Congress of the United States
House of Representatives
Washington, DC 20515

October 22, 2020

The Honorable Seema Verma, M.P.H.
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Verma,

We appreciate the work the Centers for Medicare and Medicaid Services (CMS) has done and every measure being taken to address the challengers of the ongoing COVID-19 pandemic. COVID-19 underscores the importance of enhancing access to treatments and therapies, particularly for vulnerable populations that depend on the Medicaid program. We also appreciate CMS efforts to support the availability of life-saving medications through its proposed rule entitled "Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third-Party Liability (TPL) Requirements." Like you, we support patients' access to cutting-edge therapies through the proposed value-based payment policies in the rule, but we are concerned with the redefinition of line extension and have heard concerns regarding the impact on patient assistance programs.

We thank you for outlining a strong foundation for facilitating VBP arrangements, both within state Medicaid programs and in the commercial market. For patients suffering from life-threatening conditions, these types of arrangements could prove vital for ensuring access to innovative therapies. We encourage you to continue to engage with stakeholders on avenues to further refine and then finalize this portion of the notice of proposed rulemaking, as well as to continue to work with Congress to identify necessary next steps to advance diverse payment models through legislative action.

However, we are particularly concerned that the proposed redefinition of "line extension," from section 1927(c)(2)(C) of the Social Security Act (SSA), may drastically increase the scope of the product improvements captured by the alternative unit rebate amount (URA) beyond what was established through the Affordable Care Act and amended under the Bipartisan Budget Act of 2018. We believe this may lead to less innovation.

The statute provides one example of the type of minor changes to medications that may be eligible for the URA ("extended release" formulations) and the text and legislative history of section 1927(c)(2)(C) of the SSA are clear. The congressional record demonstrates that line extensions were established to penalize manufacturers making "slight alterations" to "a drug" to avoid paying the additional rebate tied to the older parent drug and that the focus was to be on extended release formulations of a drug. CMS's proposed definition goes well beyond this

statutory intent, capturing medical advances that are neither "slight" nor within the scope of the statute. As the COVID-19 pandemic response has repeatedly illustrated, new indications can allow innovators to repurpose products to address entirely new conditions of patient populations. Yet CMS's proposal does not acknowledge either the clinical or quality of life benefits that drugs bring to patients and would now define these important innovations as line extensions. New strengths or dosage forms of an existing medication can improve choice for patients and their providers but could be lost under CMS's proposal.

The proposal also does not reflect the robust research or clinical studies oftentimes required by the Food and Drug Administration (FDA) for their approval. As the FDA has acknowledged in clear terms, combination products often result in meaningful benefits for Americans, and developers are awarded protections for these valuable innovations.

By grouping these and other game-changing enhancements and innovative discoveries with decidedly slight alterations like changes to the color of a pill or extended release formulations, you risk discouraging the development of products that could otherwise help or save millions of Americans. For that reason, we strongly urge you to reconsider the inclusion of new indications, combination products, and new strengths in the definition of line extension, as well as the change to the oral solid dosage language.

Additionally, we have heard from a number of patient and provider organizations regarding the change in the Medicaid best price determination. Like you, we believe the most vulnerable deserve the lowest price. However, we are concerned with how this policy would be implemented due to many constraints on the flow of the patient assistant programs. We would ask CMS not to implement this policy until the pandemic has ended and it can ensure it does not have any unintended consequences for patients.

In closing, we ask that CMS move forward in addressing the needs of patients, states, and other stakeholders through its VBP proposal while not finalizing the contentious line extension section or the Medicaid best price change as currently defined in the notice of proposed rulemaking. We look forward to continuing to work with you on our shared goal of modernizing Medicaid rebate rules to meet the needs of today's patients by developing payment policies that align with the FDA's innovative standard to save and improve lives.

Sincerely,

Brett Guthrie
Member of Congress

Markwayne Mullin
Member of Congress

Additional signers:

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Earl L. "Buddy" Carter
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