March 6, 2015

Sean Cavanaugh
Deputy Administrator
Centers for Medicare & Medicaid Services
Director, Center for Medicare

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

Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2016 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2016 Call Letter ("Draft 2016 Call Letter")

Dear Mr. Cavanaugh & Ms. Lazio:

On behalf of the National Association of Specialty Pharmacy (NASP), we appreciate this opportunity to submit comments to CMS' Draft 2016 Call Letter. NASP represents the largest stakeholders in the specialty pharmacy industry, including specialty pharmacies, pharmaceutical manufacturers, payers (PBM's), and others. Our members, who handle the majority of specialty medications in the U.S., stand ready to work with CMS in planning for the 2016 benefit year and share the agency's goal of providing equal and appropriate access to specialty medications. We believe that the complexities of the marketplace as shown by identifying the issues below are worthy of CMS attention and our involvement.

The need for better understanding regarding preferred or narrow networks and their potential adverse outcomes to Medicare beneficiaries and the industry as a whole is urgent. NASP's goal is to provide information to support CMS as you consider these, and other issues that may reduce access for patients. We believe this information and our involvement will help to ensure CMS policies are consistently enforced and requirements are met for all specialty therapies.

Some NASP members are concerned that the Medicare Part D market is moving quickly toward a narrower network strategy that will limit Medicare beneficiary access to specialty medications in the six protected classes. The number of patients impacted by this potential change is significant. Specialty pharmaceuticals currently represent approximately 40 percent of the U.S. prescription drug expenditures and that percentage is expected to increase in the coming years. The patients treated by these medications are typically seriously ill and depend on ready access to specialty drugs and biologics in the six protected classes.

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The 2016 Call Letter describes the agency's two pronged approach related to Preferred Cost Sharing Pharmacies (PCSPs). Currently, CMS evaluates Part D sponsor retail networks against TRICARE standards[1] in which no distinction is made between standard cost sharing and preferred cost sharing pharmacies. In the spring of 2014, CMS initiated a study, to calculate plan-level beneficiary access to PCSPs. The study found that some beneficiaries residing in all types of geographic areas, but particularly in urban areas, face limited or, in some instances, no access to PCSPs. For instance, the study showed that, of the 641 plans with PCSP networks that do not meet the urban access standard (constituting 54% of all plans), 103 provide access to a PCSP within 2 miles of a beneficiary's urban residence to less than 30% of beneficiaries (33 of those plans provide such access to less than 10% of beneficiaries). The remaining 538 plans in this category provided PCSP access within 2 miles of their residence to between 31% and 89% of urban beneficiaries in their service area.[2]

Because of this, CMS is concerned that beneficiaries residing in areas of low access to PCSPs may be unable to obtain the lower cost sharing as advertised in plan materials. In response, CMS is taking these actions. First, CMS will publish information on PCSP access levels for each plan offering a preferred cost sharing benefit structure. Second, CMS will work with plans whose PCSP networks are outliers (i.e., the bottom 10th percentile compared to all Part D plans in given geographic type) to either increase access to PCSPs in those areas or prevent plans from marketing themselves as offering preferred cost sharing in areas where the benefit is not meaningfully available. NASP supports this two-pronged approach as it is the first step in ensuring that Medicare beneficiaries have access to the therapies they need.

In this regard, many of our members were troubled by the lack of timeliness and substance of plan communications to Medicare beneficiaries at the end of 2014 related to the narrowing of pharmacy networks heading into 2015. Unfortunately, at the end of 2014 some Medicare beneficiaries who require specialty therapies that are not accessible at retail pharmacies and only available via mail order received only 30 days notice that their current specialty pharmacy will no longer be in network starting in 2015. NASP is concerned that the short timeframe provided to beneficiaries and the new smaller network will result in ongoing disruptions to drug therapy for serious medical conditions such as cancer, multiple sclerosis and rheumatoid arthritis. It seems inconsistent to NASP that Medicare is concerned about the effect that narrow networks have on those drugs accessed via a retail

[1] The minimum standard for pharmacy [preferred or non-preferred] network access, based on the

[2] 2016 Call Letter at p.149.

pharmacy, yet seems to not be equally concerned about appropriate network access for specialty drugs. NASP urges CMS to treat both channels equally and require health plans to give beneficiaries and their physicians at least 60 days notice regarding a switch of in network pharmacy at the beginning of a calendar year.

A second and equally important issue related to assuring appropriate access to the right pharmacy is CMS' representation of which pharmacies a beneficiary can access a limited distribution specialty drug on Medicare's Plan Finder website. Currently, many Medicare beneficiaries use this website to choose a prescription drug plan. Under the circumstance in which the beneficiary enters his/her specialty drug to locate an in-network pharmacy, the search results are usually inaccurate, if not misleading. Specialty medications almost always require special handling and administration, as well as extensive, in-depth patient management. As a result, these medications are typically available only through a select group of pharmacies that have the required expertise and patient management capabilities and are often specially accredited. Unfortunately, based upon NASP research, those pharmacies are **NOT** usually listed on the website, rather, only the in-network retail pharmacies are listed. As such, the Medicare beneficiary is being misled into thinking that a much-needed specialty drug is available at a local retail pharmacy. This is usually not the case.

NASP urges CMS to update its Plan Finder website with in-network information for specialty pharmacies. CMS can obtain this information from the manufacturers and health plans via the bidding process. NASP is very concerned that as specialty drugs continue to dominate the market, the norm will be that Medicare beneficiaries are misled by CMS' own website.

Effective January 1, 2016 new regulations will be in effect governing the timeliness and format of drug pricing between the Plan sponsor and the pharmacy. These new regulations were finalized early in 2014 and NASP appreciated that CMS is using the 2016 Call Letter to caution Part D sponsors that updates of MAC prices must be disclosed to network pharmacies in a manner that is usable by pharmacies in order for them to validate prices and assure appropriate access.

NASP appreciates the opportunity to submit these targeted comments. We look forward to working with CMS to assure that Medicare beneficiaries have timely access to specialty therapies and that those beneficiaries have the appropriate information available to them to select the best plan for their needs. Jayson Slotnick, NASP's health policy advisor (jslotnick@naspnet.org) or (202) 253-8780 with questions.

Sincerely yours,

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Cc: Jayson Slotnick, NASP Health Policy Advisor