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Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services (HHS)
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Docket: CMS-1770-P

On behalf of our 40,000 members, the Academy of General Dentistry (AGD) is pleased to offer comments on the Medicare physician fee schedule proposals and request for information on Medicare Parts A and B payment for dental services [p. 46033].¹ AGD dentists provide a full range of dental care to patients across all demographic and socio-economic segments throughout the country. The AGD's feedback is focused on the CMS' proposals on "medically necessary" oral health provisions included in the proposed rule.

Our representative republic is designed around a tripartite structure whereby the CMS and HHS are part of the Executive branch. As such, the Agency (CMS) is charged with administering and enforcing legislation drafted by Congress and signed into law by the President.

The AGD is aware of various legislative proposals to either 1) create a "Medicare for All" health care system or 2) add dental Medicare benefits to Medicare Part B, or physician payments. To date, Congress has not passed legislation that enacts either of these proposals. Additionally, the AGD is not aware of any new federal law relating to dental benefits that would expand the CMS' authority. If we are in error, please contact our representatives as soon as possible.

The AGD is also aware of efforts to increase the "medically necessary" provisions by "interested parties" which include Members of Congress.² A letter from Senate Democrats³ was sent to CMS on June 21, 2022, and from House Democrats on June 29, 2022.⁴ The letters "urge[d]" for an expansion of the interpretation of medically necessary dental provisions and that CMS should use existing regulatory authority for such an expansion. We are also aware of extensive advocacy efforts on behalf of dental and medical groups to do the same.

As there is no new law that would expand CMS' authority regarding medically necessary dental provisions, it is inappropriate for the Agency to seek to create an end around congressional actions in the situation where the Congress finds it challenging to pass a new law. Additionally, the Agency risks its

¹ Federal Register/Vol. 87, No. 145/Friday, July 29, 2022/Proposed Rules
<https://www.govinfo.gov/content/pkg/FR-2022-07-29/pdf/2022-14562.pdf>

² [Public Statement on Medicare Coverage of Medically Necessary Oral and Dental Health Therapies - Santa Fe Group](#)

³ [Letter-to-CMS-on-Medically-Necessary-Dental-Coverage.pdf \(senate.gov\)](#)

⁴ [Expand Medically Necessary Dental Coverage.pdf \(house.gov\)](#)

credibility if it is perceived as responding to the preferences of a single political party with new federal regulations that will impact all Americans.

Science Based Regulations

U.S. federal health policy must be based on science that is verifiable and reproducible. Studies and assessments should incorporate peer review by non-conflicted clinicians, statisticians, and epidemiologists. Evidence must be of high quality and data must be unassailable and determinative.

Information released by the Agency should be aligned with accepted best practices, which call for the Agency to annotate the data, journal articles, consensus conferences, meta-data analysis, Cochrane reviews etc. for all of its proposals. In the proposed rule, there are few sources of annotated scientific justification. One instance in which best practices were grossly overlooked is footnote number 79: this non-functional link is intended to take readers to the *AAOS Now* 2011 publication. *AAOS Now* is a member publication of the American Academy of Orthopaedic Surgeons (AAOS) that presents an overview of news stories in the popular press. Publications that aggregate recent industry news stories are insufficient to, and not intended to, be cited as references in a federal proposed regulation, while beneficial to their specific readers, these types of publications rate very low on the hierarchical scale of good quality evidence.

Moreover, it is wholly insufficient to base federal health policy and change regulations based on belief systems. In the proposed rule, CMS continually uses the phrase "we believe" when referring to proposed health policy. The federal government must demonstrate the scientific basis for declaring medical necessity for dental indications and it has not yet done so.

Since the 2020 COVID-19 public health emergency declaration, much of public policy was based on belief systems of public health officials including lockdowns,⁵ use of masks,⁶ 6-foot social distancing rule,⁷ use of plexiglass barriers,⁸ COVID-19 vaccine's ability to prevent disease or preclude transmission, amongst other measures. Those belief systems were not based in science and proved to be incorrect and caused great harm to people in America, particularly to children.

Federal agencies must become worthy and much better stewards of the limited public funds allocated to them. Our nation's resources are limited, particularly during times of high inflation, and we cannot continue to borrow our way to prosperity.

CMS Proposal on Expanding Medically Necessary Dental Applications

"P. 46037 In summary, we are proposing to amend § 411.15(i) to codify that payment can be made under Medicare Part A and Part B for dental services that are inextricably linked to, and substantially

⁵ Herby, J, Jonung, L, Hanke, SH. A literature review and meta-analysis of the effects of lockdowns on COVID-19 mortality. Johns Hopkins University, January 2022. [A-Literature-Review-and-Meta-Analysis-of-the-Effects-of-Lockdowns-on-COVID-19-Mortality.pdf \(jhu.edu\)](#)

⁶ Swiss Policy Research. Are Face Masks Effective? The Evidence. [Are Face Masks Effective? The Evidence. - Swiss Policy Research \(swprs.org\)](#)

⁷ Massetti, GM, et.al. [Summary of Guidance for Minimizing the Impact of COVID-19 on Individual Persons, Communities, and Health Care Systems — United States, August 2022 | MMWR \(cdc.gov\)](#) Centers for Disease Control and Prevention. August 11, 2022.

⁸ Cadnum, JL, et.al. Do Plexiglass barriers reduce the risk for transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). *Infect Control Hosp Epidemiol.* 2021 Nov 2; 1-4. [Do plexiglass barriers reduce the risk for transmission of severe acute respiratory syndrome coronavirus 2 \(SARS-CoV-2\)? - PubMed \(nih.gov\)](#)

related and integral to the clinical success of, an otherwise covered medical service. We further propose to amend § 411.15(i) to include examples of services for which payment can be made under Medicare Parts A and B on that basis. Specifically, we propose to include as examples the following dental services for which payment is permitted under our current policy:

- “(1) dental or oral examination as part of a comprehensive workup prior to a renal organ transplant surgery (such as services described by ICD–10 Z94.0, and codes D0150, D0180, or D0160);*
- “(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 (such as services described by CPT code sets 21440–21490);*
- “(4) extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease (such as services described by Current Dental Terminology (CDT) 77 codes D7140 and D7210 for ICD–10 C41.1 Malignant neoplasm of mandible); and*
- “(5) dental splints only when used in conjunction with medically necessary treatment of a medical condition.”*

AGD opposes the inclusion and codification of the above language in the final rule as the text is overly broad and not specific enough to differentiate appropriate application to the rule.

Site Location Neutrality

“P. 46036...regardless of where the service is performed, noting that the hospitalization or non-hospitalization of a patient has no direct bearing on the coverage, payment, or exclusion of a given dental procedure in specific circumstances.”

The AGD agrees that site location neutrality is appropriate, and that dental care can be provided at a variety of locations.

Organ Transplant, Cardiac Valve Replacement, Valvuloplasty, Joint Replacement

“P. 46038 ... We seek comment on this proposed policy and our proposed amendments to § 411.15(i)(3) to specify that payment under Medicare Parts A and B can be made for an oral or dental examination, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection, prior to an organ transplant, cardiac valve replacement, or valvuloplasty procedure.

“Similarly, in joint replacement surgery (such as total hip and knee arthroplasty surgery) we believe there may be risks to the outcome of the procedure if an oral infection is not treated. There is evidence that some joint replacement patients have significant dental pathology found before their surgery.⁹ Given the incidence of dental pathology in joint replacement patients, there may be some joint replacement patients who would experience a clinically significant benefit from a pre-operative dental exam and medically necessary treatment of oral pathology(ies). As in transplant surgery, patients having joint replacement surgery are at risk for surgical site infection, and there may be an increased risk for those patients with significant dental pathology. The presence of an overlooked oral infection may increase the risk for acute and chronic surgical site infection. ... We acknowledge there is other clinical evidence that does not support the need for a dental exam and necessary treatment prior to total joint replacement surgery, specifically total hip and knee arthroplasty...”

⁹ Reference 79 in the proposed rule: <https://aaos.org/aaosnow/2011/feb/clinical/clinical2/>.

AGD maintains that the CMS has provided insufficient scientific justification for the above indications to be included in the final rule. Furthermore, AGD members, the American Dental Association, and other dental community members have engaged with the AAOS previously on a consensus statement for the prophylaxis of antibiotics prior to joint replacement surgery. Assessing the relevant data, grading the evidence, and determining the appropriate use criteria is a time consuming and labor-intensive endeavor. The last determination was that the data were inconclusive for the need of antibiotics prior to joint replacement surgery.

In Closing

The AGD thanks the CMS for consideration of our comments on the CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies. We look forward to the opportunity to work with CMS officials throughout the year so there is adequate time to assess all upcoming proposals. Please contact Daniel J. Buksa, JD, CAE, Associate Executive Director, Public Affairs, by phone at (312) 440-4328 or via email at daniel.buksa@agd.org if you have questions or would like to discuss our comments in greater detail.

Sincerely,



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