September 6, 2022

Via regulations.gov

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1770-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Payment Policies Under the Physician Fee Schedule; Coverage of Specified Dental Services (CMS-1770-P; RIN 0938-AU81)

Dear Ms. Brooks-LaSure:

Thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) fiscal year (FY) 2023 Physician Fee Schedule (PFS) Proposed Rule, 87 Fed. Reg. 45,860 (July 29, 2022) (Proposed Rule) and for your proposal to clarify the scope of dental services covered under the Medicare benefit. As the largest state dental association, the California Dental Association (CDA) represents the profession of dentistry in California with 27,000 member dentists. These professionals know that the mouth cannot be separated from the body and, as such, that dental disease has consequences beyond the oral cavity, impacting the body's organs, systems and overall health. For over 150 years, CDA has been an innovative and vocal advocate for dentists, their teams and their patients, with the goal of advancing oral health in local communities, at the state level and nationwide and is committed to ensuring health equity for all.

CDA's commitment to the principle that everyone should have access to dental care underlies our strong support for CMS's proposal to codify its existing policy of providing Medicare coverage for dental services that are "inextricably linked to, and substantially related and integral to the clinical success of, covered medical services."[1] We strongly believe that this proposal will significantly improve patient care and outcomes for Medicare recipients, increasing population health and addressing health equity across California and the country.

The proposal to expand coverage is especially important for underserved populations that often face significantly higher rates of the chronic health conditions and medical challenges discussed below. To this end, CDA offers comments to support the proposals that have been

[1] 87 Fed. Reg. at 46,040.

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offered, to clarify how CMS should address coverage, coding and payment for specified dental services within the Medicare benefit and to urge the Agency to expand the scope of the specified dental services that are identified in the Proposed Rule.

CDA favors the use of the triple aims criteria for guidance as CMS moves forward on coverage, i.e., coverage of dental problems and procedures that are inextricably linked to the clinical success of an otherwise covered medical service and therefore are substantially related and integral to that primary medical service, reducing the boundaries and barriers between medical care and dental care. Further, covered dental services should improve one or more of the triple aims: patient experience, including quality and patient satisfaction; cost; and clinical outcomes along with population health.

In Section I of our comments, we provide a summary of our recommendations. In Section II, we offer a legal framework that we recommend the Agency use to finalize the proposed rule. In Section III, we apply that analysis to the dental services that CMS proposes to cover, urge the Agency to expand the list to include other dental services about which the Agency has requested comment and suggest that the list of covered dental services could appropriately be expanded to include services integral to the clinical success of several other covered medical management and treatment services not listed in the Proposed Rule.

In Section IV, addressing coding, we support the Agency's proposed use of the American Dental Association (ADA) codes on dental procedures and nomenclature, known as CDT codes and here referred to as D codes, and in Section V we support the Agency's proposal to pay for covered services at contractor discretion, provided that CMS issues Medicare Administrative Contractors (MACs) the needed guidance to use available market rates as the benchmark for payment. Lastly, in Section VI, we support the Agency's proposal to explore covering additional dental services through a demonstration project under the Section 1115A waiver authority to identify specific disease conditions that would see improved patient outcomes as a result of receiving dental services. Such a demonstration may identify additional medical conditions or scenarios where the dental services could be considered substantially related and integral to the clinical success of covered medical treatment or treatment for covered medical conditions.

I. Summary of Comments.

CDA's comments can be summarized as follows:

1. We support the CMS proposal to cover dental or oral examination as part of a comprehensive workup prior to a renal organ transplant surgery, reconstruction of a dental ridge performed as a result of and at the same time as the surgical removal of a tumor, wiring or immobilization of teeth in connection with the reduction of a jaw fracture, extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease and dental splints only when used in conjunction with medically necessary

treatment of a medical condition, as covered services under the Medicare Part B benefit. We agree that CMS has clear authority to cover these services, and we welcome the inclusion of these services, using the coding and payment methodology addressed below.

2. We also urge CMS to cover a dental or oral examination and necessary diagnosis or treatment of any presenting infection prior to (and following) any other organ transplant, cardiac valve replacement, valvuloplasty procedure, treatments for head and neck cancers such as radiation or immunosuppressant therapy as covered services under the Medicare Part B benefit. Sufficient scientific evidence exists to qualify these services as inextricably linked to and substantially related and integral to the clinical success of covered medical services (shorthanded below as the "medically necessary" standard) within the scope of the Medicare benefit, and we urge CMS to cover them, again within the coding and payment methodology addressed below.

3. CMS should also cover a dental or oral examination and necessary diagnosis or treatment of any presenting infection prior to joint replacement, as well as for patients with diabetes and patients undergoing bisphosphonate or immunosuppressive therapies. These procedures are not listed in the Proposed Rule, but merit coverage consistent with the dental procedures identified in the Proposed Rule. The medical evidence also clearly supports including these services as medically necessary within the scope of the Medicare benefit, and we urge CMS to cover them, again within the coding and payment methodology addressed below.

4. As to coding, we support the CMS proposal to utilize the ADA D-code set as the appropriate way for providers to code claims. The code set is well recognized within the provider and payer community and is an appropriate code set to use for Medicare billing purposes.

5. We agree with the CMS proposal to have payment for these services determined by the CMS MACs, at contractor discretion, *provided that* CMS sets a national framework for the MACs to follow in determining their pricing. The CDA recognizes that the D codes do not have associated "Relative Value Units" and that contractor pricing is thus appropriate. The MACs, however, should be required to reimburse for covered dental services in calendar year 2023 using national benchmark prices such as those in the FAIR Health database, and the dental service reimbursement should be at or near the 80th percentile of average billed charges. Going forward, CMS should require the MACs to update those payment rates annually by using the Medicare Economic Index methodology.

6. Lastly, we support the CMS proposal to seek additional ways to integrate the payment for dental and oral health care services within existing and future payment

models using the Agency's Section 1115A waiver authority. We propose that non-ventilator hospital-acquired pneumonia, Alzheimer's disease (AD), dementia and cardiovascular disease be considered for use by the Center for Medicare and Medicaid Innovation (CMMI) in demonstration projects, as providing dental and oral health care services for these specific disease conditions will improve outcomes and the quality of care provided without resulting in increased costs.

Our detailed comments are below.

II. Background on the Medical Benefits and Current Medicare Coverage of Dental Services.

a. The Medical Benefits of Dental Services.

The medical and clinical benefits of dental services have been well established for decades, even if access to proper dental services has been a major health equity concern. As advocates for dental teams, patients and improving health equity, CDA has long recognized the inequities existing in oral health and the need for improved dental coverage in both private and government-run health care models. Without coverage or with insufficient coverage, millions of older adults and people with disabilities are left with a large gap in their health care and many are unable to afford that care on their own.

Historically, the health care system separated the mouth from the rest of the body; however, in recent years, research has shown that oral health plays a large role in a person's overall health as the mouth is a gateway to most internal systems. While this connection is well known by physicians and dentists, access to dental care remains elusive to many Americans. Though significant progress has been made to improve access to oral health care in recent years, disparities persist, disproportionally affecting low-income families, those in rural communities, racial or ethnic minorities, children and the elderly.

According to the 2021 National Institute of Dental and Craniofacial Research report, Oral Health in America: Advances and Challenges,[2] older adults living in poverty were at least three times more likely to have untreated tooth decay than their higher-income counterparts (33% versus 10%). Additionally, 3 in 5 older adults are affected by periodontitis, with 9% having severe periodontitis with prevalence higher among men, non-Hispanic Blacks, Mexican Americans and those with low income. While risks are higher for oral health issues in older adults, a 2014 Centers for Disease Control and Prevention study concluded that nearly 40% of

[2] National Institute of Dental and Craniofacial Research, . Oral Health in America: Advances and Challenges., p. 412. (2021).

adults over age 65 did not have a dental visit that year.[3] Such inequities diminish health and quality of life. Poor oral health has consequences for health, and these consequences are often more significant for Black, Hispanic, and American Indian/Alaska Native individuals. CMS's Proposed Rule expanding coverage for medically necessary dental services is an essential component in addressing these health inequities.

b. Current Medicare Coverage of Dental Services.

The Social Security Act permits only limited Medicare coverage for dental services. Specifically, the statute provides:

> Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services—where such expenses are for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, except that payment may be made under part A in the case of inpatient hospital services in connection with the provision of such dental services if the individual, because of his underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services.[4]

The original statutory provision enacted by Congress only addressed coverage of any dental service "in connection with" the treatment of teeth or structures directly supporting the teeth.[5] In 1980, Congress amended the provision to expressly allow Medicare Part A coverage for inpatient hospital costs related to a dental procedure when the severity of a dental procedure *or* the patient's underlying medical condition and clinical status made hospitalization necessary.[6]

Pursuant to the plain language of the Medicare statute, aside from the provision related to inpatient hospital services described above, only coverage and payment for dental services "in connection with" the treatment of the teeth or structures directly supporting the teeth are prohibited. Indeed, CMS historically has interpreted the plain language of the statute to mean that the exclusion from Medicare coverage extends only to dental services *for which the primary*

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[3] National Center for Health Statistics. Health, United States, 2015: With Special Feature on Racial and Ethnic Health Disparities. p. 20, (2016).
[4] Social Security Act, § 1862(a)(12).
[5] CMS defines "structures directly supporting the teeth" to mean "the periodontium, which includes the gingivae, dentogingival junction, periodontal membrane, cementum of the teeth, and alveolar process." Medicare Benefit Policy Manual, Chapter 15, § 150; Medicare Benefit Policy Manual, Chapter 16, § 140.
[6] 42 C.F.R. § 411.15(i).

purpose is the treatment of the teeth or structures directly supporting the teeth.[7] Thus, if dental services are provided as a requisite to any otherwise covered Medicare service in order to improve the success of that covered Medicare service or reduce risks associated with that covered Medicare service, those dental services are also covered by Medicare. This is because, in that situation, the primary purpose of the dental services is *not* the treatment of teeth or structures directly supporting the teeth. Rather, the primary purpose of the dental services is to support the Medicare-covered service.

CMS in the past has applied this principle in establishing Medicare coverage for dental examinations prior to kidney transplantation:

> Despite the "dental services exclusion" in §1862(a)(12) of the Act . . ., an oral or dental examination performed on an inpatient basis as part of a comprehensive workup prior to renal transplant surgery is a covered service. This is because the purpose of the examination is not for the care of the teeth or structures directly supporting the teeth. Rather, the examination is for the identification, prior to a complex surgical procedure, of existing medical problems where the increased possibility of infection would not only reduce the chances for successful surgery but would also expose the patient to additional risks in undergoing such surgery.[8]

In such situations, CMS considers the dental services to be performed "as incident to and as an integral part of" a Medicare-covered procedure, which provides the basis for Medicare coverage of the dental services themselves. CMS has offered other examples of Medicare coverage of dental services in such circumstances:

1) The reconstruction of a ridge performed as a result of and at the same time as the surgical removal of a tumor (for other than dental purposes). The totality of surgical procedures is a covered service.

2) The wiring of teeth when done in connection with treatment of traumatic injuries of the teeth and jaws, such as the reduction of a jaw fracture.

3) Dental splints used in treatment of a covered medical condition (e.g., dislocated upper/lower jaw joints).

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[7] Medicare General Information, Eligibility and Entitlement Manual, Chapter 5, § 70.2 ("Because the general exclusion of payment for dental services has not been withdrawn, payment for the services of dentists is also limited to those procedures which are not primarily provided for the care, treatment, removal, or replacement of teeth or structures directly supporting the teeth.").

[8] Medicare National Coverage Determinations Manual, Chapter 1, Part 4, § 260.6. Medicare also covers dental examinations prior to heart valve replacements. *See* Medicare Dental Coverage.

4) [T]he removal of a torus palatinus (a bony protuberance of the hard palate), except when performed in connection with an excluded service, i.e., the preparation of the mouth for dentures.

5) Services such as the administration of anesthesia, diagnostic X-rays and other related procedures when the primary procedure being performed by the dentist and the dental team is itself covered. Thus, an X-ray taken in connection with the reduction of a fracture of the jaw or facial bone is covered.[9]

CMS has generally permitted coverage in situations where both the primary Medicare-covered procedure and the dental services performed "as incident to and as an integral part of" the primary covered procedure are performed by the same dentist. CMS in the past also has created an exception to this limitation. Specifically, Medicare covers tooth extractions prior to radiation treatment of neoplastic disease in the jaw, even though the extractions are performed by a dentist and the radiation treatment is performed by a physician:

> The extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease is also covered. This is an exception to the requirement that to be covered, a noncovered procedure or service performed by a dentist must be an incident to and an integral part of a covered procedure or service performed by the dentist. Ordinarily, the dentist extracts the patient's teeth, but another physician, e.g., a radiologist, administers the radiation treatments.[10]

Extraction of teeth is an established clinical requisite to radiation treatment for head and neck cancer for certain patients, without which complications may occur that can seriously compromise those patients' cancer treatment. However, medical and dental scope-of-practice requirements necessitate that tooth extractions and radiation treatments be performed by different professionals. Thus, CMS has recognized that as long as dental services are performed "as incident to and as an integral part of" a Medicare-covered procedure—regardless of who performs the covered procedure, the dental services are eligible for coverage under the Medicare statute.[11]

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[9] Medicare Benefit Policy Manual, Chapter 15, § 150. *See also* Medicare Benefit Policy Manual, Chapter 16, § 140.

[10] Medicare Benefit Policy Manual, Chapter 15, § 150.

[11] CDA appreciates that in a letter dated Sept. 18, 2019, the General Counsel of the U.S. Department of Health and Human Services took the position that the secretary of HHS did not have statutory authority to expand Medicare coverage policy for dental services, relying on the Supreme Court decision in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000). Letter from Robert P. Charrow to Eric S. Berger, dated Sept. 18, 2019. That same case, however, also stated that "although agencies are generally entitled to deference in the interpretation of statutes that they administer, a reviewing 'court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.'" Id., quoting *Chevron U.S.A. Inc. v. Natural*

As explained below, CDA strongly supports CMS's proposal to amend § 411.51(i) to codify its existing policy of making payment for dental services that are performed "as incident to and as an integral part of" a Medicare-covered procedure or service. [12].

III. CMS Should Finalize Its Proposal To Expand Coverage of Dental Services Using the Medically Necessary Standard.

As explained above, the Medicare statute excludes coverage and payment only for those dental services performed primarily for the purpose of treatment of the teeth or structures directly supporting the teeth. All other dental services—that is, dental services performed to support another Medicare-covered procedure—are eligible for coverage based on a well-established CMS policy that the dental procedures are performed "as incident to and as an integral part of" the Medicare-covered procedure. For that reason, we support Medicare covering the list of dental services included in the Proposed Rule, urge CMS to cover the list of dental services that it has requested more information about in the Proposed Rule and urge CMS to also cover an additional set of services listed below that were not specifically called out in the Proposed Rule.

For each of the instances in which CDA supports coverage of dental services related to a Medicare-covered procedure, CDA has identified the D codes that should be assigned a status code of R. As discussed in more detail below, CMS does not need to modify the status indicator for those D codes that already have R status, but the Agency should update the status indicator for those D codes that currently have a status indicator of I or N. Further, in cases where a D code with a status indicator of I represents a service that is identical to a service identified by a

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Resources Defense Council Inc., 467 U.S. 837, 842-832 (1984). In *Brown & Williamson*, the U.S. Supreme Court invalidated an FDA regulation designating tobacco as a drug only after an exhaustive review of both Congressional action and agency action, both of which demonstrated that Congress had legislated tobacco products as if they were not drugs, and the FDA's historic position had been the same. We appreciate that the Agency understands that the precedent does not apply in the way set out in the Charrow letter. For example, the 1965 Senate Report indicated that "a specific exclusion for routine dental care" was added to the Medicare statute "to make clear that the services of dental surgeons covered under the bill are restricted to complex surgical procedures," in the same way that cataract surgery was covered even though eyeglasses were not. See S. Rep. No. 89-404 (1965), reprinted in 1965 U.S.C.C.A.N. 1943, 1989-90. Building on the legislative history, in 1980 Congress further amended the statute explicitly covering the inpatient costs addressed above. The 1980 legislative history similarly indicates Congress found that "present coverage for inpatient hospital services related to certain noncovered dental procedures [wa]s inadequate" and that Congress intended to expand inpatient coverage "for a dentist (or physician's) certification that hospital inpatient services are necessary for the performance of a noncovered dental procedure either because of the severity of the dental procedure or the patient's underlying condition warrants such hospitalization." Thus the Brown & Williamson case as well as ample other precedent, supports the Proposed Rule by showing that the secretary clearly has the authority to cover the dental services addressed in the Proposal and other such services addressed in this letter. We urge the Agency to rescind the 2019 letter.

[12] 87 Fed. Reg. at 46,035.

CPT code, CDA recommends that CMS permits dentists to submit claims using the more familiar D code.

In alignment with the standard of care for dentistry, prior to any dental work being performed, the dentist should examine the patient, which includes necessary diagnostic services such as imaging, to determine an appropriate diagnosis. The diagnostic code recommendations are included for each service.

a. Services CMS Proposes To Qualify for Coverage Under the Medically Necessary Standard.

In the Proposed Rule, CMS proposes to codify coverage of the following services as consistent with the medically necessary coverage standard:

> (1) dental or oral examination as part of a comprehensive workup prior to a renal organ transplant surgery; (2) reconstruction of a dental ridge performed as a result of and at the same time as the surgical removal of a tumor; (3) wiring or immobilization of teeth in connection with the reduction of a jaw fracture; (4) extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease; and (5) dental splints only when used in conjunction with medically necessary treatment of a medical condition.[13]

CDA endorses coverage of each of these services and supports the CMS proposal to do so. We address each of these procedures below.

i. Dental or Oral Examination as Part of a Comprehensive Workup Prior to a Renal Organ Transplant Surgery.

A preoperative dental examination is critical for renal organ transplant surgery. The American Society of Transplant Surgeons has stated that "[u]ntreated dental problems can become deadly once a patient is immunosuppressed, so good dental care is a critical part of preparation for transplant." During the perioperative period, the deleterious effects of a "quiescent and potent odontogenic infection . . . can not only compromise surgical outcome, but also magnify treatment and expense." [14] The immunosuppression required for transplantation, which intentionally weakens the recipient's ability to reject the new organ, also weakens the recipient's ability to fight infection. Older adults are especially at risk for these potentially serious complications.[15] The importance of eliminating odontogenic centers of

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[13] 87 Fed. Reg. at 46,037.
[14] Yasny & Herlich, *Mount Sinai Journal of Medicine*, 79:34 – 34, Perioperative Dental Evaluation (2012).
[15] Hemmersbach-Miller, M., Wolfe, C.R., Schmader, K.E. *OBM Transplant, 3*(1), Solid organ transplantation in older adults. Infectious and other age-related considerations (2019).

inflammation in patients prior to kidney transplantation is further highlighted in multiple research discussions.[16,17,18,19]

Importantly, adding a dental examination to a pre-surgical workup is not sufficient to reduce risk or improve outcomes. If infection is identified, it is medically necessary to resolve the infection prior to transplantation surgery and initiation of immunosuppressive therapy.[20] If the infection is not resolved, Medicare beneficiaries will be forced to delay or forgo the transplant at issue if the risk to proceed with treatment is deemed too high. Alternatively, if the transplant surgery proceeds, the patient, surgeon and Medicare will all bear the burden of the untoward consequences that may result. Consequently, Medicare must cover both dental examination *and treatment* to eliminate oral infection for patients undergoing renal transplantation. As discussed in more detail below, CDA urges CMS to apply this coverage not only to renal transplants but to all organ transplantation surgeries for the same reasons. In sum, CDA urges CMS to consider coverage of dental examination and disease treatment prior to all solid organ transplantation surgery (see further discussion of this and the appropriate treatment codes in the first bullet under section b).

To enable this coverage for dental examinations only, CDA urges CMS to assign a status indicator of R to the following D codes (see first bullet under section b. for code recommendations for associated dental treatment procedures).

- Examination: D0120, D0140, D0150, D0160 and D0180.
- Diagnostic testing and oral pathology examination: D0431, D0460, and D0472-D0486 and D0999.
- Imaging: D0210, D0220, D0230, D0270-0277, D0330.

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[16] Kwak, Kim, Choi, Joo, Park, *Int. Dent. J.*, 70(6):477-481, Importance of Oral Health and Dental Treatment in Organ Transplant Recipients (Dec. 2020); *see also* National Kidney Foundation, Oral Health Before and After Transplant (Jul. 1, 2015); (discussing the importance of identifying and treating oral infections prior to kidney transplant).

[17] Campbell, Humphreys, Summers, Konkel, Knight, Augustine, & McBain, *Front Cell Infect Microbiol*,10: 558644, Does the Microbiome Affect the Outcome of Renal Transplantation? (Dec. 2020).

[18] Gašpar, Glavina, Grubišić, Sabol, Bušić ,& Mravak., *Acta Stomatol Croat.*, 49(3):204-13., The Oral Cavity State in Renal Transplant Recipients (Sept. 2015).

[19] Wilczyńska-Borawska, Magdalena, Malyszko. Annales Academiae Medicae Stetinensis, vol. 56, 2 51-4. Dental problems in a potential kidney transplant recipient: case report and literature review (2010).

[20] Parisi EP, Glick MG, The Dental Clinics of North America, 47, 709-731, Immune suppression and considerations for dental care (2003).

ii. Reconstruction of a Dental Ridge Performed as a Result of and at the Same Time as the Surgical Removal of a Tumor.

Reconstruction of the dental ridge is the standard of care after surgical tumor removal and is a medically necessary procedure to restore a patient to health and allow them to eat. The surgery typically involves removal of affected teeth and alveolar bone while avoiding a resection that would result in a discontinuity defect of the jaws, a widely accepted medical treatment that meets the Medicare statute's medically necessary requirements. Reconstruction of an alveolar defect usually includes either autogenous or alloplastic grafting and graft stabilization, as well as a procedure to harvest autogenous bone if this is deemed necessary. It is essential to provide a continuous ridge of bone upon which a denture can be seated or an implant can be placed to restore the function of the affected area. Without this, the dentist has failed to make the patient whole and compromised treatment that may be needed for the patient to eat properly.

To enable this coverage, CDA urges CMS to assign a status indicator of R to the following D codes:

- D7950 (osseous, osteoperiosteal or cartilage graft of mandible or maxilla), D7953 (bone graft), D4266 & D4267 (resorbable and non-resorbable barriers). CPT codes may be used for the tumor removal and osteoplasty of the bone, although, as noted above, CDA recommends CMS cover the relevant D codes for the surgery itself, including D7440 & D7441 (malignant tumors) and D7450 & D7451 and D7460 & D7461 (benign cysts or tumors).

iii. Wiring or Immobilization of Teeth in Connection With the Reduction of a Jaw Fracture.

Immobilization of the jaws by wiring teeth together is a standard procedure used for the treatment of traumatic injuries of the teeth and jaws. The principle is the same as placing a cast on a fractured limb: The hard tissues must be set and held in place for healing to occur. One of the advantages of this method is that it simultaneously stabilizes both the injured teeth and alveolar bone segments that may have been displaced by the injury. Again, as long reflected in the CMS manual, this procedure classically fits the Medicare statute's medically necessary criteria and should continue to be a covered procedure.

To enable this coverage, CDA urges CMS to assign a status indicator of R to the following D codes:

- D7610-D7740 dependent on the type & location of the fracture. These codes include the reduction of the fracture with the associated wiring/immobilization. There are no separate codes for only wiring/immobilization.

iv. Extraction of Teeth to Prepare the Jaw for Radiation Treatment of Neoplastic Disease.

Osteoradionecrosis of the jaws, a severe delayed radiation-induced injury characterized by bone tissue necrosis and failure to heal for at least three months, is a significant risk for patients undergoing radiation of the head and neck in the treatment of neoplastic disease.[21] Pre-radiation extraction of diseased, unrestorable teeth is considered necessary and integral to the successful radiation treatment of the underlying medical condition, which is usually oral cancer.[22] Similar to the other procedures in the manual that are proposed to be covered in regulation, this procedure also clearly meets the medically necessary requirements of the Medicare statute.

To enable this coverage, CDA urges CMS to assign a status indicator of R to the following D codes:

- D7140, D7210, D7250 (extraction of erupted tooth, including codes for exposed root removal) D7220, D7230, D7240 (extraction of impacted tooth, soft tissue, partial and complete bony), D7241 (complete bony with surgical complication), D7251 (coronectomy).

v. Dental Splints Only When Used in Conjunction With Medically Necessary Treatment of a Medical Condition.

Medical conditions for which a dental splint may be used include dislocation of the jaw and temporomandibular disorders (TMD). Splints are useful for immobilizing and stabilizing the lower jaw and are often used in conjunction with pain and anti-inflammatory medications, physical therapy and other treatment modalities.

To enable this coverage, CDA urges CMS to assign a status indicator of R to the following D codes:

- D7880 (occlusal orthotic device used for TMD), D5937 (trismus appliance), D5988 (surgical splint), D4322 & D4323 (intra and extra coronal splints that link teeth to provide stabilization and strength).

b. Services CMS Seeks Information About To Qualify as Medically Necessary.

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[21] Nadella KR, Kodali RM, Guttikonda LK, Jonnalagadda A., *J Maxillofac Oral Surg.*,14(4):891-901, Osteoradionecrosis of the Jaws: Clinico-Therapeutic Management: A Literature Review and Update (Dec. 2015).

[22] National Cancer Institute, Oral Complications of Chemotherapy and Head/Neck Radiation (PDQ®)–Health Professional Version (Updated July 2021).

CMS also has inquired as to the availability of clinical and other information that would support coverage of other services that may be medically necessary for the clinical success of covered services, such as dental or oral examinations, and necessary diagnosis or treatment of any presenting infection prior to an organ transplant, cardiac valve replacement, valvuloplasty procedure or treatments for head and neck cancers, such as radiation or immunosuppressant therapy.[23] CDA appreciates the Agency's willingness to consider the evidence and believes that the clinical and other evidence support Medicare coverage of these treatments. Our detailed comments on the proposed procedures are as follows:

i. Dental or Oral Examination and Necessary Diagnosis or Treatment of Any Presenting Infection Prior to an Organ Transplant.

CDA strongly supports including a dental and oral examination and treatment of infection before any organ transplant. As noted above, such treatment is clearly medically necessary to ensure the viability and outcome of any organ transplant – not just a renal transplant – and is a well-accepted medical standard of care. The National Institutes of Health advises that patients have a dental checkup before an organ transplant. "Your mouth should be as healthy as possible before your transplant procedure. Treating cavities, periodontal (gum) disease, and any other mouth problems ahead of time can help prevent or reduce the side effects of transplant drugs."[24] Clinical research further emphasizes that dental and oral examination and necessary diagnosis and treatment of infection is critical to medical care. As noted above, in the discussion on renal organ transplant surgery, "[d]eleterious effects of an intraoral infection may not only compromise surgical outcome but lead to an increased need for additional interventional therapy(s) along with associated expenses."[25,26]

Oral infections that go undetected and untreated before organ transplant not only risk transplant rejection due to infection but can create far more serious health risks due to immune system suppression for transplant purposes. The International Dental Journal expounds on this point, highlighting that infections frequently occur in transplant recipient patients because of their immunosuppressed state, thus necessitating the need to eliminate any infections prior to transplant and initiation of immunosuppressant drugs to ensure that those infections do not spread to other parts of the body and compromise surgical success.[27]

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[23] 87 Fed. Reg. at 46,037.
[24] National Institutes of Health, Organ or Stem Cell Transplant and Your Mouth (2015).
[25] *Conn. Med.*, 79(1):19-25, Intraoral Infection and Oral Health in the Surgical Patient: Need for Concern During the Perioperative Period? (Jan. 2015).
[26] Yasny, Herlich, *Mount Sinai Journal of Medicine,* 79:34 – 34, Perioperative Dental Evaluation (2012).
[27] Kwak, Kim, Choi, Joo, Park, *Int. Dent. J.,* 70(6):477-481, Importance of Oral Health and Dental Treatment in Organ Transplant Recipients (Dec. 2020); *see also* National Kidney Foundation, Oral Health Before and After Transplant (Jul. 1, 2015); (discussing the importance of identifying and treating oral infections prior to kidney transplant).

We agree with the NIH that it is critical for Medicare beneficiaries to have access to dental and oral examination and necessary treatment of any presenting infection prior to an organ transplant and urge CMS to include coverage of these services in the Final Rule. Medicare coverage of oral examination, infection detection and treatment clearly meet the medically necessary standard, because failure to treat the infection would compromise the surgical success of the transplant and create significant health risk for the immunocompromised patient. Thus, treating the infection prior to the transplant is integral and substantially related to the clinical success of a Medicare-covered procedure. For these reasons, we urge CMS to finalize coverage of oral examination, infection detection and treatment prior to organ transplant in the Final Rule.

To enable this coverage, CDA urges CMS to assign a status indicator of R to the following D codes:

- Examination: D0120, D0140, D0150, D0160, D0171 and D0180
- Diagnostic testing and oral pathology examination: D0431, D0460, and D0472-D0486 and D0999.
- Imaging: D0210, D0220, D0230, D0240, D0270-D0277, D0330, D0364-D0391.
- Emergency treatments: D9110, D3220, D3310-D3330 & D3921, D7140, D7210, D7510, D7511, D7520 and D7521.
- Preventive and Periodontal care: D1330, D1354, D1110, D4341, D4342, D4346 D4910, D4355, D4999.
- Fillings: D2140 to D2161, D2330 to D2332 & D2335, D2391 to D2394.

ii. Cardiac Valve Replacement and Valvuloplasty.

As noted earlier, there is significant evidence that active infection in the mouth puts successful surgical outcomes at risk.[28,29] This risk is of particular concern for **cardiac valve replacement/valvuloplasty,** where the site of surgical repair is especially vulnerable to infection. Endocarditis is a serious and frequently fatal inflammation of the tissues lining the heart can result from infection and must be avoided.

In a discussion on endocarditis in a report from the Institute of Medicine (U.S.) Committee on Medicare Coverage (2000), the committee noted that "[t]he oral cavity harbors a lot of bacteria, most commonly in the form of plaque, but also associated with gingivitis, periodontitis, and periapical disease (infection around the base of the tooth root). Oral flora, particularly streptococcus, are implicated in approximately 40 percent of cases of infective endocarditis,"

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[28] *Conn. Med.* 79(1):19-25, Intraoral Infection and Oral Health in the Surgical Patient: Need for Concern During the Perioperative Period? (Jan. 2015).
[29] Yasny, Herlich, *Mount Sinai Journal of Medicine*, 79:34 – 34, Perioperative Dental Evaluation (2012).

further stating, it is "standard clinical practice to eliminate as many potential sources of oral infection as possible before a patient undergoes a surgical procedure to repair or replace a defective heart valve. This typically involves an oral examination and X-rays, thorough cleaning, and treatment for any gingival, periodontal, or periapical disease identified."[30] For these reasons, Medicare coverage for a dental examination and treatment to eliminate infection prior to any form of cardiac valve surgery is integral to the success of that surgery. In addition, CDA urges Medicare to consider limited additional coverage for ongoing periodontal care for the one- to two-year post-surgical period, as the medical literature indicates that poor oral health, plaque accumulation and inflammation contribute to endocarditis risk.[31,32] This additional periodontal care is medically necessary to reduce the oral pathogen burden and protect the cardiac valve during this vulnerable period. Thus, because this ongoing care is medically necessary in valve replacement patients, Medicare should cover this treatment just as Medicare covers routine post-surgical care in valve replacement patients.

To enable this coverage, CDA urges CMS to assign a status indicator of R to the following D codes:

- Examination: D0120, D0140, D0150, D0160, D0170, D10171 and D0180.
- Diagnostic testing and oral pathology examination: D0431, D0460, and D0472-D0486 and D0999.
- Imaging: D0210, D0220, D0230, D0240, D0270-0277, D0330, D0364-D0391.
- Emergency treatments: D9110, D3220, D3310-D3330 & D3921, D7140, D7210, D7510, D7511, D7520 and D7521.
- Preventive and Periodontal care: D1330, D1354, D1110, D4341, D4342, D4346 D4910, D4355, D4999.
- Fillings: D2140 to D2161, D2330 to D2332 & D2335, D2391 to D2394.

iii. Treatment for Head and Neck Cancers.

As discussed above, extraction of diseased, unrestorable teeth is medically necessary prior to initiating radiation treatment of the head and neck because of osteoradionecrosis risk. However, the need to address active disease and infection in the mouth of the head or neck cancer patient goes well beyond osteoradionecrosis risk, as cancer treatment frequently also includes chemotherapy, immunotherapy and possibly stem cell and/or bone marrow transplants.

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[30] Field MJ, Lawrence RL, Zwanziger L, editors, Institute of Medicine (U.S.) Committee on Medicare Coverage Extensions, Extending Medicare Coverage for Preventive and Other Services(2000).
[31] Sconyers JR, Crawford JJ, Moriarty JD, *The Journal of the American Dental Association*, Volume 87, Issue 3, Relationship of Bacteremia to Toothbrushing in Patients with Periodontitis, , p. 616-622 (1973).
[32] Field MJ, Lawrence RL, Zwanziger L, editors, Institute of Medicine (U.S.) Committee on Medicare Coverage Extensions, Extending Medicare Coverage for Preventive and Other Services. Washington (DC): National Academies Press (U.S.) (2000).

Several debilitating oral conditions, including mucositis, candidiasis, xerostomia, medication-related osteonecrosis of the jaw (MONJ) and even sepsis, are associated with head and neck cancer treatment, making it extremely difficult to provide dental treatment to patients undergoing these cancer therapies.[33],[34,35] Dental examination to determine the extent of dental disease and treatment of identified disease prior to the initiation of medical therapies for cancer, as well as ongoing oral care to prevent new foci of infection during cancer treatment, are essential to reduce the risk of several painful and costly cancer treatment sequela, avoid cancer treatment disruption and improve overall treatment success.[36, 37] We urge the Agency to include coverage for medically necessary dental examination, treatment and follow-up care during and related to treatment for head and neck cancers.

To enable this coverage, CDA urges CMS to assign a status indicator of R to the following D codes:

- Examination: D0120, D0140, D0150, D0160, D0170, D0171 and D0180.
- Diagnostic testing and oral pathology examination: D0431, D0460, D0472-D0486 and D0999.
- Imaging: D0210, D0220, D0230, D0240, D0270-0277, D0330, D0364-D0391.
- Emergency treatments: D9110, D3220, D3310-D3330 & D3921, D7140, D7210, D7510, D7511, D7520 and D7521.
- Preventive and Periodontal care: D1330, D1354, D1110, D1206, D1208, D5986, D4341, D4342, D4346, D4910, D4355.
- Fillings: D2140 to D2161, D2330 to D2332 & D2335, D2391 to D2394.

c. Other Dental Procedures CMS Should Cover in the Final Rule.

The Proposed Rule's discussion of circumstances in which dental services could be covered is tied to specific medical or surgical procedures. For example, in the discussion of the five services for which CMS proposes to codify current practice, the first four are specific to

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[33] Phongsuphot K, Chimruang J, Intapa C. *CM Dental Journal* 42(1):159-172. Incidence and Severity of Oral Mucositis in Adult and Elderly Cancer Patients After Receiving Chemotherapy in Uttaradit Hospital (2021).
[34] Elting, L.S., & Chang , Y. *Journal of the National Cancer Institute, 53*, 116-123, Costs of oral complications of cancer therapies: estimates and a blueprint for future study, (2019).
[35] Monti CI, Maniezzo M, Campa T, et al, The experience of the National Cancer Institute of Milan. Ann Oncol. 20:137-145, Decreased occurrence of osteonecrosis of the jaw after implementation of dental preventive measures in solid tumour patients with bone metastases treated with bisphosphonates. (2009).;
[36] Riley P, Glenny A, Worthington HV, Littlewood A, Fernandez-Mauleffinch L, Clarkson JE, McCabe MG. *Cochrane Database of Systematic Reviews,* Interventions for preventing oral mucositis in patients with cancer receiving treatment: Cytokines and growth factors (2017).
[37] Keefe DMK, Bateman EH, *Research Frontiers: Oral Toxicities of Cancer Therapies,* (53): 25-29, Potential Successes and Challenges of Targeted Cancer Therapies (2019).

particular medical or surgical treatment: renal organ transplant surgery, surgical removal of a tumor, reduction of jaw fracture and radiation treatment of neoplastic disease. The discussion in the proposed rule of coverage of dental services to eradicate dental or oral infection in potentially immunocompromised patients would not limit that coverage to patients initiating immunosuppressive therapy. Rather, it states that expanding coverage of dental services to eradicate dental or oral infection is to include other patients whose treatments are likely to have a suppressant effect on that part of the immune system required to eradicate infectious agents and could be necessary to the clinical success of the therapy.

CDA agrees that coverage of dental examinations and treatment as medically necessary is warranted in each of these procedures. However, CDA also notes that several disease states similarly warrant coverage of dental examination and treatment as medically necessary to ensure proper care and management of the Medicare beneficiary. For this reason, and as explained in more detail below, CDA also urges CMS to include in the list of medically necessary services care for patients with diabetes, joint replacement and patients undergoing bisphosphonate or immunosuppressive therapies. The services proposed by CMS, as well as those proposed by CDA, meet the medically necessary standard as explained below:

i. **Joint replacement**.

Patients undergoing joint replacement also require appropriate dental examination and infection control to ensure that the Medicare-covered procedures are not compromised by infection. The literature has well documented these risks: "[p]eriprosthetic joint infections are a devastating complication after arthroplasty and are associated with substantial patient morbidity. More than 25 percent of revisions are attributed to these infections, which are expected to increase."[38] Similar to the discussion above on cardiac valve surgery, the surgery site itself, in this case the prosthetic joint, is especially vulnerable to infection, which is the most common reason for rehospitalization and significant associated costs.[39] Thus, for the reasons stated above with regard to organ transplant and cardiac valve replacement procedures, where the risk of dental infection makes dental examination and treatment medically necessary, Medicare should also cover examination and infection control before and after joint replacements to lower the threat of subsequent infection and avoid surgical failure and the associated burden to the patient. Consequently, CDA urges Medicare to provide coverage for dental examination and treatment of identified infection as part of the perioperative period for joint replacement surgery.

To enable this coverage, CDA urges CMS to assign a status indicator of R to the following D codes:

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[38] Kapadia BH, Berg RA, Daley JA, Fritz J, Bhave A, Mont MA, *TheLancet* 387(10016):386-394, Periprosthetic joint infection (Jan. 23, 2016)..

[39] Çetin Aslan E, Ağırbaş i, Turk J Phys Med Rehabil, 66(1):31-39, Rates, causes, and types of readmissions after total joint arthroplasty(Mar. 3, 2020).

- Examination: D0120, D0140, D0150, D0160, D0170, D0171 and D0180.
- Diagnostic testing and oral pathology examination: D0431, D0460, and D0472-D0486 and D0999.
- Imaging: D0210, D0220, D0230, D0240, D0270-0277, D0330, D0364-D0391.
- Emergency treatments: D9110, D3220, D3310-D3330 & D3921, D7140, D7210, D7510, D7511, D7520 and D7521.
- Preventive and Periodontal care: D1330, D1354, D1110, D4341, D4342, D4346 D4910, D4355, D4999.
- Fillings: D2140 to D2161, D2330 to D2332 & D2335, D2391 to D2394.

ii. Immunosuppressive and bisphosphonate therapy.

As previously described, treatments that depress the immune system and interrupt cell metabolism and cell division, such as chemotherapeutics, bisphosphonates and other cancer treatments that depress the immune system and interrupt cell metabolism and cell division, put patients at risk for several conditions that compromise the hard and soft tissues of the mouth and jeopardize dental treatment for persons undergoing these therapies. These conditions include, though are not limited to, mucositis, candidiasis, xerostomia and medication-related osteonecrosis of the jaw (MONJ). Bisphosphonate therapy for osteoporosis, though used at significantly lower doses, also increases the risk for MONJ, though at a much lower incidence than when used for cancer therapy.

A 2015 systematic review and international consensus has documented "the incidence of osteonecrosis of the jaw is greatest in the oncology patient population (1% to 15%), where high doses of these medications are used at frequent intervals." Risk factors for MONJ include "glucocorticoid use, maxillary or mandibular bone surgery, poor oral hygiene, chronic inflammation, diabetes mellitus, ill-fitting dentures, as well as other drugs, including antiangiogenic agents. Prevention strategies for MONJ include elimination or stabilization of oral disease prior to initiation of antiresorptive agents, as well as maintenance of good oral hygiene."[40] Simply put, there is overwhelming clinical evidence supporting the coverage of dental treatment as medically necessary in patients navigating immunosuppressive and bisphosphonate therapy, and we urge the Agency to expand the list of covered procedures to include these as well.

To enable this coverage, CDA urges CMS to assign a status indicator of R to the following D codes:

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[40] Khan, Morrison, Hanely, Felsenberg, et al. *J Bone Miner Res*, 30(1):3-23, Diagnosis and management of osteonecrosis of the jaw: a systematic review and international consensus. (Jan 2015).

- Examination: D0120, D0140, D0150, D0160, D0170, D0171 and D0180.
- Diagnostic testing and oral pathology examination: D0431, D0460, and D0472-D0486 and D0999.
- Imaging: D0210, D0220, D0230, D0240, D0270-0277, D0330, D0364-D0391.
- Emergency treatments: D9110, D3220, D3310-D3330 & D3921, D7140, D7210, D7510, D7511, D7520 and D7521.
- Preventive and Periodontal care: D1330, D1354, D1110, D1206, D1208, D4341, D4342, D4346, D4910, D4355.
- Fillings: D2140 to D2161, D2330 to D2332 & D2335, D2391 to D2394.

iii. Diabetes.

Clinical research demonstrates the bidirectional link between diabetes and periodontal disease and further shows that HbA1c levels in Type 2 diabetes patients are improved when periodontal disease is managed.[41,42,43,44] The Centers for Disease Control and Prevention (CDC) recognizes the importance of oral health care for individuals with diabetes, noting in their patient education materials that high blood sugar can weaken white blood cells, the body's main way to fight off infection, thus increasing the risk of oral infection and further compromising patient health.[45]

A recent 35-study meta-analysis (2022 Cochrane Review) analyzing the effect of periodontal treatment on HbA1c levels for people with diabetes concludes that there is now a "moderate certainty of evidence that periodontal treatment using subgingival instrumentation improves glycemic control in people with both periodontitis and diabetes by a clinically significant amount when compared to no treatment or usual care. Further trials evaluating periodontal treatment versus no treatment/usual care are unlikely to change the overall

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[41] Lamster IB. John Wiley & Sons, Inc., Diabetes Mellitus and Oral Health: An Interprofessional Approach (2014).
[42] Simpson TC, Clarkson JE, Worthington HV, MacDonald L, Weldon JC, Needleman I, Iheozor-Ejiofor Z, Wild SH, Qureshi A, Walker A, Patel VA, Boyers D, Twigg J.,Cochrane Database of Systematic Reviews, Issue 4. Art. No.: CD004714, Treatment of periodontitis for glycaemic control in people with diabetes mellitus (2022).
[43] Merchant, Georgantopoulos, Howe, Virani, Morales, & Haddock., *J. Dent. Research.* 95(4) 408-415, Effect of Long-Term Periodontal Care on Hemoglobin Alc in Type 2 Diabetes (2016).
[44] Koromantzos, Makrilakis, Dereka, Katsilambros, Vrotsos, Madianos, *Journal of Clinical Periodontology*, 38(2) 142-147, A Randomized, Controlled Trial on the Effect of Non-surgical Periodontal Therapy in Patients with Type 2 Diabetes (2011).
[45] Centers for Disease Control and Prevention, *Diabetes and Oral Health* (last reviewed May 2021).

conclusion reached in this review."[46] The review also noted that the number of studies of the issue had doubled in recent years: "Evidence from 30 trials (results from 2,443 participants) showed that periodontitis treatment reduces blood sugar levels (measured by HbA1c) in diabetic patients on average by 0.43 percentage points (e.g. from 7.43% to 7%; 4.7 mmol/mol) 3 to 4 months after receiving the treatment compared with no active treatment or usual care. A difference of 0.30% (3.3 mmol/mol) was seen after 6 months (12 studies), and 0.50% (5.4 mmol/mol) at 12 months (one study)." Thus, the evidence now shows that periodontal care is not just necessary as an adjunct to the care and treatment of Medicare beneficiaries with diabetes—it is a necessary element of care to control and reduce A1C levels in these beneficiaries.

Due to the close association of diabetes and oral disease and the clear clinical evidence directly establishing periodontal care as critical to the treatment and management of diabetes, CDA recommends that CMS include periodontal treatment as medically necessary—and thus eligible for coverage—for the treatment and management of diabetes. If, however, the Agency feels that the clinical evidence is not yet fully developed, CDA recommends that CMS consider gathering more data through a Section 1115A demonstration project, as discussed in more detail *infra,* Section VI.

IV. Coding of Medically Necessary Dental Services

In order to facilitate coverage, we also urge the Agency to maintain the ADA's CDT codes (D codes) for billing and payment purposes. More specifically, for D codes describing a Medicare-covered procedure, CDA has identified the D codes that should be assigned a status code of R, attached hereto as Appendix A. Further, in cases where a CPT and D code both describe the relevant procedure, CMS should permit dentists to submit claims using the D code.

CDT codes are the national standard for dental billing and payment purposes, regardless of payer type. A limited number of dental offices are familiar with or able to bill CPT codes.[47] To avoid creating an additional burden on dentists and dental teams that would negatively impact access to care and the improved patient care and outcomes for medical services that CMS seeks through this proposed rule, CDA believes these D codes are, and will continue to be, the best available codes for CMS to utilize for Medicare-covered medically necessary dental treatments.

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[46] Simpson et. al., Cochrane Database of Systematic Reviews, Issue 4. Art. No.: CD004714, n.63 at 2-3, Treatment of periodontitis for glycaemic control in people with diabetes mellitus (2022).

[47] Related, CDA appreciates that CMS and the MACs will need to ensure that D codes billed to Part B were actually part of a designated medical treatment, such as those described in Section III, and thereby eligible for coverage. The use of appropriate ICD Codes on the claim will allow the MACs to reach that determination so that the Agency is appropriately paying for medically necessary treatment and dental treatments unrelated to the specified diseases and treatments identified above.

Because D codes would be payable only in medically necessary situations, CDA believes that CMS should continue to use the R status indicator for covered D codes. As CMS knows, the R status indicator denotes restricted coverage and contractor pricing.[48] We urge CMS to review the D codes and assign, as appropriate, the R status indicator to ensure that the appropriate codes are billable to Medicare in medically necessary situations. As noted above, many of the codes already have an R status indicator and we urge CMS to modify the status indicator of the additional D codes which will qualify for coverage under the Final Rule from an I or N to an R status indicator, so that appropriate payment can be made subject to MAC determinations and contractor pricing.

We appreciate the Agency's attention to this detail and urge that the relevant code status indicators be updated in the Final Rule.

V. Payment of Medically Necessary Dental Services.

a. Payment Rates.

In the Proposed Rule, CMS solicited comments on potential future payment models for dental and oral health care services. [49] Medically necessary dental care should increase access to needed oral health care and allow the patient to keep their own dentist. As this Proposed Rule focuses solely on medically necessary dental services, many procedures considered part of the dental standard of care or essential for maintaining oral health will continue to be excluded from Medicare coverage. Patients should be able to easily access any Medicare-covered medically necessary dental services from the same provider where they receive their non-Medicare-covered dental service. To limit barriers that will result in increased time and cost to the patient, CDA strongly urges CMS to create a payment mechanism that limits additional burden on patients and increases access to needed oral health care.

Currently, MACs make a claim-by-claim determination as to whether a patient's circumstances do or do not fit within the coverage standard as set forth by regulation and CMS policy. [50] We support that continued use of contractor payment discretion on a claim-by-claim basis, *provided that* CMS issues national guidelines for such payment for the MACs to follow for payment of the relevant dental services. More specifically, while at present MACs do not have specific guidance for establishing prices for covered dental services, such pricing benchmarks do exist and could readily be used by CMS to set payment guidelines. CDA specifically recommends that CMS utilize existing data collected by FAIR Health, a nonprofit organization aimed at being a trusted and transparent source of health care costs and utilization

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[48] Physician Fee Schedule, *Relative Value Files (RVU22B)* (April 2022).
[49] 87 Fed. Reg. at 46,040.
[50] *Id.* at 46,033.

data for consumers and practitioners,[51] which in our view represents an accurate guidepost for MACs to follow when setting prices. FAIR Health provides cost estimates for CDT procedures in a given geographic area by utilizing both commercial and Medicare data to create the out-of-network and uninsured prices, as well as generate fee estimates for practitioners.[52] We further urge CMS to require MACs to price covered dental services at or around 80% of average charges set forth in the most recent and currently available FAIR Health Dental Benchmarks. We recommend benchmarking against billed charges as they represent a reasonably accurate estimate of the cost of dental services and as dental charges have been relatively stagnant throughout the past decade.

We recommend that the average charge be adjusted for differences in market prices across geographic markets, either by analyzing the FAIR Health data at a regional level or by adjusting the national average for geographic differences in practice costs. For 2023, we recommend CMS use the Physician Fee Schedule's Geographic Practice Cost Index (GPCI) for practice expense, although we recommend that CMS develop a dental-specific GPCI for use in later years to better reflect the costs of dental practice. Given that the Medicare pricing could influence future years' cost reporting, we suggest that the most recent and currently available FAIR Health data serve as the benchmark pricing year and that CMS update prices of dental services using the Medicare Economic Index (MEI), its methodology of estimating annual changes in physicians' operating costs and earning levels but adapted to represent the relative importance of the components of the operating costs of dental practice.[53]

We also acknowledge that in the future, CMS may seek to provide coverage for additional D codes that are shown to be integral and inextricably linked to the clinical success of other covered services. CDA thus recommends that when D codes become newly eligible for coverage and are provided with an R letter indicator, that CMS continue using 2022 FAIR Health data to set initial pricing that can then be adjusted by analyzing factors set forth in the MEI methodology. Finally, as noted above, to the extent that there are D codes that describe the same services as CPT codes, we urge CMS to allow dentists to bill the relevant D codes for consistency, coding accuracy and simplicity.

b. Location of Treatment.

CMS sought comments regarding its proposal to provide medically necessary dental services, regardless of whether the services are furnished in an inpatient or outpatient setting.[54] CDA strongly agrees with this proposal and recommends that CMS finalize its policy allowing

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[51] FAIR Health Consumer, Mission (2022).
[52] FAIR Health Consumer, Dental Services (2022).
[53] Medicare Economic Index Technical Advisory Panel, *Charter* (Accessed Aug. 8, 2022). As with the GPCI, we urge CMS to develop a dental-specific MEI for use in the future to better reflect dental cost changes.
[54] 87 Fed. Reg. 45,860 at 46,035-36.

for dental treatment to be appropriately provided by dentists and their teams in outpatient or inpatient facilities as necessary. 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. Furthermore, dentistry today is still primarily small private practices of fewer than 10 dental team members, and half of private practice dentists are the sole dentist in their dental office.[55] Treatments may also be provided in assisted living and private residences as needed and appropriate, usually by dentists who bring mobile dental equipment to the patient, setting up and taking down the surgical equipment for each location and patient. Dental offices are equipped more like surgical suites than a primary care physicians office, with significant surgical equipment, water lines, suction, sterilization and infection control such as personal protective equipment (PPE). Dentists directly employ members of the dental team, including hygienists, dental assistants and billing and scheduling staff. Thus, dental rates must be set in a way that acknowledges the full cost of dental care and services.

VI. Disease Conditions That Should Be Considered for Payment Under Section 1115A Waiver Authority.

In the Proposed Rule, CMS sought comment on additional ways to integrate the payment for dental and oral health care services within existing and future payment models using the Agency's section 1115A waiver authority.[56] As CMS knows, CMMI's waiver authority under section 1115A(d)(1) of the Social Security Act provides broad discretion to waive certain requirements set forth in the Medicare program.[57] We believe that quality could significantly be improved and costs could be saved on many procedures and treatments being provided to Medicare beneficiaries today if coverage and payment existed for even routine dental procedures.

As noted above, the mouth is part of the body, and oral health is an essential part of overall health. Oral health is not just the status of our teeth; it has broad implications for our physical and mental well-being. As the CDC notes:

> Oral health affects our ability to eat, speak, smile and show emotions. Oral health also affects a person's self-esteem, school performance and attendance at work or school. Oral diseases—which range from cavities and gum disease to oral cancer—cause pain and disability for millions of Americans and cost taxpayers billions of dollars each year.[58]

Despite significant improvements in oral health over many decades, these advances and improvements have not benefited or been available to all Americans. There are deep disparities

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[55] Health Policy Institute, American Dental Association, *The Dentist Workforce – Key Facts* (2021).
[56] 87 Fed. Reg. at 46,041.
[57] *Id.*
[58] Centers for Disease Control and Prevention, *Basics of Oral Health* (last reviewed Jan. 2021).

in access to dental care and oral health outcomes, much of which can be linked back to social determinates of health. A CMMI demonstration project would be an ideal way to demonstrate the improved care and cost savings that can be gained by the provision of dental services, particularly for disproportionately impacted populations.

CDA believes there are several disease conditions where consideration of inclusion under Section 1115 waiver authority is warranted. In particular, **Alzheimer's, dementia and cardiovascular disease** are prevalent in the aging population, are chronic, progressive and debilitating and require significant clinical resources. Research linking poor oral health to exacerbation of these conditions already exists and more is likely to emerge. Research also links poor oral health to increased risk of **non-ventilator hospital-acquired pneumonia (NV-HAP)** for individuals immobilized in hospitals or long-term care facilities, demonstrating that reducing the bacterial load in the mouths of these individuals significantly lowers the incidence of NV-HAP. Lastly, CDA urges CMS to consider providing periodontal and dental care to **diabetes** patients through a CMMI demonstration project, should the agency deem it necessary to gather more data and clinical evidence before providing coverage under the medically necessary standard. CDA proposes that CMS use this broad discretion to provide payment for dental and oral health services through a section 1115 demonstration project for the disease conditions below to identify the circumstances in which patients with the disease condition would see improved outcomes from their medically necessary medical or surgical treatments.

1) Alzheimer's disease (AD) and dementia.

Research on the association between periodontal pathogens and dementia is just beginning to emerge. For example, a 2020 study examined this association with incident all-cause and AD dementia as well as AD mortality among U.S. middle-aged and older adults. The study found that "among those ≥65 years, AD incidence and mortality were consistently associated with PPD (periodontal probing depth)."[59] The study concluded that while there is evidence for the association between periodontal pathogens and AD, especially in older adults, further study may be warranted to confirm the "effectiveness of periodontal pathogen treatment on reducing sequelae of neurodegeneration," leading CDA to urge CMMI to further study health outcomes and cost reduction for providing periodontal services to individuals considered at risk for developing AD.

2) Cardiovascular diseases.

[59] Beydoun MA, Beydoun HA, Hossain S, El-Hajj ZW, Weiss J, Zonderman AB, J Alzheimers Dis., (75(1):157-172, Clinical and Bacterial Markers of Periodontitis and Their Association with Incident All-Cause and Alzheimer's Disease Dementia in a Large National Survey (2020).

Multiple studies demonstrate an association between periodontal disease, cardiovascular diseases and stroke, an association based on the recognized burden inflammation places on the cardiovascular system.[60] There is also some evidence that periodontal treatment decreases risk factors that are proxies for cardiovascular disease, including reductions of C-reactive protein and blood pressure.[61] However, as cause and effect research for these conditions has not yet been robustly produced, CDA urges further study on health outcomes and cost savings through CMMI.

3) Non-ventilator hospital-acquired pneumonia, aka non-ventilator health-care-associated pneumonia (NV-HAP).

NV-HAP is a significant risk for non-ambulatory patients in long-term care and hospital facilities. According to the National Association of NV-HAP Prevention, "Hospital-Acquired Pneumonia (HAP) is the #1 hospital-acquired infection in the U.S. and 60% of HAP cases occur among non-ventilated patients."[62] Moreover, research shows that NV/HAP in hospitalized patients is a "serious patient safety issue, resulting in significant increases in cost, length of stay and mortality."[63]

Though NV-HAP is a dangerous and costly health condition, it is avoidable with proper care.[64] Centers for Disease Control and Prevention recommendations for pneumonia risk reduction include strategies to reduce oral pathogens, decrease aspiration of oropharyngeal pathogens into the lungs and support and strengthen the patient's own host defense mechanisms to the extent possible. The benefit of reducing the oral pathogen load in patients at risk for NV-HAP is further supported by a study of Medicaid enrollees that showed those who received preventive dental treatment in the 12 months prior, or periodontal therapy in the six months prior to a hospitalization, had a reduced risk for NV-HAP.[65]

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[60] Peruzzi M, Covi K, Saccucci M, Pingitore A, Saade W, Sciarra L, Cristalli MP, Miraldi F, Frati G, Cavarretta E, Minerva Cardiol Angiol. Current knowledge on the association between cardiovascular and periodontal disease: an umbrella review (2022).
[61] Zhou SY, Duan XQ, Hu R, Ouyang XY, Chin J Dent Res, 16(2):145-51, Effect of non-surgical periodontal therapy on serum levels of TNF-a, IL-6 and C-reactive protein in periodontitis subjects with stable coronary heart disease (2013).
[62] Veteran Affairs, VHA Innovation Ecosystems, National Organization of NV-HAP (NOHAP).
[63] Giuliano, Baker, Quinn. *American Journal of Infection Control*, Volume 46, issue 3, p. 322-7, The epidemiology of nonventilator hospital-acquired pneumonia in the United States (2018).
[64] Quinn B, Giuliano KK, Baker D., *American Journal of Infection Control,* Volume 48, Issue 5, Supplement, A23-A27, Non-ventilator health care-associated pneumonia (NV-HAP): Best practices for prevention of NV-HAP (May 1, 2020).
[65] Baker D, Giuliano KK, Thakkar-Samtani M, Scannapieco FA, Glick M, Restrepo MI, Heaton LJ, Frantsve-Hawley J., *Infect Control Hosp Epidemiol*: 1-3, The association between accessing dental services and nonventilator hospital-acquired pneumonia among 2019 Medicaid beneficiaries (2022).

CDA believes that a CMMI demonstration project whereby Medicare provides regular dental hygiene care for non-ambulatory, at-risk hospitalized patients would allow Medicare to quantify fewer NV-HAP incidents and the associated, significant savings.

4) Diabetes.

As discussed *supra,* Section III. c. iii., there is clear clinical evidence to support the conclusion that providing periodontal care is medically necessary for the treatment and management of diabetes. If, however, the Agency deems it necessary to gather more data and clinical evidence before providing coverage under the medically necessary standard, perhaps to more precisely identify the subset of patients with diabetes who would see improved outcomes, then CDA strongly urges CMS to develop a CMMI demonstration project for this purpose.

CDA is excited by the opportunities afforded by the Section 1115A Waiver Authority to demonstrate further reductions in disease and increase health equity with the provision of essential dental services. We look forward to working with CMMI to develop appropriate projects to test and support CMS' inclusion of dental services in future rule-making processes.

VII. Conclusion.

In closing, we restate a most fundamental and important truth: The mouth cannot be separated from body. Dental disease has consequences beyond the oral cavity, impacting the body's organs, systems and overall health. Thus, CDA believes there is significant opportunity for Medicare to improve patient health outcomes, increase health equity and realize significant cost savings by expanding its medically necessary dental coverage to the conditions and situations described above.

We appreciate your consideration of our comments and the Agency's willingness to add in regulation medically necessary dental procedures and services that should be covered by the Medicare program. Please contact Brianna Pittman-Spencer at brianna.pittman@cda.org if you have any questions about the above comments or if we can provide any further information.

Sincerely,

Dr. Ariane Terlet
CDA President

Peter DuBois
CDA Executive Director

Appendix A: CDA MEDICARE D CODE REFERENCE TABLE

CDA has identified CDT codes (D codes) that describe the recommended medically necessary dental services. CDA urges CMS to review the D codes and assign, as appropriate, the R status indicator to ensure that the appropriate codes are billable to Medicare in medically necessary situations. Many of the codes already have an R status indicator and we urge CMS to modify the status indicator of the additional D codes which will qualify for coverage under the Final Rule from an I or N to an R status indicator, so that appropriate payment can be made subject to MAC determinations and contractor pricing.

EXAMINATION CODES	
D0120	Periodic exam
D0140	Limited/problem focused
D0150	Comprehensive
D0160	Detailed and extensive/problem focused
D0170	Re-evaluation of a limited/problem focused condition that did not receive treatment
D0171	Re-evaluation – post operative visit
D0180	Comprehensive periodontal evaluation (new or established patient)

DIAGNOSTIC CODES	
D0431	Adjunctive, pre-diagnostic test that aids in detection of mucosal abnormalities, including premalignant and malignant lesion (not cytology or biopsy)
D0460	Pulp vitality
D0472	Accession of tissue, gross examination, preparation and transmission of written report
D0474	Accession of tissue, gross and microscopic examination, including assessment of surgical margins for presence of disease, preparation and transmission of written report
D0480	Accession of exfoliative cytologic smears, microscopic evaluation, written report preparation and transmission
D0486	Lab accession of transepithelial cytologic sample, microscopic examination, report preparation and transmission
D0999	Unspecified diagnostic procedure, by report

IMAGING	
D0210	Full mouth series
D0220	Single periapical film

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D0230	Additional periapical films
D0270 - D0274	1- 4 bitewing films
D0277	Vertical bitewing films
D0330	Panoramic film
D0364-D0371	Cone Beam CT captures with interpretation
D0380-D0384	Cone Beam CT image not associated with interpretation
D0385	Maxillofacial MRI image capture
D0386	Maxillofacial ultrasound image capture
D0391	Interpretation of diagnostic image by a practitioner not associated with capture of the image, including report

EMERGENCY/EXTRACTIONS/ORAL SURGERY/OTHER	
D9110	Palliative
D3220	Therapeutic pulpotomy
D7140	Extraction, erupted tooth or exposed root
D7210	Extraction, erupted tooth requiring bone removal, sectioning of tooth, including mucoperiosteal flap elevation
D7250	Extraction of residual tooth roots, including soft and hard tissue removal and closure
D7251	Coronectomy
D7220	Extraction, impacted tooth, soft tissue
D7230	Extraction, impacted tooth, partial bony
D7240	Extraction, impacted tooth, complete bony
D7510	Abscess, incision and drain, intraoral soft tissue
D7511	Abscess, incision and drain, intraoral soft tissue complicated (incision through skin)
D7520	Abscess, incision and drain, extraoral soft tissue
D7521	Abscess, incision and drain, intraoral soft tissue complicated (drainage of multiple fascial spaces)
D3310-D3330 & D3921	Endodontic procedures for anterior and posterior teeth followed by decoronation (used when full tooth extraction poses a risk to bone healing/tissue health)
D7950	Mandible/maxillary bone graft
D7953	Bone graft
D4266 & D4267	Resorbable and non-resorbable barriers
D7440 & D7441	Removal of malignant tumors

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D7450, D7451, D7460 & D7461	Removal of benign cysts or tumors
D7610 to D7740	Fracture repair, including wiring/immobilization of teeth
D7880	Occlusal orthotic device (used for TMD)
D4322 & D4323	Intra and extra coronal splints that link teeth together to provide stabilization and strength
D5986	Fluoride gel carrier
D5988	Surgical splint

PERIODONTAL CARE AND DISEASE PREVENTION	
D1110	Prophylaxis
D4341 & D4342	Scaling and root planning procedures
D4910	Periodontal maintenance
D4355	Full mouth debridement
D4999	Unspecified periodontal procedure, by report
D1354	Silver diamide fluoride (to prevent dental caries from progressing to oral foci of infection)
D1206 & D1208	Topical fluoride applications (in office procedure)
D5986	Fluoride gel carrier (for at home fluoride therapy)
D1330	Oral health instruction

FILLINGS	
D2140 to D2161	Amalgam fillings, 1-4 or more surfaces
D2330 to D2335	Resin based composite fillings, anterior teeth, 1-4 or more surfaces
D2391 to D2394	Resin based composite fillings, posterior teeth, 1-4 or more surfaces