

**Via Electronic Filing**

July 25, 2023

Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
Attention: CMS-2434-P, Mail Stop C4-26-05  
7500 Security Blvd  
Baltimore, MD 21244

***Re: Notice of Proposed Rulemaking: 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 Consumer Healthcare Products Association (CHPA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) *Notice of Proposed Rulemaking: Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program (MDRP) (CMS-2434-P)* (the NPRM).<sup>1</sup> CHPA is the leading voice fighting to ensure that Americans have access to over-the-counter (OTC) medications, dietary supplements, and consumer medical devices they can count on to be reliable, save money and time, and deliver new and better ways to get and stay healthy. CHPA represents over 60 consumer healthcare manufacturers.

In the NPRM, CMS proposes to revise the definition of “manufacturer” in 42 C.F.R. § 447.502 and impose new requirements on manufacturers in 42 C.F.R. § 447.510.<sup>2</sup> CMS proposes that a manufacturer must provide the Agency with all labeler codes for all of the manufacturer’s “applicable drugs” and that “if any manufacturer with a signed rebate agreement in effect that acquires or purchases another labeler, acquires or purchases covered outpatient drugs from another labeler code, or forms a new subsidiary, they must ensure that a signed rebate agreement is in effect for these entities or covered outpatient drugs consistent with the definition of manufacturer . . . , within the first 30 days of the next full calendar quarter beginning at least 60 days

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<sup>1</sup> 88 Fed. Reg. 34238 (May 26, 2023).

<sup>2</sup> *Id.* at 34254

after the acquisition, purchase, asset transfer, or formation of the subsidiary.”<sup>3</sup>

CMS proposes that the regulatory definition of “manufacturer” includes “all associated labeler entities of the manufacturer that sell *prescription drugs*, including, but not limited to, owned, acquired, affiliates, brother or sister corporations, operating subsidiaries, franchises, business segments, part of holding companies, divisions, or entities under common corporate ownership or control, must each maintain an effectuated rebate agreement in order for a manufacturer to satisfy the requirement [ ] to have entered into and have in effect a rebate agreement with the Secretary.”<sup>4</sup> CMS also proposes to incorporate a termination clause such that “each associated labeler code of a manufacturer is considered to be part of the single manufacturer, and if any of the associated labeler codes as defined . . . in the definition of manufacturer . . . do not have an [National Drug Rebate Agreement (NDRA)] in effect, or are terminated, then all of the labeler codes will be subject to termination.”<sup>5</sup>

CHPA questions whether CMS has the authority to expand the definition of manufacturer as proposed or to impose the proposed new requirements with respect to entering into a NDRA. The MDRP statute and its legislative history do not contain any reference to corporate affiliations or any indication that a “manufacturer” includes the manufacturer itself and additional entities that are affiliated with the manufacturer in some fashion. Similarly, the Social Security Act (SSA) § 1927(a) and its legislative history do not specify that a manufacturer’s drugs may not be covered by Medicaid or Medicare Part B unless all the drugs of the manufacturer itself and of manufacturer affiliates are subject to an NDRA. In fact, the legislative history that CMS relies upon to justify the proposed definition is silent regarding manufacturer affiliates.<sup>6</sup>

In addition, nonprescription drugs are not automatically considered covered outpatient drugs (CODs) under the MDRP. The MDRP statute “provides that if a state plan for medical assistance includes coverage of prescribed drugs . . . and permits coverage of OTC drugs, then such drugs are regarded as CODs

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<sup>3</sup> *Id.* at 34255.

<sup>4</sup> *Id.* at 34256 (emphasis added).

<sup>5</sup> *Id.*

<sup>6</sup> *Id.* at 34256 (citing H.R. Conf. Rept. No. 964, 101st Cong., 2d Sess. 822, 832 (1990) and H.R. Rept. No. 881, 101st Cong., 2d Sess. 996 (1990)).

and, states have the option of covering OTC drugs. [OTC drugs] must be prescribed by a physician or other authorized practitioner and must be specifically addressed in the state plan.”<sup>7</sup>

CMS intends to target prescription drug manufacturers who establish “newly formed subsidiaries,” including “associated companies, parent entities and brother-sister entities” to avoid rebate liability.<sup>8</sup> Among the nonprescription drug products marketed by consumer healthcare companies that manufacture only OTC products are common household items such as antiperspirants, laxatives, sunscreen, lip balm, and anti-dandruff shampoos. Companies that focus only on such OTC products and do not also manufacture prescription drug products have not historically participated in the MDRP, whether they are standalone companies or are affiliates or subsidiaries of prescription drug manufacturers. Their reasons for not participating in the MDRP have nothing to do with skirting the “grand bargain”<sup>9</sup> of the MDRP. Instead, there was simply a recognition that state Medicaid agencies would elect not to cover the vast majority of their products and that doctors would very rarely have a basis for writing a prescription for such products.

If consumer healthcare companies that are affiliates of participating manufacturers were required to participate in the MDRP, these companies would be forced to implement systems capable of collecting and processing the requisite pricing data to comply with the MDRP, including to report the average manufacturer price (AMP) for each OTC product. In addition, many OTC products have changed ownership multiple times in the time since the MDRP was implemented. For example, Gold Bond Medicated Powder was introduced in 1908 and has been sold or acquired at least six times. None of the former or current manufacturers of nonprescription drug products that have not historically participated in the MDRP had a reason to collect and retain the data needed to calculate base date AMP. As a result, consumer healthcare companies would find it challenging, if not impossible, to determine and report each product’s base date AMP to calculate Medicaid rebates. And, as CMS has previously acknowledged, calculating the base date AMP can be administratively burdensome.<sup>10</sup> CMS has also reiterated that manufacturers “must use actual data to calculate revised base date

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<sup>7</sup> COD Final Rule, 81 Fed. Reg. 5169, 5187 (April 1, 2016) (referring to SSA § 1927(k)(4)).

<sup>8</sup> *Id.* at 34254.

<sup>9</sup> *Id.*

<sup>10</sup> Prescription Drugs Final Rule, 72 Fed. Reg. 39142, 39211 (July 17, 2007).

AMPs” and not rely “solely on estimates or reasonable assumptions.”<sup>11</sup> If consumer healthcare companies were forced to participate in the MDRP merely because they are affiliates of pharmaceutical manufacturers, they would face costly and potentially insurmountable hurdles to implementing the requisite systems to participate in the MDRP. Because consumer healthcare companies tend to run on slim margins, establishing such systems would be detrimental to consumer healthcare businesses and would drive up prices for consumers.

Requiring consumer healthcare companies to participate as manufacturers for the purposes of the MDRP would diminish the benefits and accessibility of OTC products. In fact, OTC products have generated \$51.6 billion in drug cost savings due to their lower prices compared to higher-priced prescription drugs.<sup>12</sup> The availability of OTC products creates significant value for the United States (U.S.) healthcare system by generating \$146 billion in annual savings relative to alternatives.<sup>13</sup> Forcing consumer healthcare companies to participate in the MDRP merely because they are affiliates of participating manufacturers would drastically reduce the cost savings effectuated by using OTC products, including \$94.8 billion in clinical cost savings annually due to avoided doctor’s office visits and diagnostic testing. Moreover, for every dollar spent on OTC products, the U.S. healthcare system saves more than seven dollars.<sup>14</sup>

Holding consumer healthcare companies that have not historically participated in the MDRP to the same standard as participating manufacturers would place an inordinate financial and operational burden on such consumer healthcare companies, which would quickly lead to an increase in price for the products sold by these companies. Any benefit to state Medicaid agencies and state Medicaid beneficiaries would be minimal because it is unlikely that participation by these companies in the MDRP would result in significant Medicaid coverage of additional OTC products. CHPA encourages CMS to not move forward, and urges CMS to clarify the proposal as outlined above.

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<sup>11</sup> *Id.*; see also COD Final Rule, 81 Fed. Reg. 5169, 5194 (April 1, 2016) (explaining that manufacturers must report base date AMP based on the original market date of the drug, when the drug was first marketed).

<sup>12</sup> *OTC Sales Statistics*, CHPA <https://www.chpa.org/about-consumer-healthcare/research-data/otc-sales-statistics> (last accessed July 14, 2023).

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*

We appreciate the opportunity to provide comments and would be happy to answer any questions or concerns. Please reach out to me at 202-429-3513 or [dspangler@chpa.org](mailto:dspangler@chpa.org).

Thank you.

Respectfully submitted,

*/s/ David Spangler*

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