United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

October 27, 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 concerns with several policies included in the proposed rule "Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program" (NPRM). While we share some of the agency's objectives, including preventing certain problematic practices within the prescription drug supply chain, many of the NPRM's proposed changes defy longstanding statutory understanding and impose costly new mandates, creating fiscal uncertainty for states and risking patient access to the most innovative therapies and cures. Rather than establishing new reporting requirements or altering foundational definitions, we ask that you work with states, patients, providers and policymakers to implement reforms that promote adoption of value-based arrangements or other innovative purchasing models that improve health outcomes and reduce costs.

As enacted by Congress, the Medicaid Drug Rebate Program (MDRP) intends to ensure patients have widespread access to life-sustaining and lifesaving outpatient prescription drugs through a voluntary partnership with pharmaceutical manufacturers. The rebates required under this program, coupled with broad prescription drug coverage, aim to contain costs for states while serving the needs of Medicaid recipients and preserving incentives for medical breakthroughs.

Unfortunately, the NPRM proposes to disrupt this approach dramatically, upending more than three decades of statutory understanding and practice by rewriting the rules of the road for MDRP rebate calculations. Specifically, the proposal would require the aggregation of all manufacturer rebates and discounts to all supply-chain participants for the computation of the "Best Price" benchmark used as the basis for Medicaid rebates for numerous drugs. The Centers for Medicare and Medicaid Services' (CMS's) proposed "stacking" policy reverses the plain language of the statute, along with previous regulations and relevant caselaw, replacing Medicaid Best Price's traditional definition, as the best price provided to an individual purchaser, with a hypothetical "best price" merging any number of unrelated price concessions, offered to unaffiliated and wholly separate entities.

The operational complexities inherent in this sweeping shift could render the proposal entirely unworkable, even from a purely practical standpoint, as neither CMS nor supply-chain participants have systems in place to "stack" unrelated rebates and discounts stemming from a range of different transactions and contracts, often incorporating proprietary information, into a clear and verifiable figure. That said, even setting aside technical complications and potential legal headwinds, the substantive policy change at issue risks undercutting its own core objectives by disincentivizing, rather than encouraging, larger price concessions. Stacking rebates and discounts could result in withheld price concessions, smaller supplemental rebates for states, and a new set of hurdles for price reporting oversight. In the meantime, patients would receive no benefit from this novel departure from precedent.

The NPRM also fails to provide a patient-oriented justification for its proposed price verification survey. Gene and cell therapies have the potential to transform health care delivery, offering treatments and cures for previously incurable diseases. While the private sector has developed payment arrangements for these truly novel products, federal government programs have fallen short on providing a viable pathway to coverage for patients. Instead of addressing the access barriers identified by states, patients and providers, the NPRM seeks to establish a drug price verification survey process for certain "high cost" covered outpatient drugs, including cell and gene therapies. The new price-based listing would require manufacturers to report information related to the costs of research, development and production or prices charged outside of the United States, which the agency proposes to publish. These new reporting requirements are irrelevant to the enforcement of the MDRP and risk disclosing proprietary information without remedying the underlying statutory and regulatory barriers to value-based coverage arrangements for gene and cell therapies under Medicaid.

We urge CMS to preserve the MDRP's statutory balance consistent with Congress's intent by withdrawing the misguided proposals that risk disrupting patient care. We would welcome the opportunity to work with you to improve the Medicaid program so that patients have access to cutting-edge, live-changing prescription drugs.

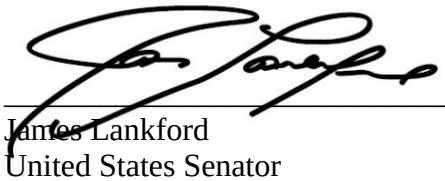
Sincerely,

Mike Crapo
United States Senator

John Cornyn
United States Senator

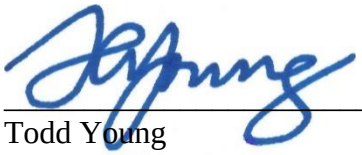
John Thune
United States Senator

Tim Scott
United States Senator



James Lankford
United States Senator

Steve Daines
United States Senator



Todd Young
United States Senator

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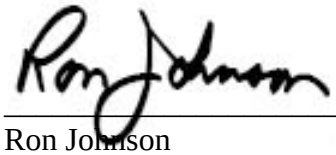
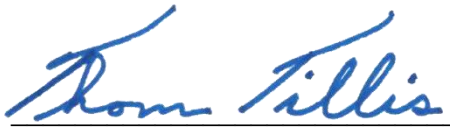
United States Senator



Ron Johnson
United States Senator



Thom Tillis
United States Senator

Marsha Blackburn
United States Senator