NATIONAL ASSOCIATION OF
SPECIALTY PHARMACY
300 New Jersey Avenue NW, Suite 900
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March 5, 2018

Demetrious Kouzoukas
Principal Deputy Administrator and Director, Center for Medicare
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

cc: Jennifer Wuggazer Lazio, F.S.A., M.A.A.A.
Director
Parts C & D Actuarial Group
Office of the Actuary
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

BY ELECTRONIC DELIVERY

Re: Advance Notice of Methodological Changes for Calendar Year (2019) for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter

Dear Mr. Kouzoukas:

The National Association of Specialty Pharmacy (NASP) appreciates this opportunity to submit comments on the Centers for Medicare & Medicaid Services' (CMS') 2019 Call Letter. NASP is a non-profit trade organization representing a wide range of stakeholders in the specialty pharmacy industry. NASP's membership includes the nation's leading independent specialty pharmacies (non-PBM owned), pharmaceutical and biotechnology manufacturers, group purchasing organizations, patient advocacy groups, integrated delivery systems and health plans, technology and data management vendors, wholesalers/distributors and practicing pharmacists. With over 100 corporate members and 1,200 individual members, NASP is the unified voice of specialty pharmacy in the United States.

NASP is the leading education resource for specialty pharmacists. Our mission is to elevate the practice of specialty pharmacy by developing and promoting continuing professional education and certification of specialty pharmacists. The association provides NASP University, an online education center offering 50 continuing pharmacy education programs, hosts an annual meeting that offers education sessions and

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continuing education credits, and is the only organization that offers a certification program for specialty pharmacists.

NASP advocates for public policies that ensure patients have appropriate access to specialty medications in tandem with critical support services because we represent an industry that focuses on providing quality patient care first with an added emphasis on clinical 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. Through this lens, NASP submits our comments below related to CMS' draft 2019 Call Letter.

I. Definition of Specialty Pharmacy

As an initial mater, NASP resubmits its definition of specialty pharmacy for CMS to incorporate into its oversight of network adequacy standards.[1] Current events continue to demonstrate the crucial role that specialty pharmacies play in the healthcare system. As new therapies continue to come to market with a greater emphasis on quality of care and outcomes, the specialty pharmacist is the caregiver that assures the physician, payer and PBM that the patient will maintain appropriate access while comforting the patient on their journey in managing their disease.

Below please find the definition of specialty pharmacy, which serves as the foundation of NASP's 2019 Call Letter comments, NASP's comments to the recently issued Proposed Part D Rule[2], and our overall advocacy efforts.

A. Definition of Specialty Pharmacy

As a result of the growth of specialty therapies, the practice of specialty pharmacy has also evolved. The expert services that specialty pharmacies provide drive adherence and persistency, proper management of medication dosing and side effects, and ensure appropriate medication use. The specialty pharmacy's patient-centric model is designed to provide a comprehensive and coordinated model of care for patients with chronic illnesses and complex medical conditions, achieve superior clinical and economic outcomes, and expedite patient access to care.

[1] See http://naspnet.org/nasp-news/
[2] 82 Fed. Reg. 56336 November 28, 2017.

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NASP defines a specialty pharmacy as a state-licensed pharmacy that solely or largely provides medications for people with serious health conditions requiring complex therapies. These include conditions such as cancer, hepatitis C, rheumatoid arthritis, HIV/AIDS, multiple sclerosis, cystic fibrosis, organ transplantation, human growth hormone deficiencies, and hemophilia and other bleeding disorders.

In addition to being state-licensed and registered, NASP believes that specialty pharmacies must be accredited by independent third parties and for network eligibility purposes demonstrate that they are accredited or in the process of accreditation.[3] Independent, third party accreditation[4] demonstrates a commitment to quality, safety, accountability, and adoption of nationally recognized standards of practice. Accreditation organizations help pharmacies develop rigorous performance measures, and verify patient-centered strategies for care, patient rights, communication and education. But most importantly, accreditation provides the general public with the understanding that the specialty pharmacy meets and /or exceeds the requirements for consumer protection, measures to ensure health information confidentiality, and access to specialty drugs that have been appropriately maintained.

Specialty pharmacies serve a critical role in the healthcare system because they connect patients who are severely ill with the medications that are prescribed for their conditions, provide the patient care services that are required for these medications, and support patients who are facing reimbursement challenges for these highly needed but also frequently costly medications. Specialty pharmacies do not establish the price of the specialty drug; rather, serve as a significant partner in driving the value of the drug by ensuring clinically appropriate, safe and effective use of specialty medications and successful therapeutic outcomes.

II. Comments to the 2019 Call Letter

On February 1, 2018, CMS issued its proposed changes for the Medicare Advantage (MA) and Part D Prescription Drug Programs (PDP) for 2019[5] with an overarching strategic goal of improving the quality of care and general health status for Medicare beneficiaries. NASP shares these goals with CMS and offers the following comments on the draft 2019 Call Letter in furtherance of these objectives.

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[3] NASP believes that the time to accreditation will become a standard condition of the AWP contract and therefore governed by the pharmacy and the PBM.
[4] For example, the current prominent accrediting bodies for specialty pharmacy are the Accreditation Commission for Health Care (ACHC), the Joint Commission, and URAC®.
[5] See https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2019Part2.pdf

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A. NASP Urges CMS to Prohibit The New Star Measures from Being Used to Collect DIR Fees from Specialty Pharmacies

CMS proposes adding two new measures to the 2019 Star Ratings which focus on statin use. The first measure is the "percentage of patients between 40 and 75 years old who received at least two diabetes medication fills and also received a statin medication during the measurement period."[6] The second measure focuses on the "percentage of males 21 to 75 years of age and females 40 to 75 years of age who were identified as having clinical atherosclerotic cardiovascular disease and were dispensed at least one high or moderate-intensity state medication during the measurement year."[7] NASP fully supports CMS adding these Star measures because each is important to a wide range of Medicare beneficiaries and should improve individual care. Historically, however, these types of measures serve as the foundation for PBMs to asses Direct or Indirect Remuneration (DIR) fees against pharmacies for failing to meet the required measure outcome. As the agency knows, PBMs are collecting DIR fees from specialty pharmacies that do not dispense these types of medications.[8]

NASP believes that CMS should finalize these two Star measures but as a guiding principle, CMS should state that any DIR or other post adjudication fee assessed to a specialty pharmacy be based on quality or performance measure that is reasonable and relevant to the patients being treated by and the medications being dispensed at the pharmacy. NASP therefore asks that CMS clearly state that these two Star measures fall within that principle and cannot be used as a reason to collect DIR fees from specialty pharmacies.

B. NASP Urges CMS to Expand Its Formulary Submission Requirements

The calendar year 2018 formulary submission window is from May 14, 2018 to June 4, 2018. During this timeframe each plan must submit a complete formulary as part of the plan's complete bid.[9] The formulary is a list of drugs that the plan covers with further details related to tiering and cost sharing for each of the covered drugs. In turn, CMS reviews each formulary to assure compliance with its "substantially all," minimum of two drugs per class and anti-discrimination requirements. NASP fully supports this

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[6] Id. at 107.
[7] Id.
[8] Medicare Part D—Direct and Indirect Remuneration, CMS (January 19, 2017), available at: https://www.cms.gov/newsroom/mediareleasedatabase/fact-sheets/2017-fact-sheet-items/2017-01-19-2.html.
[9] Id. at 193.

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process as it attempts to provide all Medicare beneficiaries with access to clinically appropriate medications.

As NASP stated in previous comments to Draft Call Letters, Part D Rulemaking, and in meetings with the agency, NASP believes, however, that this process does not go far enough to ensure access to needed medications. Just because a plan submits a formulary does not mean the Medicare beneficiary has timely and appropriate access to all therapies listed on the formulary. Rather, the beneficiary still needs to find an in-network specialty pharmacy that can fill a prescription for that specialty therapy. Not every specialty therapy is available at every specialty pharmacy.

In other words, for a specialty therapy, as defined above, accessing the specialty therapy is not as simple as using one of the many local retail chain pharmacies. Instead, the prescription must be sent to a specialty pharmacy that is in-network with both the manufacturer and the payer. As such, NASP urges CMS to require each plan sponsor to submit each specialty pharmacy or pharmacies that it has in- network for each of the formulary drugs within the oncology, immunomodulators, multiple sclerosis, HIV/AIDS, HepC and immunosuppressant classes. By doing so, CMS will know which specialty pharmacies are in-network by drug and can therefore truly determine if each Medicare beneficiary enrollee has access to each of the formulary's specialty drugs. By adopting this process, the agency will also have greater visibility into the network adequacy of each plan. This visibility will help CMS ensure that each Medicare beneficiary will truly have access to their needed specialty medications regardless of the plan he or she chooses.[10]

In turn, CMS can then provide this information on its plan finder website creating greater transparency for providers and beneficiaries when selecting a health plan as they will now know their in-network specialty pharmacy. As such, when the beneficiary researches the most appropriate plan for their needs, he or she will know which specialty pharmacy is in-network for their specialty medication. Additionally, the physician's office will also know which specialty pharmacy is in network for the drug and can immediately send the prescription to the appropriate in-network pharmacy.

By ensuring that each plan has an in-network pharmacy by specialty drug, CMS could help reduce overall health costs for the following two reasons. First, the Medicare

[10] 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 the formulary is part of the plan's complete bid, it seems to reason that the Secretary can require each plan to submit its in-network specialty pharmacy by specialty drug as part of the bid process.

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beneficiary will always be getting the financial benefit of accessing an in-network pharmacy as compared to an out-of-network pharmacy. Second, administrative costs will be reduced as the specialty pharmacy will not have to spend time and resources transferring the prescription to an in-network specialty pharmacy. This simple administrative requirement of the sponsor will greatly improve transparency for Medicare beneficiaries while potentially reducing their out-of-pocket costs. Similarly, NASP believes that plan sponsors should notify the agency of changes to the specialty pharmacy network in order to monitor and make sure that beneficiaries have continued access to specialty drugs throughout the plan year.

C. The Specialty Tier is Misnamed and Disadvantages the Most Vulnerable Medicare Beneficiaries

Since the launch of the Part D program, CMS has permitted sponsors to design its exception process so that very high cost or unique drugs are not eligible for a tiering exception. Only Part D drugs with sponsor-negotiated prices that exceed an established dollar-per-month threshold are eligible for specialty tier placement and therefore exempt from the tiering exception process. The current cost threshold is $670 for calendar year 2018, which the agency proposes to maintain for 2019.[11]

As stated above, NASP believes that the majority of specialty drugs are so designated in part because of their costs but also in larger part because of the services required to support and maintain appropriate access to that drug. When a prescription for a specialty drug is adjudicated on the specialty tier this typically results in a significant co-insurance obligation for the Medicare beneficiary, especially in the beginning of each calendar year. The Medicare beneficiary often needs further financial assistance to pay for the drug. So, in addition to worrying about managing their disease, the beneficiary must now also worry about managing their co-insurance obligation. The specialty tier policy adds to the beneficiary's stress by shifting a dramatic portion of cost of the therapy to them. This is what our specialty pharmacists experience with each of these vulnerable patients as we work with them and their families to help bridge this stressful financial gap to help ensure timely access to the therapy.

NASP therefore respectfully requests that CMS either dramatically increase the dollar per month threshold or eliminate the tier. Relative to the overall size of the Medicare population, very few Medicare beneficiaries require a specialty tier drug, yet they absorb a significant out-of-pocket cost for utilizing this type of drug. NASP believes that this is not what Congress intended in providing an insurance benefit to its Medicare

[11] Id. at 202.

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beneficiaries. The concept of insurance is to spread risk amongst a large population, not to focus costs of an unforeseen event on a select few. In fact, NASP believes that eliminating the specialty tier and spreading this specialty drug expense throughout the general Medicare population may cost as little as one dollar per month per enrollee. This is why insurance exists, to spread the risk of catastrophic events over a large population. What Medicare enrollee wouldn't pay one extra dollar per month to ensure itself against the costs of the co-insurance of a specialty drug?

In the alternative, since CMS has established the specialty tier based exclusively on cost, NASP suggests that CMS change the name of the specialty tier to "high cost tier," or something similar, which is a much more accurate reflection of the criteria for inclusion. By changing the name, the agency will help further create this distinction and can then further drill down on what product support services each plan sponsor is providing in support of specialty drugs, for example adherence and compliance programs, disease education materials and administrative support.

In fact, NASP urges CMS to consider requiring plan sponsors to disclose the nature and type of product support services that it or its downstream providers are providing for each of the specialty drugs. Without these services, such as adherence and compliance programs, beneficiary compliance can be inconsistent and disjointed which negatively impacts outcomes and usually increases overall cost of care. Therefore, NASP believes that the disclosure of these programs by the plan sponsors to the agency will help the agency further distinguish between just high cost and specialty drugs, reduce overall healthcare costs, and improve health outcomes. Finally, the list of product support services could serve as the foundation for future quality measures within the Part D program.[12]

D. NASP Urges CMS To Maintain Current Policy for its Mail Order Consent Policy for Specialty Therapies

Since January 1, 2014, Part D sponsors of non-EGWP plans have obtained consent from beneficiaries prior to shipping refills of mail-order prescriptions. NASP appreciates CMS' current policy but also supports the agency's efforts to improve medication adherence while also trying reduce waste. As stated above, specialty pharmacies have a different business model from retail and mail order pharmacies,

[12] 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." Similar to above, since the specialty tier is part of the formulary which is also part of the plan's complete bid, it seems to reason that the Secretary can require each plan to submit its product support services by specialty drug as part of the bid process.

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especially as it relates to patient engagement. Because of the type of patients we serve and the medications we dispense, specialty pharmacies are in constant contact with the patient and their physician. As a result of this high touch model and white glove service, specialty pharmacies know when to dispense medications in order to ensure continuity of care. Specialty pharmacies document the patient's verbal consent for a medication refill during one of the frequent encounters in the overall care for the patient. This is done as a matter of good practice, policy and patient care.

As such, should CMS alter its current refill policy, NASP urges CMS to consider the many different and appropriate pharmacy practices that occur on behalf of Medicare beneficiaries. In doing so, NASP believes that CMS must carefully balance administrative burden with beneficiary need for compliance and adherence, especially for specialty medications.

III. Conclusion

NASP greatly appreciates the opportunity to comment on CMS' Draft 2019 Call Letter. NASP looks forward to continuing to work with CMS to ensure that Medicare beneficiaries have access to critical medications. 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.

Respectfully submitted,

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