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American Association of Oral and Maxillofacial Surgeons

9700 W. Bryn Mawr Ave.
Rosemont, IL 60018-5701

847-678-6200
800-822-6637
fax 847-678-6286

AAOMS.org

Mark A. Egbert, DDS, FACS
President

Karin Wittich, CAE
Executive Director

September 04, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1807-P
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted online via www.regulations.gov

Re: File Code CMS-1807-P Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies Proposed Rule

Dear Administrator Brooks-LaSure:

The American Association of Oral and Maxillofacial Surgeons (AAOMS) represents more than 9,000 oral and maxillofacial surgeons (OMSs) in the United States. We appreciate the opportunity to comment on the 2025 Medicare Physician Fee Schedule (MPFS) proposed rule.

AAOMS commends CMS on efforts to improve access to high-quality and affordable healthcare, specifically, the proposals aimed at ensuring Medicare beneficiaries have access to medically necessary and essential dental services. We also appreciate CMS's acknowledgement and consideration of our association's comments and recommendations. We are grateful for the opportunity to contribute to this ongoing dialogue and look forward to continuing our collaborative efforts to enhance the quality and effectiveness of healthcare delivery.

In response to the proposed 2025 revisions, as published in the July 31, 2024, *Federal Register* (Vol. 89, No. 147, pages 61596-62648), we offer the following comments and recommendations for CMS's consideration.

CY 2025 Medicare Physician Fee Schedule rate setting and conversion factor

Medicare providers stand to face another round of significant payment cuts beginning January 1, 2025. In the proposed rule, CMS estimates a CY 2025 conversion factor — the basic starting point for calculating Medicare payments — of $32.3562, representing a 2.8 percent decrease from CY 2024.

The Medicare payment system has been devalued through recurring and drastic payment cuts year after year, undermining the financial stability of many healthcare practices. CMS's proposal fails to account for the economic pressures that have substantially increased operational costs for healthcare providers. Systemic issues of the Medicare payment system, such as the negative impact of budget neutrality

requirements and the lack of an annual inflationary update will continue to generate significant instability for clinicians moving forward, threatening beneficiary access to essential healthcare services.

While AAOMS actively addresses these issues through support of legislation to address inflationary adjustments and budget neutrality, CMS may also have the opportunity to address this matter through its rulemaking process. Specifically, the American Medical Association notes that "it is not uncommon for CMS to overestimate utilization in its budget neutrality estimates," and that once "redistributions are made through the conversion factor, they are not added back, even when utilization is lower than expected."[1] While proposed legislation includes a call for retrospective review to inform future adjustments, we would ask CMS to also act within its regulatory authority to reduce or eliminate proposed 2025 payment cuts through a more conservative outlook on utilization.

AAOMS urges CMS and HHS to reconsider the proposed payment cuts and collaborate with Congress to fundamentally reform the Medicare payment system to ensure reimbursement stability for Medicare providers moving forward.

Proposals and request for information on Medicare Parts A and B payment for dental services

Dental services linked to Medicare-covered dialysis treatment services for individuals with end-stage renal disease (ESRD)

AAOMS supports efforts to expand Medicare coverage for certain oral and maxillofacial surgery services[2] that the association considers to be "medically necessary" or "essential" because they are integral in the management of certain acute conditions especially for medically compromised patients, without being cost prohibitive in implementation. We believe such services include the evaluation and definitive treatment of infections of the head and neck prior to, or concurrently with, dialysis services necessary for treatment of ESRD.

This proposal aligns with CMS's longstanding policy of covering treatments related to ESRD, including dialysis services and kidney transplant surgeries. Further, CMS has recently expanded coverage to include dental services required to eliminate oral or dental infections related to organ transplants, including kidney transplant procedures, which may also impact individuals with ESRD.

Given the critical role of dialysis in managing ESRD and the importance of oral health in these patients, expanding coverage for dental services linked to dialysis is a logical progression. This coverage expansion, if finalized, may help ensure that individuals with ESRD have access to necessary dental services, ultimately improving their overall treatment outcomes.

AAOMS supports CMS's proposal to expand Medicare coverage and payment — in inpatient and outpatient settings —for dental examinations prior to, as well as diagnostic and treatment services to eliminate oral or dental infections prior to or at the same time as, Medicare-covered dialysis services when used in the treatment of ESRD.

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[1] American Medical Association. (2024). Medicare physician payment adequacy: Budget neutrality. https://www.ama-assn.org/system/files/medicare-basics-budget-neutrality.pdf. Accessed August 16, 2024.
[2] American Association of Oral and Maxillofacial Surgeons. (2024). Essentials of Oral and Maxillofacial Surgery Services. https://www.aaoms.org/docs/govt_affairs/advocacy_white_papers/essentials_oms.pdf. Accessed August 2, 2024.

Consistent with the policy changes finalized in the CY 2023 Medicare Physician Fee Schedule final rule,[3] **AAOMS also supports Medicare payment for services that are ancillary to, or provided in conjunction with, covered dental services such as X-rays, administration of anesthesia, use of an operating room and other facility services in relation to treatment of individuals with ESRD.** We continue to believe such services represent necessary diagnostic, clinical and procedural considerations that must be determined by the surgeon on a case-by-case basis.

Request for comment on the potential connection between dental services and covered services used in the treatment of diabetes

Diabetes is a prevalent condition that significantly impacts oral health. According to the American Diabetes Association's Standards of Care in Diabetes (2024), patients with diabetes are at a higher risk of developing periodontal disease, which can exacerbate the management of diabetes itself. The association between periodontal disease and poor glycemic control is well-documented. [4]

The consensus report by Sanz et al.[5] outlines the essential role of oral health professionals in the management of diabetes. It emphasizes that managing periodontal disease can lead to improved glycemic control and highlights the importance of regular periodontal evaluations and treatments as part of a comprehensive diabetes care plan. [4] These guidelines underscore the need for collaboration between medical and dental professionals to optimize care for diabetic patients.

On the other hand, a significant percentage of the American population – 11.6% of the total population and 26% of Medicare fee-for-service (FFS) enrollees - has diabetes.[6] Moreover, while dental diseases commonly accompany most stages of diabetes, they are not typically debilitating until end-stage disease. It is at that point that treating significant dental infections may become essential, as seen with ESRD and immunosuppressive therapies. Accordingly, a widespread expansion of coverage for medically necessary dental services associated with the treatment of diabetes may ultimately stifle payment and disincentivize care for more essential services through Part B, especially with budget neutrality at play.

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[3] Centers for Medicare & Medicaid Services, Health and Human Services. (2022, November 18). Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies Final Rule. https://www.federalregister.gov/documents/2022/11/18/2022-23873/medicare-and-medicaid-programs-cy-2023-payment-policies-under-the-physician-fee-schedule-and-other

[4] American Diabetes Association. (2024). Standards of medical care in diabetes—2024. Diabetes Care, 47(Suppl 1). https://doi.org/10.2337/dc24-SINT

[5] Sanz, M., Ceriello, A., Buysschaert, M., Chapple, I., Demmer, R. T., Graziani, F., Herrera, D., Jepsen, S., Lione, L., Madianos, P., Mathur, M., Montanya, E., Shapira, L., Tonetti, M., & Vegh, D. (2018). Scientific evidence on the links between periodontal diseases and diabetes: Consensus report and guidelines of the joint workshop on periodontal diseases and diabetes by the International diabetes Federation and the European Federation of Periodontology. *Diabetes research and clinical practice*, *137*, 231–241. https://doi.org/10.1016/j.diabres.2017.12.001

[6] Centers for Medicare & Medicare Services. (April 2024). Data Snapshot: Diabetes Disparities in Medicare Fee-For-Service Enrollees. https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Snapshots-Diabetes.pdf. Accessed August 16, 2024.

Request for comment on the potential connection between dental services and covered services for individuals with autoimmune diseases receiving immunosuppressive therapy

Patients undergoing immunosuppressive therapy are particularly vulnerable to oral infections due to their compromised immune systems. The oral cavity can harbor pathogens that may lead to systemic infections, which are especially dangerous for immunocompromised individuals. These patients are at an elevated risk for chronic infections to escalate into acute, life-threatening conditions. Comprehensive dental evaluations and treatments both prior to and during immunosuppressive therapy are essential in managing and preventing these complications.

Oral health is inextricably linked to systemic health, with periodontal disease being associated with a wide range of systemic conditions including diabetes, cardiovascular disease and rheumatoid arthritis.[7,8] Immunosuppressive therapies, used to treat conditions such as autoimmune diseases and certain cancers, often exacerbate oral health problems. These treatments can lead to significant oral and dental complications including, but not limited to, mucositis, xerostomia (dry mouth), increased risk of oral infections, periodontal disease and oral cancers.[7,8,9]

Such complications are observed in patients undergoing chemotherapy, radiation, hematopoietic stem cell transplantation and those treated for autoimmune diseases with drugs like corticosteroids and methotrexate.[10]This suggests that immunosuppressive therapies lead can lead to similar oral health issues, regardless of the underlying condition being treated.

Research published in *Frontiers in Physiology* suggests that periodontal disease and oral infections can act as focal points for systemic infections due to the intricate connection between oral and systemic health. According to Martinez-Garcia and Hernandez-Lemus,[11] periodontal disease promotes systemic inflammation through the release of inflammatory mediators into the bloodstream and the direct invasion of pathogens.[11] Locally produced pro-inflammatory mediators can enter systemic circulation, disrupting the inflammatory balance in distant organs.[11] Patients with periodontitis often exhibit elevated levels of systemic inflammatory markers, such as white blood cells and C-reactive protein, compared to healthy individuals.[11] Additionally, oral microbial dysbiosis can induce systemic inflammation either by releasing toxins or by transporting microbial products into the bloodstream.[11]

Oral and dental complications of immunosuppressive therapy can severely impact a patient's quality of life and the efficacy of their treatment. Dental infections also can significantly impact their ability to maintain adequate nutrition through proper masticatory function. Optimizing dental health is crucial for

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[7] Kapila, Y.L. (2021). Oral health's inextricable connection to systemic health: Special populations bring to bear multimodal relationships and factors connecting periodontal disease to systemic diseases and conditions. *Periodontology 2000*, 87(1).11-16. https://doi.org/10.1111/prd.12398

[8] Sedghi, L., DiMassa, V., Harrington, A., Lynch, S.V., & Kapila, Y.L. (2021). The oral microbiome: Role of key organisms and complex networks in oral health and disease. *Periodontology 2000*, 87(1). 107-131. https://doi.org/10.1111/prd.12393

[9] Kissell, D. (2022). Oral health effects of immunosuppressive medications. *Decisions in Dentistry, 8*(1). 32-35. https://decisionsindentistry.com/article/oral-health-effects-immunosuppressive-medications/

[10] Bourgoin, A., Agossa, K., Seror, R., Fumery, M., Radoi, L., & Gosset, M. (2023). Management of dental care of patients on immunosuppressive drugs for chronic immune-related inflammatory diseases: a survey of French dentists' practices. *BMC Oral Health.* 23(545). https://doi.org/10.1186/s12903-023-03258-7

[11] Martinez-Garcia, M., & Hernandez-Lemus, E. (2021). Periodontal inflammation and systemic diseases: An overview. *Front. Physiol,12*:709438. https://doi.org/10.3389/fphys.2021.709438

ensuring these patients can maintain healthy oral intake, which is vital for their overall health and recovery.

Given that CMS currently covers dental services linked to select immunosuppressive therapies — for example, chemotherapy and radiation for treatment of cancer, as well as organ transplant procedures — it seems appropriate to extend this coverage to include patients undergoing immunosuppressive therapy for additional medical conditions. The similar oral health risks faced by these patients may justify the need for broader coverage to manage and prevent severe oral or dental complications.

Request for comment on the potential connection between dental services and covered services used in the treatment of certain blood disorders

Sickle cell disease

Patients within the Medicare population with sickle cell disease (SCD) represent a particularly vulnerable group, with significant healthcare needs due to the complex nature of their condition. SCD, an inherited blood disorder primarily affecting individuals of African descent, leads to chronic complications such as pain crises, organ damage and an increased risk of infections.[12] Comorbid conditions such as chronic kidney disease, heart failure and depression further complicate their care. [12,13] Individuals with SCD are also at risk for oral health complications, including infections that could trigger a sickle cell crisis, particularly in those who are immunocompromised.[13]

Individuals with SCD often experience higher rates of emergency department visits and hospitalizations, with an estimated annual cost of $2.4 billion, reflecting the significant healthcare burden associated with managing SCD.[13] According to the 2023 CMS Sickle Cell Disease Action Plan, approximately half of individuals with SCD are enrolled in Medicaid, while 11 percent are enrolled in Medicare, often as dually eligible beneficiaries, highlighting the substantial burden of disease within these programs.[13] Furthermore, research indicates that SCD patients who are enrolled in both Medicare and Medicaid experience worse survival outcomes compared to those with single coverage.[12]

CMS's research highlights the importance of comprehensive care, including dental services, in managing SCD and preventing complications like infections that could trigger a sickle cell crisis. While CMS highlights the potential benefits of maintaining oral health for better outcomes, the broader impact of expanded dental benefits remains an area for further research. This reflects the complex relationship between dental health and overall care, suggesting that more exploration is needed without endorsing specific policy changes.

Hemophilia

Patients within the Medicare population who have inherited bleeding disorders, such as hemophilia, also represent a particularly vulnerable group. Hemophilia, which primarily affects males due to its X-linked recessive inheritance, has become more prevalent among older individuals as advancements in medical

[12] Jiao, B., Johnson, K. M., Ramsey, S. D., Bender, M. A., Devine, B., & Basu, A. (2023). Long-term survival with sickle cell disease: A nationwide cohort study of Medicare and Medicaid beneficiaries. *Blood advances*, *7*(13), 3276–3283. https://doi.org/10.1182/bloodadvances.2022009202

[13] Centers for Medicare & Medicaid Services. (September 2023). CMS Sickle Cell Disease Action Plan. https://www.cms.gov/files/document/sickle-cell-disease-action-plan.pdf. Accessed August 16, 2024.

care have extended their life expectancy.[14] These patients, now living longer, often face multiple comorbidities such as hepatitis C,[14] HIV,[14] hypertension,[15] and diabetes,[15] which can further complicate their overall health management. Within the Medicare population, the need for careful dental management is heightened due to the increased risk of bleeding during and after dental procedures, especially in those with severe hemophilia.[16]

While hemophilia is rare, managing severe hemophilia A presents a significant economic burden, with annual treatment costs ranging from approximately $600,000 to over $900,000 depending on the type of prophylactic therapy used.[17] Despite the high costs associated with managing hemophilia, a research review by the Agency for Healthcare Research and Quality (AHRQ) suggests that primary research studies and systematic reviews evaluating the effect of dental care on hemophilia treatment outcomes are lacking.[18] According to AHRQ,[18] current evidence does not provide clear data on whether dental care before, during, or after hemophilia treatment improves overall clinical outcomes.

Therefore, while dental care is essential for managing complications associated with hemophilia, particularly the prevention of bleeding complications, current evidence may not be sufficient to support expanding Medicare coverage beyond the existing provisions. The focus remains on preventing bleeding complications rather than enhancing hemophilia treatment outcomes through dental interventions.

Request for comment on potential sources of payment information for pricing of inextricably linked dental services

FAIR Health and its cost data continue to serve as a potential source for pricing dental services inextricably linked to covered medical services. According to a July 2024 press release, FAIR Health maintains a comprehensive repository of Medicare fee-for-service data, with claim records dating from 2013 to the present[19]. While we cannot confirm that this repository currently includes comprehensive information on dental services claims paid under traditional Medicare, it may hold promise as a future pricing resource under Medicare fee-for-service as more data are aggregated.

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[14] Khleif, A.A., Rodriguez, N., Brown, D., & Escobar, M.A., (2011). Multiple comorbid conditions amount middle-aged and elderly hemophilia patients: Prevalence estimates and implications for future care, *Journal of Aging Research*, 1. https://doi.org/10.4061/2011/985703

[15] Curtis, R., Manco-Johnson, M., Konkle, B. A., Kulkarni, R., Wu, J., Baker, J. R., Ullman, M., Tran, D. Q., Jr, & Nichol, M. B. (2022). Comorbidities, Health-Related Quality of Life, Health-care Utilization in Older Persons with Hemophilia-Hematology Utilization Group Study Part VII (HUGS VII). *Journal of blood medicine*,*13*. 229–241. https://doi.org/10.2147/JBM.S354526

[16] Abed, H., & Ainousa, A. (2017). Dental management of patients with inherited bleeding disorders: A multidisciplinary approach. *General dentistry*, *65*(6), 56–60.

[17] Recht, M., He, C., Chen, E., Cheng, D., Solari, P., & Hinds, D. (2022). Resource utilization and treatment costs of patients with severe hemophilia A: Real-world data from the ATHNdataset. *EJHaem*, *3*(2), 341–352. https://doi.org/10.1002/jha2.412

[18] Agency for Healthcare Research and Quality. (May 2024). Dental Care for People with Hemophilia: A Rapid Response Literature Review. https://effectivehealthcare.ahrq.gov/sites/default/files/related_files/hemophilia-dental-rapid-response.pdf. Accessed August 16, 2024.

[19] FAIR Health. (18 July 2024). FAIR Health commercial data repository surpasses 47 billion claim records. https://www.fairhealth.org/article/fair-health-commercial-data-repository-surpasses-47-billion-claim-records. Accessed August 5, 2024.

Further, FAIR Health's private claims database includes Medicare Advantage (MA) data[20]. As many MA plans frequently offer supplemental benefits, including dental coverage, such data may serve as a valuable proxy for determining dental services pricing under traditional Medicare, offering a robust foundation for establishing consistent pricing for Medicare-covered dental services. Using FAIR Health's extensive data repository ensures a more informed and evidence-based approach to pricing dental services linked to covered Medicare services.

Response to CMS Request for Information on oral appliances used for the treatment of obstructive sleep apnea (OSA)

In response to CMS's Request for Information on the classification and coverage of oral appliances used for the treatment of OSA, AAOMS provides the following insights:

Durable Medical Equipment (DME) classification

According to the proposed rule, CMS is not aware of any oral appliances used to treat OSA, regardless of their mechanics or whether custom fabricated or prefabricated, that can withstand repeated use. AAOMS agrees. Oral appliances for the treatment of OSA are patient-specific devices. Unlike splints or wheelchairs, these appliances are typically designed for individual patients, similar to custom-made orthotics or other types of patient-specific devices. These oral appliances are not designed or intended for repeated use by successive patients.

To meet the statutory definition of DME, as outlined in § 414.202 of CMS regulations, equipment must satisfy several conditions, including the ability to withstand repeated use and having an expected life of at least three years. Oral appliances for OSA do not meet these criteria as theyare custom-fitted for individual patients. Furthermore, these devices often require periodic adjustments and replacements due to wear, indicating they do not have the durability expected of DME. Additionally, while these appliances do serve a medical purpose and are used in the home, their patient-specific nature and the need for regular maintenance and replacement disqualify them from being classified as DME. Therefore, we believe the rules governing DME should not apply to these appliances.

Incident-to payment policy rules

According to § 410.26, services and supplies furnished incident to a physician's professional services must be integral, although incidental, to the physician's services and generally provided under a physician's direct supervision. However, sleep apnea-related services provided by dentists and dental specialists in the office setting should not be considered under incident-to payment guidelines.

The clinical nature of sleep apnea-related services, including the customization and management of oral appliances, differs significantly from the auxiliary and supportive services typically provided under incident-to provisions. The design, analysis, fitting and adjustment of sleep apnea appliances involve significant work by the dentist or dental specialist. This process often requires diagnostic casts or study models for the dental provider’s analysis and design, followed by the fabrication, delivery and adjustment of the appliance. Further, the materials used in sleep apnea appliances can wear over time,

[20] FAIR Health. (2024). FAIR Health Research: De-identified, aggregated datasets. https://www.fairhealth.org/who-we-serve/research. Accessed August 5, 2024.

necessitating adjustments and replacements. These ongoing maintenance services should not be subject to a one-time fee, as they involve continuous care and expertise from dental professionals.

Effective management of sleep apnea often involves a multidisciplinary approach, where dental specialists collaborate with physicians but operate independently within their scope of practice. Categorizing their services under incident to payment guidelines may undermine this collaborative, yet distinct, care model.

As such, sleep apnea-related services provided by dentists and dental specialists in the office setting should be recognized as independent services rather than falling under incident-to payment guidelines. This approach better reflects their specialized expertise, direct patient care and distinct clinical role in managing sleep apnea.

Applicability of Current Dental Terminology (CDT®)[21]codes to report sleep apnea services

Dentists and dental surgical specialists play an increasingly pivotal role in the detection, referral and treatment of patients with OSA. The Current Dental Terminology (CDT®) codes D9947 through D9957 encompass a comprehensive range of sleep apnea-related services, including the fabrication of oral appliances. Accordingly, CDT® codes are appropriate for accurately reporting sleep apnea appliances and associated services to both dental and medical insurance carriers.

Merit-based Incentive Payment System (MIPS) reform

The Merit-Based Incentive Payment System (MIPS) is in urgent need of reform, as its current structure imposes significant administrative burdens on physicians without leading to demonstrable improvements in patient outcomes or quality of care. Small practices, as well as those in rural and underserved areas are disproportionately penalized under this program. Dentists face unique challenges, as many dental EHRs are non-compliant with MIPS requirements. As a result, eligible dental providers may often choose to take the penalty rather than attempt to comply with the burdensome program requirements, further exacerbating their financial strain.

Moreover, the historically low incentive payments have proven ineffective in offsetting the reductions necessitated by budget neutrality, making the program even less viable for providers. **AAOMS urges CMS to recognize these issues and pursue significant reforms to make MIPS more equitable and less burdensome for all healthcare providers.**

[21] CDT© is a registered trademark of the American Dental Association.

Thank you for your consideration of these comments. Please contact Patricia Serpico, AAOMS Director of Health Policy, Quality and Reimbursement, with any questions at 800-822-6637, ext. 4394 or pserpico@aaoms.org.

Sincerely,

Mark A. Egbert, DDS, FACS
AAOMS President

Adam S. Pitts, DDS, MD, FACS
Chair, AAOMS Committee on Healthcare Policy, Coding & Reimbursement