Center for Medicare Advocacy

Advancing Access to Medicare and Health Care

September 9, 2024

VIA ELECTRONIC SUBMISSION

Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-8013

Re: [CMS-1807-P], Physician Fee Schedule CY2025 Proposed Rule

Dear Administrator Brooks-LaSure:

The Center for Medicare Advocacy (Center) appreciates this opportunity to comment on the Calendar Year 2025 Physician Fee Schedule Proposed Rule. The Center is a national, non-profit law organization that works to ensure access to Medicare, health equity, and quality health care. The organization provides education, legal assistance, research and analysis on behalf of older people and people with disabilities, particularly those with longer-term conditions. The Center's policy positions are based on its experience assisting thousands of individuals and their families with Medicare coverage and appeal issues annually. Additionally, the Center provides individual legal representation and, when necessary, challenges patterns and practices that inappropriately deny access to Medicare and necessary care.

A. Proposals on Medicare Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Services (section II.J.)

We energetically applaud CMS for including oral health in its cross-cutting initiatives to advance health equity, expand coverage, and improve health outcomes. We are particularly grateful for the agency's efforts to engage with stakeholders and clarify oral health coverage in Medicare using existing authorities. The important steps that CMS has undertaken under the Biden-Harris administration will expand access to essential dental care, and lay the foundation for a better, widely hoped-for future in which full dental benefits are available to all Medicare beneficiaries.

1. Proposed Addition of Dental Services Inextricably Linked to Dialysis for Treatment of ESRD (section II.J.2)

    a. Scope of applicability and payment

We firmly support CMS' proposal to allow payment for certain dental services needed by patients who *are or will be* receiving dialysis services to treat end-stage renal disease (ESRD).

We respectfully request that CMS furnish guidance to its contractors to ensure that reimbursement would be applicable not only to patients diagnosed with ESRD (ICD-10 code N18.6), but also to patients documented to have CKD stage 5 who have not yet started dialysis (ICD-10 code N18.5). The policy should also apply to claims for patients who have a diagnosis that encompasses one of those conditions, such as Hypertensive Chronic Kidney Disease with stage 5 CKD or ESRD (ICD-10 code I12.0).

Ample medical literature, research, and clinical guidelines support that the proposed policy will substantially lessen the risk of morbidity and mortality stemming from oral and dental infections in patients undergoing dialysis. We have concern though about the hypothetical CMS used in which tooth extraction is viewed as "the necessary treatment" to eradicate those infections, despite the listing of other restorative (and tooth-sparing) services that may be paid for, including fillings, periodontal and endodontic therapy. The appropriate treatment plan for an individual patient will depend on a variety of factors. We believe that any language from CMS suggesting a preference for tooth extraction may lead its contractors to improperly impose an extra burden on providers to justify choosing a procedure other than an extraction in a particular instance.

We also had concern about the assertion that "additional" services, such as a crown, would not be paid. Based on our understanding, the standard of care in some situations (e.g., certain root canal procedures) requires application of a crown to prevent infection and other complications in the immediate and longer term. Thus, we hope that the finalized proposal will not guide contractors to simply reject out of hand payment for certain additional services that are clinically necessary and part of a covered dental or oral procedure.

b. Stage 4 chronic kidney disease

We also urge CMS to reconsider whether certain dental services may be inextricably linked to treatment for stage 4 chronic kidney disease (ICD-10 code N18.4). At CKD stage 4, a patient has severe kidney damage and it is critical to slow the loss of kidney function by managing health problems, such as oral/dental infection, that directly complicate and are complicated by their kidney disease. Research has found that periodontitis is more severe in CKD patients than in the general population, and that patients with more severe periodontitis are prone to having more severe CKD.[1] Several studies reflect that CKD patients with periodontitis have lower estimated glomerular filtration rate (eGFR), and higher morbidity and mortality compared to those without periodontitis. The most recent and complete systematic review and meta-analysis suggested that

[1] da Silva Schutz J, et al. Association between severe periodontitis and chronic kidney disease severity in predialytic patients: A cross-sectional study. *Oral Dis.* 2020 Mar;26(2):447-456. doi: 10: 10.1111/odi.13236.

periodontal treatment has a positive effect on eGFR and leads to significant improvement in CKD status.[2]

Patients with stage 4 CKD commonly receive covered treatment to address other disorders that damage their kidneys, such as diabetes, high blood pressure, heart and blood vessel problems, anemia, mineral and bone problems, and poor nutritional health. Yet, it is understood now that untreated oral and dental disease worsens inflammatory markers and interferes with the management of all of these medical conditions affecting CKD. For example, research demonstrates a significant link between periodontitis and cardiovascular disease (CVD) outcomes in CKD patients.[3] On the positive side, there is evidence that treating periodontal disease in CKD patients significantly reduces the rate of cardiovascular events. A recent study found that the risk of developing CVDs over 24 months was lower in patients with CKD who were treated for periodontal disease.[4]

Compelling research underscores the significant association between clinically-defined moderate and severe periodontitis and the increased risk of mortality in patients with advanced CKD, as well as the positive impact that non-surgical periodontal treatment could have on lowering that risk.[5] Although the cited studies focus on periodontitis, it is notable that untreated dental caries

---

[2] Delbove T, et al. Effect of periodontal treatment on the glomerular filtration rate, reduction of inflammatory markers and mortality in patients with chronic kidney disease: A systematic review. *PLos One.* 2021 Jan 22;16(1):e0245619. doi: 10.1371/journal.pone.0245619.

[3] Recent meta-analysis of six cohort studies with low risk of bias and involving 7731 subjects, found that periodontitis, defined through clinical attachment loss (CAL), was significantly associated with an increased risk of all-cause and cardiovascular mortality in CKD patients. Wu H, et al. Periodontitis and risk of mortality in patients with chronic kidney disease: A systematic review with meta-analysis. *J. Periodontal Res.* 2024 Mar 19. doi: 10.1111/jre.13255. *See also,* Li W, et al. Associations of periodontitis with risk of all-cause and cause-specific mortality among US adults with chronic kidney disease. *J. Dent.* 2023 Nov: 138:104712. doi: 10.1016/j.jdent.2023.104712 (Increased risk of all-cause and cardiovascular disease-related mortality associated with moderate/severe periodontitis and high levels of mean CAL and periodontal probing depth (PPD)).

[4] Gowdak LH, et al. Treatment of periodontal disease significantly affects the rate of cardiovascular events in patients with chronic kidney disease. *J. Am Coll Cardiol.* 2019;73(9S1):168.

[5] Sharma P, et al., Association between periodontitis and mortality in stages 3-5 chronic kidney disease: NHANES III and linked mortality study. *J. Clin Periodontol.* 2016 Feb; 43(2); 104-13. doi 10.1111/jcpe.12502 (Adjusting for confounders, the 10-year all-cause mortality rate for CKD cohort increased from 32% to 41% with the addition of periodontitis). *See also,* Ricardo A, et al. Periodontal disease, chronic kidney disease and mortality: results from the third National Health

(tooth decay) can lead to periodontal disease, as well as to severe infections and abscesses inside of teeth and under the gums, which can enter the bloodstream and spread throughout the body.

We thus ask CMS to consider whether, for purposes of payment, certain dental treatment may be inextricably linked to effective treatment of stage 4 CKD. Resolving dental infections in patients at that stage can improve eGFR, inflammatory markers, erythrocyte count, and nutrition, as well as reduce the risk of cardiovascular and other serious medical events. These clinical factors are commonly exacerbated by CKD and negatively impact CKD outcomes. Since dental care can play a substantial role in addressing these factors in patients with stage 4 CKD, it can help to delay or avoid progression to stage 5 and ESRD, and the consequent need for dialysis or kidney transplantation.

2. Request for Comment on Dental Services Integral to Specific Covered Services to Treat Diabetes (section II.J.3)

We appreciate and encourage CMS' further and ongoing consideration of the connection between dental treatment and the clinical success of diabetes treatment.

In its previous pronouncements in the CY 2023 and CY 2024 final rules, CMS claimed it would review clinical evidence to assess whether dental services are a clinical prerequisite to proceeding with a primary medical procedure and/or treatment, or whether the standard of care warns against proceeding with the covered medical service absent the provision of the dental services. CMS also asserted that "section 1862(a)(12) of the Act does not apply only when dental services are inextricably linked to other covered services, **such that the standard of care for the medical service would be compromised or require the dental services to be performed in conjunction with the covered services** (87 FR 69666)." 88 FR 79015

In this year's submissions process, stakeholders heeded CMS' express directives regarding the evidence needed to support an inextricable linkage between dental services and covered diabetes treatment. They presented "clinically meaningful" medical evidence that unresolved dental and oral disease compromises the trajectories and outcomes of diabetes treatment. They referenced studies which clearly demonstrate that appropriate dental services (and periodontal therapies in particular) "result in a material difference in terms of the clinical outcomes and success" of diabetes treatment. The evidence is "compelling to support" that certain dental services

---

and Nutrition Examination Survey. *BMC Nephrol.* 2015 Jul 7:16:97. doi: 10.1186/s12882-015-0101-x; He I, et al. Demystifying the connection between periodontal disease and chronic kidney disease – An umbrella review. *J. Periodontal Res.* 2023 Oct;58(5):874-892. doi: 10.1111/jre.13161.

significantly improve HbA1c and reduce the risk and rate of morbidity and mortality in diabetes patients.

It is notable that the Veterans Health Administration (VHA) has long recognized that diabetes patients may have a medically compelling need for dental care, in that their oral condition is "negatively impacting a systemic illness."[6] The VHA has indicated, as an example, that veterans who have "poorly controlled diabetes with a HbA1c greater than 9 percent" may receive treatment for the "elimination or prevention of the foci of infection."[7] Under its policy, eligibility for medically necessary dental care is "predicated on referral (consult), followed by a new dental evaluation."[8] Since "[t]he goal of care is to provide a specific improvement of the oral conditions that directly impact the medical condition," covered dental care is "limited to the treatment of those dental conditions that are professionally determined by the examining or treating dentist to be aggravating or compromising" the medical condition.[9] As this has typically meant treatment of "dental caries, active periodontal disease, or acute and chronic dentoalveolar abscess," covered procedures have been "generally limited to supportive periodontal therapy, non-cast restorative dentistry, oral surgical procedures, and endodontics." However, "if dental care results in edentulation or significant compromise to speech or aesthetics, prosthetic rehabilitation may be authorized."[10]

We urge CMS to consider whether the nexus that the VHA has identified between aggravating dental conditions and diabetes treatment is akin to the "inextricable link" that would qualify dental services for payment under Medicare. Although the VHA has in the past delineated a HbA1c of greater than 9.0% as a concerning range requiring intervention, we feel that the threshold for uncontrolled hyperglycemia should be HbA1c above 8.0%, as defined in the

---

[6] Feeley, W. F. (2008, July 31). *Access to Dental Care for Medically Compelling Conditions* [Memorandum]. Department of Veterans Affairs.

[7] *Id.*

[8] Veterans are fully eligible for focused dental treatment if they fall within Classifications III or VI. Classification III are those veterans "referred by a treating physician who have a dental condition professionally determined by the VA dentist(s) to be aggravating or complicating the management of a service-connected medical condition under active treatment[.]" Under Classification VI, "[a]ny veteran scheduled for admission or who is receiving care under chapter 17 of title 38, U.S.C., may receive outpatient dental care if the dental condition is clinically determined to be complicating the medical condition currently under VA treatment." Veterans Health Administration Dental Program. VHA Handbook 1130.01(1). Downloadable at: https://www.va.gov/vhapublications/publications.cfm?pub=2

[9] *Id.*

[10] Feeley, W. F. (2008, July 31). *Access to Dental Care for Medically Compelling Conditions* [Memorandum]. Department of Veterans Affairs.

current literature and guidelines by the American Diabetes Association, American College of Physicians, Association of Clinical Endocrinologists, and American College of Endocrinology.

3. Request for Comment on Dental Services Integral to Specific Covered Services to Treat Systemic Autoimmune Disease Requiring Immunosuppressive Therapies (section II.J.4)

We similarly appreciate and encourage CMS' further and ongoing consideration of the important connection between dental treatment and the clinical success of immunosuppressive therapies for patients with autoimmune diseases. For persons with autoimmune diseases, including Sjogren's disease, rheumatoid arthritis, lupus, and Crohn's disease, medical management can involve immunosuppressive or immunomodulating agents, such as biological and chemotherapies, corticosteroids, infused bisphosphonates, and disease-modifying anti-rheumatic drugs. Those medications can, in turn, facilitate the systemic spread of bacteria from untreated dental lesions, placing the patient's health and continued treatment at great risk. Repeatedly prescribing antibiotics to control – but not resolve - dental infections could actually set the stage for graver complications, by increasing microbial resistance in patients who are highly susceptible to infection.

This recalls to mind the circumstances of a woman from Reno, Nevada with Multiple Sclerosis whose doctor had to take her off of the immunosuppressive drug that was controlling her MS flares out of concern that bacteria from her dental infections could spawn septicemia. That was a medical risk she could not afford to take. Timely and proper evaluation and management of her dental infections would have enabled her to safely benefit and obtain effective relief from the prescribed treatment for her debilitating autoimmune disease.

Notably, the Veterans Health Administration has also long recognized that patients with "severe immunocompromised status" or who are undergoing treatments that "result in significant immunosuppression" may have a compelling medical need for certain dental services.[11] For eligible patients in those circumstances, the VHA covers dental care focused on the "elimination or prevention of foci of infection."

We respectfully ask CMS to consider whether the link that the VHA has identified between immunosuppression and complicating dental infections is akin to the "inextricable link" that would qualify dental services for payment under Medicare. We think it is possible to delineate the parameters of such payment and advance the goals of the Medicare program while adhering to the statutory dental exclusion.

4. Submissions Received Through Public Submission Process (section II.J.1.C)

[11]Feeley, W. F. (2008, July 31). *Access to Dental Care for Medically Compelling Conditions* [Memorandum]. Department of Veterans Affairs.

We generally endorse the other recommendations submitted this year. In particular, we support payment for dental services following organ and stem cell transplants due to the development of oral chronic graft versus host disease (GVHD), which damages mucosa and salivary glands and causes sclerotic changes in the oral cavity. We have heard from Medicare beneficiaries who, in the aftermath of cancer treatment and transplantation, developed severe oral GVHD, that caused painful ulcers in the mouth and throat, all of the teeth to break off, and terrible difficulty chewing and swallowing. These patients suffered astonishing weight loss, and some even required hospitalizations and placement of feeding tubes. Receipt of recommended post-transplant dental follow-up and care could have made a material difference in and improved the quality of their transplant outcomes, and reduced the likelihood of requiring urgent inpatient intervention.

We also support the submitted recommendations to pay for dental care for a period of time following treatment for head and neck cancer and other cancer types, including blood cancers, as well as following antiresorptive therapy for non-cancer conditions, such as osteoporosis. Enduring oral complications from these treatments, combined with ongoing immunosuppression, can dramatically impair patients' quality of life and their ability to heal and recover from treatment. We know from the Medicare beneficiaries who have contacted our office that rampant tooth decay and breakage, severe mucositis, and oral infections place patients at continual, increased risk of sepsis, malnutrition, depression, and the development or recurrence of cancer.

While CMS is not accepting the above recommendations at this juncture, we appreciate that CMS is reinforcing that MACs have the flexibility to determine on a claim-by-claim basis whether payment can be made for certain dental services in circumstances not specifically listed at § 411.15(i)(3)(i). To this end, we respectfully ask CMS to monitor to ensure that MACs are duly evaluating such claims and not automatically denying payment on the basis that they do not squarely match up with a listed clinical example in the regulation. We likewise ask CMS to issue guidance directing MACs to carefully evaluate - and not simply pass on - claims in which there is indication that a patient needed dental clearance in order to qualify for a Medicare-covered procedure or treatment.

B. Implementation of Payment for "Inextricably Linked" Dental Services (section II.J.5)

1. Dental Claims Requirements

We praise and appreciate CMS' dedication and diligent efforts to operationalize the dental payment clarifications. The recent announcement that Medicare has begun to accept 837D dental claims forms electronically is a promising step that could make it easier for dental providers to furnish and bill for inextricably linked dental services. We do support the proposed use of a KX modifier to signal that a claim is being submitted for dental services inextricably linked to

covered services, and a GY modifier to expedite denials when services fall outside the scope of Medicare coverage. We also understand the rationale for requiring a diagnosis code to be included on dental claims.

We are concerned, however, that most dental providers (including hospital dental clinics) and their billing departments will not effectively know to use the KX modifier, or about proper diagnostic coding, by January 1, 2025, and that their claims will be rejected as a result. This could certainly discourage them from continuing to furnish and bill for this care for Medicare beneficiaries. Notwithstanding CMS' plan to provide additional instruction and education through subregulatory guidance, we believe it will take longer to bring providers up to speed. Thus, we feel strongly that the proposed requirements should be delayed at least through mid-2025, if not longer. Clinicians and billing entities will need more time to absorb information about Medicare's dental policy, adapt their workflows, and transition to using the 837D form. They will need guidance from MACs with respect to these claims, and it is not clear that MACs currently are or will be fully up to speed by January 1, 2025.

What we have heard from hospital-based providers who are trying to submit claims for inextricably linked dental services is that they are encountering problems with systems interoperability. Claims can't go through until hospital billing departments (which are often contracted out) identify and engage with a clearinghouse that can facilitate communication between the Medicare contractor and the provider's dental practice management system containing electronic health records and billing applications. Because inextricably linked dental claims make up such a small part of a hospital's billing, this task is more likely to be back-burnered. In light of the time needed to iron out these and other issues, granting providers latitude with claims details for a longer grace period is crucial and warranted. We feel confident that as more practitioners *successfully* obtain proper reimbursement, more dental providers may feel encouraged to participate in Medicare.

We again encourage CMS to employ all available means to educate relevant providers about the inextricably-linked dental care, address concerns and uncertainties they may have about the policy and reimbursement, and encourage dentists to enroll in Medicare. We hope that greater outreach and education can be made to Medicaid-participating dentists and dental programs about the dental clarification. Encouraging these providers to enroll in Medicare could facilitate care for dual eligibles and reimbursement for those providers.

This year, we heard several inquiries about whether "inextricably-linked" dental services are provided in federally qualified health centers (FQHCs). Many feel that FQHCs could serve as an important access point for lower income Medicare beneficiaries who need "inextricably linked" dental care. We hope CMS will provide more clarification on this point and work with FQHCs and their dental clinics to implement the payment clarification.

2. Medicare Advantage Plans

More than half (54 percent) of eligible Medicare beneficiaries are now enrolled in a Medicare Advantage (MA) plan. The number of dually eligible beneficiaries enrolled in D-SNP plans is also growing. Thus, it is vital that MA organizations understand that their plans must pay for "inextricably linked" dental services on top of any supplemental dental benefits those plans offer. This information should be included in the annual Evidence of Coverage (EOC) sent to enrollees. Moreover, plans should make sure that their customer service representatives have scripts and protocols to furnish accurate information to enrollees and providers about the requirements for payment of inextricably-linked dental services. If an enrollee qualifies for payment of inextricably-linked dental services, their plan should assist them in locating a provider who can furnish and bill for that care.

We understand from a source that some MA organizations have yet to implement the dental payment clarification, in violation of their obligation to plan enrollees. We hope CMS will take measures to ensure that all plans understand and promptly comply with this obligation.

We also understand that while enrollees may be able to access plan-delineated supplemental dental benefits from in-network dentists, the majority of those dentists cannot submit claims for "inextricably linked" dental care – because they are not enrolled in Medicare. Since 2022, CMS' rules have permitted dental providers who have opted out of Medicare participation to contract with MA plans to furnish their supplemental dental benefits. MA plans believe that they can only accept and reimburse claims for "inextricably linked" dental services from providers who are actually enrolled in Medicare. This puts MA plan enrollees in the inconvenient position of having to seek out treatment from a Medicare-participating dental provider for "inextricably linked" dental care, when they have already established care with an in-network dentist.

We believe the best solution would be for CMS to change the rule back to require that in-network dental service providers enroll in Medicare, just as other in-network health care providers are required to do. This would prevent discontinuity of care and redundancy in diagnostics when enrollees need "inextricably linked" dental services. Current shortages of Medicare-participating dentists make it particularly vital that MA enrollees can obtain care in-network. Bringing back the enrollment requirement would also serve to increase the number of Medicare-participating dentists, which could enhance fairness and accessibility for persons in Traditional Medicare as well.

Along with this, and in the interests of improving access to "inextricably linked" dental care for all Medicare beneficiaries, we ask that CMS enable dental providers wishing to terminate their opt-out status and enroll in Medicare, the ability to accomplish that immediately and not have to wait until the expiration of the 2-year opt out period (when their opt-out status automatically renews if they take no action).

C. Advancing Access to Behavioral Health Services (section II.I.)

Comment Solicitation on Payment for Services Furnished in Additional Settings

Crisis Stabilization Units, Urgent Care Centers, and Certified Community Behavioral Health Clinics

The Center supports CMS's consideration of authorizing coverage of services delivered by community-based crisis stabilization units, urgent care centers, and certified community behavioral health clinics. Coverage of MH and SUD services in these settings would greatly expand access to care in the midst of the ongoing overdose epidemic and mental health crisis, exacerbated by workforce shortages. Especially with the increased access to crisis services through 988 and the new mobile crisis psychotherapy code, expanding access to crisis receiving and crisis stabilization services at all of these settings would ensure that Medicare beneficiaries have access to the full continuum of crisis services and supports they need.

We encourage CMS to ensure that policies to expand access to these settings continue to promote patient-centered and trauma-informed care by effectively meeting the needs of people with SUDs and people who have been involved with the criminal legal system, consistent with CMS's ongoing work and these proposed rules. It is critical that crisis services and supports offer evidence-based and culturally humble care that limits the historic and ongoing criminalization of these individuals. Specifically, these facilities should have strong patient privacy protections that comply with both HIPAA and 42 C.F.R. Part 2 requirements, limit the involvement with and presence of law enforcement, and promote harm reduction.

D. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished By Opioid Treatment Programs (OTPs) (section III.F)

Audio-Only Telehealth

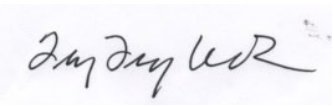
The Center supports CMS's proposal to revise the regulation at § 410.78(a)(3) to state that an interactive telecommunications system may also include two-way, real-time audio-only communication technology

Conclusion

Thank you for the opportunity to submit these comments. For additional information concerning the medically necessary oral health comments, please contact Wey-Wey Kwok at (860)456-7790

or wkwok@medicareadvocacy.org. For additional information concerning Advancing Access to Behavioral Health Services, please contact Kata Kertesz at KKertesz@medicareadvocacy.org at (202)293-5760.

Sincerely,



Wey-Wey Kwok
Senior Attorney
Licensed in NY

Kata Kertesz
Managing Policy Attorney
Licensed in MD and DC