Congress of the United States
Washington, DC 20515

December 04, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington, D.C. 20201

Dear Administrator Verma:

We are writing to express our concern regarding provisions in CMS's Notice of Proposed Rule Making (NPRM), Establishing Minimum Standards in Medicaid State Drug Utilization Review and Supporting Value-Based Purchasing for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third-Party Liability Requirements (CMS 2482-P). We are deeply troubled that certain provisions in this rule, if finalized as proposed, will make it more difficult for Americans to afford their medicines and exacerbate existing public health challenges for vulnerable patient populations caused by the ongoing COVID pandemic. Patients requiring treatment for HIV and mental health conditions are particularly at risk of negative health outcomes due to interruptions in medication access and non-adherence, and we are deeply concerned that the provisions in the NPRM relating to cost sharing assistance programs will further undermine their access to their medicines.

Millions of Americans with commercial health insurance rely on cost-sharing assistance provided by manufacturers and other third-party entities to help pay their out-of-pocket costs imposed on them by their health plans. The proposal to require manufacturers to include cost-sharing assistance in their Medicaid Best Price calculations if a health insurer fails to apply the total benefit of the assistance to the patient, will create significant barriers to manufacturers' ability to continue to offer cost-sharing assistance.

Patients with commercial health insurance coverage depend on this assistance to help them address the increasing levels of out-of-pocket costs. Unfortunately, people living with HIV and patients with mental health conditions are experiencing rapidly rising out-of-pocket costs, which increases the risks of non-adherence and corresponding dire health consequences. Between 2015 and 2019, HIV patients' average cost exposure for brand medicines grew 50 percent due to increased health plan use of deductibles and coinsurance. Similarly, out-of-pocket costs for brand antidepressants increased by 32 percent between 2015 and 2019.

Fortunately, cost sharing assistance programs have helped patients mitigate the impact of these new costs being placed upon them by their health plans. In 2019, cost-sharing assistance helped patients taking brand HIV medicines pay for over $1,600 in out-of-pocket costs on average. For brand antidepressants, cost-sharing assistance helped patients pay for 67 percent of their out-of-pocket costs on average in 2019. Given the unique challenges faced by these patient populations, it is therefore essential

for patients to preserve their access to every resource available to assist them, including cost-sharing assistance provided by manufacturers.

We are also concerned that a proposal to broaden the definition of line extensions could potentially sweep in many clinically beneficial treatments to patients. This would disincentivize important innovations that benefit patients such as simpler routes of administration and combination therapies, which are especially beneficial to patients with HIV and mental health conditions.

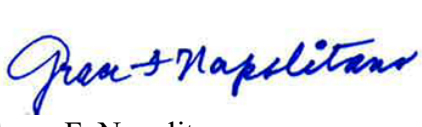
For example, recent innovations in mental health medicines are showing tremendous progress in improving adherence, which plays a crucial role in successful management of severe mental health conditions and for reducing difficult side effects. Combination products for HIV similarly improve adherence and persistence among Medicaid patients, reducing the risk of hospitalization, and lowering total healthcare cost compared to patients taking multi-tablet regimens. The proposed definition changes will discourage the development of these types of innovative therapies, including long-action injectables, combination drugs, and extended-release medications.

The current COVID-19 pandemic is already having a severe negative impact on patients' ability to access necessary medical services and treatments, and the proposed rule threatens to worsen these problems. As the national COVID-19 positivity rate, number of hospitalizations and related deaths all rapidly increase, it is unconscionable that the Administration move forward with proposals that will further undermine the public health. The consequences of finalizing the proposed changes would represent a significant failure by this Administration to protect patients' interests and ability to access health care, impairing patients' access to life-enhancing treatments by hindering affordability today and innovation tomorrow. Therefore, we strongly encourage CMS to reconsider this NPRM and not to finalize these proposals.

Sincerely,

Barbara Lee
Member of Congress

Jenniffer González-Colón
Member of Congress



Grace F. Napolitano
Member of Congress

John Katko
Member of Congress

/s
Brian K. Fitzpatrick
Member of Congress

/s
Bonnie Watson Coleman
Member of Congress

/s
Alan Lowenthal
Member of Congress

/s
Maxine Waters
Member of Congress

/s
Eddie Bernice Johnson
Member of Congress

/s
Lucille Roybal-Allard
Member of Congress

/s
David B. McKinley P.E.
Member of Congress