Questions for the Record for CMS Administrator Chiquita Brooks-LaSure
House Energy & Commerce Committee, Subcommittee on Health
Hearing on April 26, 2023
"Lowering Unaffordable Costs: Legislative Solutions to Increase Transparency and Competition in Health Care"

The Honorable Cathy McMorris Rodgers

The Inflation Reduction Act included a new program that requires every Medicare Part D plan to allow enrollees to opt in to a maximum monthly cap on their Part D out-of-pocket costs.

1) What steps is CMS taking to ensure Medicare enrollees are aware of this benefit ahead of 2025 open enrollment?

2) What steps is CMS taking to ensure enrollees who do not enroll in this "smoothing option" prior to January 1, 2025 are able to enroll throughout the year, including at the point of sale of their prescription?

Answer 1-2
Thanks to the Inflation Reduction Act of 2022 (P.L. 117-169), beginning in 2025, Part D enrollees will be able to choose to pay their out-of-pocket Part D costs in monthly amounts spread over the plan year. CMS will engage in education, communications, and outreach to inform people with Medicare about this important new option to spread out-of-pocket Part D costs over the plan year. CMS is committed to engaging with the public throughout the policymaking and implementation processes for the Inflation Reduction Act of 2022. CMS welcomes feedback on the best ways to effectively educate people with Medicare about the new option.

Medicaid Eligibility Rule and Access Rule
In the Office of the Actuary's analysis of the proposed rule titled "Streamlining the Medicaid, Children's Health Insurance Program, and Basic Health Program Application, Eligibility Determination, Enrollment, and Renewal Processes", your agency said that the rule could cost as much as $62 billion in the first five years. Other analysis says that this cost could be as much as $200 billion over 10 years for the federal government.

This increase in federal spending could trigger tens of billions in additional state spending over the next decade as well, due to the state match in Medicaid.

We hear every day about the implications of state budget crunches on Medicaid reimbursement rates, and I can't possibly imagine that putting additional stress on states like this will meaningfully improve access to care.

In regards to this rule,

3) What does CMS estimate will be the increased costs for states over the 10 year window from this rule? Does CMS anticipate changes in reimbursement rates, as a consequence of this rule?

4) What, if anything, in the proposed rule or through other efforts by the Administration would help alleviate the costs being imposed on States?

Similarly, your agency just released two sets of regulations in Medicaid regarding access and Medicaid managed care organizations.

5) What does CMS estimate will be the increased costs for states over the 10 year window from this rule? Does CMS anticipate changes in reimbursement rates, as a consequence of this rule?

6) What, if anything, in the proposed rules or through other efforts by the Administration would help alleviate the costs being imposed on States?

Across the eligibility rule, the access rule, the MCO rule, and the current Medicaid unwinding underway, States are being overwhelmed by unprecedented burdens.

7) When added together, what is the expected, cumulative burden analysis for all of these processes occurring in tandem?

Answers 3-7

Medicaid is an important lifeline for many American families. The partnership between states and the federal government is central to Medicaid, and this Administration is committed to working with states to strengthen this vital program. The Medicaid statute gives states significant flexibility to tailor their programs to meet the unique needs of their residents, within broad national guidelines established by Federal statutes, regulations, and policies. CMS works closely with states to ensure they have access to the tools and resources they need to successfully meet federal requirements.

On September 7, 2022, CMS published a proposed rule[1] to simplify the processes for eligible individuals to enroll and retain eligibility in Medicaid, the Children's Health Insurance Program (CHIP), and the Basic Health Program. In this rulemaking, we seek to streamline the Medicaid and CHIP eligibility and enrollment processes, reducing administrative burden on States and enrollees, and increasing enrollment and retention of eligible individuals. The aggregate economic impact of this proposed rule is estimated to be $61.93 billion (in real FY 2023 dollars) over 5 years. This represents additional health care spending made by the Medicaid and CHIP programs on behalf of Medicaid and CHIP beneficiaries, with $41.41 billion paid by the Federal government and $20.52 billion paid by the States.

[1] "Streamlining the Medicaid, Children's Health Insurance Program, and Basic Health Program Application, Eligibility Determination, Enrollment, and Renewal Processes" (CMS-2421-P)

CMS is examining ways to help states build stronger programs to better meet the needs of the Medicaid and CHIP populations by improving access to and quality of care provided to Medicaid and CHIP managed care enrollees. CMS is also examining ways to improve access to care, quality and health outcomes, and better address health equity issues in the Medicaid program across fee-for-service (FFS), managed care delivery systems, and in home and community-based services (HCBS) programs. CMS looks forward to working with stakeholders on these issues, and will take their feedback, including any on administrative burden and costs, into account when finalizing any policy changes. In developing any policy changes, CMS will also seek to mitigate operational concerns by limiting the number of proposals to the most impactful, limiting the scope of some proposals, providing reasonably long timeframes for implementation, and proposing to phase-in certain requirements. We will continue to work with states to ensure that they are able to move these important protections forward without negatively impacting their operations.

The Honorable Gus Bilirakis

8) Administrator Brooks-LaSure, I've previously asked Secretary Becerra about CMS's role in considering coverage determinations for FDA-approved drugs and CMS' chilling effects on innovation. Unfortunately your agency has stood in the way of potential treatments for early-stage Alzheimer's when it doubled-down on its coverage determination restricting access to the drug lecanemab, which has been shown to reduce cognitive decline by up to 27% in patients. Despite being approved for Alzheimer's, CMS has determined that it's not "reasonable and necessary" for seniors. The VA has determined that it is appropriate for Veterans, and yet somehow you've decided it's not appropriate for Medicare patients. Why is that?

9) We've heard repeatedly from your agency that should the FDA approve Leqembi under the traditional approval pathway this summer, your agency "will provide broader coverage using the framework we announced last year, under CED on the same day." The CED framework is still severely restrictive and will make it so many of my constituents in rural and underserved areas won't be able to gain access to the treatment, as well as the 73 percent of individuals living with Alzheimer's disease age 65 and older and, as such, eligible for Medicare. Will you commit that your agency will reconsider the severe restrictions if this new treatment is approved under traditional approval?

10) Leaders in my state of Florida have asked you to reconsider this decision and consider the effects it's having on patients. Do you plan to respond to their concerns?

11) If lecanemab receives traditional full FDA approval in the summer, will CMS still mandate Medicare beneficiaries participate in a registry in order to receive access to the drug?

Answer 8-11

The FDA and CMS have different authorities and requirements when it comes to the approval and coverage of drugs (and devices). The FDA determines whether to approve a new medical

product based on a careful evaluation of the available data and a determination that the medical product is safe and effective for its intended use but does not consider the specific needs of the Medicare patient populations. Under Medicare statute in section 1862(a)(1)(A) of the Social Security Act, Medicare coverage is determined whether items and services are reasonable and necessary to diagnose or treat an illness or injury or to improve the functioning of a malformed body member for an individual with Medicare. CMS looks to the evidence supporting FDA decision-making for evidence generalizable to the Medicare population, data on improvement in health outcomes, and durability of those outcomes. If there are no data on those elements, it is difficult for CMS to make an evidence-based decision whether a product is reasonable and necessary for the Medicare population.

In determining the generalizability of the results of the body of evidence to the Medicare population, CMS considers, at minimum, the age, race and gender of the study participants. When making NCDs, CMS conducts its own independent review to determine whether an item or service is reasonable and necessary for use in the Medicare population and should be covered nationally by Medicare. To date, there has not been an antiamyloid monoclonal antibody that has been approved by the FDA for the treatment of Alzheimer's disease based upon evidence of efficacy from a direct measure of clinical benefit. CMS reviews all relevant evidence and weighs the potential benefits and unknowns, and generally evaluates whether the drug is clinically beneficial to Medicare patients.

The final national coverage decision on FDA approved monoclonal antibodies (mAbs) directed against amyloid for the treatment of Alzheimer's disease allows for flexibility in a less rigorous study design for mAbs that receive FDA approval for the treatment of Alzheimer's disease based on a direct measure of clinical benefit. In addition, based on public comment, we did not finalize the patient exclusion criteria in order to allow appropriate access to patient subpopulations that may need treatment based on ongoing research. The final decision also does not restrict the setting of approved clinical trials to ensure that anti-amyloid mAbs that receive FDA approval based upon evidence of efficacy from a direct measure of clinical benefit may be given to a broader patient population.

12) Do you support the use of value-based payment arrangements in Medicaid which can help ensure a robust innovation pipeline for cell and gene therapy companies?

Answer 12

The CMS Innovation Center recently announced a new model[2] to test whether a CMS-led approach for administering outcomes-based agreements (OBAs) for cell and gene therapies (CGTs) can improve beneficiary access and outcomes and reduce health care costs. The model would establish a partnership among CMS, manufacturers and state Medicaid agencies, and would test a new approach for administering OBAs to help Medicaid beneficiaries gain access to potentially life changing, high-cost specialty drugs. In lieu of state Medicaid agencies pursuing

[2] *A Report in Response to the Executive Order on Lowering Prescription Drug Costs for Americans:* https://innovation.cms.gov/data-and-reports/2023/eo-rx-drug-cost-response-report

manufacturer agreements individually, state Medicaid agencies would have the option of assigning CMS to structure and coordinate multi-state OBAs with participating manufacturers. CMS would also take on the responsibility of implementing, monitoring, reconciling, and evaluating the financial and clinical outcomes outlined in the OBAs. This Model would target CGTs for illnesses like sickle cell disease and cancer.

A national approach for supporting OBAs related to CGTs could offer: better access to treatment for beneficiaries with rare and severe diseases, stability to payers, and payment certainty to providers who are hesitant to acquire and deliver these high-cost treatments. The use of OBAs could enable manufacturers to be compensated based on the clinical impact of CGTs, therefore increasing accountability of the manufacturer to deliver treatments that improve quality at a more sustainable cost.

13) Given the Inflation Reduction Act has had a chilling effect on the industry, what is your agency doing to promote innovation in the marketplace?

Answer 13

The law requires that at least seven years, for drugs, or 11 years, for biologicals, must have elapsed between the selected drug publication date and the FDA approval or licensure, as applicable. We are implementing the Negotiation Program in accordance with the law.

CMS has been regularly engaging with members of the public to get their feedback so that we are implementing the Negotiation Program in a thoughtful way that balances the goal of improving drug affordability and accessibility for people with Medicare while supporting innovation. We plan to get public input throughout the implementation of the Negotiation Program to make sure that we know what is occurring in the market.

The Honorable Larry Bucshon

14) The paper "Hospital Competition and Restrictions on Physician-Owned Hospitals" discusses the explosive growth in hospital and physician practice mergers over the past few years: "There were 1,412 hospital mergers from 1998 to 2015, with 561 occurring from 2010 to 2015. In 2010, 28 percent of primary physicians were employed by hospitals. By 2016, that number had risen to 44 percent. Large physician practices have been growing larger while smaller practices have been growing smaller. According to recent data, over 90% of metropolitan statistical areas have been estimated as consolidated for hospitals, 65% for specialist physicians, and 39% for primary care physicians." o Source: ***https://physiciansled.com/health-policy-thought-leaders-call-for-immediate-reversal-of-physician-led-hospital-ban-house-and-senate-bills-introduced/***

Do you believe letting physician-owned facilities grow as we did before 2010 would or would not increase healthcare competition?

Answer 14

In the Affordable Care Act, Congress limited the ability of physician-owned hospitals to expand. Section 6001 of the Affordable Care Act of 2010 amended section 1877 of the Social Security Act to impose additional requirements for physician-owned hospitals to qualify for the whole hospital and rural provider exceptions. A physician-owned hospital is now generally prohibited from expanding facility capacity. CMS, in implementing this provision, established in regulations (42 CFR §411.362(c)) a process for physician-owned hospitals to apply for an exception from the expansion prohibition. For example, a physician-owned hospital that qualifies as an applicable hospital or high Medicaid facility may request an exception to the prohibition from the Secretary. CMS is examining ways to improve that process. CMS welcomes feedback and can work with your staff to provide technical assistance on legislation you draft related to this issue.

15) You testified that CMS considers accelerated approval to be in a "different category." However, when Congress codified the accelerated approval pathway in 2012 it affirmed FDA's previous conclusion that accelerated approval did not create a different standard for drug approval, stating that accelerated approval "may result in fewer, smaller, or shorter clinical trials…without compromising or altering the high standards of the FDA for the approval of drugs." (See 158 Cong. Rec. H3825-01, H3848 (2012)).

Please explain why CMS is putting accelerated approval drugs into a "different category," and what precisely that means.

Answer 15

The FDA performs a vital and an important role. CMS recognizes the important and related – but different – roles of the respective agencies. The FDA determines whether to approve a new medical product based on a careful evaluation of the available data and a determination that the medical product is safe and effective for its intended use but does not consider the specific needs of the Medicare patient populations. Under Medicare statute in section 1862(a)(1)(A) of the Social Security Act, Medicare coverage is determined whether items and services are reasonable and necessary to diagnose or treat an illness or injury or to improve the functioning of a malformed body member for an individual with Medicare. CMS looks to the evidence supporting FDA decision-making for evidence generalizable to the Medicare population, data on improvement in health outcomes, and durability of those outcomes. If there are no data on those elements, it is difficult for CMS to make an evidence-based decision whether a product is reasonable and necessary for the Medicare population. In determining the generalizability of the results of the body of evidence to the Medicare population, we consider, at minimum, the age, race and gender of the study participants.

CMS conducts its own independent review to determine whether an item or service is reasonable and necessary for use in the Medicare population and should be covered nationally by Medicare. To date, there has not been an antiamyloid mAb that has been approved by the FDA for the treatment of Alzheimer's disease based upon evidence of efficacy from a direct measure of clinical benefit.

The Honorable Ann Kuster

Northeast Passage

16) The University of New Hampshire is home to Northeast Passage, a national leader in recreational therapy and adaptive sports. Recreational therapy promotes the physical, cognitive, emotional and social functioning of individuals with disabilities to help them achieve independence, productivity, and wellbeing. However, CMS does not currently include coverage of recreational therapy services under Medicare or Medicaid, limiting the breadth of services available to beneficiaries. Would CMS consider expanding Medicare and Medicaid coverage to include recreation therapy services, and if not, what barriers are preventing CMS from doing so?

Answer 16

Medicare coverage is limited to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury and within the scope of a Medicare benefit category as defined in the Medicare statute. For example, in an inpatient rehabilitation facility, the statute requires Medicare to cover skilled nursing care or other skilled rehabilitation services. Recreation therapy services may be provided in an inpatient rehabilitation facility if the medical necessity is well documented by the rehabilitation physician in the medical record and is ordered by the rehabilitation physician as part of the overall plan of care for the patient. Another example is in inpatient psychiatric settings, where recreational therapy services may be covered so long as the services are designated as active treatment and the therapeutic activities are expected to result in improvement in the patient's condition.

With respect to Medicaid, states establish and administer their own Medicaid programs and determine the type, amount, duration, and scope of services within broad federal guidelines. Federal law requires states to provide certain mandatory benefits and allows states the choice of covering other optional benefits. Mandatory benefits include inpatient and outpatient hospital services, physician services, laboratory and x-ray services, home health services, and the Early and Periodic Screening, Diagnostic, and Treatment benefit for children under age 21, among others. Optional benefits include services including prescription drugs, case management, physical therapy, and occupational therapy. States also have the option to provide home and community-based services (HCBS) to allow older adults and people with disabilities to live in the community, instead of institutions. HCBS are optional benefits and may include habilitation services and other services requested by the State and approved by CMS as cost effective and necessary to avoid institutionalization, so long as they are not purely for recreational purposes.

Over the Counter Narcan

According to the CDC – between November 2021 and November 2022 - over 103,000 Americans died as a result of overdose deaths. While I applaud the Administration's efforts

on combatting the opioid crisis, more must be done. I was heartened to see the first approval by FDA of over-the-counter naloxone earlier this year. I do have concerns though about how patients – particularly within CMS's purview - will understand the changes.

17) In reference to Medicaid, will CMS issue guidance to ensure practitioners and patients understand that they need an Rx in order for Medicaid patients to access OTC naloxone (in states where there is OTC coverage)?

18) For Medicare beneficiaries, will CMS be taking any steps to address the access gap that will be created with this shift?

Answer 17-18

Over the past year, the Biden-Harris Administration took unprecedented steps to expand access to naloxone and other harm reduction interventions, and CMS is working within the confines of the law to ensure individuals enrolled in our programs have affordable access to this life-saving medication.

In Medicaid, state Medicaid programs are not required to cover OTC drugs and federal financial participation (FFP) is not available for OTC drugs dispensed without a prescription. However, states may cover and receive FFP for OTC drugs when prescribed by professionals authorized to do so under state laws and regulations. Currently all states cover some form of prescription naloxone, and many states have implemented strategies to facilitate easier access, such as allowing pharmacists to dispense drugs prescribed independently, or under collaborative practice agreements, standing orders, or other predetermined protocols. CMS has been keeping states informed about naloxone's OTC status and will continue to provide technical assistance to aid states in updating their State Plan Amendments, if they choose to cover OTC naloxone when dispensed with a prescription.

By law, Medicare Fee-for-Service does not generally cover OTC services and tests.
With respect to Part D, by statute, OTC products do not meet the definition of a covered Part D drug because they are not dispensed only upon a prescription. Part D sponsors do have the flexibility, however, to provide OTCs as part of their administrative cost structure with no cost sharing at point of sale (POS) either as (1) part of general drug utilization management or (2) as part of a step therapy protocol. CMS has taken steps to ensure that Part D sponsors are aware of this flexibility.

In addition, CMS promotes improved access to prescription naloxone by requiring that the antidote appear on all Medicare Part D formularies, and by encouraging sponsors to include at least one naloxone product on a generic or Select Care Tier. Select Care Tiers provide for $0 or low cost-sharing for those plans that utilize such a tier model. CMS encourages Part D plan sponsors to ensure coverage for beneficiaries at risk and recommends targeted education of prescribers and enrollees on co-prescribing of naloxone to prevent accidental overdoses and to sensitively address the needs of beneficiaries with OUD.

Rural hospitals/rural health care

192 rural hospitals throughout the US have closed their doors since 2005. Moreover, a recent Center for Healthcare Quality and Payment Reform report found that more than 200 hospitals are at immediate risk of closing in 2023 alone because of financial losses and lack of reserves to sustain their operations. Many of these hospitals are located in isolated rural communities across the US, forcing residents to travel a long distance for emergency services or inpatient care. Rural hospitals in many small communities are often the only place where residents can access primary care services.

19) How is CMS ensuring access to care in rural communities given the rise in hospital closures?

20) How is CMS ensuring continuity of care in rural communities? Supporting access to emergency medical services, specialist, and primary care?

Answer 19-20

CMS is committed to ensuring access to care in rural communities and is implementing a range of policies to help secure that access. One such program is Rural Emergency Hospitals (REHs), a new provider type established by the Consolidated Appropriations Act, 2021 to address the growing concern over closures of rural hospitals. On November 23, 2022, CMS published a final rule (CMS-1772-FC) establishing REHs as a new Medicare provider effective January 1, 2023.[3] Eligible hospitals include Critical Access Hospitals (CAHs) and rural hospital (or one treated as such under section 1886(d)(8)(E) of the Social Security Act) with less than 50 beds, and that do not provide acute care inpatient services with the exception of skilled nursing facility services furnished in a distinct part unit. In our final rule, CMS estimated that 68 eligible hospitals could convert to an REH. Conversion to an REH allows rural hospitals to continue providing emergency services, observation care, and additional medical and health outpatient services, if elected by the REH, that do not exceed an annual per patient average of 24 hours. In addition to a monthly facility payment, REHs will receive an additional 5% payment for each covered outpatient department service of the Hospital Outpatient Prospective Payment System rate. The CY 2023 additional monthly REH facility payment is $272,866. For 2024 and each year after, this additional payment will increase by the hospital market basket percentage increase. The REH designation provides an opportunity for rural hospitals to avert potential closure, promote health equity, and continue to provide essential services for the communities they serve. Eligible hospitals can submit their applications to convert to an REH to their Medicare Administrative Contractor, at which point they will be screened for eligibility and to ensure compliance with all Medicare enrollment requirements.

[3] "Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating; COVID-19"; https://www.federalregister.gov/documents/2022/11/23/2022-23918/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment#footnote-237-p72137

The Honorable Doris Matsui

21) In 2018, I secured a bipartisan provision in the SUPPORT Act that encouraged the Center for Medicaid and Medicare Innovation (CMMI) to initiate a behavioral health information technology demonstration. However, CMMI has still not taken action to initiate this demonstration, while MACPAC reports that fewer than half of psychiatric hospitals operate health information technology systems and roughly 30 percent of Community Mental Health Centers have an IT system capable of exchanging patient information. Can you provide an update on the status of the CMMI behavioral health IT demonstration included in the SUPPORT Act?

22) Do you think that additional financial assistance would increase providers' uptake of interoperable health information systems that comply with ONC certification standards? In turn, how would this impact integrated care delivery and patient outcomes?

Answer 21-22

CMS is committed to reducing administrative burden and advancing interoperability and national standards, and its Office of Burden Reduction & Health Informatics serves as a focal point and champion for burden reduction, national standards and interoperability, and to engage our stakeholders to inform solutions. CMS has continued to seek public input on barriers to accessing health care and related challenges to inform our work and better support the populations we serve. In the December 2022 Advancing Interoperability and Improving Prior Authorization Processes proposed rule (87 FR 76323), CMS included a Request for Information that acknowledged this provision of the SUPPORT Act and sought feedback from the public on innovative approaches to addressing the need to facilitate the electronic exchange of behavioral health information, as well as approaches to support the exchange of health information to behavioral health providers to inform care and provision of behavioral health services.

In addition to these CMS activities, the Office of the National Coordinator for Health IT (ONC) is working to better enable providers to interact with health care plans and other payers for the automated, electronic completion of prior authorization tasks. More information is available here: https://www.healthit.gov/topic/laws-regulation-and-policy/request-information-electronic-prior-authorization-standards-implementation-specifications. Further, ONC recently proposed rulemaking to advance interoperability, improve transparency, support the access, exchange, and use of electronic health information, enhance health IT certification, and reduce burden and costs. More information is available here: https://www.govinfo.gov/content/pkg/FR-2023-04-18/pdf/2023-07229.pdf

In 2020, HHS released a comprehensive strategy to reduce the regulatory and administrative burden related to the use of health IT, including EHRs. Reflective of public comment, the *Strategy on Reducing Regulatory and Administrative Burdens Relating to the Use of Health IT and EHRs* targets burdens tied to regulatory and administrative requirements that HHS can directly impact through the rulemaking process. The report's strategies, recommendations, and policy shifts aim to give clinicians more time to focus on what matters – caring for their patients. This report was developed as a collaborative effort between ONC

and CMS. ONC, CMS, and HHS as a whole are working to implement strategies identified within the report to reduce burden and advance interoperable health IT.

23) Last summer, with bipartisan support, the Congress incorporated my Excellence in Mental Health and Addiction Treatment Expansion Act into legislation signed by President Biden that expanded the Medicaid Certified Community Behavioral Health Clinic (CCBHC) demonstration nationwide. I understand that HHS selected fifteen (15) states to receive planning grants. When will the first ten (10) states be selected to participate in the expanded demonstration?

24) How have the mental health and substance use crises impacted the utilization of CCBHCs and the level of acuity of patients seen at CCBHCs?

Answer 23-24

CMS recognizes CCBHCs' critical role in providing crisis services that are available 24 hours a day, 7 days a week and serve anyone who requests care for mental health or substance use, regardless of their ability to pay. The expansion of CCBHCs builds on the Administration's previous work to launch the 988 Suicide & Crisis Lifeline and further builds the crisis continuum of care and addresses the ongoing mental health crisis.

Up to ten states that received planning grants will be able to join the CCBHC demonstration program in 2024 after a separate application process. While up to 10 states can join the Medicaid demonstration in 2024, states will have another chance to join the CCBHC demonstration in 2026, and every two years thereafter. The CCBHC planning phase assists states in certifying clinics as CCBHCs, establishing prospective payment systems for Medicaid reimbursable services, and preparing an application to participate in a four-year demonstration program.

The CCBHC demonstration program provides reimbursement through Medicaid for the full cost of services that CCBHCs provide, at higher, more competitive rates than community mental health centers previously received. This sustainable funding also ensures they can provide a more comprehensive range of services rather than fragmented services driven by billing codes. The President's FY24 budget proposes to make this demonstration model permanent, thereby expanding access to behavioral health services for all Americans and calls for historic funding to support the expansion of mental health and substance use care.

25) CMS currently provides several waiver options for states to increase provider capacity for substance use disorder (SUD) and for serious mental illness (SMI) in adults or serious emotional disturbance (SED) in children by amending the IMD exclusion policy. Can you provide an update on how successful these waivers have been in achieving their goals of increasing provider capacity, reducing ER utilization among Medicaid beneficiaries with SUD/SMI/SED, and improving the continuum of care for Medicaid beneficiaries?

Answer 25

Through section 1115 demonstrations, CMS is partnering with states to test means of increasing access to the full continuum of care for SUD, including medication assisted treatment, and residential treatment, as advocated by leading SUD treatment experts. In November 2022, CMS

issued a report entitled "Medicaid Section 1115 Substance Use Disorder (SUD) Demonstrations: An In-Depth Look Into Pre-demonstration Measures of SUD Need, Treatment Use, Availability, and Outcomes Across States."[4] This report is part of a series of rapid cycle reports intended to share findings and insights about section 1115 SUD demonstrations. This report focuses on the pre-demonstration measures of SUD treatment need, treatment use, treatment availability, and health outcomes for Medicaid section 1115 SUD demonstration states that had demonstrations approved by June 1, 2020. The report also provides analogous findings for states without an approved section 1115 SUD demonstration by June 1, 2020. Understanding the pre-demonstration levels of SUD treatment need, treatment use, treatment availability, and SUD-related health and mortality outcomes among Medicaid beneficiaries in section 1115 SUD demonstration states, and how these differ from measures in states that did not have an approved section 1115 SUD demonstration by June 2020, will help ensure estimates of the impact of SUD demonstrations are valid. Rigorous impact estimates for the section 1115 SUD demonstration states support CMS's goal of improving beneficiary outcomes and reducing mortality rates among the Medicaid SUD population. This report, as well as additional evaluations of 1115 demonstrations, can be found at: https://www.medicaid.gov/medicaid/section-1115-demonstrations/1115-demonstration-monitoring-evaluation/1115-demonstration-federal-evaluation-meta-analysis/index.html.

26) Patient access to off-label, medically necessary cancer therapeutics has been dramatically increased by the change to allow Medicare coverage if the drug is recognized in certain compendia or supported by two peer-reviewed articles in journals identified by Medicare. Rare disease patients now face the same struggles that cancer patients once did in terms of accessing off-label treatments. In the absence of a compendia for rare disease patients (like the National Comprehensive Cancer Network for oncology), what would be the risks and benefits of using the two-article approach to determine CMS coverage for rare disease therapeutics?

Answer 26

In addition to coverage for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen, FDA-approved drugs and biologicals may also be considered for use in the determination of medically accepted indications for off-label use if determined by the Medicare Administrative Contractor (MAC) to be reasonable and necessary. Drugs used for indications other than those in the approved labeling may be covered under Medicare if it is determined that the use is medically accepted, taking into consideration the major drug compendia, authoritative medical literatures and/or accepted standards of medical practice. In determining whether there is supportive clinical evidence for a particular use of a drug, the quality of the published evidence must be considered. If a use is identified as not indicated by the Centers for Medicare & Medicaid Services (CMS) or the FDA, or if a use is specifically identified as not indicated in one or more of the compendia listed, or if the MAC determines,

[4] "Medicaid Section 1115 Substance Use Disorder (SUD) Demonstrations: An In-Depth Look Into Pre-demonstration Measures of SUD Need, Treatment Use, Availability, and Outcomes Across States" https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/sud-115-rcr-baseline.pdf.

based on peer-reviewed medical literature, that a particular use of a drug is not safe and effective, the off-label usage is not supported and, therefore, the drug is not covered