# Congress of the United States
## Washington, DC 20515

November 9, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Dear Administrator Brooks-LaSure,

We write to express our deep concerns regarding the Centers for Medicare & Medicaid Services' (CMS) recently proposed rule, *Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program*. The proposed rule threatens to undermine access to drugs, including restricting access for vital therapies.

Among our most significant concerns are those pertaining to the "proposal to accumulate price concessions and discounts when determining best price", or the "stacking" provision. Section 1927 of the Social Security Act allows state Medicaid programs to receive the lowest available price ("best price") for outpatient prescription drugs, otherwise known as the Medicaid Drug Rebate Program (MDRP). Since 1990, this program has allowed manufacturers to enter into agreements with state Medicaid programs to give vulnerable patients access to life-saving drugs and to help brunt the fiscal impacts of prescription medications on state budgets.

Current law uses a methodology where best price was determined under 42 CFR §447.505, as "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the United States in any pricing structure (including capitated payments) in the same quarter for which the Average Manufacturer Price (AMP) is computed. If a manufacturer offers a value-based purchasing arrangement (as defined at § 447.502) to all states, the lowest price available from a manufacturer may include varying best price points for a single dosage form and strength as a result of that value-based purchasing arrangement."[1] This methodology largely remained unchanged for the better part of thirty years. The proposed rule, however, deviates from this long-standing means of calculating best price by the lowest price available from the manufacturer to essentially any member of the supply chain. This also defies previous legal readings. In *Sheldon v. Allergan*, the District Court and the Fourth Circuit Court of Appeals found that "a plain and natural reading" of the Rebate Statute says that Best Price is "the lowest

[1] 42 CFR §447.505

price available by the manufacturer, including all price concessions, to any one of the listed entities, but not to multiple entities."[2]

Additionally, we are also troubled by other significant overreaches by the agency in rewriting several statutory definitions in the proposed rule that will curtail innovation and undercut patients' access to essential care. In regards to proposed changes to the definition of "covered outpatient drugs" (COD), CMS diverges from the original text of the statute, which excludes bundled drugs from the definition, to overturn the established precedent that governs the types of drugs that qualify as CODs, by moving towards an inclusion of all drugs identified on an invoice regardless of whether they are bundled.[3] An accurate definition of COD is critical, since drugs defined as CODs are required to pay rebates under the MDRP, which would implicate rebates and potentially 340B liabilities if the rule was finalized. CMS's redefinition of CODs puts certain state payment arrangements at risk, specifically states paying direct reimbursements of gene therapies, which ensures providers are reimbursed adequately for both drug product and services. This could lead to significant disruptions in the health care system, especially at facilities primarily administering life-saving and curative cell and gene therapies that are relying on these innovative reimbursement approaches for these treatments.

Another area with a problematic new definition is the proposed provision to define vaccines in the Medicaid program. As written, the definition is contrary to how vaccines are defined across other federal programs, such as the Vaccines for Children (VFC) program[4] or the Vaccine Injury Compensation Fund.[5] The new definition of vaccine 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. This includes certain monoclonal antibody products for the prevention of respiratory syncytial virus (RSV) in babies. The product stimulates an immune response, similar to vaccines, and will be essential in protecting newborns this fall. The exclusion of such products from the definition of vaccines could lead to less access to this new RSV vaccine and other similar vaccines for low-income families.

Finally, the proposed rule would hinder timely access to care for these vulnerable patient populations and lead to higher costs to the health care system. Under the recently proposed price verification surveys in §447.150(k), CMS has specifically targeted gene therapies while disregarding the tremendous value they bring to patients, families, and the healthcare system. If finalized, this would necessitate manufacturers of certain covered outpatient drugs to submit more than just the information authorized by statute to 'verify' reported prices. Instead, CMS proposes a survey that encompasses the following details:

1. Pricing, charges, distribution, and utilization.
2. Product and clinical information, including manufacturer data on the drug's safety, efficacy, and outcomes.

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[2] *United States ex rel. Sheldon v. Allergan Sales, LLC*., No. 20-2330 (4th Cir. Jan. 25, 2022).
[3] Section 1927(k)(3) of the Social Security Act.
[4] Section 1928(e) of the Social Security Act
[5] 42 U.S.C. §§ 300aa-10 et seq.

3. Costs associated with production, research, and marketing.

CMS further proposes to publish the received information on a public website for "further verification" and public comment. Manufacturers who cannot or refuse to provide the requested information may face civil monetary penalties. Moreover, the proposal aims to refine the list of surveyed drugs by excluding those whose manufacturers demonstrate a "willingness to negotiate further rebates."

This approach by CMS seems to represent an effort to compel additional rebates or price reductions on top of already-mandatory discounts within the MDRP. It does so not only through a threat to unfairly name and shame manufacturers of gene therapies that may have a relatively high one-time cost, but also through threats to disclose sensitive and potentially proprietary information unless supplemental rebates are offered.

Above all, this proposed rule should not be viewed in isolation, but rather within the context of the broader healthcare landscape. In the era of groundbreaking medical innovation, including with new cell and gene therapies, it is critical that the Medicaid Drug Rebate Program function as it was originally intended to help beneficiaries gain access to these lifesaving treatments. We urge CMS to withdraw the proposed rule and cease further action that could destabilize the Medicaid program.

Sincerely,

Brett Guthrie
Member of Congress

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Member of Congress

Kat Cammack
Member of Congress

Bill Johnson
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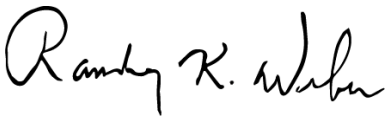

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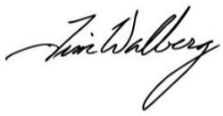

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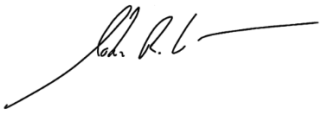

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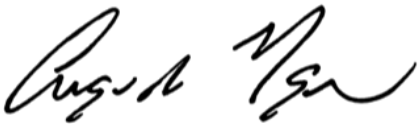

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