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Questions for the Record
House Energy & Commerce Committee, Subcommittee on Health
Responding to America's Overdose Crisis:
An Examination of Legislation to Build Upon the SUPPORT Act
Wednesday, June 21, 2023

The Honorable Earl L. "Buddy" Carter

1. Mr. Blum - How does CMS/SAMHSA promote transparency and accountability in substance use treatment facilities and behavioral treatment centers?

2. Mr. Blum - How does CMS/SAMHSA address the regulation and oversight of youth residential facilities, which may offer behavioral treatment services and substance use disorder treatment?

3. Mr. Blum - How does CMS/SAMHSA address the need for training and review the qualifications of staff working in youth behavioral treatment centers?

4. Mr. Blum How does CMS/SAMSHA handle timely reporting and data collection of substance use disorder treatment outcomes for youth?

Answers 1-4:
CMS and HHS remain committed partners in providing tools and resources to states, managed care plans, and other stakeholders in the provision of needed behavioral health services to our nation's children and youth.

Psychiatric residential treatment facilities (PRTFs), which states can choose to enroll as providers of Medicaid inpatient psychiatric services for people under 21, must meet numerous requirements and conditions of participation. PRTFs must be accredited by the Joint Commission on Accreditation of Healthcare Organizations, the Council on Accreditation of Services for Families and Children, the Commission on Accreditation of Rehabilitation Facilities, or by any other accrediting organization, with comparable standards, that is recognized by the State. Required protections and accountability measures include ones related to certifying the need for services on an inpatient basis; treatment based on a professionally developed and supervised individual plan of care; and restrictions, reporting, and training requirements regarding the use of restraints and involuntary seclusion in PRTFs.

States that chose to cover residential and inpatient mental health and substance use disorder (SUD) treatment services in institutions for mental diseases, including in Qualified Residential Treatment Programs for children, under an approved section 1115 demonstration must meet numerous requirements to ensure quality of care in such settings. These requirements include provider licensure and qualifications, oversight and auditing processes of provider qualifications, and use of utilization review and patient placement criteria.

In addition, the T-MSIS SUD Data Book is congressionally-mandated through the SUPPORT for Patients and Communities Act. HHS publishes an updated version of this book no later than

January 1 of each calendar year through 2024, with the most recent 2020 SUD Data Book released on November 28, 2022. Each SUD Data Book reports the number of Medicaid beneficiaries treated for a SUD and the services they received during the calendar year. The results reported in the SUD Data Book are based on beneficiaries ages 12 and older enrolled in Medicaid for at least one day in 2020 and receiving full or comprehensive benefits. In 2020, there were more than 10 million children, ages 12 through 18, eligible for Medicaid and approximately 118,887 (1.2 percent) of these children were treated for a SUD.

5. Mr. Blum - Much of the legislation under consideration today is centered on treating addiction after the fact, which is of course a critical piece of the puzzle. However, the number of opioid related deaths is going up, not down, so we must also focus on prevention. If we could enact policies to shift prescribing away from opioids to non-opioid medicines – do you think it would help address part of the problem – which is easy access to prescription opioids?

Answer:
CMS developed an agency-wide *CMS Roadmap: Strategy to Fight the Opioid Crisis*, including a framework that articulates three key focus areas, one of which is prevention. Leveraging this three-part strategy, CMS created the *CMS Action Plan to Enhance Prevention and Treatment for Opioid Use Disorder*, which presents actions CMS is taking, including in the area of prevention, as part of its strategic initiative to fight the opioid crisis. These actions include enhancing patient care coordination and multidisciplinary pain care and identifying and supporting the use of effective, non-opioid treatment options for pain in Medicare, supporting state Medicaid agencies by identifying and sharing best practices in pain management, promoting transparency in the Medicaid program by collecting and sharing information on program activities, and investigating innovative payment models for multidisciplinary and multimodal pain care.

Under the authority of section 6082 of the SUPPORT Act, in calendar year (CY) 2023, CMS finalized separate payment in the ASC setting for five non-opioid pain management medications that meet the established criteria. Section 4135 of Consolidated Appropriations Act, 2023 (CAA) amended the Social Security Act to provide for temporary additional payment for drugs, biologicals, and medical devices that meet the definition of a non-opioid treatment for pain relief furnished on or after January 1, 2025, and before January 1, 2028, under both the OPPS and ASC Payment System.

Additionally, Medicare Part B helps pay for the following services that may help beneficiaries manage pain and related issues: acupuncture for chronic low back pain, alcohol misuse screenings and counseling, behavioral health integration services, chiropractic services, depression screenings, occupational therapy, and physical therapy.

The Honorable Robert E. Latta

1. We have now seen the approval of multiple new therapies in the Alzheimer's space, both in disease modifying and symptomatic treatment. One of those is an anti-psychotic which faces significant barriers to use in long-term care settings. How will the Agency adapt its' policies to reflect the evolving landscape of treatment to ensure timely and appropriate patient access for those FDA approved therapies?

Answer:
Alzheimer's disease is a devastating illness that affects millions of Americans and their families, and CMS is committed to helping people get timely access to treatments and improving care for people with Alzheimer's disease and their families. CMS is committed to fostering innovation while ensuring that people with Medicare have faster and more consistent access to emerging technologies that will improve health outcomes.

Ensuring the availability of innovative interventions for people is a shared priority for both CMS and FDA. Underpinning both of our agencies' work is the unwavering commitment to use reliable data to ensure that effective treatments are made available to patients. The FDA's decision to approve a new drug is based on a careful evaluation of the available data and a determination that the drug is safe and effective for its intended use. Under Medicare law, CMS makes national coverage decisions based on whether a product or treatment is reasonable and necessary for the treatment of an illness or injury for the Medicare population.

We share a common goal of wanting to advance the development and availability of innovative medical products. Our agencies remain committed to using our distinct set of authorities to ensure the continued availability of medical products that meet our respective standards to care for the people we serve.

The Honorable Troy Balderson

1. I strongly support telehealth and other innovative care delivery systems, like remote monitoring, for the convenience they offer to patients and physicians alike. In 2018, the VA found that patients enrolled in their remote monitoring programs saw a 53% decrease in bed days and a 33% reduction in hospital admissions.

   This monitoring can be particularly beneficial for patients with opioid use disorder and for medication-assisted treatment (MAT) and for patients in rural areas, like many parts of my district.

   I had a bill included in the hearing, the Remote Opioid Monitoring Act, which will have GAO study the current use of remote monitoring for individuals who are prescribed opioids, potential cost savings from expanded remote monitoring, and recommendations to improve availability, access, and coverage for remote monitoring in the future.

   How is CMS working to expand access to innovative technologies such as remote monitoring?

2. As you know, CMS implemented many coverage and reimbursement flexibilities during the COVID 19 pandemic to enable patients to get the care they needed. Would you support such flexibilities, such as temporary coverage and reimbursement for medical devices, during the opioid crisis PHE? Why or why not?

3. The 2021 Consolidated Appropriations Act included two remote monitoring directives:

requiring the NIH to research the efficacy and benefits of continuous physiologic electronic monitoring that measures adequacy of respiration of patient taking opioids in the hospitals.

The second asked CMS to study the potential efficacy and benefits of continuous physiologic electronic monitoring of all patients taking opioids in the hospital. Does CMS have the results of these studies and have you implemented any recommendation based on the findings?

Answers 1-3:
Thank you for your interest in expanding access to digital technologies in Medicare. In recent Medicare Physician Fee Schedule rulemaking, CMS solicited public comment to help us better understand the resource costs for services involving the use of innovative technologies, including but not limited to software algorithms and artificial intelligence, and we are considering how to address this issue further for future rulemaking.

In addition, President Biden's Fiscal Year 2024 Budget includes a proposal that would allow for Medicare coverage of evidence-based digital applications and platforms that facilitate greater access to behavioral health services, especially for beneficiaries who live in rural or health professional shortage areas. If you are interested in drafting further legislation to address Medicare's coverage of digital technologies, CMS would be happy to provide technical assistance.

The Honorable Diana Harshbarger

As a pharmacist, I am all too familiar with the risk of long-term opioid abuse after a prescription for acute pain.

Over the past decade, there have been some progress in reducing unnecessary opioid prescribing — but as you know, we can't just do away with acute pain.

For surgeries in particular, we need to manage short term intense pain without the use of opioids, and avoid setting patients on a path to addiction.

This is one of the reasons why Congress passed *the NOPAIN Act* last year, which would provide Medicare payment for non-opioids for surgeries in the outpatient setting, and help reduce unnecessary opioid use.

However, I've heard from stakeholders that this new payment framework might not be implemented until the year 2025.

1. Could you give us a status update on this, and as you finalize this year's Medicare payment rules, is there any part of that law that you could implement to go into effect in 2024?

Answer:

Section 4135 of the CAA amended the Social Security Act to provide for temporary additional payments for drugs, biologicals and medical devices that meet the definition of non-opioid treatment furnished on or after January 1, 2025, and before January 2028, under both the OPPS and ASC Payment System. CMS is working on the policies and operational changes needed for timely implementation of section 4135 of the CAA. Any proposals related to implementation of this policy will go through notice and comment rulemaking.

The Honorable Paul Tonko

1. With at least 14 waivers pending that would include coverage similar to California's 1115 waiver to provide Medicaid-supported treatment for substance use disorders to incarcerated Medicaid- eligible individuals, can you please indicate your timeline for acting on each of these pending waivers?

2. What is necessary specifically for CMS to evaluate and approve these waivers, including a discussion of the priority you accord to them and your staffing and other resource needs? If you are uncertain what are the possible time range that you estimate it will take- months or a year or multiple years or decades?

Answers (1-2):
Improving health care transitions for incarcerated individuals is critically important. Many of these individuals are Medicaid eligible, and access to services pre- and post-release may provide these individuals with more stability. While CMS considers each section 1115 demonstration application on its own merits, we refer states to the State Medicaid Director Letter, *Opportunities to Test Transition-Related Strategies to Support Community Reentry and Improve Care Transitions for Individuals Who Are Incarcerated*, issued on April 17, 2023. This letter describes the Reentry Section 1115 Demonstration Opportunity, which is intended to help states submit proposals that would advance the goals of the Medicaid statute to provide medical assistance to vulnerable and low-income populations and ensure high quality care for communities and populations served. Under this demonstration opportunity, states may provide coverage for certain Medicaid services to incarcerated individuals who are soon to be released from incarceration, consistent with the statutory directive in section 5032 of the SUPPORT Act. States are encouraged to submit applications for demonstrations that would test innovative practices that are likely to assist in promoting the objectives of Medicaid.

As indicated in CMS' guidance, states with proposals already pending should review those proposals against the guidance in that letter, and should continue to engage with CMS about the state's proposed approach and any changes the state may wish to make. CMS will continue to work as expeditiously as possible to review states' proposals, and to work collaboratively with states regarding their proposals.

To facilitate CMS' review of applications for Reentry Section 1115 Demonstrations, state proposals should address key elements, including a description of the carceral settings, individuals

who are eligible for the demonstration, prerelease services to be included in the demonstration, and the timeframe for delivery of prerelease services. States should also identify for each milestone what they expect to be the key implementation challenges and at a high level how they intend to address these challenges, with the expectation that they will be further described in the implementation plan. CMS remains available to provide technical assistance to states on this matter.

3. CMS written testimony indicates nearly half of Medicare beneficiaries with OUD receiving MAT do so under the OTP benefit. What percentage of those are receiving methadone for OUD from an OTP (vs bupe or naltrexone)?

Answer:
Opioid Treatment Programs (OTPs) provide medications for opioid use disorder (MOUD) , and are the only entities that can provide methadone for the treatment of OUD in outpatient settings.. In 2021, the majority (approximately 95%) of beneficiaries getting services at OTPs were receiving methadone.

Thanks to authorities in the SUPPORT Act, CMS implemented Medicare coverage of OUD with methadone provided by OTPs. Before the SUPPORT Act, individuals with Medicare receiving MOUD at OTPs had to pay out-of-pocket. Now, Medicare pays outpatient OTPs through bundled payments made for treatments, including necessary medications, counseling, and testing. CMS will continue to work to expand access.