October 19, 2023

VIA ELECTRONIC DELIVERY

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
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]

The Council of State Bioscience Associations (CSBA) is a coalition of independent state and territory based non-profit trade associations, each of which advocates for public policies that support responsible development and delivery of innovative life-sustaining and life-saving biotechnology solutions. Convened by the Biotechnology Innovation Organization (BIO), CSBA's collective voice represents the true grassroots network of innovators, researchers, manufacturers and accelerators across the country. According to a recent industry report, U.S. bioscience industry employment in 2021 reached 2.1 million jobs in more than 127,000 businesses across every state in the U.S. and Puerto Rico. The total economic impact of the bioscience industry on the U.S. economy, as measured by overall output, totaled $2.9 trillion dollars in 2021.[1] (TEConomy/BIO, 2022)

The majority of CSBA's member companies are research-intensive small and large biotechnology companies working on cutting-edge innovations. Their pipelines have the potential to benefit millions of patients suffering from diseases for which there are no cures or treatments.

We are writing to express our deep concern with a recent Centers for Medicare & Medicaid Services (CMS) proposed rule that seeks to reinterpret the Medicaid Best Price calculation and put patients at risk of losing access to life-saving medicines and vaccines. CSBA members are very concerned that this sweeping proposal represents a statutory overreach and will result in upending more than thirty years of historical precedent without statutory authority. We are concerned that CMS has greatly underestimated the negative downstream impacts this proposed rule would have on the drug manufacturing supply chain, critical government healthcare programs such as 340B, and ultimately the patients our members seek to treat.

We strongly oppose CMS' proposal that would require manufacturers to aggregate or "stack" price concessions provided to separate entities across the supply chain for Medicaid rebate Best Price purposes. This is an abrupt departure from decades of Medicaid policy precedent that has defined "Best Price" as the single Best Price made available by the manufacturer to a particular entity. We are deeply concerned that the new calculation of Best Price to "stack" cumulative discounts,

[1] TEConomy/Biotechnology Innovation Organization. (2022). *The U.S. Bioscience Industry: Fostering Innovation and Driving America's Economy Forward.* https://www.bio.org/csba-resources-and-reports

rebates, or other arrangements across multiple distinct entities is completely unworkable as no system exists to track discounts throughout the supply chain. Manufacturers and other members of the supply chain would not be able to operationalize such a scheme. Further, CMS' proposal will have severely detrimental impacts on patients, program and the commercial sector.

Furthermore, CSBA is strongly opposed to the proposed new definition of "Covered Outpatient Drug" (COD) that contradicts Congressional intent and the requirements outlined in the Social Security Act. This would shift the reimbursement structure of drugs, particularly those administered in inpatient settings. Such an approach is counter to CMS' efforts to encourage innovative payment approaches such as value based purchasing arrangements (VBPs) and will put patient access to new innovative therapies at risk.

In addition, the rule imposes new reporting obligations on manufacturers through a new drug price verification survey. This new verification survey – which we believe is a blatant overreach of CMS' authority – would require the reporting of pricing input data that includes a significant amount of confidential and proprietary information. Such requirements would bring an additional burden on manufacturers and result in unintended barriers for patients seeking access to lifesaving therapies.

The proposed rule also prescribes a new definition of vaccine that is contrary to how vaccines are defined across other federal programs with vaccine decision-making authority, thereby creating barriers to patient access to life-saving products due to programmatic overlap and confusion. The definition does not consider products that are used in a vaccine-like manner and are intended for broad public health utilization for prevention of infectious diseases. Failure to align definitions of vaccines and vaccine-like products across agencies will cause interoperability issues and limit patient access to these products among Medicaid beneficiaries, as well as children who are un- or underinsured.

In summary, we are concerned that this proposed rule would place a substantial burden on biotechnology manufacturers and negatively impact health care programs such as the 340B program and the commercial market, leading to increased health care expenses and out-of-pocket costs for patients. CSBA members urge CMS to reconsider the proposed rule and act to preserve the original definitions and intent of the Medicaid program: to ensure that Medicaid is given the Best Price on par with a manufacturer's sale of a prescription drug to a single customer.

We, the CEOs and Executive Directors of the undersigned organizations, look forward to continuing to work with the Agency on these important issues. Should you have any questions, please do not hesitate to contact Michele Oshman, Executive Director for CSBA and Vice President of External Affairs at BIO, at 202-215-8140 or moshman@bio.org.

Sincerely,

AL - Biotechnology Association of Alabama
AR - BIOArkansas
AZ - Arizona Bioindustry Association, Inc.
CA - California Life Sciences
CA - Biocom California
CA - Southern California Biomedical Council
CO - Colorado BioScience Association
CT - BioCT

DE - Delaware BioScience Association
FL - BioFlorida
GA - Georgia Bio
IA - Iowa Bio
ID - Idaho Technology Council
IL - Illinois Biotechnology Innovation Organization
IN - Indiana Health Industry Forum
KY - Kentucky Life Sciences Council
LA - Louisiana BIO
MA - Massachusetts Biotechnology Council
MD - Maryland Tech Council
ME - Bioscience Association of Maine
MI - Michigan Biosciences Industry Association
MN - Medical Alley
MO - Missouri Biotechnology Association
MS - Mississippi Biotechnology Association
MT - Montana Bioscience Association
NC - North Carolina Life Sciences Organization
ND - Bioscience Association of North Dakota
NE - Bio Nebraska
NJ - BioNJ
NM - New Mexico Biotechnology & Biomedical Association
NV - Nevada Biotechnology & Health Science Consortium
NY - NewYorkBIO
OH - Ohio Life Sciences
OK - Oklahoma BioScience Association
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RI - Rhode Island Bio
SC - South Carolina BIO
SD - South Dakota Biotech Association
TN - Life Science Tennessee
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