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BY ELECTRONIC DELIVERY

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

Re: Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs and the PACE Program. CMS-4182-P.

Dear Ms. Verma:

The National Association of Specialty Pharmacy (NASP) appreciates this opportunity to submit comments to the Centers for Medicare & Medicaid Services' (CMS) Proposed Rule entitled, "Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs and the PACE Program" (Proposed Rule).[1] 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 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

[1] 82 Fed. Reg. 56336 November 28, 2017.

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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 detailed comments below related to CMS' Proposed Rule 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:

Over the last several years, NASP has worked with CMS to improve beneficiary access to specialty medicines while supporting the agency's commitment to maintaining benefit flexibility and efficiency throughout the MA and Part D Programs. NASP appreciates the agency's efforts to update the Medicare Part D program to improve the quality of care and transparency for Medicare beneficiaries by eliminating certain onerous Any Willing Pharmacy (AWP) contract provisions and issuing a request for information (RFI) on pharmacy price concessions.

As detailed below, NASP urges the agency to:

- Adopt NASP's proposed definition of Specialty Pharmacy
- Consider pharmacy reimbursement in totality when moving pharmacy price concessions to the calculation of negotiated price, effective CY 2019.
- Codify and enforce that unreasonably low reimbursement rates, when offered in an initial network contract, occurring as a result of mid-year rate changes and/or after rebates/concessions are factored in to the final reimbursement rate subverts the convenient access standards.
- Finalize its proposals to the Any Willing Pharmacy (AWP) changes while providing greater clarity on how the agency plans to enforce these changes.
- Tweak the definitions of retail and mail order pharmacy; and,
- Survey specialty pharmacies as part of the agency's efforts to gain a better understanding of the quality of care being provided under the Medicare Part D program.

NASP looks forward to working with the agency to implement many of these proposals.

II. CMS Must Also Consider Overall Reimbursement Amount When Moving Pharmacy Price Concessions to the Calculation of Negotiated Price

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CMS proposes to redefine negotiated price to "reflect the lowest possible reimbursement that a network pharmacy could receive from a particular Part D sponsor for a covered Part D drug."[2] The agency further states that "[u]nder this approach, the price reported at the point of sale would need to include all price concessions that could potentially flow *from* network pharmacies, as well as any dispensing fees, but exclude any additional contingent amounts that could flow *to* network pharmacies and increase prices over the lowest reimbursement level, such as incentive fees."[3] NASP appreciates this proposal but believes that the agency needs to further clarify that the final reimbursement recognized by the pharmacy must comply with current regulatory provisions related to updating any prescription drug pricing standards[4] and guidance documents pertaining to convenient access.[5]

Specifically, CMS' current policy states that "offering pharmacies unreasonably low reimbursement rates for certain "specialty" drugs may not be used to subvert the convenient access standards. In other words, Part D sponsors must offer reasonable and relevant reimbursement terms for all Part D drugs as required by 42 CFR 505(b)(18)."[6] Unfortunately, many standard contracts offered by PBMs, especially those that own a specialty pharmacy, consistently offer reimbursement rates below acquisition cost.[7] NASP therefore believes that these contracts violate the convenient access standards set out in guidance and the spirit of the agency's cited regulation that requires standard contracts to have reasonable and relevant terms that allow any willing pharmacy to participate in the network. Without initial reimbursement provisions that promote network pharmacy participation, the definition of negotiated price is irrelevant as pharmacies will still be under water. In fact, if the initial reimbursement rate is unreasonable, further reducing negotiated price only exacerbates the problem.

NASP is concerned that without further codifying that unreasonably low reimbursement rates subverts the convenient access standards, sponsors will "game" this provision. The sponsor could comply with the new definition of negotiated price provision by moving all pharmacy price concessions to the point of sale but have a total reimbursement rate below the pharmacy's acquisition cost. This will have the same

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[2] 82 Fed. Reg. 56427.
[3] Id.
[4] 42 CFR §423.505(b)(21).
[5] See, Medicare Prescription Drug Benefit Manual – Chapter 5, Section 50.3, September 20, 2011, (available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.pdf
[6] Id.
[7] Since there is no firewall, the PBMs are generally aware of the acquisition cost because their own specialty pharmacy is also purchasing the same drug and therefore sometimes offers reimbursement rates below that cost.

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market effect of excluding independent specialty pharmacy network participation as the application of post adjudication DIR fees. As such, as CMS updates the definition of negotiated price, it must also codify its convenient access standards related to specialty drugs.

NASP believes that CMS' policies related to pharmacy price concessions must take into account the entire point of sale transaction, which includes the initial offer of reimbursement and any post adjudication rebates.

NASP also urges CMS to enforce its requirement of plan sponsors to update any prescription drug pricing standard based on the cost of the drug used for reimbursement of network pharmacies by the Part D sponsor on January 1 of each contract year and not less frequently than once every 7 days thereafter.[8] NASP's members often experience a significant delay in updated reimbursement rates, this lag is particularly detrimental to specialty pharmacies due to the drug's expense. When acquisition costs and list prices increase but corresponding updates are not made in the PBM's claims adjudication system timely, this often leads to the specialty pharmacy being reimbursed less than the amount the specialty pharmacy paid for the medication it dispensed. Compounding this problem is the one-sided nature of the appeal process. If a specialty pharmacy is underpaid and appeals the price to the PBM, the appeal is almost always denied because it is in the financial interest of the PBM to deny the appeal for two reasons. First, while the specialty pharmacy is reimbursed at a low rate, the PBM is allowed to bill the plan sponsor a higher amount and keeps the difference. Second, by financially disadvantaging the independent specialty pharmacy, the PBM simultaneously creates an advantage for its own specialty pharmacy as it gains in market share because the independent specialty pharmacy can no longer afford to dispense the drug and support the patient.

NASP urges the agency to finalize its updated definition of negotiated price for plan year 2019 only if the agency also codifies the convenient access standards for specialty drugs, and clarifies how it will enforce these provisions, including eliminating spread pricing. Finally, NASP believes that the updated definition of negotiated price must consider its impact on the pharmacy's financial ability, both in terms of ingredient cost and services provided in support of the drug, to provide access to the specialty drug.

[8] 42 CFR §423.505(b)(21)(i).

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III. NASP Believes that CMS Must Use The Update to the Medicare Advantage and Part D Prescription Drug Quality Rating System To Provide Greater Network Transparency to Medicare Providers and Beneficiaries

NASP represents an industry that focuses on providing quality patient care first with an added emphasis on clinical outcomes and patient choice. It is these clinical outcomes that drive competition amongst and between NASP members and is the principle metric on which individual specialty pharmacies are judged by their contracted partners such as manufacturers and plan sponsors/PBMs. Without the ability to provide Medicare beneficiaries with high quality and timely care, independent specialty pharmacies will not survive as neither the manufacturer nor the plan sponsor/PBM will allow them to participate in their respective networks. Based upon the diverse experiences of NASP's members that provide a wide range of high quality care programs, NASP provides the following suggestions on how the agency can improve its overall Quality Strategy for the Medicare Part D Program.

A. To Improve the CMS Quality Strategy the Agency Must Also Focus on the Adjudication Process at the Pharmacy

CMS states that it is "committed to transforming the health care delivery system—and the Medicare program—by putting a strong focus on person-centered care, in accordance with the CMS Quality Strategy, so each provider can direct their time and resources to each beneficiary and improve their outcomes."[9] NASP shares these goals with CMS because they focus on the Medicare beneficiary.

The overwhelming majority of specialty prescriptions that are written by Medicare providers and covered by Medicare Part D are dispensed by a specialty pharmacist who receives the prescription from the Medicare provider. The patient's journey begins and is maintained through high impact monitoring and ongoing interaction with the specialty pharmacy staff, who are specialized and uniquely qualified to address the patient and /or caregiver's needs to ensure therapeutic adherence and desired therapeutic outcomes. From there, the specialty pharmacy manages the adjudication[10] of the prescription and the beneficiary's adherence and compliance program while also

[9] 82 Fed. Reg. at 56375.
[10] The adjudication process can include, but is not limited to benefits investigation and verification, managing a prior authorization, coordinating the satisfaction of any associated utilization management requirements, pursuing foundational financial assistance for those who cannot afford their medications.

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monitoring the beneficiary's outcome. This is the value of the specialty pharmacy upon which Medicare providers, plan sponsor/PBMs and beneficiaries rely upon.

For the Medicare beneficiary, the specialty pharmacist, nurse and technician are crucial and necessary partners in achieving their clinical goal. As such, NASP believes that for CMS' overall Quality Strategy to be robust and comprehensive it must also include and focus on the adjudication process at the specialty pharmacy.

Accessing the specialty drug may not be 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 plan sponsor/PBM. Currently, which specialty pharmacy is in-network by drug is only known by the plan sponsor/PBM. This lack of transparency is not helpful to CMS, causes significant confusion for the provider community and most importantly increased out of pocket costs for the beneficiary and delayed medication access which may negatively affect beneficiary satisfaction. Being unaware of which specialty pharmacies are in-network for their medication, the beneficiary makes an uninformed choice during open enrollment. Consequently, the beneficiary may choose a health plan believing that he/she can access a specialty medication from one of the in-network pharmacies only to learn during the plan year that the specialty drug is not available at any of the in-network pharmacies. This leads to a high level of uncertainty as to where and how he/she will access their potentially life-saving medication.

As such, NASP urges CMS to require each plan sponsor to submit to CMS annually a listing of every specialty pharmacy or pharmacies that are in-network for each of the formulary drugs within the oncology, immunomodulators, multiple sclerosis, HIV/AIDS, Hepatitis C and immunosuppressant classes. By doing so, CMS will know which specialty pharmacies are in-network by specialty drug in these drug classes and can therefore truly determine if each Medicare beneficiary has access to each of the plan sponsor's formulary specialty drugs for these disease states. By adopting this process, the agency will have greater visibility into the network adequacy of each plan. Similar to retail pharmacy, this information, as detailed below, should be made public helping the beneficiary during open enrollment and the provider to know to which specialty pharmacy they can send the prescription. This new process maximizes the provider's resources while also expediting adjudication and access to the therapy.

In addition, by ensuring that each plan has a robust network by specialty drug, CMS will reduce overall health care costs for the following reasons. First, the Medicare beneficiary will always receive the financial benefit of accessing an in-network

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pharmacy as compared to an out-of-network pharmacy consistent with some of the overall goals of the Proposed Rule. Second, specialty pharmacy administrative costs will be reduced as the specialty pharmacy will not have to spend time and resources identifying and transferring the prescription to an in-network specialty pharmacy. Lastly this confusion, which delays access and may negatively impact medication compliance and adherence which increases overall cost of care, will be reduced.

Similarly, in order to ensure that beneficiaries have continued access to specialty drugs throughout the plan year, NASP believes that plan sponsors should be required to notify the agency of changes to their specialty pharmacy network during the plan year. CMS can then monitor any changes guaranteeing that each Medicare beneficiary will truly have access to their needed specialty medications regardless of the plan he or she chooses.[11]

B. CMS Must Provide Beneficiaries with More Information on In-Network Pharmacies to Help Improve Access

CMS states that the "MA and Part D Star Ratings System is designed to provide information to the beneficiary that is a true reflection of the plan's quality and encompasses multiple dimensions of high quality care."[12] NASP urges the agency to apply this principle to one of the most important aspects of the beneficiary's experience under Medicare Part D, which is where and how the beneficiary will receive his/her life-saving specialty medicine. Similar to retail, mail, home infusion and LTC pharmacy, NASP believes that plan sponsors should be required to have a robust network of specialty pharmacies in network by specialty drug, including but not limited to the oncology, immunomodulators, multiple sclerosis, HIV/AIDS, Hepatitis C and immunosuppressant classes.[13]

As a result of collecting and validating this data from the plan sponsor 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 the in-network specialty pharmacy/pharmacies at the time of plan selection. Therefore, when

[11] 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 formulary and bid process.

[12] 82 Fed. Reg. 56376.

[13] NASP believes that current laws provide CMS with the authority to implement the requirement of network adequacy for specialty pharmacies under the convenient access requirements of the SSA. Section 1860D-4(b)(1)(C).

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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. Through these simple administrative changes, CMS can further its overall Quality Strategy goals of improving provider resources while also delivering meaningful and timely information to beneficiaries in the Medicare Part D program.

C. CMS Should Consider Including Survey Measures of Pharmacies' Experiences in the Medicare Part D Program

CMS states that it is interested in receiving stakeholder feedback on including survey measures of physicians' experiences as they interact with health and drug plans on a daily basis on behalf of their patients.[14] If the agency's criteria to receive a survey is "interaction with health and drug plans on a daily basis," then the agency must also consider including survey measures of the pharmacy's experience based on its interaction with the drug plan. In fact, the physician's interaction with the drug plan pales in comparison to that of the specialty pharmacy because as mentioned above it is the specialty pharmacy that adjudicates the prescription under Medicare Part D, not the provider. NASP therefore believes that if the agency surveys the provider it should also survey the specialty pharmacy. Here are examples of what the agency will learn about the payer/PBM from surveying the specialty pharmacy community:

- In some circumstances, the PBM will require a prior authorization from an in-network pharmacy but will waive the prior authorization if patient uses PBM owned specialty pharmacy. In addition, while the prescription is "under review" the PBM owned specialty pharmacy sometimes fills and dispenses the specialty drug thereby displacing the prescription from the independent specialty pharmacy. This occurs because the PBM's lack of firewall provides access to all of the claim transactions for the beneficiaries in their plans.

- During a contracting process, the PBM that also owns the specialty pharmacy often refuses to provide actual reimbursement rates by drug or the applicable rate schedules associated with the various PDP Sponsors further disadvantaging the independent specialty pharmacy.

- NASP members have witnessed a circumstance where an erroneous patient notification was sent by a PBM that owns a specialty pharmacy indicating that a non-

[14] 82 Fed. Reg. 56377.

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PBM owned independent specialty pharmacy can no longer service their specialty prescription needs because the specialty pharmacy is no longer in-network when in fact the non-PBM owned specialty pharmacy is contracted to be in-network. This obviously causes unnecessary stress, potential disruption in care and confusion for both patients and providers. In some documented cases, a PBM in negotiation with a specialty pharmacy to amend or re-contract with the specialty pharmacy sent notifications out to the specialty pharmacy's patients indicating the specialty pharmacy is no longer contracted with the PBM, and asking the patient to find another network pharmacy to avoid care disruptions.

- PBMs require patients to use their own specialty pharmacy even though other in-network pharmacies have same price and perhaps better patient services and outcomes.

- The PBM owned specialty pharmacy programs their own system to reject a claim at the network pharmacy that it does not own. This then prompts the PBM to reach out to physician and redirect the prescription to their own specialty pharmacy.

- PBM that owns a specialty pharmacy calls the independent specialty pharmacy stating there is an error in the information entered for a prescription and asks the pharmacist and the independent specialty pharmacy to reverse the prescription submission, correct it and resubmit the prescription. During the minute it takes for the prescription to be reversed and updated by the independent specialty pharmacy, the PBM owned specialty pharmacy will fill the prescription. If the independent specialty pharmacy asks the PBM owned specialty pharmacy to reverse the claim it will state that the prescription was processed and is in the shipping department and cannot be reversed. The independent specialty pharmacy has now lost the patient to the PBM owned specialty pharmacy.

These examples provide just a snapshot into the market dynamics between the independent specialty pharmacy and the agent of the plan sponsor, its PBM. NASP believes that in order for CMS to gain a comprehensive understanding of how its health plans are serving beneficiaries through the sponsor's downstream entities such as providers, it must also survey specialty pharmacies. Only through surveying all downstream entities of the sponsor can the agency truly know and understand how the health plan and its entities are serving Medicare beneficiaries. With more comprehensive data, NASP believes that the agency will be able to dramatically improve its overall Quality Strategy.

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IV. NASP Urges CMS to Define Specialty Pharmacy

NASP urges CMS to reconsider its decision to abstain from defining specialty pharmacy. CMS states that "because the pharmacy landscape is changing so rapidly, we believe any attempt by us to define specialty pharmacy could prematurely and inappropriately interfere with the marketplace, and we decline to propose a definition of specialty pharmacy at this time."[15] NASP respectfully believes that CMS could define specialty pharmacy without prematurely and inappropriately interfering with the marketplace if the definition focuses on quality and third party independent accreditation. The basic concept of a Specialty Pharmacy is to meet the unique needs of and to service patients who have serious health conditions requiring complex medication therapies.

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.[16] Independent, third party accreditation[17] demonstrates a commitment to quality, safety, accountability, and adoption of nationally recognized standards of practice. Independent, third party accreditation plays an important role in establishing rigorous performance measures and high-quality standards for specialty pharmacies that aim to deliver patient-centered care to those diagnosed with chronic illnesses and complex medical conditions requiring highly specialized, comprehensive drug therapies that achieve superior clinical and economic outcomes and expedite patient access to care.

NASP believes that CMS can define specialty pharmacy without compromising the evolving specialty pharmacy business model. In fact, by focusing the definition of specialty pharmacy on types of drugs dispensed and accreditation and licensing the agency will set a baseline from which it can determine if the convenient access

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[15] 82 Fed. Reg. 56410.
[16] 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.
[17] For example, the current prominent accrediting bodies for specialty pharmacy are the Accreditation Commission for Health Care (ACHC), the Joint Commission, and URAC®.

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standards are fulfilled by sponsors for specialty drugs. Further, as discussed below, by implementing NASP's suggested changes to AWP requirements, and mandating that sponsors include in-network pharmacy by specialty drug, the agency will solidify appropriate and cost-effective access to specialty therapies for Medicare beneficiaries.

V. NASP Urges CMS to Further Clarify the Definitions and Applicability of the Any Willing Pharmacy Standard Terms and Conditions

CMS states that the convenient access provisions, as currently codified, require Part D plan sponsors to secure the participation in their networks a sufficient number of pharmacies that dispense (other than by mail order) drugs directly to patients to ensure convenient access.[18] Clearly, CMS is implementing the statutory convenient access standard to refer to a pharmacy in order for the Medicare beneficiary to access their prescribed drug. As stated above, NASP believes that this view is misguided as it focuses on the pharmacy with the presumption that the drug will be available at that pharmacy. NASP members know first-hand that this is not the case. Just because the pharmacy is in-network does not mean each drug is available at each pharmacy. Therefore, NASP reiterates that for certain classes of specialty drugs CMS should be implementing the convenient access requirement by specialty drug and not by the pharmacy type. In order to achieve this, CMS should require the sponsor to demonstrate that it has a robust-network by drug for each specific class of drugs mentioned above.

The Medicare Part D Program requires Medicare Part D plans to offer any willing pharmacy (AWP) an in-network pharmacy contract with standard terms and conditions that are reasonable and relevant.[19] Congress therefore clearly created the AWP provisions to help lower costs and improve beneficiary access to all types of pharmacies by encouraging competition in the marketplace. NASP agrees with CMS that unfortunately "this has resulted in the development of "standard" terms and conditions that in some cases has had the effect, in our view, of circumventing the any willing pharmacy requirements and inappropriately excluding pharmacies from network participation."[20] Of particular concern to NASP, and as generally stated above, are the reimbursement provisions contained within the standard terms and conditions and urges CMS' to provide greater regulatory clarity regarding the role that reimbursement terms have within standard terms and conditions.

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[18] 82 Fed. Reg. 56408.
[19] Social Security Act (SSA) §1860D-4(b)(1)(A).
[20] 82 Fed. Reg. 56407.

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For example, the Proposed Rule generally addresses payment terms as part of the standard terms and conditions by stating "we indicated that standard terms and conditions, particular for payment terms, could vary to accommodate geographic areas or types of pharmacies, so long as all similarly situated pharmacies are offered the same terms and condition."[21] NASP believes that CMS must clarify, consistent with its sub regulatory guidance, that regardless if "all similarly situated pharmacies are offered the same reimbursement terms" should those terms be unreasonably low they are never acceptable. Specifically, NASP believes and reiterates that the agency should codify its sub regulatory guidance regarding reimbursement terms that states "offering pharmacies unreasonably low reimbursement rates for certain "specialty" drugs may not be used to subvert the convenient access standards. In other words, Part D sponsors must offer reasonable and relevant reimbursement terms for all Part D drugs."[22] Many NASP members are offered AWP contracts with standard terms and conditions with unreasonably low reimbursement rates that are non-negotiable. Specialty pharmacies currently do not receive additional reimbursement for the comprehensive patient care support services they provide which promote adherence, compliance and effective disease management. These low reimbursement rates create a no-win situation for the specialty pharmacies. If they accept these contracts, many drugs are reimbursed below acquisition cost resulting in a negative financial impact which is not sustainable. If the specialty pharmacies choose not to accept the contracts this not only affects beneficiary access, choice and continuity of care but also negatively affects the relationship between the specialty pharmacy and their providers. Providers partner and refer patients to a high-quality specialty pharmacy with the ability to service all patients regardless of the patient's insurance plan. By opting not to participate with Medicare Part D, the pharmacy's overall viability can also be negatively impacted as prescriber referral patterns change for all patients not just Medicare beneficiaries. NASP therefore urges the agency to codify that unreasonably low reimbursement rates are unacceptable and then monitor this requirement of Part D Sponsors, especially for specialty drugs.

A. NASP Supports CMS' Requirement that the AWP Provisions Apply to All Business Models

NASP's membership validates CMS' proposition that the pharmaceutical distribution and pharmacy practice landscape evolves rapidly. As stated above, NASP's

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[21] Id.

[22] See, Medicare Prescription Drug Benefit Manual – Chapter 5, Section 50.3, September 20, 2011, (available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.pdf

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membership is uniquely diverse and many of our members have diverse lines of pharmacy businesses. NASP completely agrees and exemplifies CMS' assertion that "some Part D plan sponsors have declined to permit willing pharmacies to participate in their networks on the grounds that they do not meet the Part D plan sponsor's definition of a pharmacy type for which it has developed standard terms and conditions."[23] Each year, NASP members are denied network access or their network contract is terminated purely based on the fact that it violated the description of the pharmacy type in the network contract. In other words, the network denial or termination was not at all connected to pharmacy performance or beneficiary outcome.

In order to address this abuse of power by the plan sponsor, CMS proposes that "Part D plan sponsors must not exclude pharmacies from their retail pharmacy networks solely on the basis that they, for example, maintain a traditional retail business while also specializing in certain drugs or diseases or providing home delivery service by mail to surrounding areas. Or as another example, a Part D plan sponsor must not preclude a pharmacy from network participation as a retail pharmacy because that pharmacy also operates a home infusion book of business, or vice versa."[24] In light of the agency not defining specialty pharmacy, NASP believes that this is a step in the right direction but urges the agency to provide further clarity related to how specialty pharmacies fit in and are afforded equal access under this requirement. Specifically, NASP requests that the agency specify that specialty pharmacies are eligible and must be offered an in-network contract pharmacy consistent with all other pharmacy types. Further, as detailed below and above, that contract must contain reasonable reimbursement rates and general standard terms and conditions that are relevant to the Medicare beneficiaries that the specialty pharmacy intends to serve, not to network participation as asserted by the PBM.

B. NASP' Urges CMS to Add 'Predominately' to the Definition of Mail Order Pharmacy

CMS states that "its classification of certain types of pharmacies were never intended to limit or exclude participation of pharmacies, such as pharmacies with multiple lines of business, that do not fit into one of these classifications. Additionally, we have recognized since our January 2005 final rule that pharmacies may have multiple lines of business, including retail pharmacies that may offer home delivery services."[25] NASP appreciates that CMS is now defining mail order pharmacy to be "a licensed pharmacy that dispenses and delivers extended days' supplies of covered Part

[23] 82 Fed. Reg. 56408.
[24] Id.
[25] 82 Fed. Reg. 56409.

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D drugs via common carrier at mail order cost sharing."[26] CMS proposes this definition because the agency believes that it is inappropriate to classify pharmacies as ''mail-order pharmacies'' solely on the basis that they offer home delivery by mail."[27]

NASP agrees with this approach but urges the agency to further clarify the definition of mail order by adding "predominately" before the words "dispenses and delivers." This addition will assure that specialty pharmacies cannot be classified as a mail order pharmacy if it dispenses some limited quantities of 90-day supplies of drugs.

C. NASP Urges CMS to Not Include "Walk-in General Public" In Its Definition of Retail Pharmacy

CMS proposes to clarify the definition of retail pharmacy because it currently "may be a source of some confusion given that it expressly excludes mail-order pharmacies, but not other non-retail pharmacies such as home infusion or specialty pharmacies.[28] NASP believes that this "confusion" affords PBMs that also own their own specialty pharmacy significant contractual latitude that is often used to either exclude independent specialty pharmacies (non-PBM owned) or terminate network contracts because of commercial activities of the independent specialty pharmacy and appreciates the agency's efforts to update the definition of retail pharmacy.

In response to this confusion, CMS proposes that the new definition of retail pharmacy be "any licensed pharmacy that is open to dispense prescription drugs to the walk-in general public from which Part D enrollees could purchase a covered Part D drug at retail cost sharing without being required to receive medical services from a provider or institution affiliated with that pharmacy.''[29] CMS' proposal focuses on the dual concepts of being open to the walk-in general public and retail cost-sharing. NASP believes that the requirement of being open to the walk-in general public is an outdated concept of retail and therefore will only serve to narrow those entities eligible to receive a retail pharmacy contract, especially in light of the fact that the agency does not further define other pharmacy types. This does not seem to be consistent with the spirit of the Proposed Rule, which is to broaden beneficiary access to pharmacies, regardless of business model.[30]

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[26] Id.
[27] Id.
[28] Id.
[29] Id.
[30] For example, Amazon is not open to the general public, but is considered a retailer. In fact, it is estimated there are over 110,000 retail businesses performing their business over the internet and using common carriers to deliver their products to consumers. Almost 12% of retail is now performed over the

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NASP is concerned that because the agency is not defining specialty pharmacy and is requiring a retail pharmacy to be open to the walk-in general public, the independent specialty pharmacy will still be denied network access by PBMs, especially those that also own a specialty pharmacy as those PBMs will use that clause to deny network access. As such, CMS should focus its definition of retail pharmacy on the cost sharing and its distinction from a long-term care pharmacy. The new definition should therefore read "any licensed pharmacy that is ~~open~~ *able* to dispense prescription drugs ~~to the walk-in general public~~ from which Part D enrollees could purchase a covered Part D drug at retail cost sharing without being required to receive medical services from a provider or institution affiliated with that pharmacy." This definition will ensure broader network access for the many pharmacy types that the agency does not define in the Proposed Rule.

D. NASP Urges CMS to Prohibit PBMs From Using Unreasonable Accreditation and Other Similar AWP Requirements in Standard Terms and Conditions to Exclude Specialty Pharmacies from Network Participation

NASP agrees with CMS's statements that the use of unreasonable accreditation and credentialing strategies by PBMs have proliferated, and that some PBMs are using such strategies to exclude pharmacies that provide predominately specialty drugs from their standard networks. As stated above in NASP's definition of specialty pharmacy, NASP does support the use of industry accepted, third party independent accreditation as a requirement for pharmacies to participate in the dispensing of specialty drugs.

NASP believes, consistent with the Proposed Rule's solutions, that 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, do not focus on ensuring the quality of care being delivered and are not sensitive to the beneficiaries being served.

NASP provides the following examples of standard terms and conditions, in addition to those related to accreditation, that are routinely used by plan sponsors that are clearly unreasonable and support the agency's understanding that they are being used to exclude pharmacies and not to include.

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web. https://marketingland.com/report-e-commerce-accounted-11-7-total-retail-sales-2016-15-6-2015-207088

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Examples of Unreasonable AWP Requirements

- Specialty Pharmacies must be licensed in all 50 states, Guam and Puerto Rico. This unfairly excludes regional specialty pharmacies that often have a better understanding of the care required and expected in their community.
- Because of the lack of a specialty pharmacy class of trade contract, specialty pharmacies are presented with a retail pharmacy contract. This contract generally contains provisions that the pharmacy cannot mail, courier, or otherwise deliver any of its prescriptions without the network's express written permission. Since many specialty therapies are sent via the mail, the specialty pharmacy cannot comply with these AWP standard terms and conditions.
  - As a side note and described in greater detail above, by CMS including the clause "open to the general walk-in public" in the definition of retail pharmacy, the agency is not solving this problem. Rather, the agency is further cementing the fact that specialty pharmacies can be excluded under retail pharmacy definition if it is not open to the general walk-in public.
- Require that specialty pharmacies carry certain limited distribution drugs that are only accessible by a few pharmacies thereby disqualifying all specialty pharmacies outside of those particular drugs' networks.
- Carry a broad array of specialty therapies such as medications for hepatitis c, hemophilia, oncology, and Rheumatoid Arthritis. This provision excludes specialty pharmacies that focus on a certain disease state thereby eliminating beneficiary access to experienced caregivers for their disease.
- Meet a threshold for obtaining patient financial assistance for its patients, which is typically not achievable.
- Provide evidence of onsite inventory with capability to dispense and ship at least fifteen hundred (1,500) specialty prescriptions per day, which is an arbitrary number aimed and excluding smaller specialty pharmacies.
- The standard condition that requires each specialty pharmacy to employ at least one registered nurse per state for each of the fifty (50) states discriminates against the regional and smaller specialty pharmacies.

As mentioned above, NASP believes that plan sponsors must demonstrate to CMS how each of the AWP standard terms and conditions complies with CMS' and Congress' intended goal of broadening and ensuring appropriate access to a wide

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range of pharmacy types. As such, each standard term and condition should be connected to a regulatory principle that demonstrates that it is reasonable and relevant to the population of Medicare beneficiaries that the pharmacy intends to serve.

In light of all of these examples, NASP offers an alternative or supplement to the current standard terms and conditions requirement. CMS should develop Specialty Pharmacy Network adequacy standards similar to the Long-Term Care Pharmacy (LTCP) Performance and Service Criteria developed by the agency in March 2005.[31] CMS developed this policy to assist Medicare Part D plans in developing their policies for pharmacies serving Medicare beneficiaries residing in long-term care facilities (LTCFs). In developing this guidance, CMS recognized special service standards (e.g., special packaging, pharmacist on-call services, and comprehensive inventory and inventory capacity) that LTCPs must meet to care for the unique beneficiary population served in LTCFs.

Similar to LTCPs, specialty pharmacies provide services to beneficiaries that are more complex than retail and, therefore, require a greater level of care. Specialty pharmacies 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. As such, NASP urges CMS to require Part D plans to maintain an adequate specialty pharmacy network to ensure performance and service standards that protect beneficiaries similar to CMS guidance for LTCPs. In developing this guidance, CMS should require, as mentioned above, that the sponsor demonstrate to CMS that is has an in-network pharmacy, with reasonable reimbursement rates, for each of the classes of drugs mentioned above.

This overall process and the specific reimbursement and in-network requirements will help strengthen the AWP provisions because it will ensure that each Medicare beneficiary has an in-network pharmacy that will, in turn, expedite access, at a lower cost, to specialty therapies.

E. NASP Urges CMS to Finalize Its Timing of Contracting Provisions Proposal

CMS proposes to require Part D sponsors to make available on September 15 its standard terms and conditions. After that date sponsors must provide either the

[31] Medicare Prescription Drug Benefit Manual, Chapter 5: Benefits and Beneficiary Protections. Section 50.5 Long-Term Care (LTC) Pharmacy Access. Centers for Medicare & Medicaid Services. Accessed at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/LTCGuidance.pdf

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standard terms and conditions or a confidentiality agreement within two business days. Further, CMS states that for those sponsors that require a confidentiality agreement, the standard terms and agreement must be provided within two days of receiving that executed agreement. NASP generally supports these proposals but urges the agency to further clarify the implications of noncompliance by sponsors. CMS does not provide any recourse to those pharmacies that do not receive a timely contract nor state any harm to the sponsor for failure to provide the contract in a timely fashion.

In addition, NASP urges CMS to require plan sponsors to notify CMS of the pharmacies that were included in their bid submission but do not come to terms with the plan sponsor during this time period and are therefore not in-network for the next plan year. Plan sponsors use these pharmacies to meet the minimum network adequacy standards and the bid is accepted by CMS based on this network. Without this requirement, CMS does not know if the final network is consistent with the network contained in the approved bid.

VI. NASP Supports CMS' Examining the Definition of Negotiated Price

As we shared with CMS, since 2015 NASP's members have seen a dramatic growth in the collection of DIR fees by PBMs. As CMS notes, the collection of DIR fees provides a significant financial advantage to the sponsor. Specifically, CMS states that "sponsors sometimes opt for higher negotiated prices in exchange for higher DIR and, in some cases even prefer a higher net cost drug over a cheaper alternative" because any DIR received that is above the projected amount factored in a plan's bid contributes primarily to plan profits, not lower premiums.[32] NASP agrees with CMS that this puts upward pressure on Part D program costs and shifts costs from the sponsor to the beneficiaries and the overall Part D program. In response to this dynamic, CMS issued a RFI seeking information on how to better define negotiated price to stem this upward trend. NASP provides the following additional comments related to the definition of negotiated price.

A. Effective for CY 2019, CMS Should Prohibit the Collection of DIR Fees from Specialty Pharmacies That Are Based on Inapplicable Measures

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

[32] 82 Fed. Reg. 56420.

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account for all Direct and Indirect Remuneration (DIR).[33] This disparity is occurring because of the post adjudication fees that some PBMs are collecting from specialty pharmacies. Instead of focusing on clinical outcomes, these "performance-based" fees are typically assessed months after claims are submitted and reimbursed, and are based on wholly inapplicable performance or quality metrics applicable to drugs that are NOT dispensed by specialty pharmacies.

DIR fees ultimately shift financial liability from the Part D Plan sponsor to the beneficiary, to the Medicare program and ultimately, to taxpayers.[34] As detailed above, 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 optimal clinical outcomes for Medicare beneficiaries.

In response to this trend, the Proposed Rule contains a RFI on how the agency can better capture the post adjudication discounts between manufacturers and PBMs and the assessment of post adjudication DIR fees between PBMs and specialty pharmacies within the definition of negotiated price. NASP believes that as a guiding principle, CMS should protect Medicare beneficiaries, the Medicare trust fund, and taxpayers by ensuring that any DIR or other post adjudication fees assessed to a specialty pharmacy are based on quality or performance measures that are reasonable and relevant to the patients being treated by and the medications being dispensed by the pharmacy. NASP is currently working with the Pharmacy Quality Alliance (PQA) to standardize and adopt independent specialty pharmacy, drug, patient and disease management specific metrics focused on patient satisfaction, clinical safety, efficacy and appropriateness and financial accountability that can be universally applied to specialty pharmacies to measure quality and benchmark performance.

NASP fundamentally believes that until these measures are adopted, DIR pharmacy based fees should be suspended starting with the 2019 Plan Year for specialty drugs since there are only limited universally established and adopted quality measures for specialty drugs. Otherwise, Medicare beneficiaries and the Part D

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[33] 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.
[34] Id.

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Program will continue to overpay for life-saving specialty drugs while the agency further determines the updated definition of negotiated price.

B. NASP Urges CMS to Pass Through a Portion of Manufacturer Rebates to the Point of Sale as Long as it Preserves the Confidentiality of Proprietary Information

NASP applauds CMS for its efforts to foster greater transparency in the distribution channel, particularly related to the fees and rebates paid and collected by various entities in the channel. As a result of the proposals contained in the RFI, NASP believes that the agency now has a much greater understanding of these financial transactions and their detrimental impact that some are currently having on the Medicare beneficiary and the Part D program. NASP is concerned, however, that some of the proposals related to manufacturers rebates could revel confidential contractual rebate terms. As such, NASP urges CMS to proceed cautiously with creating transparency in manufacturer rebates as to not disrupt the integrity of the competitive, free-market structure that has made the Part D program successful.

C. CMS Should Finalize its Pharmacy Price Concessions Proposal for Contingent Incentive Payments for CY 2019

NASP supports CMS' proposals related to incentive payments as good public policy. The agency states that "we are considering requiring that all contingent incentive payments be excluded from the negotiated price because including the actual amount of any contingent incentive payments to pharmacies in the negotiated price would make drug prices appear higher at a ''high performing'' pharmacy, which receives an incentive payment, than at a ''poor performing'' pharmacy, which is assessed a penalty."[35] The agency supports this proposal by stating that the "pricing differential could potentially create a perverse incentive for beneficiaries to choose a lower performing pharmacy for the advantage of a lower price."[36]

NASP encourages CMS to work with PQA to ensure that the specialty pharmacy-specific measures are consistent across and among sponsors. Similar to accreditation requirements, many sponsors either have or are developing "performance programs" based on measures designated by them. Many different types of quality/performance programs are as unhelpful and unproductive as having many

[35] 82 Fed. Reg. 56427.
[36] Id.

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different accreditation programs. Therefore, any final policy should include a process that creates consistency amongst quality programs. Further, NASP also believes that CMS should place a cap on performance-based fees on a per prescription basis, limiting the amount of performance fees that can be collected related to a specific drug. Such a cap would facilitate greater transparency and predictability for pharmacies with fee amounts and ultimately reimbursement. Patients would benefit because costs variability would be minimized from drug to drug, as only a limited amount of fees could be subject to performance and outside of negotiated price.

VII. Conclusion

NASP greatly appreciates the opportunity to comment on the Proposed Rule and the 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,

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