January 16, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
P.O. Box 8013,
Baltimore, MD 21244-8013

RE: CMS-4182-P

Dear Ms. Verma,

On behalf of the American Society of Addiction Medicine (ASAM), a national medical specialty society representing more than 5,100 physicians and allied healthcare professionals who specialize in the treatment of addiction, thank you for the opportunity to provide comments on the Centers for Medicare and Medicaid Services (CMS) proposed rule to revise the Medicare Prescription Drug Benefit program (Part D) regulations to implement certain provisions of the Comprehensive Addiction and Recovery Act (CARA). Specifically, this proposed rule includes a regulatory framework for Part D plan sponsors to voluntarily adopt drug management programs through which they may address potential overutilization of frequently abused drugs identified retrospectively through the application of clinical guidelines/criteria that identify potential at-risk beneficiaries and conduct case management which incorporates clinical contact and prescriber verification that a beneficiary is an at-risk beneficiary.

ASAM recommends that such a drug management program be designed to encourage behavior change and support recovery from substance use disorders, rather than as punitive measures. The potential for unintended consequences from limiting a patient's access to certain medications can be high if a trained professional does not assess the circumstances of each patient's unique clinical needs.

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ASAM appreciates that CMS proposes to require Part D plan sponsors to conduct case management which incorporates clinical contact and prescriber verification that the beneficiary is at risk before limiting beneficiaries' access to coverage for frequently abused drugs. ASAM also appreciates that CMS proposes to require prescriber agreement to enroll the beneficiary in the drug management program. **ASAM recommends CMS issue guidance to plan sponsors directing them to encourage prescribers, as part of the required clinical contact, to perform a comprehensive substance use disorder screening and/or assessment of the patient deemed potentially at-risk. If indicated, the patient should be referred for follow-up treatment with a specialist pain and or addiction treatment provider**. Since addiction is a chronic brain disease, limiting access to controlled substances for beneficiaries deemed at-risk of substance misuse or addiction without assessing them for a substance use disorder or connecting indicated patients to treatment will not effectively address the root problem or reduce the morbidity or mortality associated with untreated addiction.

ASAM understands that, for the purposes of these drug management programs, CMS proposes to define "Frequently abused drug" to mean a controlled substance under the federal Controlled Substances Act that the Secretary determines is frequently abused or diverted. For plan year 2019, CMS proposes to designate all opioids as frequently abused drugs except buprenorphine for medication-assisted treatment and injectables. **ASAM strongly supports the exclusion of buprenorphine for medication-assisted treatment from the definition of "Frequently abused drug"**. In the midst of the current opioid addiction and overdose epidemic, it would be highly problematic for plans to potentially limit patients' access to one of only three medications available to treat opioid use disorder.

ASAM also understands that CMS proposes to use clinical guidelines to determine whether a patient is potentially at-risk or at-risk. CMS proposes that the clinical guidelines (1) be developed with stakeholder consultation; (2) be based on the acquisition of frequently abused drugs from multiple prescribers, multiple pharmacies, the level of frequently abused drugs, or any combination of these factors; (3) be derived from expert opinion and an analysis of Medicare data; and (4) include a program size estimate. For plan year 2019, CMS proposes the clinical guidelines to be the Overutilization Monitoring System (OMS) criteria established for plan year 2018, which incorporate a 90 morphine milligram equivalent (MME) threshold consistent with the recommendations of the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain. It also includes a multiple prescriber and pharmacy count (4 or more opioid prescribers and 4 or more opioid dispensing pharmacies OR 6 or more opioid prescribers, regardless of the number of opioid dispensing pharmacies**). These criteria reinforce the need to exclude buprenorphine for addiction treatment from the definition of "Frequently abused drug", as CMS has proposed**, because the recommended daily dosage of buprenorphine would exceed the 90 MME threshold. CDC specifically excludes buprenorphine from its MME table because it is not likely to be associated with overdose in the same dose-dependent manner as are pure opioid agonists.

ASAM commends CMS for proposing to ensure beneficiaries who are enrolled in a drug management program have reasonable access to needed medication, and agrees that plan sponsors should consider group practices and chain pharmacies when limiting a beneficiary to one prescriber and/or pharmacy for access to opioids. It is appropriate

that group practices and chain pharmacies that share real-time data should be considered single entities for the purposes of the drug management program.

Finally, ASAM is pleased that CMS will require Part D plan sponsors to report to CMS the status and results of case management and any beneficiary coverage limitations they have implemented. These data, coupled with claims from beneficiaries' medical plans, will be invaluable to help determine the clinical effectiveness of drug management programs in reducing substance use disorders and their resulting complications. More research is needed to determine whether these programs, and which specific elements of these programs, if any, contribute to reduced incidence of substance use disorders, reductions in diversion, and reduced morbidity and mortality from substance use disorders among enrollees.

Thank you again for the opportunity to provide comments on this important proposed rule. ASAM looks forward to continuing to partner with CMS to promote evidence-based addiction prevention and treatment services.

Sincerely,

Kelly J. Clark, MD, MBA, DFASAM
President, American Society of Addiction Medicine