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July 16, 2018

The Honorable Alex M. Azar II Secretary Department of Health and Human Services 200 Independence Avenue, SW Room 600E Washington, DC 20201

RE: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs; Request for Information

Dear Secretary Azar:

The National Association of Specialty Pharmacy (NASP) welcomes the opportunity to provide comments on the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs and Request for Information [83 Fed. Reg. No. 95, May 16, 2018; RIN 0991-ZA49). NASP represents the entire spectrum of the specialty pharmacy industry from the nation's leading independent specialty pharmacies and practicing pharmacists to small and mid-size pharmacy benefit managers (PBMs), pharmaceutical and biotechnology manufacturers of specialty drugs; group purchasing organizations; wholesalers and distributors; integrated delivery systems and health plans; and technology and data management companies. With over 100 corporate members and 1,200 individual members, NASP is the unified voice of specialty pharmacy in the United States.

Background

NASP agrees with the administration that the status quo as it relates to increased drug costs for seniors is no longer acceptable and an examination of the overall system is warranted, particularly as it affects access to specialty medications. We agree that a national focus on lowering out-of-pocket costs has the potential to create new and positively disruptive alternatives to the current system in a way that strengthens access to needed medications and related services.

Specialty pharmacy is focused on controlling total cost of care through medication adherence and patient support services, not only the cost of drugs. With the HHS Blueprint and RFI for policy reforms, we see an opportunity to take a harder look at what ultimately impacts a Medicare beneficiary's drug costs, including a retroactive DIR fee process that ultimately results in seniors paying more upfront for the cost of their drugs, particularly high-cost drugs, and frequently entering the catastrophic phase of their benefit within just a few short months. Current processes where PBM's clawback DIR fees from specialty pharmacies after a senior has paid a higher cost at the counter weeks or months earlier have no direct benefit for seniors as the metrics used to assess these fees anunrelated to the speclaty drug being dispensed or disease being managed. As HHS noted in its request for comments, a reexamination of the system and opportunities for reform is long overdue.

Over the years, NASP has worked with HHS and specifically with the Centers for Medicare and Medicaid Services (CMS) to improve beneficiary access to specialty medicines while supporting benefit flexibility and efficiency throughout the Medicare Advantage and Medicare Part D Programs. NASP recognizes the administration's efforts, particularly over the last couple years to focus on improving the quality of care and transparency for Medicare Part D beneficiaries by addressing Any Willing Pharmacy (AWP) contract provisions of concern, examining the need to define specialty pharmacy to ensure network access for seniors and improved competition, and focusing on pharmacy price concessions and options for reform. These initial efforts are a strong step in the right direction, and NASP looks forward to working with HHS and particularly CMS to make continued strides in both of these areas. Our comments on the issues, statements and questions posed in the HHS Blueprint and RFI, focus on these core issue areas and also address issues as they relate to specialty pharmacy practice and improving access to specialty medications for patients with complex, life-threatening conditions. We offer comments in relation to questions and statements posed in the RFI to address: creating incentives to lower list prices; better negotiations; and reducing patient out-of-pocket spending.

NASP Response to the Solicitation of Comments – Request for Information

Create Incentives to Lower List Prices

Fiduciary Duty for Pharmacy Benefit Managers -

• Do PBM rebates and fees based on the percentage of the list price create an incentive to favor higher list prices (and the potential for higher rebates) rather than lower prices? Do payers manage formularies favoring benefit designs that yield higher rebates rather than lower net drug costs? How are beneficiaries negatively impacted by incentives across the benefits landscape (manufacturer, wholesaler, retailer, PBM, consultants and insurers) that favor higher list prices? How can these incentives be reset to prioritize lower out of pocket costs for consumers, better adherence and improved outcomes for patients? Should PBMs be forbidden from receiving any payment or remuneration from manufacturers, and should PBM contracts be forbidden from including rebates or fees calculated as a percentage of list prices?

NASP applauds HHS 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. NASP was so pleased to see CMS offer proposals in the RFI that accompanied the CY 2019 Part D proposed rule¹, to specifically address pharmacy price concessions otherwise known as DIR fees, and we are encouraged to see HHS reference that proposal in the Blueprint and new RFI.

Since 2015, NASP's members have seen a dramatic growth in the collection of DIR fees by PBMs. As CMS noted in the proposed Part D rule for CY 2019², the collection of DIR fees provides a significant

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

² Id.

financial advantage to the plan sponsor. Specifically, CMS stated 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.³ NASP agrees that this ultimately increases Part D program costs and shifts costs from the sponsor to the beneficiaries and the overall Part D program, as beneficiaries are pushed into catastrophic coverage sooner than they otherwise would.

CMS has highlighted the 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 DIR.⁴ This disparity is occurring partly because of the post adjudication fees that some PBMs are collecting from specialty pharmacies, who are pointedly impacted by this practice. Instead of focusing on clinical outcomes, these fees are typically assessed months after claims are submitted and reimbursed, and are based on wholly inapplicable performance or quality metrics tied 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. Specialty pharmacies 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 and ultimately reduce overall health care costs through care management.

NASP believes that as a guiding principle, HHS 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. Allowing PBMs and PDPs (including Medicare Advantage PDPs) to set and control quality and performance metrics without oversight is of concern, as they have no incentive to ensure that measures appropriately apply to the services being provided by a given pharmacy. This system merits oversight and reform, particularly by HHS. NASP recommends that HHS work with the broad stakeholder community to establish a new process for the creation of measures that will incentivize quality and performance improvement.

NASP believes that until measures that appropriately apply to specialty drugs and the services provided by specialty pharmacies are adopted, DIR pharmacy-based fees should be suspended for specialty drugs. Otherwise, Medicare beneficiaries and the Part D Program will continue to overpay for life-saving specialty drugs.

³ 82 Fed. Reg. 56420.

⁴ 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.

Better Negotiation

Transparency - What steps can be taken to improve price transparency so that consumers can seek value when choosing and using their benefits?

For a beneficiary with complex and life-threatening health conditions, to access specialty drugs, a prescription essentially 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 causes significant confusion for the provider community and most importantly increased out-of-pocket costs for the beneficiary with sometimes-delayed medication access. 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 and at what cost.

NASP urges reform to require each plan sponsor, prior to annual open enrollment, to submit to CMS a listing of every specialty pharmacy(ies) 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. This information 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 a therapy.

By ensuring that each plan has a robust network by specialty drug, CMS will reduce overall health care costs. The Medicare beneficiary will always receive the financial benefit of accessing an in-network pharmacy as compared to an out-of-network pharmacy. 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. Beneficiary confusion, which delays access and may negatively impact medication compliance and adherence which increases overall cost of care, will be reduced.

Network Adequacy – Defining Specialty Pharmacy and Amending Any Willing Pharmacy Terms and Conditions

NASP urges HHS to work with CMS to reconsider the need to define specialty pharmacy. NASP believes that specialty pharmacy can be defined without inappropriately interfering with the market-place, and the growth of the specialty pharmacy market necessitates definition to support network adequacy requirements and patient care management for those with serious health conditions requiring complex medication therapies and reduced health care costs. Providing a definition for specialty pharmacy will also set a baseline from which HHS/CMS can determine if the convenient access standards are being fulfilled by sponsors for specialty drugs. This definition is also necessary to address ongoing

and significant concerns with plan sponsor adherence to Any Willing Pharmacy (AWP) requirements to ensure sponsors include independent specialty pharmacies as in-network providers.

There is currently no negotiation that takes place between the PBM that owns its own specialty pharmacy and an independent specialty pharmacy seeking to become a participating network provider, because the PBM managing the network also owns its own specialty pharmacy, clearly providing a significant disincentive from allowing any other specialty pharmacy in the network. By excluding other specialty pharmacies from its network, the PBM therefore drives more distribution revenue to its own subsidiary specialty pharmacy such that the PBM is using its status as a "gatekeeper" in one line of business to drive business to another line of business that it owns, which is a specialty pharmacy. The PBM that owns its own specialty pharmacy is therefore incentivized to exclude other competitor specialty pharmacies. In doing so, the PBM that owns a specialty pharmacy achieves two important financial goals. First, to drive greater revenue and profit to its own specialty pharmacy given that the PBM-owned specialty pharmacy is obviously in network with its parent corporate entity. Second, to create greater leverage in its purchasing power against manufacturers and wholesalers as a result of its greater influence in the network.

Since the PBM-owned specialty pharmacy has such a large market presence it dictates many of the financial terms between itself and its commercial partners such as sellers and even its own health plan clients. In order to achieve this financial goal, the PBM uses its network contracting process to exclude other specialty pharmacies from its network.

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. Congress created the AWP provisions to help lower costs and improve beneficiary access to all types of pharmacies by encouraging competition in the marketplace. Despite CMS offering limited clarifications in the FY Part D final rule regarding AWP requirements, NASP remains concerned that plan sponsors are circumventing AWP requirements and inappropriately excluding pharmacies from network participation. 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.

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." 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

⁵ Social Security Act (SSA) §1860D-4(b)(1)(A).

⁶ 83 Fed. Reg. No. 73, April 16, 2018

⁷ 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

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 that 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. 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.

Current AWP requirements mandating reasonable terms and conditions do not protect against the practices outlined above, and necessitate revisiting by HHS/CMS to ensure network adequacy requirements are being met and a competitive marketplace is available to improve access to specialty drugs and services. 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 pharmacy contract 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.

By shutting out independent specialty pharmacies from its network, the PBM is not only increasing its financial power but also reducing patient and physician choice as to how to access the specialty drug. With fewer in network pharmacies comes reduced competition amongst and between specialty pharmacies in addition to fewer choices. Without this competition the incentives to compete on quality of care and patient outcomes are also dramatically reduced. Since the PBM owns the specialty pharmacy and there is little to no competition in its network, why would the PBM owned specialty pharmacy create quality of care programs and measure outcomes to attract physician prescriptions, patients or drug contracts from the manufacturers? Without the competition, the PBM owned specialty pharmacy receives all the prescriptions from the physicians without the need to innovate or improve patient services.

There are many examples of contract provisions and requirements offered by PBMs that also own a specialty pharmacy that NASP believes are used to exclude the independent specialty pharmacy from the network. Many, if not all of these provisions have nothing to do with the dispensing of a drug or servicing the patient.

• Complex credentialing and staffing requirements—Many PBM networks require in-network specialty pharmacies to be accredited by at least one of the independent accrediting bodies such as URAC, the Joint Commission, and ACHC. NASP supports accreditation by nationally recognized, independent, third-party accreditation organizations, as a tool to drive competition based on uniformly applied measures, standards and processes. Independent third party accreditation demonstrates the specialty pharmacy's commitment to providing quality patient care and service excellence. Recently, however, many PBMs that also own a specialty pharmacy are requiring accreditation by their own PBM as a condition for network participation. In addition to charging a fee for this accreditation, the PBM accreditation process in-

cludes a detailed audit of business processes, capturing photos and reviewing other proprietary and strategic documents all under the auspices of network credentialing.

Most of this entire process is not relevant at all for the independent specialty pharmacies' ability to dispense drugs and take care of patients. Rather, independent specialty pharmacies believe that it is an attempt to gather sensitive competitive business intelligence that may be used in the PBM's own specialty pharmacy. In other words, there is very little confidence in the fire wall that is supposed to exist between the two entities.

For example, recently a NASP member applied to be in network and after going through the credentialing process was notified that the specialty pharmacy did not meet the PBM's standards. This specialty pharmacy is dually accredited in specialty pharmacy by nationally recognized, independent, third-party accreditation organizations, and has provided impeccable service to several IDN / health system clinics that require a very high service standard. From this denial, it is apparent that the PBM devised its own credentialing standards, making current non-biased third-party accreditation less relevant.

• Providing contract terms that under reimburse drugs— As mentioned above, independent specialty pharmacies contract with PBMs to be in network. Since the PBM owned specialty pharmacy is also a purchaser of that same drug from the manufacturer/wholesaler it knows the purchase price. Because the PBM knows the purchase price and is incentivized to keep independent specialty pharmacies out of network, it often offers drug reimbursement rates below the purchase price of the independent specialty pharmacy. For example, many of the current Pharmacy Services Administration Organization contracts contain a take it or leave reimbursement rate that is below acquisition cost. This ability is driven by the PBM in its obvious attempt to favor its own specialty pharmacy that has either a better reimbursement rate given its size or can sustain the loss also because of its size and dominance in marketplace as detailed above.

Star Ratings – Updating the methodology used to calculate Drug Plan Customer Service star ratings for plans that are appropriately managing utilization of high-cost drugs

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." NASP urges HHS to support reforms that will 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.⁹

As a result of collecting and validating this data from the plan sponsor, CMS can then provide

⁸ 82 Fed. Reg. 56376.

⁹ 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).

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 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.

Medicare Part B to Part D - Which drugs or classes of drugs would be good candidates for moving from Part B to Part D?

NASP appreciates the Administration's want to improve competition in the Medicare drug market by expanding negotiating authority for certain drugs under Medicare; however, NASP wants to advise that HHS exercise caution and an incremental approach to coverage in this way. The Medicare Part B medical benefit was intended to cover drugs that required administration by a physician. However, as drug products have evolved, some drugs covered under Part B are now able to be self-administered, provided in an outpatient setting, or directly provided to a beneficiary by a pharmacy. NASP encourages HHS to carefully consider which drugs currently covered under Part B require physician administration and work to continue coverage for these drugs under Medicare Part B to ensure patient safety and well-being.

NASP advises that HHS give consideration as to the cost to beneficiaries if drugs are moved from Part B to D, given that Medicare supplemental and Medigap benefits are not available under Part D as they are under Part B. For high-cost specialty drugs in particular, it is critical that HHS work to fully understand the impact on beneficiaries' cost sharing prior to implementing a transition of certain drugs from Part B to Part D, as the increased costs could significantly impact patients' access to or adherence to treatment. We are also concerned about those beneficiaries that do not currently have coverage under Medicare Part D. Any new policy would need to incentivize seniors to participate in Part D, and establish terms that can be met as individuals transition from Parts B to D.

While the intent of a switch in some drugs from Part B to D is to increase price competitiveness, NASP must re-raise concerns about the anti-competitive practices that exist under Part D today, particularly as it relates to specialty drugs and services. Reforms to Part D are needed to ensure beneficiaries receive a fair price at the point of sale, and are not paying excessive copays for higher list prices that a PBM plans to re-capture through retroactive and escalating DIR clawback payments. NASP is concerned that many seniors fall into catastrophic coverage sooner than expected due to paying higher prices at the point of sale for high cost drugs. We must first alter this system if we are to consider putting more high cost drugs into Part D.

In light of these concerns, we urge CMS to proceed cautiously with any plan to transition certain drugs from Part B to D and we welcome the opportunity to work with the agency in understanding the possible consequences of such a transition on beneficiary access to life-saving medications.

Reduce Patient Out-of-Pocket Spending

Part D End-of-Year Statement on Drug Price Changes and Rebates Collected

 What additional information could be added about the rate of change in prices over the course of a benefit year? Could pharmacists be empowered to inform beneficiaries when prices for their drugs have changed?

Inform Medicare Beneficiaries with Medicare Part B and Part D About Cost-Sharing and Lower-Cost Alternatives

Does this create unreasonable burden for prescribers or pharmacists?

Part D plans' Explanation of Benefits (EOBs) currently provide beneficiaries with information about the negotiated price for each of the dispensed prescriptions and the associated cost-sharing. EOBs provide beneficiaries with other important information, such as a summary of claims from the last EOB, summaries of year-to-date costs to the plan, and information about the beneficiary's current drug payment stage. The EOB may, but does not always include, information about formulary changes. Formulary changes are uniformly announced in the Annual Notice of Change (ANOC). As CMS looks to improve transparency regarding the rate of change in prices over the benefit year, NASP recommends that CMS consider including in the EOB and ANOC information about which drugs are provided by pharmacies that are innetwork, in a preferred-network, or out-of-network. Specialty drug beneficiaries are particularly vulnerable to high out-of-pocket costs, and very few beneficiaries can afford to pay for drugs that are out of network. Furthermore, while a Part D plan sponsor may accurately list which drugs are on their formulary, the corresponding information regarding which specialty pharmacies provide in-network or preferred network coverage is needed to ensure that beneficiaries can access a specialty pharmacy to dispense these medications. As we have noted in comments in previous sections, independent specialty pharmacies face burdensome network access issues. Revising CMS' definition of "formulary change" to include information on changes to the network status of specialty pharmacies will provide beneficiaries with more information to ensure they can access their life saving medications.

As outlined in the HHS Blueprint, patients frequently abandon their prescriptions at the pharmacy counter when they are unaware of the exorbitant costs of some medications. Adherence issues caused by financial burden are of great concern to NASP, and we applaud the administration's efforts to explore how to lower beneficiary out-of-pocket costs. Specialty pharmacies play an integral role in containing costs for the system at large, and to patients and beneficiaries in particular through high-touch medication management. A principle role of specialty pharmacies is to provide assistance by way of guidance and recommendations on options available to afford their medication (e.g., copay support systems). When a prescription is filled by a specialty pharmacy, the pharmacy will contact the beneficiary to discuss the specific medical and financial responsibilities associated with the medication(s), including the financial share or burden to the beneficiary.

Specialty pharmacies do not, however, have access to information concerning price adjustments made to drugs, and unlike prescription drugs used to treat common chronic health conditions, there are a limited number of generic options available to treat most specialty medical conditions to which a specialty pharmacist could recommend as an alternative to more costly brand drugs. NASP is not familiar with

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technology systems that can be seamlessly implemented across independent specialty pharmacies to support pharmacists in revised formulary options and lower cost alternatives for patients. We believe it would create unreasonable burden and economic consequences for independent specialty pharmacists to be required to implement new technology systems with this specific intent.

Conclusion

We thank HHS for consideration of NASP's comments on the HHS Blueprint and RFI. NASP looks forward to continuing to work with the Department to support policy reforms that will reduce costs to Medicare beneficiaries and the Medicare program for specialty drugs and ensure access to the specialty drugs and services they need to improve health and reduce overall healthcare costs. If we can provide additional information, please contact me at 703-842-0122 or sarquette@naspnet.org.

Sincerely,

Sheila M. Arquette, R.Ph.

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Executive Director