



September 6, 2022

Honorable Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1770-P
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted electronically to: <http://www.regulations.gov>

Re: CMS-1770-P

Administrator Chiquita Brooks-LaSure:

On behalf of the undersigned members of the Consortium for Constituents with Disabilities (CCD) Health Task Force, we are pleased to provide the Centers for Medicare & Medicaid Services (CMS) comments on the proposals, request for information, and modifications on:

- II.L – Medicare Parts A and B Payment for Dental Services
- II.K – Allow Audiologists to Furnish Certain Diagnostic Tests Without a Physician Order
- III.B – Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)
- II.D – Payment for Medicare Telehealth Services Under Section 1834(m) of the Act
- III.F – Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

Introduction to Comments

CCD is the largest coalition of national organizations working together to advocate for federal public policy that ensures the self-determination, independence, empowerment, integration, and inclusion of children and adults with disabilities in all aspects of society free from racism, ableism, sexism, and xenophobia, as well as LGBTQ+ based discrimination and religious intolerance. As advocates for equitable access to health care for people with disabilities and complex conditions, we recognize the need for improved dental and audiology coverage in Medicare. Without this coverage, millions of older adults and people with disabilities in our nation cannot afford the care they need to get and stay healthy. Now, the Biden Administration has an opportunity to deliver a critical piece of this popular, much needed benefit to our nation's older adults and people with disabilities.

Dental and Audiology Services

We applaud CMS for recognizing the need to maximize its authority to cover “medically necessary” dental care and audiology services in Medicare. Medicare’s lack of dental coverage not only leaves oral health care unaffordable for millions of Americans, it also exacerbates underlying racial, geographic and disability-related health and wealth disparities.[1] Improved Medicare coverage for medically necessary dental care would help millions of people get healthy without having to make impossible financial tradeoffs and would mitigate some of these health inequities.

Acting to maximize this authority as is being proposed and explored in this proposed rule would help some of the very people who need dental coverage the most. **Overall, we strongly support the proposed clarification of CMS’s authority on “medically necessary” dental coverage, and we will address several of the specific issues and questions that CMS has solicited input in the comments that follow.**

Currently, Medicare regulations for audiology assessment services require a physician or nonphysician practitioner order, creating delays in care and additional costs for Medicare beneficiaries. Medicare proposes to use its administrative authority to remove this requirement, however; implementation creates administrative and financial challenges for Medicare beneficiaries and audiologists, undermining the impact this proposal could have. **CCD believes there are specific changes that could be made to these provisions to maximize access to audiology assessment services for beneficiaries and improve health outcomes for those with hearing or balance disorders.**

II.L – Proposals and Request for Information on Medicare Parts A and B Payment for Dental Services

A. Comment on Proposal to Clarify Interpretation of the Statutory Dental Exclusion

CMS proposes to clarify and codify the agency’s interpretation that certain dental services may not be subject to the Medicare’s payment exclusion for dental services under Section 1862 (a)(12) of the Act because they are “inextricably linked to, and substantially related and integral to the clinical success of, a certain covered medical service.”

This proposal is an important recognition and clarification of CMS’s existing authority, which will help to ensure that Medicare beneficiaries can access and afford more of the dental care they need to advance their health. The Medicare statute does not bar payment for dental services needed in connection with the covered treatment of a medical condition. We agree with a wide array of stakeholders that CMS’s existing interpretation of its authority in this area is unnecessarily restrictive and may contribute to inequitable access to dental services—and thus inequitable health outcomes-- for Medicare beneficiaries. Moreover, this updated interpretation of authority would be consistent with

coverage in other areas, such as the “medically necessary” exemption with respect to the statutory exclusion of payment for foot care.[2]

We are pleased to see that CMS is considering dental coverage related to a variety of clinical scenarios, including certain surgical procedures, transplants, cancer treatments, diabetes and other chronic disease management, immunosuppression, heart disease treatments and other circumstances. There is strong legal consensus supporting the actions CMS has proposed, as well as adding coverage for additional medical scenarios that CMS is considering.[3] Additionally, we know there is clinical consensus from many leading medical experts and professional associations about the importance of dental care in these and other medical treatments.[4] **We strongly support the proposed clarification and codification of existing authority, and, as discussed below, we encourage CMS to apply this authority in all settings and clinical circumstances where it is appropriate.**

B. Comment on Additional Proposals and Requests for Information

1. Clarifying and Codifying Payment Policies for Certain Dental Services

CMS proposes to clarify and codify existing examples of “medically necessary” dental coverage. Medicare’s dental policy already recognizes the following examples of dental services that are payable because they are integral to a covered medical service: the wiring of teeth when done in connection with an otherwise covered medical service, the reduction of a jaw fracture, the extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease, dental splints when used in conjunction with covered treatment of a medical condition, and an oral or dental examination performed as part of a comprehensive workup prior to renal transplant surgery. CMS also proposes to codify additional specific examples in which the proposed coverage standard applies, including dental examinations and necessary treatment performed as part of a comprehensive workup prior to organ transplant surgery, cardiac valve replacement or valvuloplasty procedures.

We support CMS’s proposal to clarify and codify the existing examples of “medically necessary” dental coverage. We also support CMS’s proposal to recognize, as additional specific examples, dental examinations and necessary treatment performed as part of a comprehensive workup prior to organ transplant surgery, cardiac valve replacement or valvuloplasty procedures.

2. Covering medically-related dental services in inpatient and outpatient settings

CMS proposes to interpret the statute to permit Medicare payment for dental services “inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services” and “to allow payment to be made, *regardless of whether the services are furnished in an inpatient or outpatient setting*”. CMS is also specifically proposing to revise the regulation at § 411.15(i) to ensure that the covered

dental care that is part of a comprehensive workup prior to renal transplant surgery can take place in an inpatient or outpatient setting.

We believe that coverage—and thus care-- should not be unnecessarily limited by the care setting, and that CMS is not constrained by its statutory authority. **We agree with CMS’s proposal to implement this Medicare coverage and payment in *either an inpatient or outpatient setting as it is clinically appropriate and in line with the statutory authority in the legislation passed by Congress.***

3. Comments on covering additional clinical scenarios under “medically necessary” authority

CMS is seeking public comment on the clinical evidence connecting oral health care with outcomes for a number of other specific clinical scenarios, including joint replacement surgery, head and neck cancer treatment, therapies and treatments that cause immunosuppression, jaw reconstruction, and other medical and surgical procedures. CMS also asks whether there are “types of surgery, or clinical scenarios involving acute or chronic conditions that would have an improved patient outcome if certain dental services are furnished, such that those dental services should be considered so integral to the standard of care that the preclusion on Medicare payment should not apply”. CMS is also seeking comment on the “clinical evidence supporting the necessity of oral health care *after* the provision of certain medical procedures and treatments”.

Our constituents have made it clear to us that access to oral health care would make a huge difference in their health outcomes, including in these instances. Moreover, lack of access to oral health care exacerbates health inequities in many of these disease areas, such as diabetes, heart disease, and cancer. We also understand that clinical evidence linking oral health care to improved health outcomes is extensive in many of these scenarios and growing quickly in others. **We encourage CMS to apply “medically necessary” authority in as broad a range of clinical scenarios as possible.** Further, dental care may be needed to prevent or effectively manage systemic nondental illnesses, especially in immunocompromised or immunosuppressed people or those with underlying chronic health conditions.

4. Establishment of a Process to Consider Additional Clinical Scenarios for Future Updates.

CMS proposes the establishment of a process within the annual rulemaking cycle by which the agency would review and consider additional clinical scenarios that may fall under this “medically necessary” dental authority. Given the breadth of health issues connected to oral health and proper oral health care, the “medically necessary” coverage standard needs to be able to keep up with growing clinical evidence and evolving standards of care in order to be meaningful to our

constituents. **We strongly support CMS’s proposal to implement a process that provides for the future review and addition of further clinical scenarios that meet the criteria laid out in CMS’ proposed “medically necessary” dental coverage authority.**

5. Expand Medicare coverage to include cases where oral healthcare services are directly necessitated by the medication side-effects of the antipsychotic medication, Clozaril/Clozapine, in patients under treatment for chronic paranoid schizophrenia (SCZ).

Over the past 50 years, Clozaril/Clozapine has proven the most effective medication for the treatment of symptoms of SCZ. It has been a game-changer for those patients with access to it. In most cases, patients' hallucinations and delusions disappear entirely and patients experience significantly improved cognitive awareness and communications capabilities, leading to a vastly improved quality of life and ability to interact with others.

Yet, Clozaril's uptake for SCZ has been slow for 3 reasons: (a) its negative side-effects, (2) a small but existent risk of increase in white blood cell count addressed by biweekly blood draws, and (3) the family/social support system needed to meet the mandatory regular blood draws throughout the entire course of treatment. The two most negative/harmful side-effects of this drug are: metabolic syndrome, leading to risk of diabetes and/or cardiovascular disease, and secondly the loss of nearly all teeth. The ensuring dental care, if patients are to maintain essential baseline dental health, requires extraction of dead teeth and replacement with dentures.

Therefore, we recommend CMS consider this co-morbidity instance as a Medicare-covered medically necessary dental care and hence covered in the Medicare program, thus enabling more individuals living with the gravest of all mental illnesses to be able to access a life-changing medication, and while on it, maintain basic dental health

II.K Proposal to Allow Audiologists to Furnish Certain Diagnostic Tests Without a Physician Order

A. Comment

CCD supports the removal of the order requirement for audiology assessment services but is seeking specific improvements to the implementation process to ensure access to care for Medicare beneficiaries. Audiologists are educated, trained, and qualified to provide a range of hearing and balance assessment services and do not require a physician/practitioner order under state law to safely provide these services to patients. The order requirement places Medicare beneficiaries at undue additional risk because of the potential for increased cost sharing and delays in care while waiting for the order and should be removed.

CCD is concerned that the reimbursement methodology created in the proposed rule for audiology assessment services provided without a physician order skews payment for these services, in some cases overpaying the audiologist for an assessment service (and increasing beneficiary financial liability) and in other cases underpaying audiologists for these services. For beneficiaries on fixed incomes, the increased cost sharing might lead them to delay or forgo care. Audiologists, in the most extreme case, would lose approximately \$100 in reimbursement which might lead them to require an order delaying care or turn away Medicare beneficiaries entirely because they could not sustain such significant financial losses. **CCD recommends that CMS utilize the existing fee schedule for these services at the established reimbursement rates.**

CMS also restricts the proposal to once per 12-calendar months per Medicare beneficiary artificially restricting the efficacy of this proposal without considering clinical circumstances under which a beneficiary might need to safely and appropriately see an audiologist more than once a year.

Without adjusting the proposal to reflect the practical challenges it creates, CMS will not achieve its goal of better understanding the impact from removing the physician order requirement nor will it increase beneficiary access to care.

III.B Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

A. Proposed Rule re Behavioral Health Integration Services in RHCs; FQHCs; Primary Care Settings

CCD supports the proposed rule policy changes related to payment for behavioral health integration (BHI) services provided in RHCs and FQHCs. Namely that clinical psychologists (CPs) and clinical social workers (CSWs) are acknowledged to be practitioners that can provide services, for which they will be reimbursed, in RHCs and FQHCs as long as they work as part of a patient's primary care team.

We also, however, urge CMS to address this specific policy change with a wider lens, keeping in mind the larger context: i.e., of a larger, evolving transformation of our entire health system to make it more wholistic, coordinated, efficient, value-producing, and patient-centered. Much work needs to be done across our entire healthcare system to support and incentivize the building of new, integrated medical-behavioral care teams working seamlessly in the primary care clinic setting. CCD supports proposed enhanced behavioral health-primary care codes for the purpose of integration.

Integrated medical-behavioral care team members must be open and flexible to building a new integrated care culture that is based on teamwork, rigorous data collection, tracking, monitoring of measurement-based care, and stepped care to adjust when improvements are not achieved. These integrated medical-behavioral care teams will need to demonstrate flexibility, creativity and shared accountability. There should be established mechanisms of shared accountability across the silos of current organizational, regulatory and financial

structures. And most importantly, these integrated medical-behavioral care teams must focus on those patients with complex and co-occurring health conditions.

II.D Payment for Medicare Telehealth Services under Section 1834(m) of the Act

A. Recommendation re ‘Incident To’ Provisions

We recommend that providers of peer support services (also known as peer support specialists and peer recovery support specialists) may be reimbursed as incident to physician and psychologist services. This phrasing recognizes the two most common terms used in state government certifications.

III.F Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPS)

We support the CMS proposed initiative.

Conclusion

CCD appreciates the opportunity to provide comments about these proposed rules. If finalized, the proposed rules will make a considerable difference for our nation’s older adults and people with disabilities who are struggling to afford and access the health care they need to stay healthy. We are grateful to Administration officials, the scores of advocates, and Members of Congress, who have worked for years to get us to this point. For additional information, please contact Cinnamon St. John at cstjohn@medicareadvocacy.org.

Sincerely,

American Association on Health and Disability
American Speech-Language-Hearing Association
Autistic Women & Nonbinary Network
Disability Rights Education & Defense Fund
Epilepsy Foundation
Justice in Aging
National Association of Councils on Developmental Disabilities
National Disability Rights Network (NDRN)
United Spinal Association

[1] Christ, A., G. Burke and J. Goldberg. Adding a Dental Benefit to Medicare: Addressing Racial Disparities. Justice in Aging. October 2019. <https://www.justiceinaging.org/wp-content/uploads/2019/10/Addressing-Oral-Health-Equity-by-Adding-a-Dental-Benefit-to-Medicare.pdf>.

[2] Medicare Benefit Policy Manual, Ch. 15, § 290.

[3] “Medicare Coverage of Certain Dental Diseases.” King and Spalding LLP. July 30, 2020. Available upon request. See also “Legal Memorandum: Statutory Authority Exists for Medicare to Cover Medically Necessary Oral Health Care.” Center for Medicare Advocacy. January 3, 2019. <https://medicareadvocacy.org/medicare-info/dental-coverage-undermedicare/#legal-memorandum-statutory-authority-exists-for-medicare-to-cover-medically-necessary-oral-health-care>.

[4] Clinical Consensus on Medically Necessary Dental Care. Santa Fe Group. Accessed June 30, 2022. <https://santafegroup.org/wp-content/uploads/2020/08/clinical-consensus-on-medically-necessary-dental-care.pdf>