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Sean Cavanaugh
Deputy Administrator & Director
Center for Medicare
Centers for Medicare & Medicaid Services
Department of Health and Human 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

BY ELECTRONIC DELIVERY

Re: Advance Notice of Methodological Changes for Calendar Year (2017) for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2017 Call Letter

Dear Deputy Administrator Cavanaugh:

The National Association of Specialty Pharmacy (NASP) appreciates this opportunity to submit comments on the Centers for Medicare and Medicaid Services' (CMS') 2017 Call Letter. NASP is a non-profit trade organization representing a wide range of stakeholders in the specialty pharmacy industry. NASP has 71 corporate members and 1,200 individual pharmacists making it the leading unified voice of specialty pharmacy. Our members include the nation's leading independent specialty pharmacies, 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. NASP is also 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 27 education sessions, 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. Through this lens, NASP submits our comments below related to CMS' draft 2017 Call Letter.

I. Definition of Specialty Therapy and Specialty Pharmacy

For the past several months, the NASP membership has focused on developing definitions of both a specialty drug and a specialty pharmacy. Below please find the definitions of both, which serves as the foundation of NASP's comments and overall advocacy efforts. The definitions share the significant theme of high touch patient services. For example, a specialty drug is defined by the many services provided in support of appropriate access, and a specialty pharmacy is the state licensed and third party accredited entity providing those high touch patient services.

A. Definition of Specialty Therapy

Specialty drugs, or medications, are more clinically complex than most prescription medications and are used to treat patients with serious and often life threatening conditions including cancer, hepatitis C, rheumatoid arthritis, HIV/AIDS, multiple sclerosis, cystic fibrosis, organ transplantation, human growth hormone deficiencies, hemophilia and other bleeding disorders. Because of the complex clinical profile, intensive and extensive patient engagement by the specialty pharmacist is required. For example, many specialty therapies require significant patient education on both the disease and the prescribed therapy. Many specialty pharmacists have specialized areas of clinical expertise, which the prescribing physician relies upon to help explain the nature of the disease. Furthermore, this pharmacist then explains to the patient the prescribed regimen for the prescribed drug. It is through these services that the specialty pharmacist acts as an extension of the physician's office to educate the patient on his/her disease and empowers the patient to use the therapy appropriately. This education is a very important part of improving beneficiary outcomes and reducing unnecessary drug spend.

Further, the specialty therapy may be classified as such due to the way it is administered, the side effect profile, the disease or condition it is used to treat, special access conditions required by the manufacturer, payer authorization or benefit requirements, patient financial hardship, special handling, or any combination of these. Based on these characteristics, the payer, provider, specialty pharmacy and/or the manufacturer can or will identify the therapy as requiring the aforementioned specialized services. As a result, specialty prescription medications cannot be routinely dispensed at a typical retail community pharmacy because the typical retail pharmacy is not designed to provide the patient care or other support services that specialty medications require. Lastly, specialty drugs are often confused as being

only a "limited distribution drugs (LDD)". This is not the case as there are specialty drugs that are not part of a limited distribution network.

Cost should not be the only reason a therapy is classified as specialty. In fact, there are many low cost therapies that are classified as specialty because of the unique and labor intensive services required to assure proper utilization and maximize the clinical outcome. For example, select generic oral chemotherapy medications and certain generic immunosuppressant medications require special handling processes and a comprehensive, coordinated care approach to ensure successful therapeutic outcomes similar to those of higher cost therapies. Even though these therapies are low cost, they are still considered specialty therapies by plan sponsors. A therapies classification should be based on the services provided in support of the therapy and not just its cost.

B. 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.

A specialty pharmacy is 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 regulated, NASP believes that specialty pharmacies should also be accredited by independent third parties. Accreditation represents a commitment to quality, safety and accountability.

Accreditation organizations help pharmacies develop their specialty pharmacy capacity and verify their capabilities to manufacturers and third-party payers. The prominent accrediting bodies are URAC®[1], the Accreditation Commission for Health Care (ACHC)[2], the Center for Pharmacy Practice Accreditation (CPPA)[3] or the Joint Commission.[4] Each of these organizations create standards that are designed to create a consensus around the practice of specialty pharmacy and guide the accreditation process In general, the standards can address four primary areas of specialty pharmacy practice, which encompass the overall provision of pharmacy care for patients receiving these medications. These areas of focus include the

[1] https://www.urac.org/accreditation-and-measurement/accreditation-programs/all-programs/specialty-pharmacy/
[2] http://www.achc.org/programs/pharmacy/pharmacy-accreditation-process
[3] https://pharmacypracticeaccredit.org/our-programs/specialty-pharmacy-practice-accreditation-program
[4] http://www.jointcommission.org/accreditation/accreditation_main.aspx

organizational infrastructure to support the provision of specialty pharmacy care, patient access to medications via manufacturer requirements and benefits investigation, clinical management of the patient, and quality. The accreditation process further ensures that Medicare beneficiaries receive consistent quality of care.

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, but are a significant partner in driving the value of the drug towards a successful therapeutic outcome.

II. **Comments to the 2017 Call Letter**

On February 19, 2016, CMS issued its proposed changes for the Medicare Advantage (MA) and Part D Prescription Drug Programs (PDP) for 2017[5] with a "commitment to making both programs high quality options for all Medicare beneficiaries."[6] NASP shares these goals with CMS and offers the following comments on the draft 2017 Call Letter.

A. NASP Urges CMS to Expand Its Formulary Submission Requirements

The calendar year 2017 formulary submission window is from May 16, 2016 to June 6, 2016. During this timeframe each plan must submit a complete formulary as part of the plan's complete bid.[7] 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 process as it attempts to provide all Medicare beneficiaries with access to clinically appropriate medications.

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 that therapy. 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

[5] See https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2017.pdf
[6] https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-02-19.html
[7] Draft Call Letter at page 178.

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.[8]

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 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.

B. NASP Supports CMS Proposed Policy Related to Improving Clinical Decision Making for Certain Part D Coverage Determinations

As mentioned above, the specialty pharmacist plays a critical role in helping the patient and physician navigate a prior authorization process and/or manage step therapy edits. Often the specialty pharmacy coordinates the submission of the clinical documentation in support of the prescribed therapy. As such, we have firsthand knowledge of how burdensome and time consuming this process can be and therefore support the agency's efforts to improve the overall coverage determination process.

By way of background, the Medicare Part D program requires a plan sponsor to notify the enrollee of its coverage determinations no more than 72 hours from receipt of the request

[8] 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.

for standard requests for benefits, and no more than 24 hours from receipt of the request for an expedited requests for benefits. The regulations further provide that a decision to deny the coverage request based solely on the lack of clinical information places the burden on the enrollee to request an appeal in order to have the request reviewed on its merits based on appropriate clinical documentation. NASP shares the agency's concerns that not permitting Part D plans to extend the coverage determination timeframe in certain limited situations may result in increased program costs and patient confusion due to the fact that all redeterminations related to medical necessity must be made by a physician.

CMS states that any regulatory proposal that addresses this situation would require the sponsor to provide written notification to the enrollee whenever an extension is taken. NASP appreciates the spirit of the proposal in that the enrollee has a clear understanding of the process going forward. NASP, however, provides the following example of how this proposal may actually confuse the enrollee under this requirement.

For example, the sponsor receives a coverage determination request late on a Friday afternoon and immediately determines that it does not have all the information it needs to make a determination. Due to the timing of the submission of the request and availability of the prescriber or lack thereof, the sponsor decides to extend the time frame. If the sponsor is required to send written notification of its decision to extend the timeframe to the beneficiary, it prepares the written notification to the enrollee and mails it late Friday evening or Saturday morning. Then on Monday morning the sponsor is able to obtain the required information from the prescriber and issues either an approval or adverse determination. The sponsor then contacts the beneficiary by phone to notify the enrollee of the decision. The next day the enrollee, however, receives the sponsor's letter stating that the sponsor is extending the adjudication time frame. The beneficiary is now confused as to which communication is accurate. NASP understands that the agency wants to keep the enrollee updated and informed, but this new process could actually be more harmful than helpful and therefore urges the agency to proceed cautiously with any new written notification requirements.

CMS is seeking input on the following proposals that would permit Part D plans to extend the adjudication timeframe for certain coverage determination requests for drugs subject to prior authorization or step therapy where: (1) the plan has been unable to obtain needed clinical information from the prescriber despite reasonable efforts to do so, and (2) the adjudication timeframe has been impacted by a weekend or holiday.[9] NASP believes that these proposals provide the necessary flexibility for the health plan to ensure appropriate access, however, NASP urges the agency to install appropriate safeguards as a safety net to this flexibility to ensure that access is not unnecessarily delayed as a result of this new policy. For example, NASP believes that the agency should provide examples of what it understands the meaning of "reasonable efforts" is as it relates to outreach to the physician. Are reasonable efforts defined in terms of how many times the outreach occurred and/or what was the mode of outreach? Is it via phone? Email? Second, NASP agrees with CMS' philosophy that changes to

[9] Draft Call Letter at page 184.

the extension policy must only occur when it is in the best interest of the beneficiary and therefore asks CMS to consider how long the extension can be if the adjudication has been impacted by a weekend/holiday or both. It seems that the agency can limit the length of this extension to only a few days post-holiday/weekend. By doing so, CMS provides the flexibility the plan needs but also assures timely beneficiary access to needed medications.

As the agency prepares for rulemaking on the issues of notification timeframes, NASP provides the following general comments. First, NASP also urges CMS to consider not starting the clock start with respect to timeframes until the start of the next business day for a coverage determination request submission that occurs after normal business hours. Sometimes a physician's office may not be able to submit this type of request during the day or it may submit the request on a weekend. Under those circumstances it can be very challenging for the plan sponsor to obtain the information needed from the physician to make a determination. As such, NASP believes that starting the timeframe clock the next day is more reasonable, which in turn could reduce the number of unnecessary adverse determinations.

Second, NASP suggests that the adjudication timeframes change to business days from hours, in other words to 3 business days instead of 72 hours and that business day be defined as 8am-8pm east coast standard time. Under these new definitions, requests received after the end of the business day, on a weekend or a recognized holiday would be documented as received the next business day for the purposes of determining timeliness. This would accommodate late in the day submissions as well as weekends and holidays and reduce the number of inappropriate adverse determinations that are rendered. NASP appreciates CMS' willingness to create greater flexibility for plan sponsors while reducing beneficiary confusion.

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 <u>not</u> 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 of $600 was established in calendar year 2008 and now the agency proposes a $670 cost threshold for calendar year 2017.

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 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?

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. As we discussed above, there is a difference between a specialty medication and a high cost medication. 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.[10]

D. NASP Supports CMS' Proposal to Allow Sponsors to Cover Up to a One Month Supply Under Certain Circumstances

Starting in 2017, CMS proposes to permit plan sponsors to have the option to indicate if any drugs are available for an extended days' supply on all but the first fill. CMS states, and

[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." 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.

NASP agrees, that this change provides an opportunity to limit drug waste when a new therapy is not working for the patient or has adverse effects. As mentioned above, this is a routine patient service provided by the specialty pharmacy. Typically, shortly after the new specialty prescription is filled, the specialty pharmacist checks in with the patient and not the physician. In doing so, the specialty pharmacist can encourage compliance, coach the patient through side effects, and/or preliminarily judge the drug's effectiveness. With this information the specialty pharmacist communicates with the provider to help further coordinate the care for the beneficiary. In fine tuning this proposal, CMS may consider limiting this option to those specialty therapies with a high incidence of side effects and/or to patients that are new to this therapy in addition to being a new prescription. Some policies may require renewal prescriptions for a tolerated therapy such that a first fill may be inappropriate. In general, NASP supports this proposal because it can reduce waste and improve overall quality of care

III. Conclusion

NASP greatly appreciates the opportunity to comment on CMS' Draft 2017 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 (631) 793-6388 if you have any questions regarding our comments. Thank you for your attention to this very important matter.

Respectfully submitted,

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NASP