June 20, 2020

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMD-2482-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Establishing Minimum Standards in Medicaid State Drug Utilization Review and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third-Party Liability Requirements

Administrator Verma:

The Consortium for Citizens with Disabilities (CCD) is the largest coalition of national organizations working together to advocate for federal public policy that ensures the self-determination, independence, empowerment, integration and inclusion of children and adults with disabilities in all aspects of society.

We, the co-chairs of the CCD Health Task Force thank you for the opportunity to comment on the proposed rule. Our comments are limited to the definitions of value-based purchasing arrangements.

The proposed rule defines a value-based purchasing (VBP) arrangement as an “agreement intended to align pricing and/or payments to an observed or expected therapeutic or clinical value in a population” and provides two examples of such an arrangement:

1) Evidence-based measures, which substantially link the cost of a drug to existing evidence of effectiveness and potential value for specific uses of that product; and

2) Outcome-based measures, which substantially link payment for the drug to that of the drugs’ actual performance in a patient or a population, or a reduction in other medical expenses.

This definition leaves significant uncertainty about the permissible measures used to assess “value.” Moreover, CMS does not include important safeguards to ensure that measures of “cost-effectiveness” are not discriminatory or lead to unlawful health care rationing.

The proposed rule provides little explanation on evidence- or outcomes-based measures, making it difficult for stakeholders to comment. CMS also invites suggestions on additional measures “to reflect value from a drug therapy,” as well as how to interpret the term “substantially” in the context of its proposed definition. This suggests that CMS should engage in a Request for Information process on VBP, and should have more clearly developed concepts and proposals before embarking on formal rulemaking.
If CMS does move forward with final rulemaking, it should ensure that measures of value or effectiveness are person-centered and based on what matters most to the individuals receiving treatment. At a minimum, in CMS’ establishment of the criteria for an evidence or outcomes-based measure, the agency must mandate substantive input from people with disabilities and chronic conditions on factors such as disease mitigation and management, impact on patient out-of-pocket spending, ease of adherence, and improved aspects of day-to-day life.

If CMS moves forward with Medicaid prescription drug regulations defining VBPs, it should also make clear than any analysis of a drug’s “cost effectiveness” should not be based on measures which are discriminatory. Measures that devalue the lives of persons with disabilities and older adults based upon quality of life or age should not serve as the basis for any analysis of a drug’s cost-effectiveness. CMS should make a clear statement that such measures are discriminatory and not approve VBP arrangements that rely on such measures.

Thank you for the opportunity to comment. Please reach out to Rachel Patterson at rpatterson@efa.org with any questions.

Sincerely,

Health Task Force Co-Chairs:

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