July 20, 2020

Ms. Seema Verma
Administrator, Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: 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

Dear Ms. Verma,

On behalf of the Coalition to Transform Advanced Care (C-TAC), we appreciate the opportunity to provide comments on this proposed rule in regard to its effects on those living with serious illness.

C-TAC is a national non-partisan, not-for-profit organization dedicated to ensuring that all those living with serious illness, especially the sickest and most vulnerable, receive comprehensive, high-quality, person- and family-centered care that is consistent with their goals and values and honors their dignity. C-TAC is composed of over 140 national and regional organizations including patient and consumer advocacy groups, practitioners, health plans, faith-based and community organizations, and others who share a common vision of improving care for serious illness in the U.S.

Our comments are focused on the sections of the proposed rule related to the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act. Specifically:

**Opioid Safety Edits Including Initial Fill Days’ Supply for Opioid-Naïve Beneficiaries, Quantity, Therapeutically Duplicative Fills, and Early Refill Limits**

Overall, we are very concerned that this proposed rule gives too much autonomy to the states regarding setting initial fill days’ supply, duplicative and early refill limits, dosing limits, etc. There is no valid evidence to support defined limits for any of these protocols and we fear that, as a result, leaving this up to the states’ discretion will exacerbate an
already highly heterogeneous set of state requirements where minimum fill days range from 3 to 14 days and dosing limits vary significantly across states.

Further, while the proposed rule includes a thorough and nuanced section on the issues surrounding the CDC pain management guidelines, we fear such nuance will get lost at the state level, where well-meaning but uninformed policymakers will implement components of the guidelines without further direction. We therefore recommend that you revise this proposed rule to provide more specific guidance to the states. Managing pain is no different in Alabama than it is in Alaska, and it makes more sense for CMS to provide a national standard on these issues for all states to have more uniform Medicaid opioid policies. We would be most willing to work with you on developing such a standard.

**Tapering Opioid Guidelines**

Related to the above, we also urge you to develop standard guidance on prior authorization to avoid abrupt opioid withdrawal when tapering opioids. We agree this is necessary for patients who will need clinical intervention to taper off high doses of opioids to minimize potential symptoms of withdrawal and manage their treatment regimen, while encouraging pain treatment using non-pharmacologic therapies and non-opioid medications, where available, and appropriate.

In addition, we also suggest that CMS should require states, when implementing these requirements, to offer and require education and training and to provide consistent messaging across all healthcare providers. Education and training of all providers on new opioid-related provisions, on the treatment of acute and chronic pain, and on behavioral health issues related to pain will help minimize workflow disruption and ensure beneficiaries have access to their medications in a timely manner. Again, we would be happy to assist in developing such requirements.

**Exclusions**

While we appreciate that the SUPPORT elements do not apply to those receiving hospice or palliative care, in treatment for cancer, or residents of a long-term care facility, we recommend that those with sickle cell disease (SCD) also be excluded from these requirements, as was the case in the Medicare Advantage (MA) final rule earlier this year. CMS’ rationale for excluding people with SCD from the MA Drug Management Programs (DMPs) applies here as well. The clinical nature of the disease, unique presentation of SCD crises, limited evidence to guide opioid administration in SCD, limited knowledge of SCD among providers, and lack of other available therapies or modalities for treatment, are all valid for this Medicaid regulation. However, many of these reasons could apply to other populations living with chronic pain, such as those with either osteo or rheumatoid arthritis or other painful musculoskeletal conditions. We therefore encourage you to explore possibly excluding additional painful conditions in future proposed rules.

Thank you for the opportunity to comment on this proposed rule. If you have any questions, please contact Dr. Marian Grant, Senior Regulatory Advisor, C-TAC, at 443-742-8872 or mgrant@thectac.org.
Sincerely,

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