July 25, 2023

The Honorable Chiquita Brooks-LaSure
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: Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program [CMS-2434-P]

Dear Administrator Brooks-LaSure:

The National Association of Specialty Pharmacy (NASP) welcomes the opportunity to provide comments in response to the Centers for Medicare and Medicaid (CMS) proposed rule, *Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program.* NASP is pleased to see CMS working to address spread pricing concerns in the Medicaid program and evaluating how specialty drug and pharmacy drug dispensing costs are captured in the rule. However, NASP encourages CMS to evaluate NASP's comments on which pharmacies dispense specialty drugs and why there are unique considerations for the dispensing of these drugs (e.g., limited distribution networks) that determine when a specific pharmacy can be recognized for dispensing specialty drugs and also how to appropriately capture the cost of drugs that require special handling through a specialty pharmacy. We also wish to provide comments to raise concern over CMS' proposal to require a diagnosis code on pharmacy orders.

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 represents the entire spectrum of the specialty pharmacy industry, including the nation's leading specialty pharmacies and practicing pharmacists; nurses and pharmacy technicians; pharmacy benefit managers (PBMs); pharmaceutical and biotechnology specialty drug manufacturers; group purchasing organizations; wholesalers and distributors; integrated delivery systems and health plans; patient advocacy organizations; and technology, logistics and data management companies. With over 170 corporate members and 3,000 individual members, NASP is unifying the voices of specialty pharmacy.

Spread Pricing/Enhanced Drug Cost Transparency

CMS proposes to address spread pricing by PBMs in state Medicaid programs. CMS notes that current practices by Medicaid managed care plans (MCOs) that contract with subcontractors, such as PBMs, make it challenging to know how much of a payment for a covered outpatient drug (COD) to a PBM is an administrative fee versus how much is to pay for the dispensing of a drug. CMS asserts that this lack of clarity on how much of the fee is administrative results in incorrect medical loss ratio (MLR) calculations, which are used by managed care plans to determine capitation rates.

In response, CMS is proposing to Medicaid MCOs, Prepaid Inpatient Health Plans (PIHPs), and Prepaid Ambulatory Health Plans (PAHPs) that provide coverage of CODs to "structure any contract with any subcontractor, including PBMs, for the delivery or administration of the COD benefit to require the subcontractor to report separately the amounts related to the incurred claim… such as reimbursement for the CODs, payments for other patient services, and the dispensing or administering providers fees, and subcontractor administrative fees."

NASP appreciates CMS' efforts to impose requirements on PBMs to address the practice of Medicaid spread pricing. Evidence shows that PBMs have overcharged state Medicaid Managed Care programs in states such as Ohio, Kentucky, Illinois, Arkansas and others by more than $415 million due to spread pricing.[1] Economists speculate states could achieve significant savings if spread pricing reforms were implemented for both Medicaid fee-for-service and Medicaid Managed Care arrangements.

It is important that CMS ensure that reporting requirements imposed on PBMs also apply to any subcontract arrangement a plan may have. Including PBMs and other subsidiaries of PBMs will help prevent any loopholes in the regulatory requirements as proposed.

NASP also urges CMS to go further in its efforts to ensure that with the reforms envisioned, CMS clarifies that pharmacies are paid appropriately for the ingredient cost of the drug and dispensing fee/professional service fees and that such reimbursement to pharmacies at a minimum covers the pharmacies' acquisition costs and cost to provide such services. This is particularly of concern for specialty medications dispensed by a specialty pharmacy that typically incurs significantly higher costs due to accreditation requirements, shipping/handling requirements, clinical staff training, extensive patient counseling and clinical support, and 24/7 call center support.

New Survey Process to Verify Manufacturer Drug Prices

In the proposed rule, CMS notes that since the inception of Medicaid Drug Rebate Program (MDRP) the type of drugs developed and launched by manufacturers, as well as the distribution of drugs by manufacturers have changed, necessitating a new way to survey manufacturers to help Medicaid determine how it sets payment rates.

[1] Kaiser Family Foundation. "Prohibition of Spread Pricing in Medicaid MCO Contracts." July 2019.

CMS proposes to provide authority through current regulations to verify prices and charges from wholesalers and manufacturers that distribute their own drugs, including when the manufacturer distributes drugs directly to pharmacies and other providers. CMS believes the Secretary should be permitted to verify prices reported in both situations in which a manufacturer sells to wholesalers and/or distributes drugs directly on their own and that surveying is necessary to obtain this information.

NASP agrees that survey mechanisms are best for obtaining the sought after information. Many of the drug prices where CMS seeks this information will be for drugs dispensed by specialty pharmacies, including through limited distribution models; however, not all such high-priced drugs are dispensed by a specialty pharmacy. NASP recommends that the manufacturers would be the best source for such information.

Limited Distribution Models and Accredited Specialty Pharmacy

Under a limited distribution model, manufacturers identify specialty pharmacies accredited by a national independent accrediting body to meet specialty pharmacy accreditation standards such as URAC or ACHC. These specialty pharmacies are relied upon to manage the distribution of complex (specialty) treatment regimens that can be difficult for other pharmacies and patients to administer. Manufacturers select specialty pharmacies that have proven to have the highest standards for clinical excellence, patient education, treatment monitoring, and customer support based on their record of accomplishment in the disease area being addressed. Pharmacies are selected that have the clinical expertise based on their years in operation and direct experience distributing the same or similar therapies to the specific patient base, evaluating the number of patients served by a pharmacy with the given condition under consideration. Medications under this model also include risk evaluation and mitigation strategies (REMS) programs.

Manufacturers who establish limited distribution models look to ensure that the specialty pharmacies they work with for distribution of their drugs have care coordinators with expertise in the given disease-state the medications address, including adherence tools and patient support services and whether those services are available 24/7. They also look to see what tools a pharmacy has developed identify financial solutions for patients and to manage prior authorization requirements for costly medication services. Essential to manufacturer consideration of a specialty pharmacy is whether that pharmacy, as part of its standard operations, is able to provide adherence data and information on drug management concerns to the manufacturer so that they can better ensure proper prescribing and approaches toward adherence to reduce drug waste and to monitor treatment effectiveness and deliver improved patient outcomes.

The size of a limited distribution network is determined in part by anticipated patient utilization. Because limited distribution allows for closer patient relationships with pharmacies, patients are typically more adherent to prescribed medications and more likely to have optimal

treatment outcomes, saving the Medicaid program money through avoided or early-detected adverse events which can often lead to hospitalization or a patient to stop taking their medication. Limited distribution models for specific drugs that are for a smaller high-risk patient population focus on specialty networks in an effort to allow for greater oversight and quality, ensuring that only highly trained clinical staff are dispensing medications and supporting patients, controlling mistakes and emergencies, and therefore, costs to the Medicaid system.

NASP urges CMS to consider the purpose behind the limited distribution model as it surveys manufacturers on drug prices, appreciating the savings that can result from such models for the Medicaid program.

Surveying Drug Costs

To subsidize and expand upon information CMS may collect from manufacturers for those drugs dispensed by a specialty pharmacy, NASP recommends that CMS consider expanding upon the current NADAC survey to include specialty drugs within the survey. The current NADAC survey is limited in information concerning specialty drugs that are dispensed by a non-retail specialty pharmacy that is not a community pharmacy. Such pharmacies may include independent specialty pharmacies, hospital/health system-based specialty pharmacies, and other specialty pharmacies. Inclusion of a broader set of data through the voluntary NADAC survey instrument could be of benefit to CMS in understanding pharmacy drug acquisition costs.

Clarifying and Establishing Requirements for FFS Pharmacy Reimbursement

Survey Pharmacy Dispensing Costs

CMS is proposing to clarify the data requirements that States must submit in their state plan to CMS for establishing the adequacy of both the current ingredient cost and professional dispensing fee reimbursement. In particular, CMS specifies that professional dispensing fees cannot simply be determined by a market-based review of what other third-party payers may reimburse for dispensing prescriptions and that a state cannot rely on the amounts that pharmacies are accepting from other third-party payers as a means of determining professional dispensing costs. “The data that are acceptable could be a State's own survey, a neighboring States' survey, or other credible survey data, but it must be adequate and must reflect the current cost of dispensing a prescription in the state.”

CMS states that it is observing States submitting proposed changes to either or both of the components of the reimbursement methodology without adequate supporting data that reflects current drug acquisition cost prices or actual costs to dispense.

To support state and CMS efforts to understand the cost to dispense medications by specialty pharmacies and other pharmacies that serve the Medicaid program, NASP urges state Medicaid programs and CMS to seek and support ongoing pharmacy cost-to-dispense study resources. A

study was most recently conducted by the broad pharmacy community in 2019 that provides available data for this purpose, outlining cost to dispense for all medications, including those dispensed by accredited specialty pharmacies.[2] CMS should consider establishing an ongoing survey mechanism to support state Medicaid programs in understanding these costs, including costs by medication type and those high-touch complex medications provided to patients through a limited distribution model.

Requiring Diagnoses on a Prescription – Request for Information

CMS issued a RFI on a proposal to require a diagnosis on Medicaid prescriptions as a condition for claims payment under the MDRP. CMS is looking for feedback on any operational implications for such a requirement. Medicaid COD claims do not currently require a diagnosis code as a condition for payment; however when reviewing claims without a diagnosis, CMS states that it is difficult to determine whether a drug is being used for a medically-accepted indication and appropriately satisfies the definition of a COD, and therefore, is rebate eligible. This problem seems to be most pervasive with drugs that have several indications. CMS states that with e-prescribing being the most dominant approach to prescription orders, the requirement would likely not create additional burden on the dispensing system.

NASP is concerned about the impact such a requirement for a diagnosis code on Medicaid prescription orders would have on the timeliness of patient access to medications. While e-prescribing may allow for a field to easily be entered on a prescription drug order, the challenge with such a requirement comes when a pharmacy receives an order where this information has not been filled in or has been filled in incorrectly – if and when that can be determined by the pharmacy. A pharmacy would have to seek clarification from the ordering clinician, potentially delaying medication access. For specialty patients with complex medications for challenging conditions like cancer or HIV/AIDS, delays in medication access can adversely – sometimes severely adversely – impact their course of treatment, creating an emergency situation. NASP is concerned about relapses in treatment or emergency clinical situations from delayed treatment for patients with such conditions.

NASP is also concerned about what such a requirement may mean for pharmacy liability when pharmacies and pharmacists have no such control over clinician compliance with such a requirement. If a diagnosis code is incorrect, the question becomes who is liable for that code once a drug is dispensed to a patient. NASP would want to ensure there are protections for pharmacies under such circumstances. Pharmacy audit requirements are intense already, and NASP is concerned about additional requirements that could lead to further auditing, especially when a pharmacy has no control over clinician compliance with such a requirement or how a pharmacy is to handle a situation where a clinician inappropriately lists a diagnosis code for the drug dispensed or how to manage when a clinician lists an off-label diagnosis code for a drug.

[2] https://www.nacds.org/pdfs/pharmacy/2020/NACDS-NASP-NCPA-COD-Report-01-31-2020-Final.pdf.

NASP encourages CMS to seek input from NCPDP on whether and how such a requirement could work within the fields provided on an e-prescription and to work further with pharmacy stakeholders beyond the comment period, including national professional associations representing all fields of pharmacy, including specialty pharmacy, to determine considerations for addressing the challenges CMS believes exist from not having a diagnosis code on prescription orders.

Conclusion

NASP appreciates the opportunity to provide comments for consideration and is happy to work with CMS to support and supplement information based on the recommendations offered. For additional information, please contact me at Sheila.arquette@naspnet.org or (703) 842-0122.

Sincerely,

Sheila M. Arquette, R.Ph.
President and Chief Executive Officer