

July 24, 2023



Daniel Tsai
Deputy Administrator and Director
Center for Medicaid and CHIP Services
Centers for Medicare & Medicaid Services
Attention: CMS–2434–P, Mail Stop C4–26–05
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Massachusetts Biotechnology Council
700 Technology Square, 5th Floor
Cambridge, MA 02139

Re: CMS–2434–P, Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program

Dear Deputy Administrator Tsai:

MassBio appreciates the opportunity to comment on CMS’s recently proposed rule for the Medicaid Drug Rebate Program (“Proposed Rule”).¹ MassBio represents the premier global life sciences and healthcare hub of Massachusetts, which has a vibrant biomedical research and development community that is a global leader for medical discovery and innovation. MassBio’s 1,600+ member organizations are dedicated to preventing, treating, and curing diseases through transformative science and technology that brings value and hope to patients. MassBio’s mission is to advance Massachusetts’ leadership in the life sciences to grow the industry, add value to the healthcare system, and improve patient lives.

We are deeply concerned by major elements of this proposed rule, which would undermine the careful balance between delivering drugs at a low cost to the Medicaid program and ensuring important, high-value prescription drugs are available for Medicaid beneficiaries. We are most concerned by CMS’s legally unsupported proposals regarding: (1) disclosure requirements for drug manufacturers; (2) changes to the definition of covered outpatient drug as it relates to separate payment; and (3) potential stacking of cumulative price concessions. We address each of these issues, in turn, below and also support and incorporate by reference the comments on these issues raised by the Biotechnology Innovation Organization (BIO) in their comment letter on the Proposed Rule.

CMS’s proposal to “survey”² drug manufacturers regarding pricing data exceeds the Agency’s statutory authority and would disrupt the complex innovation ecosystem. In the Proposed Rule, CMS proposes to impose an unprecedented and burdensome public investigation of drug companies’ proprietary data. In describing this proposal, CMS cites to its authority to survey manufacturers under section 1927(b)(3)(B) of the Social Security Act. This provision cannot support CMS’s invasive and far-ranging survey because it is limited to verifying specific prices reported under the Medicaid Drug Rebate (MDRP) Program.

The survey also appears designed to compel manufacturers to enter into supplemental rebate agreements (SRAs), notwithstanding that such arrangements are inherently voluntary per statute. Specifically, as proposed, the onerous reporting requirements would apply to manufacturers unless they meet certain exceptions, such as providing significant levels of rebates or discounts under other government channels programs.

¹ 88 Fed. Reg. 34,238 (May 26, 2023).

² Social Security Act Section 1927(b)(3)(B).

We are also concerned that the survey does not represent good public policy. CMS is imposing a one-size-fits-all approach to a complex ecosystem that delivers significant but appropriately determined discounts for drugs covered by Medicaid. What's worse, the proposal is unnecessary because states have existing tools to obtain discounts from manufacturers—the MDRP already provides for two statutory forms of price discounts for states, access to a manufacturer's Best Price and an inflationary rebate. And the proposal may derail efforts to encourage the adoption of value-based arrangements by state Medicaid programs. Under existing law, states are free to negotiate drug-specific supplemental rebates with manufacturers, which may take the form of value-based arrangements. We remain strongly supportive of innovative contracting arrangements with states, such as value-based arrangements, and encourage CMS to focus on ensuring states have the flexibility to reach such agreements rather than moving forward with the deeply problematic drug pricing survey.

CMS' proposal to redefine "covered outpatient drug" would undermine efforts states have made to ensure providers can deliver high-value, transformative drug therapies in the inpatient setting, such as cell and gene therapies. Today, states can make separate payments for inpatient-administered therapies, which are often life-saving or life-transforming, covering the provider's costs and ensuring patient access to drugs with costs that are not accounted for in the inpatient bundle. Importantly, because this separate payment amounts to "direct reimbursement" for the drug, these drugs become covered outpatient drugs and the Medicaid program receives rebates. By proposing to dramatically expand the scope of drugs that might be eligible for separate payment to include any drug which is itemized on a bundled inpatient claim, CMS risks undermining this successful arrangement and potentially compromising patient access to high-value therapies with a real need for separate payment.

We are concerned that CMS's proposal to "stack" discounts received by multiple entities throughout the prescription drug supply chain in order to calculate Best Price is neither a sound interpretation of the statute nor a reasonable approach to determining discounts for the Medicaid program. Best Price is defined as the lowest price offered "from the manufacturer" "to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity."³ This statutory language clearly contemplates a price and set of discounts offered to one particular entity, not an aggregation of discounts offered to multiple entities throughout the supply chain.

We are deeply concerned that the Proposed Rule will upend the MDRP, which has served Medicaid beneficiaries and states well for decades. MassBio thanks CMS for consideration of our comments and remains available to meet with CMS to discuss these comments and other Medicaid-related issues of interest to our members.

Best regards,

Kendalle Burlin O'Connell, Esq.
CEO & President
MassBio

³ Social Security Act Section 1927I(1)(C)(i).