July 25, 2023

Chiquita Brooks-LaSure
Administrator
The Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Brooks-LaSure,

On behalf of the nation's Medicaid Directors, NAMD is pleased to offer comments on the proposed rule, Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program [CMS-2434-P].

This proposed rule would create a drug price verification survey, under which manufacturers would be required to provide detailed data to CMS on certain high-cost drugs. The rule would also make definitional and operational changes to the Medicaid Drug Rebate Program (MDRP).

Medicaid Directors report serious concerns over the increasing costs of prescription drugs. In fiscal year 2021, Medicaid programs spent $38.1 billion on outpatient prescription drugs – a 45 percent increase since 2018. This trend is projected to accelerate as new high-cost cell and gene therapies enter the market. While these therapies have the potential to transform care for Medicaid members, they may also create severe budgetary challenges for Medicaid agencies. Almost every state has balanced budget requirements, so large increases in prescription drug spending can lead to benefit or eligibility cuts elsewhere in the program. Due to the constraints of the Medicaid Drug Rebate Program, Medicaid agencies do not currently have the tools they need to ensure that they are paying a fair and sustainable price for these therapies.

NAMD appreciates CMS's focus on high-cost drugs and strongly supports many of the provisions in this rule, including the proposed drug price verification survey, dispute time limits, and pharmacy benefit manager spread pricing policies. Medicaid Directors do, however, report concerns in response to CMS's request for information on the impact of requiring a patient's diagnosis be on a prescription as a condition of receiving federal match.

NAMD is a professional community of state leaders who provide health insurance to more than 93 million individuals and families through Medicaid and the Children's Health Insurance Program in each of the 50 states, the District of Columbia, and the U.S. territories. NAMD elevates thought leadership on core and emerging policy matters, amplifies the experience and expertise of Medicaid and CHIP directors,

supports state programs in continuous improvement and innovation, and optimizes federal-state partnerships to help millions live their healthiest lives.

Drug Price Verification Survey

NAMD strongly supports CMS's proposal to establish a drug price verification survey. Medicaid Directors report serious concerns over the impacts of high-cost drugs, including new cell and gene therapies, on the fiscal stability of the Medicaid program. Many of the cell and gene therapies in the development pipeline address conditions where there are no good alternative treatments, which leads to higher launch prices and fewer incentives for manufacturers to negotiate supplemental rebates.

The proposed drug price verification survey would help address these challenges in two ways. First, it may incentivize drug manufacturers to negotiate larger supplemental rebates with Medicaid programs. Second, increased transparency around drug pricing and expected utilization would help Medicaid agencies make more accurate budget projections.

CMS seeks comment on if they should include accelerated approval drugs in the survey when manufacturers have failed to complete required confirmatory trials. NAMD strongly supports this proposal. The accelerated approval pathway uses surrogate clinical endpoints rather than clinical outcomes, so confirmatory trials are necessary to establish clinical efficacy and long-term safety. Per the MDRP, Medicaid programs are required to cover accelerated approval drugs. This means that, when confirmatory trials are delayed, Medicaid agencies must cover high-cost drugs with unclear clinical benefits for extended periods of time. This challenge is highlighted in a recent study from the U.S. Department of Health and Human Services Office of Inspector General (OIG) that found that 34 percent of accelerated approval drugs have at least one confirmatory trial past its original planned completion date. The OIG study estimates that, from 2018 to 2021 alone, Medicaid spent $3.6 billion on drugs with delayed confirmatory trials. By including these types of drugs on the survey, CMS may incentivize manufacturers to submit required confirmatory trial data.

Medicaid Directors recommend strategies to strengthen implementation of the drug price verification survey. First, CMS discusses collecting information from Medicaid agencies on manufacturers' level of effort to lower drug prices if more than 10 covered outpatient drugs (CODs) remain after the first two steps in the process. CMS should use a valid, standardized, and simplified reporting tool to collect this data; CMS may also want to utilize value-based payment information that is already submitted by states. Second, Medicaid agencies note that the cap on the fiscal penalty for manufacturers who do not comply with the survey may limit its usefulness, as manufacturers typically incorporate anticipated penalties into revenue projections.

Medicaid Drug Rebate Program: Definitional Changes

CMS proposes to clarify that a drug provided as part of a bundled payment could be a COD eligible for rebates "if the drug and the itemized cost of the drug are separately identified on the claim." This could make drugs paid for under a diagnostic-related group or other bundled payment newly subject to rebates. In general, Medicaid agencies support this option. Some agencies note that they currently carve certain high-cost drugs out of diagnostic-related groups; this change would ensure states have the authority to collect rebates regardless of the state's COD delivery system (carved-in, carved-out, or mixed). This may be particularly important for new high-cost cell and gene therapies which are typically administered in medical facilities.

Medicaid agencies do note, however, some implementation challenges associated with collecting rebates under the new definition. One state notes that it would be extremely difficult to understand all of the scenarios where the payment for a code was inclusive of the drug reimbursement, which would complicate implementation and could lead to an increase in disputes. Medicaid agencies also note that maximizing this opportunity would require substantial changes in billing and claims systems, as many systems are not currently set up to capture information about the specific services that are included in a bundled payment.

Due to these implementation challenges, claiming rebates on drugs provided as part of bundled payments should be at state option. If states were required to claim rebates on all such drugs, NAMD would have serious concerns around systems and administrative burden. There would also be complexities with 340B, Federally Qualified Health Centers (FQHCs), and managed care. By giving states the flexibility to only claim rebates on some drugs that are provided as part of some bundled payments, CMS would give states additional tools to manage high-cost drugs without adding substantial burden.

CMS also proposes new definitions or definitional clarifications for "vaccines," "manufacturer," "drug classification 'N'," and "market date." Medicaid agencies do not report concerns with these changes.

Medicaid Drug Rebate Program: Operational Changes

For Medicaid programs that provide pharmacy benefits using fee-for-service, CMS proposes to clarify that market-based research does not qualify as support data for reimbursement methodologies. Medicaid agencies have differing views on this proposal. Some states report that this is in line with current practice, and that invoices/expense information is needed to set rates for ingredient costs and cost of dispensing. However, other states report concerns that some pharmacies and wholesalers may be adversely incentivized to display higher on book acquisition invoice costs, while receiving off book discounts. National wholesale and regional wholesale costs vary and some pharmacies may fail to competitively shop for best prices or may enter into unfair wholesale

purchase agreements; this can result in price inflation. Some states note that valid market-based research can help Medicaid agencies determine if price inflation exists and eliminate ingredient acquisition anomalies. **CMS should consider allowing states to use market-based research in addition to invoice- or expense-based data to address these concerns.** By allowing states to use market-based research alongside invoice- or expense-based data, CMS would ensure that Medicaid agencies can incorporate the fair market value of drugs into their methodologies, maximizing the value of healthcare spending. This would also facilitate the alignment of Medicaid drug pricing with that of private insurers and other payers, which would promote transparency and consistency across the healthcare system.

CMS proposes to require states to collect national drug code (NDC) information on all covered physician-administered drugs and invoice for rebates for all physician-administered drugs. Medicaid agencies do not report concerns with this proposal; many agencies already collect NDC information for all physician-administered drugs and invoice for rebates.

CMS proposes policies to limit the time drug manufactures have to recoup overpaid rebates or restate pricing data. NAMD supports these changes. Medicaid agencies report that it is time-consuming and administratively burdensome to resolve disputes submitted beyond 12 quarters. Resolving disputes requires the claim to be reversed and resubmitted; states do not receive federal match on these resubmitted claims if the dates of service are outside the timely filing window. The current system can also create fiscal challenges for states, as dollars associated with claims that are several years old have already been reallocated in budgeting and expenditure processes. The proposed time limit would address these challenges by requiring manufacturers to submit timely disputes. Some states note that they would support a shorter time limit (8 quarters) to correspond with the timely filing window; others note that 12 quarters is appropriate given medical claims lags. One state recommends not imposing a time limit (or using a longer time limit) for 340B entities. If this policy is finalized, Medicaid agencies would appreciate technical assistance on how to address outstanding disputes that were previously submitted but beyond the proposed 12 quarter limit.

CMS proposes a new oversight mechanism under which CMS could suspend the National Drug Rebate Agreement of a labeler for no fewer than 30 days if the labeler continuously fails to provide required data. While Medicaid agencies agree with the need to enforce compliance with data requests, they report serious concerns over the on-the-ground implications of this proposal. If a National Drug Rebate Agreement is suspended, Medicaid agencies are no longer required to cover the manufacturers' drugs, but also cannot receive federal match. To avoid paying for claims that are ineligible for federal match, states would need to switch members onto new drugs; this would be extremely logistically challenging for Medicaid agencies and providers, and could have negative impacts on member care. In reality, it is unlikely that all or even

most members would have their prescriptions switched within the proposed 30-days notice, so states would often need to cover the full cost of the claim to avoid disruptions to care. Medicaid agencies also note technical challenges with this proposal: how would a state handle 340B and Medicare crossover claims from a suspended manufacturer, how would systems differentiate suspended vs. terminated manufacturers, and how would CMS ensure labeler files are always up to date with suspensions? **Due to these potential impacts on member health and on state operations, NAMD recommends that CMS not finalize this proposal.** Instead, CMS should consider using fines or other tools to ensure manufacturer compliance with reporting requirements.

Medicaid Managed Care Requirements

CMS proposes to require managed care plans to assign and exclusively use Medicaid-specific BIN, PCN, and group number identifiers for all Medicaid managed care member ID cards for pharmacy benefits. Medicaid agencies do not have concerns with this proposal. States report that they either already require unique BIN, PCN, and group-identifier numbers or believe that this would be feasible to implement.

To address spread pricing, CMS proposes that Medicaid managed care organizations require pharmacy benefit managers (PBMs) to report separately on reimbursement for CODs, payments for other patient services, and administrative fees. NAMD strongly supports this proposal. As CMS discusses in the rule, spread pricing often leads to Medicaid agencies being overcharged for drugs; an Ohio study found that spread pricing cost the state's Medicaid program $224.8 million in single year, and a Michigan study estimated costs of $64 million per year. CMS's proposal would help increase transparency around spread pricing and support states' PBM oversight efforts. Some Medicaid agencies report that they already require managed care organizations to report this type of data and have found it very helpful; additional federal requirements would strengthen the ability of these agencies to secure data around drug costs.

Request for Information: Diagnosis on a Medicaid Prescription

In this rule, CMS includes a request for information on the potential impact of requiring a patient's diagnosis be included on a prescription as a condition of receiving Medicaid FFP for that prescription. **Although NAMD understands CMS's intent to ensure compliance with the statutory requirement that covered drugs are being used for a "medically accepted indication," Medicaid agencies report serious concerns over the impact of this policy.** This requirement would be administratively burdensome for providers, pharmacies, and Medicaid agencies, and could lead to significant disruptions in member care.

Broadly, Medicaid agencies highlight challenges with determining what qualifies as a "medically accepted indication." Prescription drugs are constantly being studied for additional indications but drug manufacturers have little financial incentive to apply to

the FDA for additional indications after the drug has become a generic. However, based on research, drugs are often recommended for additional indications in medical literature and clinical guidelines. Although these drugs are clearly “medically accepted” for these new indications, cataloguing current research and clinical guidelines to ensure compliance would be a massive undertaking. Medicaid agencies also note situations in which a patient may not have a formal diagnosis, may have a diagnosis for which there isn’t a clearly indicated medication, or may have a condition that is non-responsive to FDA-indicated medications; providers often prescribe medications “off label” in these circumstances.

In practice, operationalizing this requirement would be extremely challenging. States would need to program their systems for all medically accepted indications (on and off label) of all covered outpatient drugs and screen for mismatches with diagnosis codes (i.e., ICD-10 codes) when processing claims. This would be technically challenging, as ICD-10 codes and FDA-approved indications do not map perfectly onto each other and, as discussed above, “medically accepted” indications change rapidly. Developing this system configuration would take significant cost and time. States report they would need to hire multiple additional FTEs to keep track of changing indications and corresponding systems changes.

This requirement would also create significant burden for pharmacists, who may need to assess in real-time if a drug is being used for a medically accepted indication. Medicaid agencies also note that some pharmacy systems (typically independent pharmacies) are not set up to accept ICD-10 codes on electronic prescriptions. These pharmacies would need to establish new systems to accept ICD-10 codes, which would be time-intensive and costly, and would disproportionately impact independent pharmacies over chain pharmacies.

Medicaid agencies cite serious concerns around disruptions to patient care. First, this policy would likely lead to increases in point-of-sale rejections, claim denials, and delays in care. For example, if a provider inadvertently forgets to include a diagnosis code on a prescription, pharmacies may not fill the prescription or may need to use emergency fills. Similarly, mismatches between ICD-10 codes and NDC codes may lead to claims denials. States also raise the example of medications like ibuprofen or muscle relaxants that may be prescribed to treat acute symptoms before a member can see their provider for a formal diagnosis; how would these prescriptions be filled? Finally, states note concerns around patient privacy, especially for highly stigmatized diagnoses like HIV/AIDs, substance use disorders, and mental health conditions. In addition to federal regulations like 42 CFR Part 2, many states have laws that afford additional privacy protections to these diagnoses, further complicating implementation. Delays in receipt of medications for substance use, mental health conditions, and many other conditions can have serious consequences for patient health.

NAMD is also concerned with the unintended consequences of this requirement on the volume of disputes with manufacturers. States cite serious concerns that, in situations where the diagnosis code does not match the FDA-approved indication code exactly, manufacturers will dispute that the drug is not being used for a medically accepted indication and therefore does not qualify for a rebate. This could lead to real administrative and fiscal challenges for states, without generating improvements in patient care. Similarly, this requirement could lead to significant audit vulnerabilities in cases where diagnoses do not match FDA-approved indications, even when the care was clinically appropriate. Multiple agencies note past audits and litigation around Medicaid claims, centering on if medications were prescribed for specific indications.

Given these concerns, NAMD strongly recommends that CMS not formally propose a requirement for a patient's diagnosis be included on a prescription as a condition of receiving federal match. Medicaid Directors report that they do not think this policy would substantially improve assurances that CODs are only being used for medically accepted indications. They also report serious concerns about the potential risks to patients, including service disruption and delayed receipt of prescriptions.

Medicaid agencies note that, in practice, prior authorization and Drug Utilization Review are used to ensure that covered drugs are being prescribed for a medially accepted indication. States report that they often use prior authorization for medications that, through clinical review and stakeholder discussion, appear to have a high risk of being used for non-medically accepted indications. Additionally, retrospective Drug Utilization Review activities are designed to identify drugs being prescribed outside of medically accepted indications and address any inappropriate prescribing.

Thank you for the opportunity to provide comments on this proposed rule. NAMD looks forward to continuing to work with CMS on the challenges posed by high-cost drugs. We appreciate CMS's efforts to ensure that Medicaid agencies can provide innovative new therapies to their members while maintaining fiscal stability.

Sincerely,

Cynthia Beane, MSW, LSCSW

Cindy Beane
NAMD Board President
Commissioner
West Virginia Department of Health and Human Resources

Lynnette R. Rhodes

Lynnette Rhodes
NAMD Board President-Elect
Executive Director
Medical Assistance Plans Division,
Georgia Department of Community Health