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BY ELECTRONIC DELIVERY

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

cc: Jennifer Wuggazer Lazio, F.S.A., M.A.A.A.
Director
Parts C & D Actuarial Group
Office of the Actuary

Re: 2017 Transformation Ideas in Response to Final Part D Call Letter's Request for Information (RFI)

Dear Ms. Verma:

The National Association of Specialty Pharmacy (NASP) appreciates this opportunity to submit comments to the Centers for Medicare & Medicaid Services' (CMS') Request for Information (RFI) contained in the 2018 Final Call Letter.[1] NASP is a non-profit trade organization representing a wide range of stakeholders in the specialty pharmacy industry. NASP has 104 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, specialty pharmacies affiliated with health plans and hospitals, 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. With this guiding principle, NASP is 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 education sessions and continuing education credits, and operates a certification program for specialty pharmacists.

[1] Centers for Medicare & Medicaid Services (CMS), Announcement of Calendar Year (CY) 2018 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter and Request for Information (Apr. 3, 2017), available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2018.pdf

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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' RFI knowing that should the agency implement the changes below, cost of care will decrease while quality of care for Medicare beneficiaries will improve.

I. Background:

NASP share's CMS commitment to maintaining benefit flexibility and efficiency throughout the MA and Part D programs. NASP believe that the following recommendations could be implemented within the law and will increase benefit flexibility, innovation and more affordable plan choices for beneficiaries.

A. NASP Urges CMS to Expand Its Formulary Submission Requirements

The calendar year 2018 formulary submission window is from May 17, 2017 to June 5, 2017. During this timeframe each plan must submit a complete formulary as part of the plan's complete bid.[2] 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.

As NASP stated in previous comments to Draft Call Letters 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 drug is available at every specialty pharmacy.

In other words, for a specialty drug, as defined below, accessing the specialty drug 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.

[2] Id. at 141.

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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 specialty 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.[3]

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 Urges CMS to Expand its Network Adequacy Requirements to Protect Beneficiary Access to Specialty Drugs

Similar to retail, mail, home infusion and LTC pharmacy, NASP believes that health plans should be required to have a certain number of specialty pharmacies in network by specialty

[3] 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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drug, including but not limited to the oncology, immunomodulators, multiple sclerosis, HIV/AIDS, HepC and immunosuppressant classes. NASP believes that current laws provides CMS with the authority to implement NASP's proposal.

Section 1860D-4(b)(1)(C) of the Social Security Act (SSA) states:

> (C) Convenient access for network pharmacies.—
>
> (i) In general.—The PDP sponsor of the prescription drug plan shall secure the participation in its network of a sufficient number of pharmacies that dispense (other than by mail order) drugs directly to patients to ensure convenient access (consistent with rules established by the Secretary).
>
> (ii) Application of tricare standards.—The Secretary shall establish rules for convenient access to in-network pharmacies under this subparagraph that are no less favorable to enrollees than the rules for convenient access to pharmacies included in the statement of work of solicitation (#MDA906-03-R-0002) of the Department of Defense under the TRICARE Retail Pharmacy (TRRx) as of March 13, 2003.
>
> (iii) Adequate emergency access.—Such rules shall include adequate emergency access for enrollees.
>
> (iv) Convenient access in long-term care facilities.—Such rules may include standards with respect to access for enrollees who are residing in long-term care facilities and for pharmacies operated by the Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations (as defined in section 4 of the Indian Health Care Improvement Act).

Based on this provision, CMS has the authority to require a certain number of SPs in network in order to provider Medicare beneficiaries with convenient access and choice to specialty drugs. The number of specialty pharmacies per drug should vary and fulfilling the requirement should exclude specialty pharmacies that are owned by a PBM.

C. NASP Urges CMS to Define Specialty Drug in Order to Protect Beneficiary Access to The Specialty Drug and Choice of Specialty Pharmacy to Dispense the Specialty Drug

As stated in NASP's previous comments to proposed Part D Call Letters, specialty drugs, or medications, are more clinically complex than most prescription medications and are used to

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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 drugs 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 drug 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 drugs. Even though these therapies are low cost, they are still considered specialty therapies by plan sponsors. A drugs' classification should be based on the services provided in support of the therapy and not just its cost.

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i. CMS' Authority to Define Specialty Drug

Current law, SSA §1860-2(e), defines a covered Part D drug as:

> "Covered Part D Drug Defined.—
>
> (1) In general.—Except as provided in this subsection, for purposes of this part, the term "covered part D drug" means—
>
> (A) a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i), (A)(ii), or (A)(iii) of section 1927(k)(2); or
>
> (B) a biological product described in clauses (i) through (iii) of subparagraph (B) of such section or insulin described in subparagraph (C) of such section and medical supplies associated with the injection of insulin (as defined in regulations of the Secretary),
>
> and such term includes a vaccine licensed under section 351 of the Public Health Service Act (and, for vaccinations administered on or after January 1, 2008, its administration) and any use of a covered part D drug for a medically accepted indication (as defined in paragraph (4))."

NASP therefore believes that CMS has the authority to further define covered Part D drug to create a subset of drugs entitled, "Specialty Drugs" for the purposes of ensuring appropriate access to these therapies for Medicare beneficiaries. This definition is a critical first step to ensuring beneficiary access to these lifesaving classes of Covered Part D drugs.

D. **NASP Urges CMS to Define 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

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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®[4], the Accreditation Commission for Health Care (ACHC)[5], the Center for Pharmacy Practice Accreditation (CPPA)[6] or the Joint Commission.[7] 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 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.

E. **NASP Urges CMS To Update its Any Willing Pharmacy Requirements**

Current AWP contracts neither promote competition nor advance care for Medicare beneficiaries because the contracts contain provisions that are not related to cost sharing, do not seek to broaden the network, and are not sensitive to the beneficiaries being served. CMS states that the standard provisions of the AWP contract must be "reasonable and relevant" to participate in the PBM's network. NASP believes that standard is insufficient and urges CMS to focus on the beneficiary by requiring PBMs to demonstrate how each of the AWP provisions

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

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complies with CMS' goal of broadening and ensuring appropriate access and are reasonable and relevant to the population of Medicare beneficiaries that the contracting specialty pharmacy serves.

Current law provides that any willing pharmacy must have access to the network if it meets the terms and conditions of the plan. Specifically, §1860D-4(b) states"

> "Access to Covered Part D Drugs.—
>
> (1) Assuring pharmacy access.—
>
> (A) Participation of any willing pharmacy.—A prescription drug plan shall permit the participation of any pharmacy that meets the terms and conditions under the plan.
>
> (B) Discounts allowed for network pharmacies.—For covered part D drugs dispensed through in-network pharmacies, a prescription drug plan may, notwithstanding subparagraph (A), reduce coinsurance or copayments for part D eligible individuals enrolled in the plan below the level otherwise required. In no case shall such a reduction result in an increase in payments made by the Secretary under section 1860D-15 to a plan."

CMS has further defined the clause "terms and conditions" to require the terms and conditions to be "reasonable and relevant" for network participation.[8] NASP believes that the agency should take the next step in defining terms and conditions. CMS clearly has the authority to amend and expand the definition of terms and conditions to focus on the Medicare beneficiary. NASP believes that the agency should regulate the PBM's AWP standard terms and conditions to focus on their relevance for providing access to Specialty Drugs and caring from the Medicare beneficiary in the proposed service area.

Further, NASP believes that CMS should separate out clinical and financial terms and conditions for the purpose of network participation. Creating narrow networks should be focused on financial terms and not on clinical services that must be required by a network participant that have nothing to do with providing care to the enrollee.

[8] August 13, 2015 Guidance Document issued by CMS, entitled, "Compliance with Any Willing Pharmacy Requirements." http://www.ncpa.co/pdf/any-willing-parmacy-guidance.pdf

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F. CMS Should Suspend the Application of Pharmacy Based Direct and Indirect Remuneration (DIR) Fees Starting with Plan Year 2019 Until Appropriate Quality Measures For Specialty Drugs are Developed

CMS recently observed a growing disparity between gross Part D drug costs, calculated based on costs of drugs at the point of sale, and net Part D drug costs, which account for all Direct and Indirect Remuneration (DIR).[9] This disparity is occurring because of the post adjudication fees that some PBMs are collecting from specialty pharmacies, typically months after claims are submitted and reimbursed, under the guise of "performance-based" fees, which are based on wholly inapplicable performance or quality metrics on drugs that are NOT dispensed by specialty pharmacies instead of clinical outcomes. DIR fees ultimately shift financial liability from the Part D Plan sponsor to the beneficiary, to the Medicare program and ultimately, taxpayers.[10] Specialty pharmacies now face significant financial uncertainty, as their actual reimbursement rate cannot be determined until well after they have dispensed the medication. Often times when the reimbursement is reconciled it is far less than the actual cost of the drug plus the requisite services needed to support the patient's journey on the drug. This situation thus threatens the ability of the specialty pharmacy to continue to provide the high touch, white glove, clinical support services required to ensure maximal clinical outcomes for Medicare beneficiaries.

CMS should protect Medicare beneficiaries, the Medicare trust fund, and taxpayers by ensuring that any DIR or other fees apply quality or performance measures that are reasonable and relevant to the patients being treated and the medications being dispensed. Until this is developed, DIR pharmacy based fees should be suspended starting with the 2019 Plan Year for specialty drugs. Otherwise, Medicare beneficiaries and the Part D Program will continue to overpay for life-saving specialty drugs.

NASP believes that under Section 1860D-11(d)(2)(A) of the SSA, CMS has the authority to suspend these types of DIR Fees. Specifically, the statute 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 total amount of DIR fees collected by the health plan is part of the plan's complete bid, it seems to reason that the Secretary can suspend the collection of these types of DIR fees due the fact that the fees are part of the bid process.

[9] Medicare Part D—Direct and Indirect Remuneration, CMS (January 19, 2019), available at: https://www.cms.gov/newsroom/mediareleasedatabase/fact-sheets/2017-fact-sheet-items/2017-01-19-2.html.
[10] Id.

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II. Conclusion

NASP greatly appreciates the opportunity to comment on CMS' RFI and looks forward to continuing to work with the agency to ensure that Medicare beneficiaries have access to critical specialty drugs. 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.

Sincerely,

Sheila Arquette
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