July 20, 2020

The Honorable Seema Verma
Administrator, Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Verma:

On behalf of the undersigned organizations, representing millions of taxpayers and free market advocates across the country, we write to express our concerns over the Agency's Proposed Rule, Docket No. CMS-2482-P, specifically those portions that would significantly expand the definition of "line extension" and "new formulation" for prescription drugs.

All of us have applauded your leadership on a number of important issues thus far at the Centers for Medicare and Medicaid Services (CMS). During your tenure, you have promoted fiscal accountability in the Medicare and Medicaid programs, enhanced the market structure of Medicare Part D and Medicare Advantage, and, most recently, removed barriers to the widespread use of telehealth services across the nation.

Unfortunately, the Agency's proposed changes to how it defines "line extensions" and "new formulations" of prescription drugs, for the purpose of extracting additional rebates in the Medicaid Drug Rebate Program (MDRP), run counter to years of successful deregulatory efforts across the Agency and the Administration.

The Affordable Care Act included a very limited definition of "line extension," specifically:

> "...a new formulation of the drug, such as an extended release formulation, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary), regardless of whether such abuse-deterrent formulation is an extended release formulation."[1]

As you know, under the Affordable Care Act, a "line extension" requires manufacturers to pay additional rebates to state Medicaid agencies and the federal government, on top of significant standard rebates in the MDRP that can exceed 50 percent of the value of a drug.[2]

As free market advocates, our organizations believe the MDRP is flawed. While these rebates may, at face value, be paid by manufacturers, the distortion of market dynamics pushes the costs of providing health goods and services onto nearly every payer, including patients, providers, insurers, and manufacturers. The MDRP also leads to less capital for manufacturers developing new treatments and less private sector negotiation over drug prices.

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[1] 42 U.S.C. 1396r–8(c)(2)(C)
[2] Medicaid and CHIP Payment and Access Commission. (February 2019). "Medicaid Drug Spending Trends." Retrieved from: https://www.macpac.gov/wp-content/uploads/2019/02/Medicaid-Drug-Spending-Trends.pdf (Accessed July 8, 2020.)

More importantly, though, we believe that a pandemic is the worst time for the regulatory state to expand the MDRP. The Agency's proposed rule would take a fairly limited definition from the Affordable Care Act and apply it to numerous drug innovations and improvements not included in the original statute. We do not believe the Agency has the "discretion and authority to interpret the term 'line extension' broadly," despite the Agency's claims.[3]

Most concerning during the pandemic, though, is that one specific type of innovation, new indications, would be subject to these additional rebates. This proposed change could inadvertently punish manufacturers who are seeking to repurpose existing drugs in the fight for COVID-19 treatments and cures. That punishment could not come at a worse time for patients, providers, or manufacturers, given hundreds of clinical trials are testing the safety and effectiveness of using existing drugs to treat COVID-19.[4]

We urge you to withdraw this portion of the Proposed Rule, at minimum, and return to the Agency's years-long focus on deregulation and market-driven reforms to the Medicare and Medicaid programs. Thank you for your consideration, and we look forward to working with you more in the future.

Sincerely,

National Taxpayers Union
60 Plus Association
AMAC Action
American Consumer Institute Center for Citizen Research
Americans for a Balanced Budget
Americans for Tax Reform
Center for a Free Economy
Center for Freedom and Prosperity
Center for Individual Freedom
Center for Innovation and Free Enterprise
Citizens Against Government Waste
Competitive Enterprise Institute
Conservatives for Property Rights
FreedomWorks
Frontiers of Freedom
Galen Institute
The Heartland Institute
Heritage Action for America
Hispanic Leadership Fund
Independent Women's Voice
Institute for Liberty
Less Government
Market Institute
Rio Grande Foundation
Secure America's Future Economy
Small Business & Entrepreneurship Council
Taxpayers Protection Alliance
Trade Alliance to Promote Prosperity

[3] Centers for Medicare & Medicaid Services. (June 19, 2020). "Medicaid Program; 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." 85 FR 37286. Retrieved from: https://www.federalregister.gov/documents/2020/06/19/2020-12970/medicaid-program-establishing-minimum-standards-in-medicaid-state-drug-utilization-review-dur-and (Accessed July 15, 2020.)

[4] National Institutes of Health (NIH) U.S. National Library of Medicine. (July 8, 2020). ClinicalTrials.gov Search for "COVID-19." Retrieved from: https://clinicaltrials.gov/ct2/results?cond=COVID-19 (Accessed July 8, 2020.)