National Association of Specialty Pharmacy
April 2016

Summary of 2017 Medicare Part D Final Call Letter

On April 4, 2016, the Centers for Medicare & Medicaid Services (CMS) issued the 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter.[1] On March 4, 2016 the National Association of Specialty Pharmacy (NASP) submitted comments to CMS' draft Call Letter[2] that suggest changes to the Part D program that could enhance Medicare beneficiary access to specialty therapies.[3] Below please find a summary of NASP's comments and CMS' responses.

[1] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2017.pdf
[2] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2017.pdf
[3] https://d2gegc87xuuo99.cloudfront.net/web/NASP_SITE/NASP-CMS-2017CallLetter-Comment-FinalFull.pdf

Issue	Draft Call Letter	NASP Comments	Final Call Letter
Definitions of Specialty Therapy and Specialty Pharmacy	CMS did not address this in draft Call Letter.	NASP submitted its definitions of specialty therapy and specialty pharmacy.[4]	CMS did not respond to NASP's definitions.
Formulary Submission Requirements	The draft Call Letter requires health plans to submit its formulary between May 6 and June 6, 2016.	NASP urged CMS to require health plans to disclose each in-network specialty pharmacy for each therapy within the oncology, immunomodulators, multiple sclerosis, HIV/AIDS, HepC and immunosuppressant classes.	CMS did not address this comment in the Final Call Letter.
Improved Clinical Decision Making for Certain Part D Coverage Determinations	CMS asked for 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.	NASP supported this proposal and further urged CMS 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 stated that CMS should provide examples of what it understands the meaning of "reasonable efforts" is as it relates to outreach to the physician.	"After review of all comments submitted, CMS does not intend to move forward with any proposed regulatory changes for extensions in Part D at this time. As we stated in the draft Call Letter, we recognize the challenge posed by the short adjudication timeframes for plans to successfully obtain needed information from prescribers and provide a fully informed decision within the timeframe. However, we agree with the commenters who noted that written notice of the extension—an important beneficiary protection—would not be

[4] http://www.prweb.com/releases/2016/02/prweb13234685.htm

		NASP also suggested 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.	feasible, and that the limitations we suggested could be confusing for plans, beneficiaries and prescribers, and difficult for plans to implement and oversee effectively. We also agree with the numerous commenters who expressed concerns about making broader changes to adjudication timeframes, including a more expansive extension opportunity, given the more immediate need for access to drug therapy and that fact that coverage must be approved before the enrollee can access the drug."[5]
Renaming the Specialty Tier and Increasing the Threshold	CMS proposes to increase the threshold from $600 to $670.	First, NASP suggested 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	CMS finalized its $670 proposal and did not further address any other NASP comment on this issue.

[5] Final Call Letter page 193.

		inclusion. Second, NASP respectfully requested that CMS either dramatically increase the dollar per month threshold or eliminate the tier because of its dramatic effect on out of pocket cost sharing for Medicare beneficiaries.	
Providing One Month Supply	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.	NASP supported this proposal and added that CMS should consider limiting this option to those specialty therapies with a high incidence of side effects and/or to patients that are new to the particular therapy.	CMS finalized its proposal stating that "starting in 2017, plan sponsors will now also have the option to indicate in the plan benefit package (PBP) at the tier level if any drugs are available for an extended days' supply on all but the first fill. This change allows sponsors to designate drugs where they will only cover up to a one month supply the first time the drug is filled, providing an opportunity to limit drug waste when a new therapy is not working for the patient or has adverse effects."[6]
MTM Annual Cost Threshold	CMS finalized the cost threshold of $3,919 for 2017. Targeted beneficiaries for a Part D plan's MTM program, in general, are enrollees who meet all of the following criteria: have multiple chronic diseases, are taking multiple Part D drugs, and are likely to incur annual Part D drug costs that meet or exceed a certain threshold.		
Mail Order Pharmacies	"CMS has received beneficiary complaints about mail order pharmacies indicating that they will rush ship an urgently needed order, but the order does not arrive when promised or at all, potentially resulting in gaps in therapy. To protect beneficiaries from inconsistent or unreliable practices that may jeopardize timely access to medications, CMS expects Part D sponsors to work with their mail order pharmacies to develop and		

[6] Id. at 220.

	implement protocols for providing access to urgently needed medications. Further, beneficiaries should be informed of their options when requesting a rush order, with clear steps detailed in all applicable beneficiary materials. Having established protocols and beneficiary information in place can streamline how sponsors respond to such needs. We expect sponsors to have protocols in place to address how to handle urgently needed medication requests from beneficiaries by CY 2017 if not sooner and to be able to clearly communicate this to their beneficiaries. We will continue to monitor complaints for issues related to mail order or access to urgently needed medications."[7]

[7] Id. at page 221.