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Ms. Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-4180-P

Dear Administrator Verma:

The National Association of Specialty Pharmacy (NASP) is pleased for the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS) proposed regulation, "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses" [83 Fed. Reg. No. 231, November 30, 2018; CMS-4180-P; RIN 0938-AT92). NASP shares the administration's goals of lowering out-of-pocket costs for beneficiaries under Medicare Part D, improving the transparency of fees, and ensuring competitive balance under the Medicare Part D program. We want to acknowledge and thank the administration for its ongoing focus and dialogue on these and other key issues that affect specialty patients and the pharmacies that work to address their complex health care needs.

NASP's members are committed to the practice of specialty pharmacy with a focus on the patients served to ensure better clinical outcomes while reducing overall healthcare costs. NASP defines a specialty pharmacy as a state licensed and registered pharmacy that is accredited by, or in the process of specialty pharmacy accreditation by an independent, third-party accreditor and solely or largely provides medications and patient medication management services to patients with serious health conditions requiring treatment with complex medication therapies. 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 1,500 individual members, NASP is the unified voice of specialty pharmacy in the United States.

The proposed rule offers additional reform proposals to address issues concerning beneficiary cost, price transparency and market competitiveness affected by the pharmacy supply chain. Building on the Request for Information included in the proposed Calendar Year (CY) 2019 Medicare Part D rule[1] and the administration's Blueprint *to Lower Drug Prices and Reduce Out-of-Pocket Costs*[2], the proposed rule includes important policy adjustments related to direct and indirect remuneration (DIR) fees, and recognizes that current fees have resulted in increased costs for seniors and the Medicare program while negatively impacting competition within the Medicare Part D program. NASP commends CMS for addressing this significant issue in the proposed rule. We support CMS's efforts to improve drug prices at the point-of-sale and offer our analysis, thoughts, and recommendations on how to implement such reforms to specifically address the needs of specialty patients and the pharmacies that serve their needs. NASP remains committed to continuing to work with CMS to advance these important reforms. We also offer our comments and recommendations on other important sections of the proposed rule, including reforms toward coverage of drugs within the six protected classes, establishment of a new real-time benefit tool to support beneficiaries and providers, and reforms that address the use of step therapy for Part B drugs.

Summary of NASP's Comments

Medicare Part D Proposals

Negotiated Price (at Point-of-sale)

- NASP urges CMS to finalize the proposed changes to the "negotiated price" definition in 42 C.F.R § 423.100 that seeks to include all pharmacy price concessions at the point-of-sale, beginning in calendar year 2020.
- NASP also urges that CMS establish and oversee standardized metrics for pharmacy performance that would be calculated separate and apart from the negotiated price to ensure: (1) any incentive payments tied to metrics do not increase costs for beneficiaries; and (2) appropriately assess the actual quality performance of a pharmacy in a manner that is specific to the pharmacy type, drugs dispensed, and disease states being managed. Such metrics can initially be stood up beginning in calendar year 2020, along with a new process for deriving additional metrics in the years that follow.

Lowest Price

- NASP requests regulatory protections to ensure that plan sponsors and PBMs that own their own specialty pharmacy business cannot provide more advantageous pricing to their own entities in an effort to limit a pharmacy network and gain greater market share.

[1] 82 Fed. Reg. 56419–56428.
[2] Department of Health and Human Services. "American Patients First," May 2018: https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf.

- NASP urges CMS to codify provisions in existing CMS guidance and manuals to protect pharmacies against reimbursement that is below a pharmacy's drug acquisition cost. We also ask that protections be put in place through the plan bid process that allow pharmacies to appeal when reimbursement is below a pharmacy's drug acquisition cost.

Definition of Pharmacy Price Concession

- NASP believes codifying a definition is necessary to support consistent accounting of amounts that are pharmacy price concessions by Part D sponsors as the agency seeks to revise the definition of negotiated price.
- NASP recommends that CMS oversee the operation of the changes to the negotiated price definition by requiring plans to provide an attestation from the Chief Executive Officer (CEO), Chief Financial Officer (CFO), Chief Operating Officer (COO) or other delegated individual as to the accuracy and completeness of the pharmacy price concessions included in negotiated price at the point of sale.
- NASP asks that CMS clarify through plan bid contract requirements that pharmacy claw back arrangements of any fees that would otherwise lower the price of a drug at the point-of-sale are not permitted and will be considered in violation of regulatory requirements at outlined through the definition of negotiated price.

Standardized Pharmacy Metrics

- NASP asks the administration to formalize its proposal to develop or approve a standard set of metrics through a stakeholder process. Metrics should reflect achievable goals and be specific to pharmacy type, drug dispensed, and disease state being managed, on which plans and pharmacies would base their contractual agreements. We ask that CMS oversee this process.

<u>Proposed Regulations</u>

Plan Flexibility to Manage Protected Classes

- NASP urges CMS to give due consideration as to whether the exceptions proposed would cause a disproportionate shift and negatively impact patients who currently rely on the protected class policy for their uniquely complex medical needs. Changes should be examined through a critical lens to ensure a proper balance is maintained and that patients will not experience delays in accessing medications or be prevented from utilizing the most appropriate and effective medications recommended by their providers for their specific condition(s).

- NASP recommends that CMS require Part D sponsors to distinguish between new and existing patients if any of the proposed exceptions are finalized, maintaining existing protections for patients already receiving a protected class drug.
- NASP submits that step therapy for protected class drugs should follow the process already established for step therapy for non-protected class drugs with respect to: the submission, review and approval of step therapy protocols; the exception request process; and processing timelines.
- NASP does not support CMS's proposal to permit Part D sponsors to exclude a drug within a class because the drug's price increased at a rate beyond the CPI-U.

E-Prescribing and Updating E-Prescribing Standards

- To properly implement the RTBT system, verifying data accuracy and completeness and to do so in a cost effective manner, NASP recommends that CMS delay the proposed implementation date past January 1, 2020, and consider first testing the system through a demonstration within the CMS Center for Medicare and Medicaid Innovation (CMMI).

Medicare Advantage and Step Therapy for Part B Drugs

- NASP supports CMS's proposed requirement to permit step therapy only for new patient starts, as specialty patients on established therapies cannot easily have their treatment plans altered without the risk of huge implications on their care and health.
- NASP strongly supports CMS's requirement to have any step therapy or other utilization management plan reviewed by a P&T Committee before implementation of any change occurs, allowing time to address any concerns that might negatively impact patient care.
- NASP supports CMS's proposal to ensure timely appeals and other determinations and believes it is important to ensure that timeframes are shortened and strictly adhered to so that patient access to medication therapies needed as guided by a clinician are not jeopardized.
- NASP recommends that if CMS proceeds with codifying the use of step therapy for Part B MA-PDPs, that it also consider requiring MA plan sponsors to post the list of Part B drugs with a step therapy requirement and the description of what is required on MA plan sponsors' websites so that the information is easy for prescribers and patients to access as opposed to only including the information in the Annual Notice of Change (ANOC) or Evidence of Coverage (EOC) as proposed.

NASP Comments on Medicare Part D Proposals and Proposed Regulations

Medicare Part D Proposals

Pharmacy Price Concessions in the Negotiated Price (42 C.F.R § 423.100)

Appreciation of CMS's Recognition of the Negative Impact of Pharmacy Price Concession DIR on Beneficiary Out-of-Pocket Costs and Access to Independent Specialty Pharmacies

NASP applauds CMS for its efforts to foster greater transparency in the distribution channel, particularly related to the fees paid by pharmacies to plans sponsors and pharmacy benefit managers (PBMs) in the channel. NASP is so pleased to see CMS offer proposals in the proposed rule to amend regulation and move all pharmacy price concessions, including DIR fees, to the point-of-sale. We support and encourage the administration's efforts to move forward and offer our recommendations on how to successfully achieve the administration's goals in a way that is of most benefit to specialty patients served by the Part D program.

NASP's members have seen a dramatic growth in the collection of pharmacy DIR fees by PBMs since 2012. Plan 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 be.

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 of "performance-related" fees that some PBMs are collecting from pharmacies, especially specialty pharmacies that are pointedly impacted by this practice. **Instead of focusing on clinical outcomes, these DIR 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 and disease states not being managed by specialty pharmacies. Often times, such broader pharmacy measures are not even appropriate for pharmacy evaluation, as the pharmacy cannot influence the measure (e.g., generic pricing performance; formulary compliance).**

DIR fees ultimately shift financial liability away 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

[3] 82 Fed. Reg. 56420.
[4] 82 Fed. Reg. 56419–56428.

they have dispensed the medication. Oftentimes when the reimbursement is reconciled, it is far less than the actual cost of the drug, which is further complicated by the cost of the requisite services needed to support the patient's journey on the drug. This situation threatens the ability for specialty pharmacies – particularly independent specialty pharmacies that simply do not have the ability to offset lost revenues or costs with other portions of their businesses – to remain network providers, risking access for beneficiaries.

In the proposed rule, CMS explains that data shows pharmacy price concessions grew more than 45,000 percent between 2010 and 2017[5] with much of that growth occurring after Part D sponsors stood up "performance-based" pharmacy payment arrangements that only served to institute sizeable reductions in pharmacy reimbursement and zero savings for beneficiaries. Plan sponsors and their PBMs collected such fees by interpreting the current regulatory definition of "negotiated prices" to exclude DIR-related pharmacy price concessions at the point-of-sale. As a result, Medicare beneficiaries pay far more in cost-sharing and a larger share of the actual cost of the drug when purchasing their medications. The drug price at the time of purchase does not reflect additional payment reductions that are made to a pharmacy by the plan sponsor/PBM. Beneficiaries never receive a discount or financial adjustment to their drug costs from fees collected by plan sponsors/PBMs after the point-of-sale. **In the proposed rule, CMS appropriately characterizes the current treatment of price concessions under Part D as a system that has resulted in "distorted incentives" for Part D sponsors. They are the only ones to benefit by the growing fees, collecting profit on any DIR fees that exceed those they initially included in plan bids. Such profit is not reported to the agency and is never utilized to reduce premium or other cost-sharing for beneficiaries.**

As pharmacy price concessions increase on gross drug costs and are applied after the point-of-sale, specialty patients are paying higher and higher cost-sharing (copays and coinsurance). CMS acknowledges in its discussion on the rule that these beneficiaries pay far more upfront for the cost of their drugs and are forced into the catastrophic phase of Part D much sooner than if pharmacy price concessions were accounted for at the point-of-sale. Specialty pharmacies have seen first-hand how higher cost-sharing impedes beneficiary access to medications. For specialty patients, missing doses or stopping therapy altogether often results in serious setbacks in treatment, and increased visits to emergency departments, and in some cases can result in death.

Beneficiary Savings at Point-of-sale with Likely Less Negative Premium Impact Than Projected

CMS estimates that beneficiaries would save $7.1 to $9.2 billion over 10 years from reduced cost-sharing if pharmacy price concessions were included in negotiated price.[6] NASP believes the savings could be considerably higher for those beneficiaries who are prescribed higher cost drugs to manage their care, particularly those that have limited alternative drug treatment

[5] 83 Fed. Reg. 62174.
[6] 83 Fed. Reg. 62154.

options, such as when a generic or another lower cost drug option is unavailable or not clinically appropriate to address the specialty condition being managed.

CMS acknowledges that there would be a limited projected increase of $10.16 per month in premiums if all pharmacy price concessions were moved to the point-of-sale. However, that estimated increase would be offset by reductions in patient cost-sharing, which CMS estimates to be a reduction of $26.29 per month.[7] **NASP also believes that premium increases would likely be less than those projected by CMS, given that some plan bids submitted by Part D plan sponsors understate in their submission an estimate of net plan liability. Any premium increases will be more than offset by additional cost-sharing reductions.** These sponsors submit a lower bid, estimating DIR-related pharmacy price concessions to be collected. As CMS acknowledges in its preamble to the proposed rule, for many plans, collection of DIR-related pharmacy price concessions after the point-of-sale have well exceeded the estimates submitted by the plans at the time of bid.

DIR-Related Pharmacy Performance Cuts Not Based on Specialty-Specific Metrics

CMS also correctly highlights that PBMs have been recouping increased sums from network pharmacies after the point-of-sale for "poor performance" at a rate far greater than those paid to network pharmacies for "high performance." For specialty pharmacies, there has never been an upside in regard to the application of such PBM performance metrics. **Since PBMs began to utilize their own select metrics that do not undergo a certification process overseen by CMS specialty pharmacies have found themselves unfairly subjected to metrics that are largely unrelated to the drugs the pharmacies dispense, conditions they treat, or the services they provide.** For example, specialty pharmacies that dispense medication and provide patient care services for conditions like cystic fibrosis, hemophilia, or multiple sclerosis encounter DIR-related pharmacy performance scores associated with conditions like diabetes and cardiovascular disease applied against them with the purpose of reducing their reimbursement in the form of claw back fees.

CMS accurately relays that the variation in the treatment of price concessions by the plan sponsors may have a negative effect on the competitive balance under Medicare Part D– resulting in unnecessary spending by Medicare and its beneficiaries. With the dynamics noted above, independent specialty pharmacies have found themselves in a no-win situation, being disproportionately affected by so-called performance measure cuts they have no ability to affect. Non-transparent and often excessive pharmacy price concessions in the form of claw backs well after the point-of-sale, limit a specialty pharmacy's ability to remain in-network. Less market competition ultimately results in higher costs to the Medicare program and restricted patient access for beneficiaries, especially specialty patients with complex medication needs that often need the care management provided by independent specialty pharmacies.

[7] Id.

Regulatory Changes to the Definition of "Negotiated Price" to Achieve Lowest Possible Reimbursement

As soon as CY 2020, CMS is considering changing the existing regulatory definition of "negotiated prices" at 42 C.F.R § 423.100 to "negotiated price," to mean "the lowest amount a pharmacy could receive as a reimbursement for a covered Part D drug under its contract with the Part D sponsor or the sponsor's intermediary (that is, the amount the pharmacy would receive net of the maximum possible negative adjustment that could result from any contingent pharmacy payment arrangement)."[8] All pharmacy price concessions and any dispensing fees would be included in negotiated price. Additional, positive contingent amounts such as incentive fees that increase prices, would be excluded from the definition, as would select contract and administrative fees.

NASP very much appreciates CMS' significant effort to make negotiated price more transparent and the agency's acknowledgment of the need to amend the definition of negotiated price as finalized in the agency's rule in 2014[9]. We support CMS's efforts to amend the definition of negotiated price as a way to ensure that all pharmacy price concessions are accounted for and reported by plan sponsors and their intermediaries at the point-of-sale. We believe this change would effectively eliminate retroactive pharmacy price concessions, which NASP has long advocated for. We strongly believe that revising negotiated price to ensure all pharmacy price concessions are included at the point-of-sale would also accomplish our shared goal of lowering beneficiary out-of-pocket costs.

NASP is concerned, however, that as outlined, the proposed definition of negotiated price would continue to permit plan sponsors and PBMs to include the maximum negative adjustments from DIR-related pharmacy payment arrangements that use plan-established measures to assess pharmacy performance regardless of whether such measures are appropriate to the drug dispensed or disease state being managed by a given pharmacy – particularly given that, to date, all such metrics simply are not applicable to specialty pharmacies. As addressed earlier, specialty pharmacies have seen significant, double-digit growth in DIR fees tied to performance being negatively applied as plan sponsors claim that metrics have not been met by in-network pharmacies. With few exceptions, there are no specialty-specific metrics consistently used by Part D plan sponsors today for the purpose of DIR-related performance evaluations. The majority of metrics used to assess pharmacy performance by Part D plans and Medicare Advantage pharmacy drug plans are not relevant to the drugs used to treat specialty medical conditions or the specialty indications themselves.

If plan sponsors and their intermediaries are permitted under a revised regulatory definition of negotiated price to utilize current DIR performance metrics for the purpose of achieving the lowest price at the point-of-sale, NASP is very concerned that independent specialty pharmacies will continue to be placed at a market disadvantage, thereby jeopardizing

[8] 83 Fed. Reg. 62153.
[9] 79 Fed. Reg. 29844–29968.

beneficiary access to care and choice of pharmacy. Reimbursement to specialty pharmacies will be far less than it would be. If, for the purpose of deriving lowest price, the plan was only permitted to use metrics that apply to the drugs and patient services provided by the pharmacies. This concern extends beyond direct pharmacy reimbursement at the point-of-sale; more importantly, it threatens independent specialty pharmacy participation in contract networks, threatening access to needed specialty pharmacy services and choice of pharmacy provider for beneficiaries.

NASP sincerely appreciates CMS's efforts to establish a revised definition of negotiated price that includes all pharmacy price concessions at the point-of-sale and addresses this revised definition in a manner that minimizes the impact such changes will have on patient premiums. We likewise appreciate the agency's efforts to ensure greater transparency in the fees applied at the point-of-sale. Our concern is that by allowing plans and their sponsors to utilize performance criteria for the purpose of a negative adjustment in order to achieve lowest price when such criteria is not relevant to the drugs being dispensed or disease state(s) being managed, the fees outlined under negotiated price will continue to not be transparent for beneficiaries or pharmacies. A beneficiary will continue to have no understanding of what metrics were used to alter the price of the drug and whether their price was affected based on their own pharmacy's performance for their medication management.

NASP Recommendations

While NASP is concerned about the inclusion of existing DIR-related metrics for the purpose of deriving lowest price, NASP agrees that given the significant implications of the current payment system on beneficiaries, CMS must proceed with moving all pharmacy price concessions to the point-of-sale in order to reduce drug costs for beneficiaries and improve predictability and stabilization for pharmacies. NASP is committed to continuing to work with CMS to ensure that efforts to amend negotiated price are achieved in a timely manner, as soon as CY 2020.

If CMS opts to proceed with re-defining negotiated price as outlined in the proposed rule, NASP strongly requests that CMS simultaneously establish standardized metrics for pharmacy performance that would be calculated separate and apart from the negotiated price to ensure: (1) any incentive payments tied to metrics do not increase costs for beneficiaries; and (2) appropriately assess the actual quality performance of a specific pharmacy in a manner that is specific to pharmacy type, drugs dispensed, and disease states being managed. Reforming the definition of negotiated price to revise the payment system for Part D drugs necessitates a new system for measuring pharmacy quality – the two efforts are inextricably linked if: a beneficiary is to understand the price of the drug; a beneficiary and prescriber are able to select a pharmacy they believe to provide high quality services; and if we are to sustain a competitive pharmacy marketplace to serve beneficiary pharmacy needs.

Moving forward with standardized metrics in tandem with reforms to negotiated price will ensure that pharmacies can be appropriately assessed for performance, and that CMS can monitor Part D Plans to ensure that they are working to improve quality care so that appropriate information is available to support beneficiary choice in the selection of their pharmacy provider. Pharmacy metrics should be standardized across Part D and MA Part D plans. Today, many Part D plans have "performance" metrics that are based on measures designed by the plans themselves. CMS notes that incentive payments from measures designated by plans themselves are virtually non-existent. As NASP addressed, measures that are associated with specialty conditions are virtually non-existent. At worst, specialty pharmacies are not measured by appropriate metrics associated with the diseases being managed, and at best, specialty pharmacies are subject to inconsistent and confusing performance measures across plans. Because the plans devising the performance metrics today ultimately stand to profit when pharmacies are found to not meet such metrics, there is a perverse incentive for metrics to be set up by plans in a manner where they are not achievable. CMS oversight of such a system where the agency selects an unbiased third-party entity to develop metrics that are based on achievable and proven criteria that accurately measures pharmacy performance is needed. **Just as a health plans directly interact with a patient, a pharmacy directly interacts with a patient. As such, it is entirely appropriate that CMS and not a plan oversee the development of a new system for standardizing pharmacy performance metrics.** CMS also has substantial interest in ensuring that specialty pharmacies are providing quality services, given that spending on specialty drugs is the largest portion of spending under Medicare Part D.

For all of these reasons, NASP requests that CMS move forward with amending the definition of negotiated prices, and in doing so, also move forward in establishing and overseeing standardized performance metrics for pharmacies to be utilized outside of negotiated price and for which a new performance-based pharmacy incentive program can be built. We provide recommendations for establishing a standardized system of metrics for pharmacy performance later in these comments.

CMS raises the question of whether it should require plan sponsors to include pharmacy price concessions in the negotiated price in the coverage gap. NASP is concerned that having more than one definition of negotiated price as it relates to pharmacy price concessions would result in significant complexity during the bid process and CMS oversight and operations going forward, and would have direct implications on pharmacy payment. NASP recommends that CMS maintain a consistent definition of negotiated price throughout the Medicare Part D benefit as it relates to pharmacy price concessions.

CMS asks for comment on a considered alternative to lowest price that would require Part D sponsors to apply less than 100 percent of pharmacy price concessions at the point-of-sale. CMS states that this alternative might grant sponsors additional flexibilities in regard to the application of price concessions in an effort to reduce impact on premiums. NASP is concerned that the same problems that occur today as a result of the reasonably determined exception

will persist if plans are permitted to omit certain pharmacy price concessions at the point-of-sale. As CMS notes in its discussion on negotiated price, moving all pharmacy price concessions to the point-of-sale has a small impact on premiums and allows for significant reductions in cost-sharing for beneficiaries. As referenced above, CMS also believes that plan bids have, at times, underestimated DIR fees and contributed to growth in plan profit as opposed to reductions in cost to beneficiaries. Also, allowing plans to in any way limit the percentage of pharmacy price concessions that can be applied at the point-of-sale threatens a continuation of the financial instability faced by pharmacies today.

Lowest Price

NASP appreciates and supports CMS' effort to lower beneficiary costs under Part D and to ensure patients are offered the lowest price possible in an effort to reduce out-of-pocket expenses. Access to prescribed medications is critically important for specialty patients, and missed doses due to lack of drug affordability can be life threatening. Such prices have previously had no transparency, and CMS's proposal brings new transparency into what has historically been a black box for seniors. NASP wants to ensure that in making regulatory adjustments to derive lowest price, CMS also ensures greater transparency within the market itself and that the revised regulation protects against anticompetitive practices and gaming within the system.

Reform to negotiated price needs to ensure that plan sponsors and PBMs that own their own specialty pharmacy business cannot provide more advantageous pricing to their own entities in an effort to limit a pharmacy network and gain greater market share. This protection is all the more important when addressing pricing for drugs where there are limited drug alternatives for patients, such as those with rare and other specialized conditions. Specialty pharmacies provide medication and services that are tailored to managing these unique populations, and network adequacy is essential to ensuring access to these medications for patients. CMS's proposed definition of negotiated price includes, in part one of the definition, that the "Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the lowest possible reimbursement such network entity will receive, in total, for a particular drug . . . ."[10] CMS's proposed language seems to state that the price needs to be the lowest price that *a particular network entity* will receive for a particular drug but does not need to be the lowest price that *any network entity* will receive for a particular drug. **NASP requests that CMS amend this language to read a "Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the lowest possible reimbursement ~~such~~ *any* network entity will receive, in total, for a particular drug…" .** Amending this language as recommended would continue to permit plan sponsors to determine negotiated price on a contractual basis while ensuring a competitive advantage is not inappropriately provided, particularly on higher priced drugs, for plan/PBM-owned pharmacies.

[10] 83 Fed. Reg. 62179.

Most importantly, it would clarify CMS's intent to provide beneficiaries access to the lowest price in any given network with any in-network pharmacy (plan-owned pharmacy or contracted pharmacy).

In an effort to ensure revisions to negotiated price do not result in additional anti-competitive practices as it relates to deriving lowest price, NASP also urges CMS to ensure that a mechanism is in place to allow pharmacies to appeal plan sponsor decisions to offer reimbursement to pharmacies that is below a pharmacy's drug acquisition cost. Negotiated price should be determined on a contractual basis, but appropriate safeguards must protect lowest prices offered allow for the reimbursement of Part D drugs to be appropriate when all pharmacy price concessions are applied at the point-of-sale. To date, there has been little-to-no transparency for pharmacies under the Part D payment system with final reimbursement often being far below a pharmacy's net costs. For specialty pharmacies that provide extensive care management services to support medication therapy and oversight, reimbursement pressures are all the more immense when reimbursement is below cost. The net effect of unreasonable reimbursement is restricted pharmacy networks as pharmacies cannot accept network terms, limiting beneficiary and provider access to a pharmacy needed to support beneficiary needs.

With a revised and/or new definition of negotiated price and pharmacy price concessions, a system for the oversight and reporting of plan/PBM administrative costs, and a system for standardizing performance metrics, NASP is hopeful that a revised system for payment of Part D drugs will allow for improved transparency and a competitive market environment. However, we ask that CMS utilize and enforce a process for ensuring safeguards are in place to protect a pharmacy from any effort by plan sponsors to reimburse a given pharmacy below cost when deriving the lowest reimbursement through negotiated price at the point-of-sale. Without protections in place, plan sponsors could comply with the new definition of negotiated price but have a total reimbursement rate below the pharmacy's acquisition cost. This would have the same market effect of excluding independent specialty pharmacy network participation as the application of post adjudication DIR fees. NASP offers the following recommendations to CMS for addressing this significant issue:

- Codify terms outlined in the Medicare Prescription Drug Manual that state "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 423.505(b)(18)."[11] CMS should then monitor Part D Sponsor compliance.
- Require Part D plans sponsors to outline in their submitted plan year bids in CY 2020 and thereafter a process to facilitate appeals from pharmacies, particularly appeals in relation to the plan's reimbursement falling below a pharmacy's drug acquisition costs.

[11] Centers for Medicare and Medicaid Services. Medicare Prescription Drug Benefit Manual: Chapter 5; Section 50.3; September 20, 2011: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.pdf.

- Ensure that the Complaints Tracking Module (CTM)[12] in place today for Part D plans is utilized to provide timely response to pharmacy complaints, including complaints regarding reimbursement being below a pharmacy's costs. The CTM currently allows for the receipt of provider and pharmacy complaints and outlines a process for timely response. NASP asks that CMS clarify in revised guidance on the CTM that plans are to be responsive to complaints addressing reimbursement falling below cost in relation to lowest price under negotiated price as defined.

Definition of Pharmacy Price Concession

CMS seeks to establish a regulatory definition for "pharmacy price concession" to mean "any form of discount, direct or indirect subsidy, or rebate received by the Part D sponsor or its intermediary contracting organization from any source that serves to decrease the costs incurred under the Part D plan by the Part D sponsor."[13] **NASP believes codifying a definition is necessary to support consistent accounting of amounts that are pharmacy price concessions by Part D sponsors as the agency seeks to revise the definition of negotiated price.** Such a definition will work to ensure that Part D plan sponsors and PBMs are not permitted to issue fees in a manner that would manipulate bid amounts and ultimately be excluded from lowering costs for beneficiaries at the point of sale. CMS must appreciate that "pharmacy price concession" needs to be broadly defined, given the evolving contractual terms offered by plans and their intermediaries, and should include any remuneration that reduces reimbursement to a pharmacy for dispensing a drug under Part D, other than limited administrative fees utilized to administer contracts.

NASP also recommends that CMS oversee the operation of the changes to the negotiated price definition by requiring plans to provide an attestation from the Chief Executive Officer (CEO), Chief Financial Officer (CFO), Chief Operating Officer (COO) or other delegated individual as to the accuracy and completeness of the pharmacy price concessions included in negotiated price at the point of sale. There is precedent in regulation for such a requirement to ensure accurate reporting.[14] Such a requirement will provide CMS with documentation of impropriety if such price concessions are not included in the negotiated price.

NASP understands that in establishing the definition, CMS intends to ensure that with minimal exceptions to address contract-related administrative costs, all pharmacy fees are to be applied at the point-of-sale and reported on the reported Prescription Drug Event (PDE). **As CMS seeks to formalize the definition of pharmacy price concession through regulation and establish a revised definition for negotiated price, NASP asks that this intention be made clear in bid contract requirements and that CMS also state that pharmacy claw back arrangements of any**

[12] Centers for Medicare and Medicaid Services. Complaints Tracking Module (CTM) Standard Operating Procedures:https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/UpdatedGuidanceStandardOperatingProcedures.pdf
[13] 83 Fed. Reg. 62180.
[14] 81 Fed. Reg. 41099.

fees that would otherwise lower the price of a drug at the point-of-sale are not permitted and will be considered in violation of regulatory requirements.

Pharmacy Administrative Service Fees

CMS addresses certain fees that are charged to network pharmacies today (network access fees, administrative fees, technical fees and service fees). CMS says that it plans to restate previous regulatory guidance[15] reminding Part D sponsors that when pharmacy administrative service fees are deducted from payments made to pharmacies for purchases of Part D drugs, such costs are price concessions and must be treated as such in Part D cost reporting. If there are other costs that the plan believes should be treated as administrative costs, such costs should be accounted for in the administrative costs of the plan sponsor's Part D bid. NASP agrees with CMS' proposal for addressing so-called plan administrative service fees and ensuring such fees are transparent and appropriately categorized and reported.

NASP recommends that just as CMS tracked changes in the growth of DIR fees over multiple years, CMS should also consider conducting oversight in the growth and appropriate reporting of "administrative fees" as the agency moves to define negotiated price. Understanding the type and volume of fees that fall outside of price concessions could potentially impact the price beneficiaries pay at the point-of-sale, and will help in improving program efficiencies over time as CMS seeks to lower drug prices. Likewise, given that administrative fees to date have had minimal-to-no value to pharmacies with the exception of network participation, it is important that CMS understand whether and how such fees are adjusted over time and the impact such fees have on pharmacy network participation by pharmacies, especially independent specialty pharmacies when plan sponsors/PBMs own their own specialty pharmacy. It is in CMS's interest to ensure that a competitive pharmacy market exists to serve Part D beneficiaries.

Standard Set of Metrics for Contractual Agreements

NASP very much appreciates CMS's consideration of how to address metrics outside of the definition of negotiated price. As stated earlier, when regulating changes to the definition of negotiated price, NASP urges CMS to also establish a new system to standardize pharmacy performance metrics.

NASP believes such metrics can be implemented through a two-part process: (1) there are existing metrics being tested and validated through a stakeholder engagement process that can be put in place as soon as CY 2020; and (2) a formalized process can and must be stood up for future plan contract years that appropriately allows for stakeholder engagement in the development and approval of new standardized metrics that are specific to the disease/indication being treated by the drugs dispensed with appropriate oversight of such metrics. NASP believes that CMS should allow for metrics to be put in place to both establish a

[15] 83 Fed. Reg. 62179–62180.

system that encourages quality and improved pharmacy services for beneficiaries, and provides pharmacies more predictability in their reimbursement in order to support market competitiveness.

Existing Metrics for CY 2020

A standard set of metrics from which plans and pharmacies can base their contractual agreements can initially be stood up today and overseen by CMS. Such a system should be separate and apart from negotiated price, as proposed by CMS, to ensure any incentive-based payment that results from metric evaluation do not increase costs for beneficiaries. Such a pharmacy-specific metric system should be overseen by CMS, with the agency requiring plans to determine pharmacy performance on achievable and proven criteria that accurately measures performance based on the disease state/indication being managed by a pharmacy.

Metric developing organizations like the Pharmacy Quality Alliance (PQA) offer a transparent, consensus-based approach toward the development of pharmacy metrics. Established in 2006 as a public-private partnership by CMS, PQA has grown to have over 240 members across the pharmacy community, including specialty pharmacies, other pharmacies, health plans, pharmacy benefit managers, life science companies, government agencies, and others. NASP's Clinical Outcomes Committee is currently engaged with the PQA and its convened group of stakeholders to plan, test, and validate standardized measures that specialty pharmacy providers can impact. PQA has developed a Specialty Pharmacy Measures Roadmap, outlining several draft measures for validation with the first measure expected for release as soon as CY 2020 that will provide a standardized way of measuring the time between a specialty pharmacy receiving a referral for a first prescription fill for a new medication to the specialty pharmacy dispensing or scheduling delivery of the drug product. Turnaround time is a metric used today by specialty pharmacy independent, third party accreditation programs.

Working in collaboration with PQA, CMS could move to quickly adopt an initial standard set of metrics from which plans and pharmacies would base their contractual agreements. As PQA is a consensus-driven organization, feedback from stakeholders on an initial set of metrics that are appropriate to addressing the disease state managed by given pharmacies could be recommended to CMS for initial adoption.

New Metric Process for Additional Plan Contract Years

Currently, through the existing pharmacy price concession rubric, Part D plan sponsors (including PDPs and Medicare Advantage Prescription Drug Plans (MA PDPs)) utilize quality measures they select to evaluate pharmacy performance, regardless of whether such measures are applicable to the indications for which a given pharmacy is dispensing drugs or providing services. An average performance score is assessed by the plan sponsor, typically in the negative, and applied against all pharmacies in a given network having the net effect of

reducing payments to pharmacies. As CMS correctly noted in its discussion in the rule, rarely do pharmacies see a positive outcome in the form of incentive payments from current Part D plan-operated metric-based evaluations. The current metric system has long had a negative and disproportionate impact on independent specialty pharmacies where metrics and validation processes specific to specialty conditions/indications are lacking and in need of development in collaboration with stakeholders that include but are not limited to development by Part D plan sponsors and PBMs.

A standard metric program must be stood up that allows for managed stakeholder input and oversight and engagement by CMS and the Office of the Secretary. Metrics should be based on achievable criteria, based on the disease state/indication being managed, including specialty diseases and conditions. We encourage CMS to develop and oversee such a system by selecting established and experienced measure developers for Medicare Part D, such as the PQA.[16] Such a developer must serve as a neutral convener of stakeholders, including: independent pharmacies, including independent specialty pharmacies; chain pharmacies; hospital pharmacies; health plans; pharmacy benefit managers; and others as appropriate. Metrics must be developed through a fully transparent and consensus-driven process with a fair system for validation. CMS oversight of this process is important toward ultimately ensuring that beneficiary quality is paramount through any metric-based system. Allowing PBMs and PDPs (including MA PDPs) to set and control quality and performance metrics without oversight, particularly when such entities own their own pharmacy business is concerning as they have no incentive to require that measures appropriately apply to the services being provided by a given competitor pharmacy.

In designing standard pharmacy metrics, the CMS-selected metric developer must utilize achievable and proven criteria that takes into account patient minimums, consistent use of endorsed measure specifications, consistent setting of thresholds and cut points, and should be based on overall pharmacy performance for all beneficiaries an individual pharmacy serves. CMS should ensure that pharmacies being evaluated with such metrics are provided with suitable and actionable metric-related data in a timely fashion during a plan year. Access to such data will allow network pharmacies to provide better targeted interventions and patient counseling to improve not only their individual performance but the patient health outcomes of those they serve.

A new standardized metric process will require time for development. NASP requests that CMS agree to move forward with its development for a stakeholder and evaluation process to proceed as soon as CY 2021.

[16] Pharmacy Quality Assurance (PQA) Performance Measures: https://www.pqaalliance.org/pqa-measures.

Proposed Regulations – NASP Comments

Plan Flexibility to Manage Protected Classes

Exceptions to the Protected Class Policy

CMS states in the proposed rule that the agency believes the existing "open coverage" protected class policy hinders Part D sponsors' ability to negotiate competitive prices from manufacturers, resulting in higher prices for protected class drugs as compared to those offered outside of the Part D program through other federal programs and commercial health plans. CMS also expressed concern that the existing protected class policy restricts Part D sponsors' ability to manage protected class drugs and address overutilization of drugs within the classes and/or the misuse of drugs that are not considered medically necessary.

In an effort to address these concerns, CMS is proposing three exceptions to the protected class policy including (1) broader use of prior authorization and step therapy as well as other utilization management and formulary design tools based on protected class indications; (2) exclusion of new drug formulation from the protected class drug formulary if the drug does not provide a unique route of administration of an existing single-source drug or biological product; and (3) exclusion of a drug from the formulary if its price has increased beyond the rate of inflation, as measured by the Consumer Price Index for all Urban Consumers (CPI-U), for a particular period of time.

Protected Class Policy and Existing Exceptions

As acknowledge by CMS, the protected class policy originated out of a need to ensure the most vulnerable beneficiaries enrolled in Medicare or as dual-eligible for Medicare and Medicaid maintain uninterrupted or unimpeded access to medications covered under the Part D program that are critical to safely and effectively treating patients with specified conditions such as mental health disorders, epilepsy, cancer, HIV/AIDS, and organ transplantation. Since its establishment in 2005, CMS and Congress have revisited the protected class policy and have reinforced current requirements through subsequent regulatory action and statutory adjustment to address the unique vulnerabilities of these populations. Current Part D policy requires sponsors to include on their formularies all drugs in the six protected classes: (1) antidepressants; (2) antipsychotics; (3) anticonvulsants; (4) immunosuppressants for treatment of transplant rejection; (5) antiretroviral; and (6) antineoplastics; except in limited circumstances.

Limited Circumstances

While NASP generally supports CMS's efforts to give Part D Sponsors greater flexibility to negotiate prices for protected class drugs, we wish to draw attention to the circumstances where some flexibility already exists to allow Part D sponsors the ability to negotiate and control costs as well as utilization of protected class drugs. These tools include formulary placement and limited prior authorization and step therapy. In order to determine appropriateness of the expanded exceptions proposed by CMS, we believe it's important to examine the current usage and effectiveness of these current tools to estimate the potential for additional costs savings as well as any potential impact the exceptions could have on the specified patient populations as a result.

According to a November 2018 analysis by Avalere, nearly three-quarters of all drugs included in the six protected classes are placed on higher, non-preferred or specialty tiers.[17] Approximately 78% of branded drugs and 66% of generics are categorized as non-preferred or specialty drugs. Across all protected classes, plans only cover an average of 67% of available drugs (brand and generic) and only an average 60% of the brand name products. Brand name products offered for the antidepressants and anticonvulsants classes are 37% and 46%, respectively. In addition, while only 35% of drugs covered across all protected classes are generics, 91% of the prescriptions filled in 2016 were for generic products. For the following three categories of protected class drugs, generics represented more than 90% of the prescriptions filled: anticonvulsants (90%), antidepressants (97%), and antipsychotics (91%); and more than 70% of prescriptions filled for antineoplastics (76%) and immunosuppressants (79%) were generics. Using current flexibilities, it appears plans have had notable success in driving patients toward lower cost generics.

In addition to, and as mentioned by CMS, a 2018 study by the Pew Charitable Trusts found the average rebate for protected class drugs included in the 40 drugs identified by Medicare as having high total spending, high per-user spending, or large price increases in 2014, were consistent with rebates across all Part D brand-name drugs. [18] As noted by CMS, this does not mean that if given greater flexibility to negotiate or exclude products from coverage, that plans could not achieve "higher-than-average" rebates for protected class drugs.

In its proposal, CMS demonstrates a thorough consideration of the costs and possible savings associated with its proposed policies. The agency has expressed a strong desire to bring prices for protected drug classes in line with other programs and ensure rebates are commensurate with those for certain drugs outside of the Part D program. While we share the agency's goal in

[17] Avalere Health. Partnership for Part D Access: "*Medicare Part D's Six Protected Drug Classes Policy: A Balanced Approach to Provide Patients Access to Medications While Allowing Powerful Tools to Control Costs*." November 29, 2018: http://www.partdpartnership.org/uploads/8/4/2/1/8421729/partnership_for_part_d_report_2018.pdf.
[18] The Pew Charitable Trusts. ''*Policy Proposal: Revising Medicare's Protected Classes Policy.*'' March 7, 2018: https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2018/03/policy-proposal-revising-medicaresprotected-classes-policy.

generating additional costs savings for beneficiaries and the Medicare program, we believe the current protected class policy strikes a critical and appropriate balance to ensure patients with specialized treatment needs maintain access to a full range of drugs, while also giving plans important tools to control costs and drug utilization.

We urge CMS to give due consideration as to whether the changes proposed would cause a disproportionate shift and negatively impact patients who currently rely on the protected class policy for their uniquely complex medical needs. Changes should be examined through a critical lens to ensure a proper balance is maintained and that patients will not experience delays in accessing medications or be prevented from utilizing the most appropriate and effective medications recommended by their providers for their specific condition(s). Given the increased access to and utilization of generic drugs in the protected classes as well as the commensurate amounts of rebate for select drugs, we do not believe that the potential for savings is so great that it supports policies that would overly restrict and risk patient access to protected class drugs.

We are particularly concerned about the effect newly proposed exceptions would have on existing patients currently utilizing protected class drugs and recommend that CMS require Part D sponsors to distinguish between new and existing patients if any of the proposed exceptions are finalized, maintaining existing protections for patients already receiving a protected class drug.

Broader Use of Prior Authorization and Step Therapy

NASP generally supports CMS's proposal to allow plans broader use of prior authorization for protected class drugs, including the use of step therapy and determinations for protected class indications, subject to the agency's annual formulary review process**.** NASP believes these changes can serve as important tools to bring Part D plans closer to market standard by more closely mirroring commercial plan management of protected class drugs. However, CMS proposes that expanded prior authorization be used without distinguishing between new starts and existing therapy management. As mentioned previously, NASP has concerns that the expanded use of prior authorization and utilization management tools, if allowed for patients already receiving particular therapies, threatens to be disruptive and potentially harmful to the health and well-being of patients.

Protected class drugs are used to treat patients with serious health conditions, including those with multiple or complex chronic conditions. For patients that are stabilized and on an established, effective treatment regimen, new prior authorization requirements could cause severe disruption and destabilization that could in turn cause significant adverse events

requiring additional physician visits, emergency room encounters, or hospitalizations. Patients treated with such drugs as immunosuppresssants, antiretrovirals or antineoplastics, could be of most significant risk of patient relapse, transplant organ failure, or even death. Because little downside exists for drug plans if a patient experiences adverse events or hospitalization, we feel there is greater risk to patients if plans are allowed to increase prior authorization requirements for existing patients. **We strongly recommend that CMS limit the exception for broader use of prior authorization to new patient starts in order to not disrupt ongoing medication therapy or drug access for existing patients.**

NASP also urges CMS to proceed carefully in allowing expanded use of step therapy among the protected classes for patients other than those newly starting therapy. Given the complex nature of the conditions treated with drugs in the protected classes and the likelihood of patients having multiple comorbidities, many medicines may not be interchangeable. Specific consideration also needs to be given for specialty patients that are newly starting therapy or already on a therapy with conditions where treatments need to be specifically tailored. For example, for antirejection or immunosuppressant medications, varying levels of response to treatment can jeopardize the success of organ transplantation and cause patients significant harm. Additionally, step therapy is not considered a clinically acceptable practice for HIV treatment due to the potential side effects and risks of developing a resistance to all drugs within the class.

NASP recommends that CMS exercise caution in allowing the use of step therapy for protected class drugs as outlined above, and any initial effort be focused only on new starts with consideration of specific conditions where treatment regimens must be uniquely tailored and where step therapy could be disruptive to meeting clinical needs. NASP also advises that step therapy for protected class drugs should follow the process already established for step therapy for non-protected class drugs with respect to: the submission, review and approval of step therapy protocols; the exception request process; and processing timelines.

Allowed Exclusion for New Formulations

NASP has concerns with CMS's proposal to allow plan sponsors to exclude a new drug formulation even if the old formulation has been removed from the market and ask that there be careful review and consideration of patients' needs before doing so. For existing patients, exclusion of a new drug formulation when no other versions of the drug exist on the formulary would potentially disrupt patient care and destabilize patients on existing therapies. While we understand CMS's concerns that some new and more expensive drug formulations may provide no significant and improved benefit to patients, we believe efforts to address this must not

violate the protections that exist to ensure patients have necessary access to protected class drugs.

If CMS chooses to move forward with this policy, **we recommend that existing patients are not included and that requests to exclude a protected class drug under this exception undergo a heightened level of scrutiny and otherwise rigorous annual review to ensure adequate protections remain for new patients. Additionally, NASP is concerned this exception could increase Part D sponsors' attempts to narrow the formulary in such a way that it becomes discriminatory and inappropriately discourages participation of select patient groups and would require close oversight.** The protected class policy was established to ensure plans are prohibited from enacting such discriminatory formularies. It remains critically important that CMS ensure in its annual formulary review that proposals are not inherently discriminatory against specific patient populations.

Threshold for Allowed Exclusion Based on Price Increases

NASP does not support CMS's proposal to permit Part D sponsors to exclude a drug within a class because the drug's price increased at a rate beyond the CPI-U. Excluding a drug by using a CPI measure would be extremely unreasonable for specialty drugs. Reasons for such price increases can vary significantly based on various market forces, and we do not believe such a policy can or would appropriately allow for justifiable price increases. **If such a policy were to move forward, we are concerned that it could lead to higher launch prices. In addition, we believe any such limit as outlined by CMS is dangerously close to constituting government price fixing.**

E-Prescribing and the Part D Prescription Drug Program; Updating E-Prescribing Standards

Real-Time Benefit Tool (RTBT)

CMS currently requires certain standards for Part D plans, prescribers, and dispensers who electronically transmit and receive prescription and certain other information for covered drugs prescribed for Medicare Part D eligible beneficiaries. These standards are updated periodically, with the latest electronic prescribing (eRx) standard update published in the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard, implementation Guide Version 10.6. Beginning January 1, 2020, the standards will be based on Guide Version 2017071[19]. Part D plan sponsors and prescribers are also required to convey electronic formulary and benefits information using NCPDP Formulary and Benefits (F&B) Standard Implementation Guides.

[19] 83 Fed. Reg. 62164.

SCRIPT and F&B are important components of quickly transmitting and receiving prescription and related information for covered drugs. As CMS notes, F&B data in particular is not uniformly accessed or accurate. F&B data can be transmitted in batches on irregular schedules, and is typically provided on a contract and not patient level. Thus, those prescribers that have electronic medical record (EMR) software that aligns with a plans software to view batch F&B information may not have current and accurate information for a patient.

In the proposed rule, CMS would require that Part D sponsors build upon SCRIPT and F&B electronic standards to gain a complete view of a beneficiary's prescription benefit information. CMS proposes to require that the RTBT be capable of integrating with prescribers' eRx and EMR systems to provide patient-specific coverage information at the point of prescribing. CMS believes that this would enable the prescriber and patient to collaborate in selecting a medication based on clinical appropriateness and cost. Under the proposed RTBT system outlined in the proposed rule, prescribers would be presented with the full scope of patients' specific formulary and benefit options under their drug benefit plan in real time.

CMS notes that it is familiar with several existing technologies capable of connecting across multiple EMR systems, which would thus meet the standards of a RTBT system as proposed. NASP wants to caution that some specialty pharmacies are also familiar with the technologies discussed and have experienced data-accuracy and data gap concerns with the systems in their current form. When using such tools, some specialty pharmacies have needed to call providers, plans, and patients to confirm information that was originally entered inaccurately or incompletely, thus negating the benefit purported to be created by the eRx system described by CMS. Additional testing and validation of the data comprehensiveness of such tools will be needed if CMS proceeds with implementation of the RTBT.

A critical function of the specialty pharmacy is to perform benefits investigations on behalf of beneficiaries. NASP members note that when submitting claims for beneficiary fills, plans will frequently reject claims, thus requiring specialty pharmacies to contact Part D plans to determine beneficiary's benefits. NASP members thus are supportive, in theory, of an RTBT system that would enhance specialty pharmacy efforts to support patients. However, given specialty pharmacies' experiences with tools that would be relied on for an expanded RTBT, as outlined by CMS, NASP is reluctant to endorse the expansion of this system to the entire Part D population without additional testing and validation of data completeness and accuracy.

NASP members also caution CMS to ensure that any RTBT systems reflect accurate information in regard to specialty drugs that are covered by plans and specialty pharmacies within a given plan's network. The RTBT should also clarify which in-network specialty pharmacies provide for limited distribution medications. Part D Plan formularies are updated annually in the Explanation of Benefits (EOBs) and must be announced in the Annual Notice of Change (ANOC). NASP members have witnessed EOB and ANOC formulary inaccuracies within current RTBT-like

technologies, inaccurately outlining which drugs are covered and which pharmacies are in the preferred network, thus depriving a beneficiary of basic information needed to accurately pick a Part D plan.

NASP is concerned about the timeframe and potential costs brought on by the proposed implementation of the RTBT system. Should CMS require all Part D plans to implement a system for the millions of beneficiaries, specialty pharmacies are concerned that such an endeavor would be costly and ultimately may not accurately convey patient-level benefits to prescribers, dispensaries, or beneficiaries. **To properly implement the RTBT system and verify data accuracy and completeness in a cost effective manner, NASP recommends that CMS delay the proposed implementation date past January 1, 2020, and consider first testing the system through a demonstration within the CMS Center for Medicare and Medicaid Innovation (CMMI).**

Medicare Advantage and Step Therapy for Part B drugs

Part B covers drugs, including specialty drugs that are administered by infusion or injection in physician offices and hospital outpatient departments, some oral anti-cancer drugs, some oral anti-nausea drugs, and some oral transplant/immunosuppressive drugs under limited conditions. Medicare Advantage plans that offer Part B pharmacy prescription drug benefits (MA-PDPs), until recently, have not been permitted to use formularies or other utilization management tools, such as step therapy. In August 2018, CMS issued a memo to plan sponsors, stating that MA plans would be permitted to use utilization management, including prior authorization and step therapy for Part B drugs in Contract Year 2019. In the proposed rule, CMS seeks to codify its decision to permit MA-PDPs to use certain utilization management tools as step therapy and the conditions that would be required.

Restriction to New Starts

CMS outlines in the proposed rule that step therapy could only be used for patients who are newly starting treatment. Patients already on established medication regimens could not be required to change medication therapies. **NASP supports CMS's proposed requirement to permit step therapy only for new patient starts, as specialty patients on established therapies cannot easily have their treatment plans altered without the risk of huge implications on their care and health.**

Review by a Pharmacy and Therapeutics (P&T) Committee

Under the proposed rule, MA-PDPs must have their utilization management process, including step therapy requirements reviewed by a plan's P&T Committee. **NASP strongly supports CMS' requirement to have any step therapy or other utilization management plan reviewed by a**

P&T Committee before implementation of any change occurs, allowing time to address any concerns that might negatively impact patient care.

Appeals Process

In the proposed rule, CMS discusses the need for an organizational determination and appeals process to allow for expedited exceptions. The proposed rule would not permit MA PDPs to extend the time frames for appeals. **NASP supports CMS' proposal to ensure timely appeals and other determinations and believes it is important to ensure that timeframes are shortened and strictly adhered to so that patient access to medication therapies needed as guided by a clinician are not jeopardized.**

Administrative and Process Burden – Patient Impact

In the proposed rule, CMS addresses the anticipated administrative burden and process challenges step therapy requirements may have on providers.[20] NASP advises CMS to also consider the informational challenges that may also occur for beneficiaries and others as a new step therapy process is put into place. **NASP recommends that if CMS proceeds with codifying the use of step therapy for Part B MA-PDPs, that it also consider requiring MA plan sponsors to post the list of Part B drugs with a step therapy requirement and the description of what is required on MA plan sponsors' websites so that the information is easy for prescribers and patients to access as opposed to only including the information in the Annual Notice of Change (ANOC) or Evidence of Coverage (EOC) as proposed.** MA plan sponsors should be required to update their websites at regular and specified intervals when changes are made by the plan either to the drugs or criteria being applied. Ensuring transparency in this process will support beneficiaries when they are selecting plans that can best meet their medication therapy needs.

Conclusion

We thank CMS for its effort and engagement with the pharmacy community and the opportunity to comment on the proposals included in the rule "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses." Again, we wish to express our sincere appreciation for the agency's clear interest in moving pharmacy price concessions to the point-of-sale and addressing claw back DIR fees that pharmacies face in order to lower out-of-pocket costs for Part D enrollees. NASP looks forward to continuing to work with CMS and the Office of the Secretary to support policy reforms that will reduce costs to Medicare beneficiaries and the broader Medicare program for specialty drugs and ensure access to the specialty drugs and services needed to improve health and reduce overall

[20] 83 Fed. Reg. 62169.

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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