**September 6, 2022**

Honorable Chiquita Brooks-LaSure
Administrator
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 (Section II.L.)**

Administrator Chiquita Brooks-LaSure:

Families USA is pleased to provide the Centers for Medicare & Medicaid Services (CMS) comments on the proposals and request for information on Medicare Parts A and B Payment for Dental (Section II.L.) in the proposed rule on Medicare and Medicaid Programs: CY2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies, Medicare Shared Savings Program Requirements, etc. (CMS-1770-P).

**Introduction**

Families USA is a leading national voice for health care consumers dedicated to the achievement of improved health and health care for all. As advocates for health equity and improving our nation's overall health, we have long recognized the need for improved dental 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.

We applaud CMS for recognizing the need to maximize its authority to cover "medically necessary" dental care 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.[i] 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 persistent health inequities. This proposal would help to improve equitable access to dental services and lead to better health outcomes, in line with the Administration's goals of increasing equitable access to high quality and affordable health care.[ii] It is also an important first step towards more comprehensive Medicare dental coverage, as it will help build the infrastructure and provider participation that would support a full dental benefit when it is eventually enacted by Congress.

**Overall, we strongly support the proposal to clarify and codify CMS's authority to cover "medically necessary" dental care in Medicare, and we will address several of the specific issues and questions for which CMS has solicited input in the comments that follow.**

**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 are not subject to the Medicare 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 can 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.[iii]

We are additionally 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 for adding coverage for additional medical scenarios that CMS is considering.[iv] There is also clinical consensus from many leading medical experts and professional associations about the importance of dental care in these and other medical treatments.[v]

However, we do share the concern of several Medicare advocates and legal experts that the proposed wording of the legal standard exempting from the statutory dental exclusion could be unnecessarily restrictive. As proposed, the exemption applies to "dental services that are *inextricably linked* to, and substantially related and integral to the clinical success of, a certain covered medical service". We anticipate that the phrase "inextricably linked to" will not be interpreted consistently, and could lead to uneven decisions on claims, appeals, and prior authorizations, and create frustrations for patients, medical providers, and adjudicators alike.

The policy goals of CMS' proposal can be effectively achieved, while keeping the legal standard narrow and rigorous, by covering payment to dental services that are "substantially related and integral to the clinical success of certain covered medical services." This standard is specific and precise, as well as clearer and easier to implement. It would be more straightforward for contractors, plans, and adjudicators to apply in analyzing claims. They will be able to determine, without speculation, if a claim meets this requirement based on whether the clinical evidence demonstrates that the standard of care for a covered medical treatment necessitates dental clearance, or the provision of ancillary dental

services, or appropriate measures to address dental infections and other oral problems, to avoid undue risk and promote a positive outcome.

**We strongly support the proposal to clarify and codify existing authority to cover "medically necessary" dental care, and encourage CMS to consider changes to the language that will make this authority as clear as possible. As discussed below, we also encourage CMS to apply this authority in all settings and clinical circumstances where it is appropriate.**

## Comments on Additional Proposals, Requests for Information, and Concerns

### 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 regulation at § 411.15(i) to ensure that the covered dental care that is part 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. Currently, the vast majority of dental services are provided by dentists and their teams in a dental office that is not connected to a hospital or inpatient setting. Dental treatments are also often provided in residential care settings including nursing facilities and assisted living facilities through mobile clinics. Residents in facilities face significant barriers in accessing health care outside of the facility and are simultaneously more likely to have a chronic condition or disease and unmet oral health needs.[vi] Providing "medically necessary" dental services in outpatient settings would help to address the disparities in access for residents in nursing facilities and other congregate care settings.

**We agree with CMS' proposal to implement this Medicare coverage and payment in *either an inpatient or outpatient* setting.**

### Clarifying and Codifying Payment Policies for Certain Dental Services

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 has proposed to clarify and codify the coverage of these examples as well as additional specific examples in which the proposed coverage standard applies. These additional examples include: 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 and additional examples of "medically necessary" dental coverage, which include 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, dental examinations and necessary treatment performed as part of a comprehensive workup prior to organ transplant surgery, cardiac valve replacement or valvuloplasty procedures.**

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 specific clinical scenarios, including organ transplants, immunosuppression and cancer treatment, and chronic conditions.

The partner organizations and communities we work with have made it clear to us that access to oral health care would make a huge difference in people's 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.

**Overall, we encourage CMS to apply "medically necessary" authority in as broad a range of clinical scenarios as possible, and consider it to be legally sound and clinically appropriate to cover dental care in each of the specific scenarios mentioned in the proposed rule. We elaborate on several of these scenarios below.**

**I.** Organ transplantation

CMS proposes to amend § 411.15(i) to provide that a dental or oral examination as part of a comprehensive workup and the necessary dental treatments and diagnostics to eliminate identified oral or dental infections prior to an organ transplant, along with any ancillary services, are payable services under Medicare Parts A and B, whether furnished in an inpatient or outpatient setting.

Nearly 25% of people on solid organ transplant waitlists are 65 years of age and older.[vii] Poor oral health, particularly periodontal disease and xerostomia, is a risk factor for compromising transplant outcomes, especially for older adults who may have weakened immune systems. Recent research provides clear evidence that many transplant patients have need for oral health care before and after transplantation, and that this care improves transplant outcomes[viiiix,x]

**We strongly support the coverage of all dental care necessary to support organ transplantation. If dental problems are not identified and resolved and/or stabilized, thereby lowering the risk for infection and sepsis pre-transplant, this procedure may not be able to proceed.**

II. Cancer treatment and immunosuppressant therapy

CMS invites comment and evidence as to whether certain dental services prior to cancer treatments are integral to the clinical success of those treatments. CMS also invites comment and compelling evidence as to whether certain dental services prior to initiation of immunosuppressant therapies are integral to the clinical success of the covered medical service.

Immunosuppression has considerable oral health side effects.[xi,xii,xiii] Most major cancer treatments, aside from surgery, cause immunosuppression with related oral health side effects.[xiv,xv,xvi] A significant concern, especially for older adults, is that immunosuppression increases the potential for sepsis and risk for infections, which can be severe health setbacks in and of themselves, are costly to treat, and severely reduce the success of cancer treatments.[xvii] Studies have shown that appropriate oral health care can considerably reduce these side effects, improving health outcomes and reducing costs.[xviii,xix,xx,xxi,xxii]

**We strongly support the coverage of all dental care necessary to address the oral effects of immunosuppression and cancer treatment. If dental problems are not identified, managed, and resolved, thereby lowering the risk for infection and sepsis, cancer treatments will be less effective and more costly.**

III. Diabetes and other chronic disease management

CMS is interested in public feedback on whether there are circumstances – such as in the case of some diabetic patients - where the ongoing disease management of the patient receiving a medically necessary treatment may have an improved outcome or see a clinical benefit from the performance of dental services, even if they may not be inextricably linked to the medical treatment.

Covering oral health care as part of chronic disease management is a critical equity issue. As a result of longstanding discrimination in health care and across societal sectors like housing, employment, and education, Medicare enrollees of color and low-income Medicare enrollees are more likely to both 1) experience worse oral health outcomes; and 2) be diagnosed with a chronic condition that is negatively impacted by poor oral health. For example, nearly 25% of Mexican American and 20% of Black older adults have severe periodontitis compared to just 8% of white older adults.[xxiii] Meanwhile, the prevalence of diabetes is much higher among Medicare enrollees of color with 47% of Black and 46% of Hispanic Medicare enrollees diagnosed with diabetes compared to 29% of white Medicare enrollees.

Periodontal disease is strongly associated with chronic diseases, including diabetes, as well as cardiovascular disease and stroke. People with diabetes are three times more likely to develop periodontal disease and periodontal disease hinders the ability to control diabetes.[xxiv] Numerous studies show an association between dental treatment (including preventive treatment) and improved health outcomes and reduced healthcare costs for people with diabetes.[xxv,xxvi,xxvii]

Periodontal disease is also associated with cardiovascular disease and stroke – two chronic conditions that are also more prevalent in communities of color.[xxviii] While there is somewhat less research on the impact of oral health care on these conditions, both widespread clinical understanding and several smaller scale studies demonstrate improved outcomes.[xxix] [xxx,xxxi, xxxii,xxxiii]

**We strongly support CMS extending Medicare "medically necessary" dental coverage to as broad a range of clinical scenarios as possible, and specifically urge the inclusion of care related to diabetes and other chronic disease management.**

Removing "Direct Supervision" Requirement on Dental Hygienists/Therapists

In the proposed rule, CMS makes several mentions of "direct supervision", in particular on page 444, by saying that "Medicare payment could be made for services furnished incident to the professional dental services by auxiliary personnel, such as a dental hygienist, dental therapist, or registered nurse who is *under the direct supervision* of the furnishing dentist or other physician or practitioner, if they meet the requirements for "incident to" services as described in § 410.26 of our regulations".

We are concerned that the requirement for "direct supervision" would unnecessarily impede access to care. Requiring "direct supervision" would restrict qualified, certified providers from delivering care they are otherwise allowed to provide in their states. The proposed rule should reflect that supervision and scope of practice laws vary by state, which often allows for different types of dental providers, including dental hygienists and dental therapists, to work in ways that maximize the scope of their authority. These providers are critical to advancing equity, as they more often practice in community settings and can extend the capacity of a dental office. Today, forty-two states are "direct access" states in which dental hygienists are authorized to provide services without the prior authorization or physical presence of a dentist.[xxxiv] Section 410.26 of CMS regulations, which is referenced in the proposed rule, provides a definition of general supervision, which is a more appropriate standard. This definition reads: "the service is furnished under the physician's (or other practitioner's) overall direction and control, but the physician's (or other practitioner's) presence is not required during the performance of the service".

**We recommend removal of any language related to requirements for supervision, since there is no evidence to suggest that supervision improves health outcomes. Too often, "direct supervision" requirements further exacerbate oral healthcare inequities, particularly among low income, communities of color, tribal nations, and individuals with disabilities.**

Potential future payment models for dental and oral health care services

CMS seeks feedback on additional ways to integrate the payment for dental and health care services within existing and future payment models - including models focused on equity, care coordination, total cost of care and specific disease conditions - using the Innovation Center's waiver authority under section 1115A(d)(1) of the Act.

We appreciate CMS soliciting comments on additional ways to integrate the payment for dental and health care services using the Innovation Center's waiver authority. We encourage CMS to consider models that 1) improve oral health outcomes and reduce health inequities for people facing multiple

health conditions; 2) ensure that people with diabetes and other chronic conditions can access all of the preventive dental care they need to manage these health conditions as well as treatment; and 3) improve oral health outcomes in residential care settings like nursing facilities as well as for Medicare enrollees with disabilities who utilize home and community-based services.

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 access to necessary oral health care, the "medically necessary" coverage standard needs to be able to keep up with the growing body of clinical evidence and evolving standards of care in order to be meaningful.

**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's proposed "medically necessary" dental coverage authority.**

**Conclusion**

Families USA **greatly** 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 oral health care they need to stay healthy. We are grateful to the Administrative officials, the scores of advocates, and Members of Congress, who have worked for years to get us to this point, and look forward to continuing to work with you to build upon this critical progress. For additional information, please contact Melissa Burroughs at mburroughs@familiesusa.org.

Sincerely,

Eliot Fishman

Senior Director of Policy, Families USA

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