Friday, February 16, 2018

The Honorable Orrin G. Hatch
Chairman, Senate Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member, Senate Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, DC 20510

Re: Recommendations for Action

Dear Senators Hatch and Wyden,

On behalf of the American Society of Addiction Medicine (ASAM), a national medical specialty society representing more than 5,500 physicians and allied health professionals who specialize in the treatment of addiction, thank you for the opportunity to provide recommendations to the Senate Committee on Finance on combating the opioid epidemic in the Medicaid and Medicare programs.

As you may know, the Substance Abuse and Mental Health Services Administration (SAMHSA) reports that over 2 million people suffered from opioid addiction in the United States in 2016. At the same time, only about 20% or 500,000 individuals received specialty treatment for addiction that included the use of pharmacological therapies, despite widespread evidence of the safety and effectiveness of FDA-approved medications for the treatment of opioid use disorder.[1] This represents a treatment gap of almost 1.5 million people.[2] Many factors contribute to the low utilization of addiction treatment medications and this treatment gap, including inadequate provider reimbursement overall for the treatment of substance use disorder (SUD) by both public and private payers, the bifurcation of medical and behavioral health insurance benefits, and a shortage of well-trained physicians and other clinicians to treat opioid addiction.

Combating these issues requires a comprehensive approach to strengthening prevention, treatment, and recovery services for patients with addiction. ASAM appreciates the opportunity to respond to the Senate Committee on Finance's request and we are pleased to

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offer the recommendations below which would offer preventive care and increase access to quality addiction treatment.

Prevention

The opioid epidemic has taken an enormous toll on the Medicaid and Medicare populations. The proliferation of prescribing was one of the contributors to the opioid epidemic, including among those persons served by Medicaid and, according to more recent data, Medicare.[3] These facts require a new approach that ensures the safe and responsible prescribing of opioid medications.

As a result, ASAM encourages the Committee to consider effective preventive measures that would serve the Medicaid and Medicare populations by ensuring safe, responsible prescribing. ASAM was pleased to sponsor ***S. 892, The Opioid Addiction Prevention Act*** which would require prescribers of controlled substances to certify that they will limit opioid prescriptions for the treatment of acute pain. We hope that the Committee will consider similar measures and work to find opportunities to incorporate the CDC Guideline for Prescribing Opioids for Chronic Pain as one strategy to prevent the prevalence of opioid addiction involving opioid use in the Medicaid and Medicare populations.

Treatment

IMD Exclusion Waiver

Medicaid enrollees who are in need of residential treatment for a substance use disorder are currently limited by the IMD exclusion which prohibits federal Medicaid dollars from covering services provided to patients in facilities with more than 16 beds. This exclusion arbitrarily limits access to higher intensity treatment modalities for the thousands of people for whom residential levels of care are medically necessary, especially in the current circumstanes in which nearly two million people need treatment for addiction involving opioid use and are not receiving it. Currently, the IMD exclusion completely excludes patients from residential treatment for addiction involving opioid use even if their severity of illness would call for such care. While ASAM appreciates the Section 1115 Waiver opportunity provided by CMS, ASAM supports the statutory elimination of the IMD exclusion only for those residential treatment providers that are able to deliver services consistent with the ASAM Criteria and provide evidence-based substance use disorder treatment, including FDA-approved agonist and antagonist medications for opioid use disorder treatment.

Medicare Coverage of Methadone

Currently, Medicare provides coverage in Part B for medications provided in outpatient settings that cannot be self-administered by patients (e.g. long-acting injectable buprenorphine and/or naltrexone formulations), and in Part D where medications can be dispensed by a pharmacy with a prescription (e.g. sublingual buprenorphine/naloxone products). However, given that current federal regulations prohibit the dispensing of methadone for the treatment of addiction in outpatient settings outside of a federally-certified opioid treatment program (OTP) and because methadone is usually self-administered by patients, this limitation prevents Medicare Part B coverage of methadone for Medicare beneficiaries who may benefit from the use of methadone to treat addiction involving opioid use. ASAM supports ***HR 4097, the Medicare Beneficiary Opioid Addiction Treatment Act*** and urges the Committee to consider proposed legislation that would

provide critical access to outpatient opioid addiction treatment using methadone that is currently inaccessible to Medicare beneficiaries. At the same time, we urge the Committee to also remove this restriction for Medicare coverage of buprenorphine/naloxone products when delivered in an OTP setting.

Specialty Pharmacy Delivery of Medicine

Additionally, the advent of long-acting injectable medications to treat opioid addiction has opened up new avenues of treatment for patients. However, access to these medications continues to be hampered by the requirement that practitioners anticipate demand, buy the medication in advance, store it on site, and hope they estimated the correct number of doses needed to meet demand and avoid waste. This requirement -- often referred to as "buy and bill" -- significantly hampers the ability of practitioners to offer new treatment pathways to patients. This exclusion may disproportionately affect patients who are served by Medicaid given the already historically low provider reimbursement rate of the program. ASAM is proud to support ***Section 3 of S. 916, the Protecting Patient Access to Emergency Medications Act of 2017*** which would allow pharmacies to deliver controlled substances to prescribing or administering practitioners, including opioid receptor partial agonists and opioid receptor antagonists, that are formulated to be administered by implantation or injection for the treatment of addiction involving opioid use. We encourage the Committee to consider legislation that would increase access to these new treatment pathways and remove uncertainty for Medicaid enrollees, who are often affected by the opioid epidemic.

Utilization Management

Private and public payers, including Medicaid and Medicare continue to use utilization management techniques that control the choice of treatment modalities for patients with opioid use disorder, albeit sometimes inadvertently and inappropriately limiting access to treatment. ASAM believes that when established utilization management criteria such as the ASAM Patient Placement Criteria are used to determine the appropriateness of placement in a given level of addiction treatment, then insurance benefits should be applicable to any of those levels of care.[4] Therefore, the Committee should consider prohibiting Medicaid and Medicare from excluding coverage for any medication for the treatment of an opioid use disorder in all ASAM Levels of Care. In addition, to ensure that patients are receiving the necessary access to medications and to reduce the possibility of diversion, the Committee should also consider prohibiting the Medicaid and Medicare programs from imposing any prior authorization requirements on any opioid agonist therapy, taken by mouth within FDA daily dosing limits. Furthermore, ASAM recommends that the Committee consider mandating that Medicaid and Medicare include coverage for an emergency opioid antagonist (e.g. naloxone) and allow plans to apply a prior authorization requirement for an emergency opioid antagonist only if such plan or coverage provides coverage for at least one formulation of the emergency opioid antagonist without a prior authorization requirement. We believe this provision allows CMS to appropriately provide access to treatment while accounting for state budgetary concerns.

We also recommend that the Committee consider legislation that prohibits the ability of CMS to impose any step therapy requirements before the plan or coverage will authorize coverage for an opioid agonist therapy taken by mouth or an injectable maintenance naltrexone product. Finally, recognizing that prior authorizations sometimes impose a significant administrative burden on providers and their practices, we urge the Committee to consider directing CMS to study the

benefits and provide recommendations to Congress on implementing a universal, electronic prior authorization transaction form for use in Medicare and Medicaid benefit plans.

Alternative Payment Models

We recognize that reimbursement for physician services has historically been driven by volume over value. We encourage the Committee to consider directing CMS to implement alternative payment models (APMs) in Medicaid and Medicare such as the American Medical Association (AMA) and ASAM's Patient Centered Opioid Addiction Treatment (P-COAT) model that incentivizes value over volume in the delivery of high quality care. As ASAM described in the request for information from CMS regarding new APM approaches, P-COAT responds to the opioid epidemic, the underutilization of medication to treat it, and the numerous problems with current payment systems. P-COAT is a two-tiered, bundled APM and is primarily designed to incentive practitioners to deliver high quality, evidence-based outpatient addiction treatment to patients. We welcome the opportunity to discuss the model with you further.

Prescription Drug Rebate Program

Prescription drug manufacturers are required to pay the Medicaid program a drug rebate in exchange for coverage of their products on states' Medicaid prescription drug formularies. As the need for treatment services continues to increase, the Committee should direct a study to evaluate the impact of levying an additional rebate on prescription pain medications. This additional rebate may disincentivize the inappropriate use of pain medications, and state governments may find use for these additional monies as treatment options expand.

Thank you for the opportunity to provide recommendations to the Senate Committee on Finance on solutions to combat the opioid epidemic in the Medicaid and Medicare programs. If you have any questions, comments, or concerns, please contact Corey Barton, Manager, ASAM Private Sector Relations at 301-547-4016 or via email at cbarton@asam.org.

Sincerely,

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

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[1] Park-Lee, E., Lipari, R. N., Hedden, S. L., Kroutil, L. A., & Porter, J. D. (2017, September). Receipt of services for substance use and mental health issues among adults: Results from the 2016 National Survey on Drug Use and Health. NSDUH Data Review. Retrieved from https://www.samhsa.gov/data/

[2] Ibid

[3] Song, Z. (2017). Mortality quadrupled among opioid-driven hospitalizations, notably within lower-income and disabled white populations. Health Affairs, 36(12), 2054-2061.

[4] American Society of Addiction Medicine. Parity in Publicly Funded Health Insurance Benefits for Treatment of Addiction. Rockville, MD: American Society of Addiction Medicine; 2019. https://www.asam.org/advocacy/find-a-policy-statement/view-policy-statement/public-policy-statements/2011/12/15/parity-in-publicly-funded-health-insurance-benefits-for-treatment-of-addiction