy-related measures are fairly developed, assessed, and appropriately tested before recommendations are issued on new measures.

NASP agrees with CMS that under the current pharmacy performance system, in the absence of CMS/HHS oversight and management of such a system, Part D sponsors should use a third party, independent organization that is free of conflicts of interest to assess pharmacy performance on such measures (including data aggregation, development of measure thresholds and cut points, and definition of applicable pharmacy types for each measure).

Principles of Part D Pharmacy Performance Measures

CMS recommends that pharmacy performance measures established for use in Part D should adhere to the following principles.

- Improve medication use and outcomes for the beneficiaries served;
- Be specified at the right level of attribution and appropriate level of comparison considering pharmacy type;
- Factor in both pharmacy accountability and drug plan performance goals;
- Have clear specifications and be established prior to the measurement period;
- Be reliable, transparent and fair; and
- Use threshold minimums if appropriate.

NASP encourages CMS to ensure that any such measures, when considering pharmacy type, review the drugs being dispensed by such a pharmacy and the disease states being managed.

Future Star Ratings

CMS states that in the future, it may develop measures to consider for use in the Part D Star Ratings that, for example, assess Part D plan sponsors' uptake of a standard set of pharmacy performance measures or that evaluate the percent of high-performing pharmacies in the sponsors' pharmacy network. NASP strongly encourages CMS to move in the direction of developing star-level ratings to ensure Part D sponsors are utilizing standardized measures that are developed through a stakeholder consensus development process. To rely on a voluntary system of adoption is not satisfactory. We must ensure the effort to establish fair, transparent and standardized metrics is utilized and can truly assess pharmacy performance and provide helpful information to patients.

Permitting a Second, ''Preferred'' Specialty Tier in Part D (§423.104, §423.560, and §423.578)

The proposed rule would allow Part D plans to add a second specialty drug tier to plan formularies beginning January 2021. NASP is concerned that plans are already using the wide regulatory authority granted to them to steer patients to the lowest cost option available, often times without giving sufficient regard to specialty services and nuanced clinical requirements associated with the specialty drugs. For the Medicare patients who need a specific formulation of a drug, the six protected classes policy was intended to ensure that patients were able to access carefully prescribed and monitored medications. Yet, even with this protection, many

patients already must overcome restrictive barriers to access these necessary medications. NASP believes that, by adding a second specialty tier, plan sponsors may further undermine CMS' intention behind the six protected class regulation and restrict patient access to specialty medications. As such, the cost to Medicare would increase due to readmissions and adverse clinical outcomes.[1]

The Two Specialty Tier Model Will Increase Beneficiary Out-of-Pocket Expenses Due to Spread Pricing

The two specialty tier structure provides leverage for Part D sponsors to negotiate rebates for the preferred specialty tier; however, the proposed rule provides no incentive for such rebate amounts to be passed to beneficiaries at the point of sale. These rebates will likely increase the placement of expensive brand drugs onto the preferred specialty tier, while increasing expenditures for beneficiaries through cost sharing of such high cost brand named drugs. NASP believes that this outcome is contrary to other goals of the administration (expressed in prior publications and proposed rules) aimed at reducing drug rebates and ensuring that patients receive the benefit of rebates, rather than payers or PBMs.[2] The proposal for a second specialty tier would give the payers or PBMs more control without transparency in the process as they would seek to negotiate larger rebates on drugs that they considered placing in a preferred specialty tier. Rebates would grow and spread pricing could increase – again, something the administration has previously expressed a desire to rein in. Moreover, increases in cost-sharing, even if capped at 33%, will increase Medicare expenditures as beneficiaries reach catastrophic coverage more rapidly.

A Generic and Biosimilar-Only Preferred Specialty Tier Will Result in Increased Out-of-Pocket Expenses for Beneficiaries that Require Non-Preferred Specialty Drugs

A generic or biosimilar-only preferred specialty tier will not curb the prescribing of brand drugs, but it would rather risk increasing the price for such drugs and the overall cost to beneficiaries, such as through out-of-pocket cost sharing or premium increases. This cost shift could result in medication non-adherence, which can be fatal for specialty-related disease states and extremely costly for the Medicare program. Again, increases in cost-sharing, even if capped at 33%, will increase Medicare expenditures as beneficiaries reach the catastrophic coverage phase more quickly.

The Two Specialty Tier Model Will Increase Beneficiary Premiums

While the proposed rule would prohibit increases in cost-sharing for non-preferred specialty drugs under the two-specialty tiering structure, there would likely be a resulting increase in premiums. Maximum cost-sharing and tiering exception requirements could have a negative

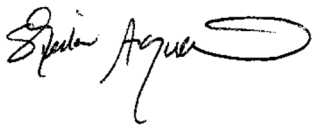
[1] *See* 84 Fed. Reg. 2340; Seema Verma, *Increasing Access to Generics and Biosimilars in Medicare*, Centers for Medicare & Medicaid Services (Feb. 05, 2020), https://www.cms.gov/blog/increasing-access-generics-and-biosimilars-medicare.
[2] *Id.*

impact on actuarial value and premiums. To retain actuarial equivalence, plan sponsors would alter other aspects of their formulary and benefit design. For example, offering lower cost-sharing on a preferred specialty tier may require plans to increase cost-sharing on other tiers. Plan sponsors may additionally shift these costs to consumers by increasing premiums. This increase could steer patients away from certain plans, even if these plans are otherwise best for addressing their specialty health care needs. This could ultimately result in additional costs to Medicare in the form of re-hospitalizations and adverse clinical incidents.

****

NASP greatly appreciates the opportunity to comment on the proposed rule for "Medicare and Medicaid Programs; Contract Year 2021 and 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". NASP looks forward to continuing to work with CMS on the issues addressed, specifically the standing up of a new pharmacy performance measure data and evaluation process and consensus-driven system for pharmacies and patients. Please contact Julie Allen at 202-494-4115 or Julie.allen@powerslaw.com if you have any questions regarding our comments or if we can provide additional information.

Respectfully submitted,



Sheila M. Arquette, R.Ph.
Executive Director