



July 20, 2020

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

BY ELECTRONIC DELIVERY

RE: CMS-2482-P

Dear Administrator Verma:

The National Association of Specialty Pharmacy (NASP) is pleased to provide comments on the Center for Medicare and Medicaid Services' (CMS) proposed rule, "Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered Under in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements" at 85 Fed. Reg. 37286 et seq. NASP understands that with the proposed rule the administration is looking to promote transparency, flexibility and innovation in drug pricing through new regulatory policies to assist manufacturer and state participation in value-based payment (VBP) arrangements while maintaining the integrity of the Medicaid Drug Rebate Program. We also understand the proposed rule would revise regulations concerning pharmacy manufacturer copay assistance programs and PBM accumulator programs.

NASP's members are committed to the practice of specialty pharmacy and to serving specialty patients to ensure better clinical outcomes and responsibly managing 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 including the nation's leading independent specialty pharmacies and practicing pharmacists; 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. NASP is the unified voice of specialty pharmacy in the United States.

We support efforts to improve patient quality of care and ensure access to needed medications while reducing overall healthcare costs. With these goals in mind, we offer the following recommendations on sections of the rule to specifically address the needs of specialty patients and the pharmacies that serve their needs.

A. Value-Based Purchasing Arrangements

Value-Based Purchasing (VBP) Definition

CMS seeks to define value-based purchasing (VBP) arrangements as “an agreement intended to align pricing and/or payments to an observed or expected therapeutic or clinical value in a population.” Evidence- and outcomes-based measures are to be utilized, and the VBP arrangements must “substantially” link the cost of a drug to the measures. NASP understands the need to tie cost to performance under a VBP arrangement. However, the rule does not define what is meant by “substantially” linking cost and measures. The rule also does not outline specific terms for evidence-based or outcomes-based measures, leaving such measures unclear; nor does the rule provide information concerning the process for the development of performance measures and how such measures will be established for newer treatments. NASP encourages CMS to provide additional clarity on these issues to ensure that these outstanding issues do not ultimately have a negative impact on patient access to needed specialty medications.

VBP Arrangements and the Role of Specialty Pharmacy

Establishing measurable value-based purchasing arrangements where the price of a drug is directly linked to the value it provides patients and overall health care savings, must focus on patient management and support services to ensure patient medication compliance and adherence. Specialty pharmacies connect patients who are severely ill with the medications that are prescribed for their conditions. However, the provision of the drug itself is simply transactional – the value of a specialty pharmacy is directly related to the services and patient interaction they provide that is necessary to maximizing the patient’s chances of achieving a successful outcome.

Specialty pharmacy plays a unique role in our healthcare system by assuring that patients initiate therapy and avoid preventable discontinuation of therapy. Specifically, specialty pharmacies provide medication administration instructions; drug-disease education; drug-interaction monitoring; side-effect management awareness and recommendations; care coordination with the patient, prescriber, payer and pharmacy; and overall therapy orientation vital to achieving a successful treatment outcome. In addition, the specialty pharmacy helps patients to minimize financial toxicity associated with many high-cost therapies today.

Specialty pharmacies often play a critically important role in the ongoing clinical management and data collection process used to assess the success of newer therapies administered through such value-based contract arrangements. In addition, specialty pharmacies provide patient engagement tools such as telehealth programs for adherence and resources to providers that enable them to effectively manage value-based arrangements.

In closing, we support the spirit of value-based payment arrangements, and ask CMS to consider providing guidance regarding appropriate fair market value reimbursement for pharmacy services performed as part of a VBP contract.

B. Copay Assistance Programs and Medicaid Best Price

Under current law, drug manufacturer cost sharing assistance programs are not available to Medicaid (or Medicare) beneficiaries. In the rule, CMS argues that despite this, such cost sharing/copay assistance programs in the commercial sector should be applicable to best price calculations under the Medicaid Drug Rebate Program. The rationale is that the administration of copay accumulator programs by payers and PBMs in the commercial market may result in a drug cost, net of formulary rebates and patient assistance, that is lower than best price and therefore impact the rebates that Medicaid receives from manufacturers.

CMS proposes to permit manufacturers to exclude the value of copay assistance/coupon programs from the calculation of Medicaid best price and average manufacturer price (AMP) if the full value of the copay assistance is passed on to the consumer and not subject to a payer or PBM copay accumulator program. The responsibility for determining whether this occurs under the rule's requirements is fully on the drug manufacturers, and the proposed rule does not offer any actions or guidance on how manufacturers can successfully make this determination. The proposed rule also does not place any requirements on payers or PBMs to report, or otherwise clarify when they apply an accumulator program for any drugs.

It is important to note that many commercial plan designs contain a large deductible and a high copayment or coinsurance for specialty drugs. This plan design puts many specialty patients at significant risk of not being able to afford their therapy. In order to eliminate this risk, manufacturers of specialty products have significantly increased the availability of funding for patients that helps offset these high out-of-pocket costs. This funding is critical to a patient's ability to initiate and remain on therapy. Disruption to medication adherence due to cost provides extreme risks to specialty patients, resulting in hospitalizations, significant care setbacks and in some cases, health complications that make re-starting the same therapies impossible.

The high deductible and coinsurance elements are common in commercial benefits to keep the premium costs lower for all beneficiaries. These elements of the plan design, by their nature, help lower the plan cost by shifting cost to the patient. We find that this dynamic may make it problematic to truly identify who benefits from a manufacturer copay assistance program. The patient certainly initially benefits from the manufacturer assistance funding due to the ability to lower their upfront, out-of-pocket expense, but the payer benefits too because their cost is lower

and the manufacturer funding allowed this design to be implemented without compromising medication access.

If CMS insists that copay assistance funding must only benefit the patient, many manufacturers may struggle with how to interpret this requirement, and the elimination of such assistance programs may result. Thus, NASP is concerned that the proposed rule could threaten manufacturers' willingness to offer copay funding assistance programs, and significantly jeopardize patients' ability to afford their specialty therapies. If manufacturer funding programs were diminished, we do not foresee plan designs changing. Employers and insurers will continue to demand that patients maintain the same plan cost as previously experienced.

NASP is very concerned that the requirement to have manufacturers alone verify that their patient copay assistance programs are not subject to plan/PBM copay accumulator programs presents four key threats to specialty patients:

1. Copay assistance programs could become financially impossible for manufacturers if they were required to include the full value of their assistance programs in best price calculations, resulting in them opting to drop their assistance programs.
2. A manufacturer of specialty drugs could determine they will be unable to identify when a payer or their PBM will impose a copay accumulator program, and as a result decide to proactively scale back or no longer offer copay assistance/coupon programs for its specialty drugs.
3. Self-funded plans have flexibility to change benefit designs and could adjust their accumulator policies within a given plan year. A patient could initially benefit by a copay assistance program, only for that policy to adjust and no longer be available to the same patient at a later date. A manufacturer would likely have no knowledge of such policy changes, and it is unclear how such changes would then be reflected in best price calculations and their implications.
4. There is no CMS proposal in place to oversee or monitor manufacturer response to, or success for meeting this new requirement, and the rule does not outline any protections for patients if copay assistance programs go away as a result of this new requirement being placed on manufacturers.

NASP is concerned the new requirement proposed on manufacturers will threaten or eliminate access to cost sharing support programs and therefore recommends that CMS reconsider placing the onus on manufacturers to ensure the full value of the copay assistance is passed onto the consumers. If copay assistance programs do not exist, in the absence of larger policy reforms, NASP is very concerned about drug affordability for specialty patients, especially those with limited-to-no available alternative drug therapies to support and manage their complex health conditions.

C. Impact on 340B

The 340B drug discount program's ceiling price for covered entities under the 340B program is calculated as Average Manufacturer Price (AMP) minus the Medicaid Unit Rebate Amount (URA). For most brand drugs, URA is the greater of 23.1% of AMP or AMP minus best price.


URA relies on best price, however, the proposed rule permits VBP contract arrangements that allow for multiple best prices to be used. If multiple best prices are reported the rule does not provide clarity on whether or not the ultimate VBP rate would be extended to 340B covered entities. It is critically important that the contract and reporting flexibilities being considered within the proposed rule do not disrupt the 340B drug discount program by raising 340B prices and ultimately threatening patient access to this important drug discount program.

D. Patient Mobility Between Commercial Coverage and Medicaid or Medicaid Managed Care Plan

The intent of the proposed rule is to facilitate more widespread commercial adoption of VBP arrangements, and the extent to which such arrangements will extend to additional Medicaid programs is uncertain. The rule does not address how patient outcomes data will be assessed under a VBP arrangement when a patient changes plans – either commercial, Medicaid, or Medicaid Managed Care – prior to a completed evaluation under a VBP contract arrangement. More detail is needed on how data would be fairly and fully compiled and assessed to determine drug performance.

NASP appreciates the opportunity to comment on CMS's proposal. Please contact me at sarquette@naspnet.org, (703) 842-0122 or NASP's Washington Representative Julie Allen at julie.allen@powerslaw.com, 202-494-4115 if there are any questions regarding our comments. Thank you for your attention to this important matter.

Respectfully submitted,



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President and Chief Executive Officer