

September 6, 2022

The Honorable Chiquita Brooks-LaSure, Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Attention: CMS-1770-P  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Submitted via [regulations.gov](https://www.regulations.gov)

**Re: CMS-1770-P: Medicare and Medicaid Programs; CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts**

Dear Administrator Brooks-LaSure:

### **I. Introduction/Overview**

The Center for Medicare Advocacy (the Center) is a national, non-profit law organization that works to ensure access to Medicare, health equity, and quality healthcare. The organization provides education, legal assistance, research and analysis on behalf of older people and people with disabilities, particularly those with long-term conditions. The Center's policy positions are based on its experience assisting thousands of individuals and their families with Medicare coverage and appeal issues. Additionally, the Center provides individual legal representation and, when necessary, challenges patterns and practices that inappropriately deny access to Medicare and necessary care. We appreciate the opportunity to submit these comments to the above-referenced rule.

We appreciate the opportunity to submit these comments. In particular, we want to commend CMS for the proposal to allow Medicare payment in more circumstances where dental services are important to the outcome of primary, covered medical treatments. As discussed in our comments below, we strongly support CMS' proposal to clarify the exception to Medicare's statutory dental exclusion whereby payment may be made for certain dental services that are "inextricably linked to, and substantially related and integral to, the clinical success of other covered medical services."

In addition, the Center respectfully asks CMS to consider the thoughtful recommendations offered by the Legal Action Center (LAC) regarding behavioral and mental health and substance use treatment, and hereby incorporates their comments in full.

## II. Comments to Proposed Rule

### II. D. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

#### A. Comment on Extending Telephone E/M Services to Services Outside of Mental Health Care

We support CMS' decision to permit telehealth service coverage for the diagnosis, evaluation, and treatment of mental health conditions that is furnished through audio-only technology after the end the PHE.

**We strongly believe, however, that CMS should extend coverage of audio-only services to other services outside of mental health care, where clinically appropriate.** While the Center contends that telehealth options should supplement, not replace, in-person care, we also recognize that significant unmet needs exist for beneficiaries.

Advancing health equity is critical. An aspect of achieving that is increasing accessibility to quality health care. Unfortunately, inherent issues in telehealth include disparities in the ability to connect to the services, especially for beneficiaries with limitations such as geography, low or non-English proficiency, and age-related issues.

Approximately one in four Americans live in rural areas, but only about 10% of physicians practice there.<sup>1</sup> According to the Government Accountability Office, over 100 rural hospitals closed between January 2013-February 2020, which means that people living in those areas must travel at least 20 miles further to get to inpatient care and double that distance to get more specialized care.<sup>2</sup> Moreover, research indicates that patients with limited English proficiency have lower rates of telehealth use compared with English proficient speakers.<sup>3</sup> Furthermore, households with older adults tend to have lower levels of both computer ownership and internet subscriptions.<sup>4</sup>

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<sup>1</sup> U.S. Government Accountability Office. *Rural Hospital Closures: Affected Residents Had Reduced Access to Health Care Services*. (December 22, 2020). <https://www.gao.gov/products/gao-21-93>.

<sup>2</sup> Ibid.

<sup>3</sup> Rodriguez, J. A., Saadi, A., Schwamm, L. H., Bates, D. W., & Samal, L. *Disparities in Telehealth Use Among California Patients with Limited English Proficiency*. Health Affairs. (March 1, 2021) <https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.00823>.

<sup>4</sup> U.S. Census Bureau. *Computer and Internet Use in the United States: 2018*. Census.gov. (October 8, 2021). <https://www.census.gov/newsroom/press-releases/2021/computer-internet-use.html>.

## B. Comment on Proposal to Extend Flexibilities of the Consolidated Appropriations Act, 2022

CMS proposes to align Medicare telehealth services that are planned to end after the PHE terminates with the 151-day extension of flexibilities enacted in the Consolidated Appropriations Act, 2022.

We believe that there is real and significant opportunity to provide telehealth services for the Medicare population, including increasing access to primary and specialist care, improving communication and coordination of care between individuals and their care teams, and providing more consistent support for self-management of health care.<sup>5</sup> **We support CMS’s proposal to extend telehealth flexibilities for these services for the 151-day period after the PHE ends.**

### **II.K. Proposal to Allow Audiologists to Furnish Certain Diagnostic Tests Without a Physician Order**

The Center supports the removal of the order requirement for audiology assessment services. Audiologists are educated, trained, and qualified to provide a range of hearing and balance assessment services and do not require a physician/practitioner order under state law to safely provide these services to patients. The order requirement places Medicare beneficiaries at undue additional risk because of the potential for increased cost-sharing and delays in care while waiting for the order and should be removed.

### **II.L. Proposals and Request for Information on Medicare Parts A and B Payment for Dental Services**

#### I. Comment on Proposal to Clarify Interpretation of the Statutory Dental Exclusion.

The Center strongly supports CMS’ proposal to clarify and codify its interpretation of section 1862(a)(12) of the Act to recognize Medicare payment for dental services that are essential to certain covered medical services. For decades now, the cost of dental care has hindered Medicare beneficiaries from being able to safely undergo or see optimal outcomes from important medical treatments. Historically minoritized and under-resourced populations have faced disproportionate barriers in affording medically-related dental care. The agency’s proposal paves the way toward ameliorating disparities in access to critical health services and bringing Medicare’s dental coverage policy up to date with clinical standards of care.

We have concern, though, about the proposed wording of the legal standard exempting from the statutory exclusion “[d]ental services that are inextricably linked to, and substantially related and integral to the clinical success of, a certain covered medical service[.]” We anticipate that

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<sup>5</sup> St. John, C. *Telehealth and the Medicare Population: Building a Foundation for the Virtual Health Care Revolution*. Center for Medicare Advocacy. (May 2022). [https://medicareadvocacy.org/wp-content/uploads/2022/05/Telehealth-Report\\_CMA\\_final.pdf](https://medicareadvocacy.org/wp-content/uploads/2022/05/Telehealth-Report_CMA_final.pdf).

uncertainty about the meaning of the phrase “inextricably linked to” could lead to inconsistent decisions on claims, appeals, and prior authorizations, and create frustrations for patients, medical providers, and adjudicators alike.

*Oxford Languages* defines the term “inextricably” to mean “in a way that is impossible to disentangle or separate.” *Merriam-Webster* defines “inextricable” as “forming a maze or tangle from which it is impossible to get free.” The phrase “inextricably linked” thus connotes an absolute inseparability, and could be unduly restrictive if employed as a coverage standard without guiding criteria. In evaluating whether a dental service is inextricably linked to a medical service, a contractor might incorrectly deny coverage if the two services could, as a practical matter, *ever* be considered independently. Another contractor might construe the standard as a temporal one, akin to the current “same time/same dentist” rule requiring that the two services be furnished simultaneously. This would not align with the fact that Medicare payment is allowed in some scenarios where dental services are performed separate from the covered medical service (e.g., extraction of teeth to prepare the jaw for radiation treatment, oral or dental exam prior to kidney transplant). A legal standard that raises ambiguity or inconsistency would demand further clarification from the agency in the future.

## Recommendation

The policy goals of CMS’ proposal can be effectively achieved just by narrowly tailoring payment to dental services that are “substantially related and integral to the clinical success of certain covered medical services.” This is a rigorous, yet clearer and workable, standard that contractors, plans, and adjudicators can apply in analyzing claims. They will be able to determine, without speculation, if a claim meets this requirement based on whether the clinical evidence demonstrates that the standard of care for a covered medical treatment necessitates dental clearance, or the provision of appropriate remedial measures to address dental infections and other oral problems, to avoid undue risk and promote a positive outcome.

## II. Proposals to Clarify and Codify Current Payment Policies

### A. Covering medically-related dental services in inpatient and outpatient settings

The Center agrees with codifying that payment for dental services falling outside of the exclusion can be made whether furnished on an inpatient or outpatient basis. Situations may arise, whether because of a patient’s condition or the need for certain equipment or accommodations, when it will be clinically appropriate for such dental services to be furnished in a hospital setting rather than a dental office.

These situations still raise the question of whether a patient will be admitted as an inpatient or treated and billed as a hospital outpatient. Since dental treatments are not included on the “Inpatient Only” list, and rarely are dental patients expected to need 2 or more midnights of medically necessary hospital care, most or many of these patients will not be admitted and billed

as hospital inpatients. This may have a significant impact on how much they will pay for their hospital services.

For example, there are beneficiaries who must receive treatment in hospital because no dental office within reasonable distance has the proper modalities or adaptive equipment to accommodate their special needs. Although their physician services and hospital outpatient services are covered by Part B, if they are not admitted as inpatients then these beneficiaries could incur liability for other hospital costs that may exceed the Part A deductible. Thus, we request that CMS examine the impact of how services are billed in these scenarios, and develop policy and guidance to both ensure adequate reimbursement and that Medicare beneficiaries do not experience undue financial burden if their medically necessary dental procedures need to be performed in a hospital setting.

#### B. Professional services during and prior to a dental-related hospitalization

The Center lacks expertise to address CMS' separate inquiry about what professional services may occur during Part A-covered hospitalizations in connection with the provision of excluded dental procedures due to (1) the patient's underlying medical condition and clinical status or (2) the severity of the dental procedure. However, we similarly suspect that such covered hospitalizations may be a rarity under the "2-Midnight Rule" since most patients who must have dental services performed in the hospital are now placed on outpatient observation status post-procedure and stay less than two midnights. We respectfully request that CMS evaluate current billing practices in these scenarios, the resulting impact on beneficiaries' out-of-pocket costs, and whether the statutory goal of minimizing liability for such beneficiaries is being achieved.

#### C. Setting of oral examinations and treatment prior to covered medical treatments

Under current policy, Medicare pays for an oral or dental examination performed on an inpatient basis as part of a comprehensive workup prior to renal transplant surgery. The Center supports CMS' proposed revision of 42 C.F.R. § 411.15(i) to make Medicare coverage and payment available for such examinations in either an inpatient *or outpatient* setting prior to Medicare-covered *organ* transplant, cardiac valve replacement, or valvuloplasty procedure.

#### D. "Direct supervision" requirement on services of allied dental professionals

The Center welcomes the proposal to amend § 411.15(i) to provide that payment can be made for ancillary services and supplies that are furnished incident and integral to covered (non-excluded) professional dental services. But, we question CMS' suggestion that the services of auxiliary practitioners -- such as a dental hygienist, dental therapist, or registered nurse -- must be "under the dentist's or physician's direct supervision." By our understanding, legislation in 42 states<sup>6</sup> authorizes licensed and certified dental hygienists and dental therapists to perform appropriate services without the directing physician being physically present. Such laws have served to

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<sup>6</sup> [https://www.adha.org/resources-docs/7513\\_Direct\\_Access\\_to\\_Care\\_from\\_DH.pdf](https://www.adha.org/resources-docs/7513_Direct_Access_to_Care_from_DH.pdf)

increase access to dental care and improve health outcomes among low-income, tribal, and disabled populations and communities of color.

Providing that the professional services of auxiliary personnel be furnished under the physician's "general supervision" within the meaning of 42 C.F.R. §§ 410.26(a)(3) and 410.32(b)(3)(ii), rather than "direct supervision," would advance health equity while aligning more closely with state scope of practice and supervision laws.

### III. Proposed Updates to Current Payment Policies for Dental Services.

#### A. Services to identify and eliminate infection prior to covered organ transplant

The Center applauds and urges CMS to finalize its proposal to provide Medicare payment for a dental or oral examination as part of a comprehensive workup *and* the medically necessary dental diagnostics and treatments to eliminate identified oral and dental infections prior to an organ transplant, whether furnished in an inpatient or outpatient setting. If finalized, this rule will ease a barrier to life-saving transplants that has disproportionately impacted systemically marginalized groups.

During a listening session hosted by CMS this year, transplant surgeon Dr. Matthew Cooper stated unequivocally that in order to ensure optimal outcomes, "everybody who presents for a transplant...requires a dental evaluation and certainly treatment, if indicated." Dr. Cooper serves as President of the Board of Directors for the United Network for Organ Sharing (UNOS), the organization that manages the U.S. organ transplantation system under contract with the federal government. He described the extensive screening of transplant candidates to identify risk factors for complications, such as cancers and infections that may later necessitate reduction in immunosuppression and lead to organ graft rejection and loss. Dr. Cooper stressed the importance of remedial oral/dental care because "even minimal inflammation, in combination with immune suppression, portends a very poor outcome." As support for this, he referenced a recent study showing that patients presenting with even one dental problem pre-kidney transplant had 7.23 times greater chance of being hospitalized in the first 2 months post-transplant, and that risk of rehospitalization increased with patient age.<sup>7</sup>

We humbly request that CMS reconsider its position that "[n]o payment would be made for services that are not immediately necessary prior to surgery to eliminate or eradicate infection." First, dental clearance may be needed to be placed on the wait list, well in advance of actual transplant surgery. Second, as pointed out by Dr. Cooper and in comments submitted by the Society for Transplant Social Workers (STSW), Santa Fe Group, and the Oral Health Nursing Education and Practice Program (OHNEP), care for transplant patients does not end after the operating room. They reference several studies demonstrating the importance of post-transplant oral care to clinical outcomes. Older adults especially are at increased risk for infectious

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<sup>7</sup> DJ Sarmiento, R Caliento, R Maciel, P Braz-Silva, JOM Pestana, P Lockhart, M Gallottini. Poor oral health status and short-term outcome of kidney transplantation. *Special Care Dentist*. 2020 Nov; 40(6); 549-554.

complication following solid organ transplants. (Hemmersbach-Miller, et al., 2021). We therefore echo their recommendations to continue coverage for dental treatment as appropriate during immunosuppression therapy, to prevent sepsis and organ rejection.

B. Services to identify and eliminate oral or dental infection prior to Medicare-covered cardiac valve replacement or valvuloplasty procedures

The Center similarly lauds and urges finalization of CMS' proposal to recognize Medicare payment for a dental or oral examination as part of a comprehensive workup and the necessary dental treatments and diagnostics to eliminate oral or dental infections prior to cardiac valve replacement or valvuloplasty procedures. Statements issued by The American College of Cardiology, American College of Emergency Physicians, American College of Physicians, and The Society of Thoracic Surgeons highlight the risk of life-threatening complications that dental infections pose to cardiac patients.

This risk, though, is not confined to valve replacement and valvuloplasty surgeries. We thus encourage CMS to extend dental coverage under the proposed standard to patients undergoing other cardiothoracic, vascular, and cardiovascular invasive procedures, where there is general agreement that dental bacteria sources should be eliminated to prevent serious medical complications. These may include ventricular assisted device (VAD) and extracorporeal membrane oxygenator (ECMO) procedures, which involve implantation of a large component of prosthetic material into a patient that could seed infection. We also ask that CMS not limit coverage to only those dental services "immediately necessary prior to surgery" in contexts where clinical studies and accepted standards of practice recommend perioperative dental management.

IV. Other Clinical Scenarios that CMS May Consider or Has Not Yet Identified

CMS seeks comment and evidence regarding other examples of where dental care may be vital to the clinical success of covered medical treatments and approved for payment under the proposed exception. As an organization that strives to advance quality health care for Medicare beneficiaries, we urge CMS to exercise its authority to cover medically necessary dental care in as broad a range of clinical situations as possible.

Not a week passes that the Center does not hear from beneficiaries who are facing serious health challenges that require the provision of dental treatment. We talk to people who are forced to delay vital chemotherapy and/or radiation of Stage 4 breast cancer and other cancers until their dental infections have been addressed. We get many calls from beneficiaries whose disease conditions, traumatic injuries, treatments, and/or medications have resulted in extreme oral devastation that makes it a daily struggle for them to chew, swallow, speak clearly, smile, and manage ongoing oral infections and pain. We hear of others who have been repeatedly hospitalized for pneumonia or sepsis seeding from odontogenic infections.

While their health conditions are diverse, those who contact us have in common a medically urgent need for dental care that they cannot readily afford, either because of limited income and

resources, lack of coverage, or underinsurance. We believe the agency has legal authority to advance a dental policy that can address the most medically pressing dental needs, and directly improve care delivery to the least advantaged patients. Thus, we endorse the expanded coverage recommendations and clinical data shared by the California Dental Association (CDA), and elaborate on the scenarios below.

#### A. Joint replacement surgery

Many if not most orthopedic surgery practices require dental clearance before elective total joint arthroplasty (TJA), a common surgery among Medicare beneficiaries. This is because bacteria from caries and periodontal disease, a common condition among Medicare beneficiaries (76% of adults over 65 have some degree of gum disease), can enter and travel through the bloodstream and infect the vulnerable tissue around joint and surgery sites. Since blood does not circulate through replacement joints, antibiotics may not effectively treat site infections. In such circumstances, the options would be to surgically excise the infected tissue surrounding the new joint, flush the site, and aggressively administer antibiotics to the patient, or to remove the entire prosthesis and reattempt the joint replacement after the infection has resolved. Failure of revision surgeries to eradicate infection can necessitate amputation. All of these results come at great cost to the patient, the health care system, and the Medicare program.

Notwithstanding that very limited research has been conducted on whether pre-operative dental clearance decreases the incidence of prosthetic joint infections, it is axiomatic that active infections, regardless of their source, should be identified and eliminated safely in advance of arthroplasty, just as with organ transplant and cardiac valve surgeries, to minimize the risk of serious complication. The orthopedic community recognizes that patients who have active oral infections are at higher risk for sepsis and joint infection, and should have their TJA procedures delayed until dental clearance is obtained.<sup>8</sup> As marginalized patient populations are disproportionately burdened by the cost of dental clearance and longer delays in receiving TJA, we urge CMS to consider allowing payment under Medicare for recommended dental examinations and treatment necessary to safely undergo TJA.

#### B. Head and neck cancer treatment

Medicare makes payment for tooth extractions to prepare the jaw for cancer radiation, but no other dental care needed in conjunction with oral, head and neck cancer treatment. The various therapies used to treat these cancers can cause an array of challenging oral problems that have a terrible impact on a patient's quality of life. These oral problems include rampant radiation caries, mucositis, candidiasis, xerostomia (dry mouth), and osteoradionecrosis (bone cell death) of the jaw. The latter can necessitate surgery that may disfigure and functionally impair the patient's face and jaw. For these reasons, it is widely understood that dental care is absolutely

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<sup>8</sup> WV Arnold, J Ottolenghi, M Belzino. Question 24: Should routine dental clearance be obtained prior to total joint arthroplasty (hip/knee/shoulder/ankle)? Orthopaedic Research Society 2019 Delegates Meeting <https://www.ors.org/wp-content/uploads/2019/01/Question-24.pdf>



integral to the clinical success of head and neck cancer treatment and survivorship.<sup>9</sup> We support the comments of the American Association of Oral and Maxillofacial Surgeons (AAOMS) and California Dental Association (CDA) recommending expansion of payment for medically necessary dental examinations, treatments, and follow-up care to address infections impacting or resulting from head and neck cancer therapies.

### C. Cancers and immunosuppressing diseases and treatments

As reinforced in comments by the Sepsis Alliance, the significance of dental care in the context of immunosuppression cannot be understated:

“A dental abscess or other infection of the teeth and supportive tissues should, like all infections, be treated as quickly as possible to reduce the risk of complications, including sepsis. This is especially important for individuals who are immunosuppressed because of disease (Diabetes, Leukemia, HIV, Chronic Kidney Disease), pharmaceuticals (cancer chemotherapies, biologics for management of autoimmune diseases), and/or natural aging (immunosenescence).”

**Leukemia, lymphoma and other cancers.** Dr. Gwen Nichols, Chief Medical Officer for the Leukemia & Lymphoma Society (LLS), asserted at a CMS-hosted listening session this year that oral organisms are “the number one or number two most common cause of sepsis in patients who are treated for acute leukemia.” She explained how this was “potentially life-threatening” for patients who do not have normal neutrophils to show that they have infection, which is why “dental evaluation for these patients is critical” before starting therapy. The majority of LLS’ patient population are Medicare-eligible, and they receive weekly calls from patients who “cannot get their life-saving bone marrow transplant (BMT) or CAR T-cell therapy because they cannot afford the dental care they need.” Dr. Nichols explained that oncologists have to be “very careful” prior to CAR T-cell therapy and BMT to ensure that patients are “ready to be immunosuppressed for 100 days.”

BMT patients have a higher risk of infection for almost two years while their immune system returns to full strength. If donated stem cells are transplanted, they usually need to take immunosuppressant medications to reduce the risk of the transplanted cells attacking or being rejected by their body. For this reason,

“A dental clearance is required for all patients prior to BMT. Poor dentation such as dental caries, periodontitis, and other issues may lead to complications such as:

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<sup>9</sup> Even in year 2000, the National Institute for Dental and Craniofacial Research (NIDCR) felt there was enough evidence to conclude that given “the severe consequences of radiation-induced osteoradionecrosis, and Medicare’s investment in treating patients with head and neck cancer, it is reasonable for Medicare to cover both tooth-preserving care and extractions, which may be medically appropriate for certain patients.” *Extending Medicare Coverage for Preventive and Other Services*. Institute of Medicine (US) Committee on Medicare Coverage Extensions; Field MJ, Lawrence RL, Zwanziger L, editors. Washington (DC): National Academies Press (US); 2000. <https://www.ncbi.nlm.nih.gov/books/NBK225261/#ddd00104>.

delayed healing of mucositis, need for parenteral nutrition and pain medications, increased length of stay, and increased risk for infection, sepsis, and death. Delays in obtaining dental clearance can place patients at a higher risk for relapse creating the need for additional therapy prior to BMT or cancellation of the BMT.”<sup>10</sup>

This was the rationale behind a recent study that found that the percentage of patients who delayed BMT decreased from 4.6% to 1.8%, and the percentage that canceled BMT decreased from 2.8% to 0%, after BMT nurses worked with social workers to identify dental resources in the community that could provide dental work and clearance for those who did not have dental insurance or coverage.

There is also concrete data, as presented in the Santa Fe Group’s comments, to support the recommendation that Medicare coverage for dental services begin prior to cancer therapy and continue as appropriate during and post-treatment until immunosuppression ends, infections are resolved, and restorative interventions when indicated are completed.

**Sjogren’s Syndrome and other Autoimmune diseases.** Patients with difficult cases of Sjogren’s Syndrome may need to be treated with chemotherapeutic, immunosuppressive, and steroidal drugs that lower their immune response. The use of such agents, in the setting of dry mouth that is the hallmark of Sjogren’s Syndrome, can lead to a host of challenging oral and dental issues, including infections that may compromise their course of treatment. Medications used to treat individuals with other autoimmune diseases, including rheumatoid arthritis and lupus, can have a similar effect.

Individuals with **Multiple Sclerosis (MS)** are typically treated with Disease Modifying Therapies (DMT) that work by suppressing or modifying the immune system, and many are linked to an increased risk of infection. Comments submitted by the National Multiple Sclerosis Society affirm, “Coverage of dental examinations and treatments is unquestionably needed for beneficiaries requiring long-term use of immunosuppressing medications to help manage MS. It is vital for patients with MS to receive appropriate dental evaluation and prompt treatment so they can continue their DMT use.”

#### D. Bisphosphonate Therapy

The Center believes that dental treatment can be essential to preventing complications of bisphosphonate therapy and merits coverage under the proposed exception. Bisphosphonate therapy is used in some cancer treatments, and also widely prescribed in treating osteoporosis and rheumatoid arthritis. A relatively rare but serious side effect of this toxic medication is osteonecrosis (bone and tissue death) of the jaw, which can have devastating health consequences for some patients. Because of this, some individuals taking bisphosphonates may

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<sup>10</sup> DeNinno M, Cobb D. Impact of Delaying Stem Cell Transplant Related to Dental Work Clearance (abstract). *BBMT: Transplantation and Cellular Therapy*. Vol. 26:3S (3/1/20). [https://www.astctjournal.org/article/S1083-8791\(19\)31019-5/pdf](https://www.astctjournal.org/article/S1083-8791(19)31019-5/pdf).

need routine dental management to identify and address symptoms of pain, swelling and infection, loosening of teeth, drainage and exposed bone.

E. Dental services associated with stabilizing and/or repairing the jaw after accidental injury or trauma

The Center cannot speak with authority to whether, besides the wiring or immobilization of teeth in connection with the reduction of a jaw fracture, there are other dental services associated with stabilizing and/or repairing the jaw after accidental injury or trauma that similarly would not be subject to the dental exclusion and should be covered by Medicare. However, beneficiaries have shared with us situations where Medicare has covered the immediate, preliminary interventions needed (sometimes in an emergency room) to stabilize and/or repair their jaw, but denied coverage of associated dental services (e.g., treatment of fractured and dislocated teeth) that could only be effectively provided after swelling had significantly gone down. Their coverage denials may have resulted from Medicare dental policy's restrictive same time/same dentist rule. We respectfully ask that the agency evaluate whether that rule unfairly restricts coverage in circumstances where a course of treatment to completely stabilize and/or repair the jaw after injury or trauma may, for practical or clinical reasons, need to be performed on different days, by different personnel, in different settings.

We also take this opportunity to endorse the American Association of Oral & Maxillofacial Surgeons' (AAOMS) recommendation, based on its membership's long experience in furnishing covered care to Medicare beneficiaries, that payment be extended to the "extraction of problematic teeth and incision and drainage when a delay in surgical treatment could result in the impairment of the patient's condition or a delay in pending treatment that should be performed in a timely manner."

V. Establishing a Process to Review Additional Clinical Scenarios for Future Updates.

We firmly support the finalization of a process within the annual rulemaking cycle whereby the agency could review and consider for payment additional scenarios in which dental services may be integral to the overall clinical success of a covered medical treatment. An established process will effectively enable Medicare dental coverage policy to adapt to evolving standards of clinical practice, backed by growing medical evidence, data on patient outcome measures, and input from experts across relevant disciplines. We praise CMS' forethought and initiative in conceiving this strategy to facilitate ongoing progress towards medical-dental integration and evidence-based coverage in this area.

VI. Dental Services Integral to Covered Medical Services Which Can Result in Improved Patient Outcomes.

We commend CMS's recognition that there may be clinical scenarios where the ongoing disease management of a patient receiving medically necessary care may have an improved outcome or see a clinical benefit from the performance of dental services. We believe there are situations in

which dental services should be considered so integral to the standard of care for an otherwise covered medical service that the statutory payment preclusion does not apply. Prime examples are where rampant, untreated periodontal disease is complicating the management of a patient's diabetes, or recurrent aspiration or nosocomial pneumonia is seeding from oral periodontopathic bacteria. There is also strong evidence to support the provision of dental services to end-stage renal patients. A retrospective study published this year concluded that intraoral surgical and conservative dentoalveolar treatment in end-stage renal disease patients is essential to optimize subsequent kidney transplantation.<sup>11</sup>

The non-profit coalition, Kidney Care Partners, offered the view that “[a]ccess to dental services not only is important for dialysis patients as part of their ability to access kidney transplants, but also to access cardiovascular procedures given that many dialysis patients also live with serious, chronic cardiovascular conditions, and to reduce the risk of systemic infections developing from an oral source.” In company with comments of other organizations, the American Nephrology Nurses Association (ANNA) expressed strong belief that regular dental exams and necessary follow-up treatment curb future complications and “are integral to the standard of care for patients receiving dialysis and therefore should not be precluded from covered services.”

The Center believes that access to targeted dental care can optimize outcomes for patients in the above clinical scenarios, and that the statute does not bar Medicare payment for such care. Medicare's foot care policy offers a precedent here. Section 1862(a)(13) of the Act unambiguously excludes payment for routine foot care. Nevertheless, there is longstanding policy guidance allowing payment for routine foot care determined to be a necessary and integral part of otherwise covered services (e.g., diagnosis and treatment of ulcers, wounds, or infections), or where an individual has an underlying systemic medical condition (i.e., metabolic, neurologic, and peripheral vascular diseases) that has caused severe circulatory problems or diminished sensation in the individual's legs or feet. Applying similar authority and clinical justification, CMS could duly cover certain dental treatments integral to the standard of care for patients presenting with certain underlying medical conditions and clinical findings.

## VII. Other Potentially Impacted Policies

The Center respectfully asks CMS to consider the thoughtful recommendations offered by the California Dental Association concerning the coding of and reimbursement rates for covered dental items and services under the exception to the statutory exclusion. We have every faith that with the specialized expertise of the agency and continued input from relevant stakeholders, the policies around implementation and payment may be optimized to ensure that Medicare beneficiaries can realize the crucial benefits of the proposed coverage.

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<sup>11</sup> T Moest, R Lutz, AE Jahn, K Heller, M Schiffer, W Adler, J Deschner, M Weber, MR Kesting. Frequency of the necessity of dentoalveolar surgery or conservative treatment in patients before kidney transplantation depending on the duration of dialysis and causative nephrological disease. *Clin Oral Investig.* 2022 Mar;26(3): 2383-2390. Data showed that the greatest necessity for conservative treatment (73.3%) and surgical intervention (80%) could be detected for patients in the second and third years of dialysis.

## VIII. Potential Future Payment Models for Dental and Oral Health Care Services.

We agree that the Innovation Center’s waiver authority under section 1115A(d)(1) of the Act can test ways to integrate the payment for dental and health care services within existing and future payment models - including models focused on equity, care coordination, total cost of care and specific disease conditions. We encourage CMS to consider the models that have been suggested in comments submitted by our cohorts at FamiliesUSA, Justice in Aging, California Dental Association, and the Santa Fe Group.

## IX. Conclusion

The Center for Medicare Advocacy values the opportunity to comment on these important dental policy proposals and information requests. The agency’s leadership and vision in this area truly reflects its exemplary aim to build a better health care future on the foundation of six strategic pillars - advancing equity, expanding access, engaging partners, driving innovation, and protecting programs. If finalized, CMS’ proposals will mark a watershed in the effort to integrate dental into overall health care, and equitably reduce the burden of dental disease on Medicare beneficiaries for generations to come.

### **III.D. Expansion of Coverage for Colorectal Cancer Screening and Reducing Barriers**

The Center supports CMS’ proposals to expand coverage of colorectal cancer (CRC) screening, as enumerated in Section III.D:

- reducing the minimum age from 50 to 45 for stool-based tests, barium enema test, blood-based biomarker tests, and direct visualization test of flexible sigmoidoscopy
- continuing to forgo a minimum age limitation for screening colonoscopies
- including, as part of CRC screening, a follow-on screening colonoscopy after a noninvasive stool-based test returns a positive result, and waiving beneficiary cost sharing (coinsurance and deductible) for both

We concur with CMS that the preceding proposals will expand access to quality care and improve health outcomes for beneficiaries through prevention, early detection, more effective treatment, and reduced mortality.

We also encourage CMS to maintain coverage for a screening colonoscopy as the first step in CRC screening when determined appropriate by the beneficiary and their health care professional, thereby realizing CMS’s goal as stated in the proposed rule: “that the patient and their healthcare professional make the most appropriate choice in CRC screening, which includes

considerations of the risks, burdens and barriers presented with an invasive screening colonoscopy in a clinical setting as their first step” (p. 46085).

### **III.E. Removal of Selected National Coverage Determinations**

Removing National Coverage Determinations (NCDs) that no longer reflect current medical practice or have later been determined to be reasonable and necessary or have been replaced by more beneficial technologies or clinical paradigms, are legitimate and purposeful reasons to eliminate NCDs. However, removing NCDs that involve items and services infrequently used by beneficiaries is not a prudent or useful action, especially for any beneficiaries who need the item or service for which the NCD was originally and painstakingly developed. Eliminating existing NCDs should not occur unless the NCD is truly obsolete for all beneficiaries.

An NCD that provides national coverage has gone through an extensive analysis and approval process. Once approved, it should be retained so long as there are any beneficiaries who will benefit from the NCD. However, an existing NCD that bars national coverage should be eliminated if more current analysis shows immediate access to that service or item will be beneficial. CMS should develop a less onerous, more stream-lined expedited process to review new evidence to support an existing non- coverage NCD. The amount of time that NCD considerations currently languish in the analytic review pipeline is too long, particularly for beneficiaries waiting for critical coverage decisions.

Removing an existing NCD in favor of leaving a coverage determination to local contractor discretion may result in inconsistent national coverage application. Unless there are legitimate geographic reasons for local determinations, existing NCDs should remain program-wide to accomplish fair application of coverage standards for all Medicare beneficiaries.

The proposed rule addresses the removal of NCD 160.22 Ambulatory EEG Monitoring (06/12/1984). The proposed rule shows the NCD has continued clinical value for beneficiaries, but in the almost 40 years since implementation, the NCD (and likely most other NCDs) has not been regularly updated to appropriate clinical standards and current technology. The NCD should be brought up to date with current standards of care and more modern reporting techniques.

CMS is considering three NCD options for NCD 160.22, and other NCDs, for which it is soliciting comments:

1. Remove the NCD to allow for local determinations by contractors (CMS proposal),
2. Retain current NCD policy, or
3. Reconsider the NCD by opening a national coverage analysis to revise rather than eliminate the NCD.

The Center supports option 3, to reconsider the NCD, and not option 1 to remove the NCD, as proposed by CMS, for reasons of programmatic consistency not available at the local contractor

level, as stated above. Retaining current outdated NCD policy would not be safe or effective for beneficiaries or support the integrity of the Medicare program. Given the Center's endorsement of option 3, however, CMS must give timely attention to address all outdated NCDs in urgent need of updating. Time is of the essence for beneficiaries and the Medicare program. The fact that it appears that NCDs have not been regularly reviewed and updated, as indicated by this proposed rule, may be driving CMS's preference to eliminate NCDs in favor of local determinations. The correct answer, for beneficiaries and for the Medicare program, is to ensure each previously approved NCD is current, relevant, and available to confirm coverage.

### **III.G. Medicare Shared Savings Program**

#### **6. Reducing Undue Administrative Burden and Other Policy Refinements**

The Center agrees with CMS that it is essential for beneficiaries to “understand the advantages of their participation in ACOs, that their data is secure, that only the minimum necessary data is collected, and how this data is used for purposes of improving the quality of care for beneficiaries in the Shared Savings Program” (p. 46204). In addition, we appreciate CMS' intent “to improve the beneficiary notice to ensure that the content of the notice utilizes plain language and is beneficiary-friendly, as well as affirming patient choice and clarifying the beneficiary's opportunity to decline claims data sharing” (p. 46204). We assert that several of the proposals outlined in the rule, however, appear to work against these goals.

Specifically, the Center is concerned about CMS' “burden reduction proposals” to: eliminate the requirement for an ACO to submit marketing materials to CMS for review and approval prior to disseminating notifications to beneficiaries and participants; reduce the frequency of certain beneficiary notifications from once annually to once in an agreement period (5 years); and streamline the SNF 3-day waiver application process by requiring ACO attestations rather than submitted documentation, particularly without additional requirements to ensure that beneficiaries can access this benefit. In short, as discussed further below, we urge CMS to withdraw these proposals.

Medicare Advantage (MA) plans are appropriately required to provide annual information to their enrollees, including the Annual Notice of Change and Evidence of Coverage documents, that explain plan benefits and rules. In addition, MA plans are also generally required to submit marketing materials to CMS for review. In general, while there remains much beneficiary confusion around the MA program and the multitude of varying plan options available to individuals in a given service area, the public generally has a better understanding of the way that MA plans work, including restrictions such as narrow provider networks and prior authorization. ACOs, however, are generally opaque to the public. While those attributed to ACOs, in theory, retain free choice of provider, there are nonetheless financial incentives for ACO participating providers to refer patients to other participating providers – a fact not often explained or promoted. There are benefits not covered by traditional Medicare that can be available to those in ACOs, but information about such benefits can be difficult to ascertain (see, e.g., discussion below re: waiver of 3-day inpatient stay for SNF care).

At a time when CMS aims to have all Medicare beneficiaries not in a Medicare Advantage plan part of some accountable care relationship by 2030, and new entities emerge to offer ACOs, including investment firms and other for-profit entities with little or no experience in managing medical care (let alone ensure consumer protections), it makes little sense that notice and marketing standards are being weakened in the manner proposed in the rule. File and use requirements – even with a short window of time before materials can be used - serve as a check against erroneous or misleading marketing. Reviewing materials on request, identifying misleading materials, and disapproving them only after they have been distributed cannot undo damage already caused by misleading information, and does not serve the public interest. We urge CMS to retain the requirement that CMS collect, review and approve marketing materials before their use.

CMS notes that ACOs continue to complain about the administrative burden of providing annual notices, and:

state that such notices may confuse beneficiaries, who misinterpret the notice and believe that it signifies a change to their Medicare benefits or otherwise represents an undesirable or disadvantageous change regarding their health care services. ACOs assert that this confusion may cause a beneficiary to opt out of data sharing, which could result in less cohesive care, duplicative or unnecessary medical tests, or contraindicated prescription drug therapy. (p. 46204)

Diminishing required communication with beneficiaries is not an effective strategy to reduce confusion about ACO attribution. Rather, better and more frequent communication with beneficiaries can foster better understanding of any drawbacks and benefits to their relationship with an ACO. We support the proposal to require a new follow-up beneficiary communication, including the attempt to provide “a meaningful opportunity for beneficiaries to ask questions and engage with a representative of the ACO or ACO participant with regard to the beneficiary notice” (p. 46205). We also support the proposal to clarify that ACO participants are required to post beneficiary notification signs in all of their facilities (whether or not primary care services are provided in every facility). However, we strongly urge CMS to retain the current notification requirements for ACOs while collaborating with beneficiaries, family caregivers, health care professionals, ACOs, and other stakeholders to improve the quality of communication about the health and economic implications of ACO enrollment for beneficiaries.

With respect to streamlining the SNF 3-day rule waiver application review process, while we appreciate the intent to make it easier for ACOs to obtain a waiver, we are disappointed that CMS is taking no further action to ensure that this benefit is actually available to beneficiaries.

As the Center noted in a 2020 *CMA Alert*<sup>12</sup> outlining the difficulty that those attributed to an ACO can have accessing the waiver,

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<sup>12</sup> Center for Medicare Advocacy Alert “Accountable Care Organizations and Observation Status” (January 30, 2020), available at: <https://medicareadvocacy.org/accountable-care-organizations-and-observation-status/>.



neither federal law nor federal regulations require ACOs to give beneficiaries sufficient information on how to use and benefit from the waiver. Telling beneficiaries that nothing changes for them when they are in an ACO is inaccurate and misleading.

Moreover, ACOs benefit financially if they *do not inform* beneficiaries of the waiver and how to benefit from it. Since a beneficiary who goes to a SNF without a prior three-day inpatient hospital stay does not have his or her SNF stay covered by Medicare, the cost of the SNF stay (paid out-of-pocket by the beneficiary) is not attributable to the ACO.

In short, we noted that “[u]ntil CMS and ACOs more fully and more accurately explain beneficiaries’ rights to them, however, the burden is on beneficiaries to ask questions and to be persistent.”

The proposal here to change information previously required to be reported to merely be attested to by the ACO, coupled with the changes in notice and marketing requirements outlined above, will make it more, not less, difficult for those attributed to an ACO to access the 3-day waiver. Instead of weakening ACO requirements, CMS should take additional measures to ensure that individuals are aware of any waivers as well as all SNF affiliates from whom they can receive services covered by a waiver.

### **III.H. Medicare Part B Payment for Preventive Vaccine Administration Services**

The Center supports the proposal to continue waiving beneficiary cost sharing (coinsurance and Part B annual deductible) in calendar year (CY) 2023 for COVID-19 vaccination and the services to administer those vaccines. Likewise, for beneficiaries for whom vaccination with any available COVID-19 vaccine is not recommended because of a history of severe adverse reaction to a COVID-19 vaccine or any COVID-19 vaccine component, the Center supports coverage under the Part B vaccine benefit, without beneficiary cost sharing, of monoclonal antibody products used as preexposure prophylaxis for prevention of COVID-19. We also support CMS’ proposal to continue increased reimbursement for COVID-19 vaccines throughout CY 2023 when such vaccines are administered in a beneficiary’s home under the circumstances described above in section III.H.3.b of the current proposed rule. Consequently, the Center supports CMS’ proposal to finalize the following regulatory changes, which were adopted in the November 6, 2020, interim final rule with comment period:

- § 410.152 (l)(1), which includes the COVID–19 vaccine to the list of vaccines for which Medicare Part B pays 100 percent of the Medicare payment amount
- § 410.160 (b)(2), which includes the COVID–19 vaccine in the list of vaccines that are not subject to the Part B annual deductible and do not count toward meeting that deductible
- § 411.15 (e)(5), which adds an exception for COVID–19 vaccinations to the general exclusion of coverage for immunizations

- §§ 414.701 and § 414.900(b)(3), which include the COVID–19 vaccine in the list of statutorily covered drugs
- §§ 414.707 (a)(2)(iii) and 414.904(e)(1), which include the COVID–19 vaccine in the list of vaccines with a payment limit calculated using 95 percent of the AWP

The Center also supports the following proposals:

- amending § 410.10(l) to list pneumococcal, influenza, and COVID–19 vaccines and their administration
- amending § 410.10(p) to list both Hepatitis B vaccine and its administration, as defined in § 410.63(a)
- amending § 410.57(a) to state only that Medicare Part B pays for pneumococcal vaccine and its administration, as well as adding paragraph (d) to state that Medicare Part B pays for the Hepatitis B vaccine and its administration, as defined in § 410.63(a)

### **III.J. Medicare Provider and Supplier Enrollment and Conditions of DMEPOS Payment**

CMS is proposing several changes to existing Medicare provider enrollment regulations to ensure the integrity of the Medicare program and to protect beneficiaries.

#### **1. Expand Authority to deny or Revoke [Enrollment] Based on OIG Exclusion (and Associated Definitions)**

CMS would expand the parties subject to denial and revocation provisions to include managing organizations and officers and directors of the provider or supplier if the provider or supplier is a corporation (FR 46232). A “managing organization” would be defined as an entity that directly or indirectly conducts the day-to-day operations of the provider or supplier; an “officer” would be someone who exercises control over the provider or supplier; a “director” would include any member of the corporation’s governing body, even if they have less day-to-day control of the provider or supplier.

As a beneficiary advocacy organization with a deep commitment to Medicare’s programmatic integrity, the Center agrees with CMS that provider and supplier legitimacy is critical. However, we offer several concerns for CMS’s consideration regarding enrollment:

1. The Office of Inspector General (OIG) does not always accurately identify actual fraud and abuse, casting a too-wide net of “unnecessary utilization”, identifying mistakes and incomplete paperwork as fraud 92% of the time.<sup>13</sup> Targeting actual fraud for elimination will serve the program and beneficiaries better.
2. Based on current regulations, CMS has authority to deny or revoke enrollment to individuals who may have day-to-day operational responsibilities or who have a corporate officer role. The current proposal, to include directors, would expand that

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<sup>13</sup> [2015-32506.pdf \(govinfo.gov\)](#).

- authority to individuals who do not have a day-to-day role, but rather a governance role. Directors are typically appointed to a board based on their expertise in the business. If directors are to be held responsible, CMS should consider if this includes director's actions in a related type of business but not in their actions as a director of the corporation, which may result in unfair application to a corporation.
3. Some potential enrollees, anticipating nefarious activities, may choose not to incorporate but instead to form some other type of legal structure to avoid involving directors.

Some of these concerns may be addressed through the reversal of revocation or denial as described in section c. (FR 46233), but the statement as presented is unclear:

...the revocation or denial may be reversed if the provider or supplier terminates and submits proof that it has terminated its business relationship with that party within 30 days of the revocation or denial notification.

In the context of this statement, what does the word "terminates" refer to? Is it termination of enrollment or termination of the relationship with the individual? If the former, is based on the activity of the director in a capacity unrelated to the enrollee, would termination from enrollment in Medicare be an unintended consequence of nothing more than a poor choice in directorship, rather than an otherwise legitimate Medicare enrolled supplier or provider?

#### f. Categorical Risk Designation – Skilled Nursing Facilities (SNF) (FR 46235)

CMS proposes to revise 42 C.F.R. §424.518, Screening levels for Medicare provider and suppliers, to change the categorical designation of SNFs (for purposes of reviewing initial applications and revalidation applications for Medicare reimbursement) from the limited-risk screening category under 42 CFR §424.518 to the high level of risk. The Center fully supports this change.

In support of the change, CMS cites "The disconcerting number of recent cases involving fraud and improper billing by nursing home owners and operators, as well as the OIG [Office of Inspector General] and GAO [Government Accountability Office] reports concerning patient abuse at the nursing homes these individuals oversee [which] requires, in our view, strengthened protections of the Medicare program and its nursing home beneficiaries." 87 Fed. Reg. at 46235. CMS identifies multiple reports by the GAO and OIG about "patient abuse" ("CMS in recent years has become increasingly concerned about certain problems within the SNF community, particularly potential and actual criminal behavior," including patient abuse) and cases of financial "fraud or improper billing among nursing home owners or operators." *Id.* These multiple cases of patient abuse cases and financial fraud more than justify the modest change that CMS proposes.

CMS refers to the discretionary nature of its authority to denying or revoking Medicare certification, 42 C.F.R. §§424.530(a)(3), 424.535(a)(3), respectively, based on felony convictions. The Center for Medicare Advocacy urges CMS to use its authority aggressively to deny or revoke Medicare certification whenever a Medicare enrollee has a felony conviction.

In addition, the Center urges CMS to look more closely at the accuracy of information provided by SNFs and to exercise its authority to revoke Medicare certification for false or misleading information. 42 C.F.R. §424.535(a)(4). Nursing home owners often create new companies when they want to purchase a facility in order to assure that there is no “record” to be reviewed by the state. For example, in 2018, William Rothner and Allied Health Services, Inc. sought to purchase and convert to for-profit ownership the Champaign County, Illinois county nursing facility. In August 2018, the County Review Board asked the potential purchasers to identify any adverse actions taken against them or any facilities owned or operated by them. A certification signed by Rothner on August 15, 2018 indicated that no action had been taken against University Rehabilitation Center of CU, LLC and University Rehab Real Estate, LLC. However, neither University Rehabilitation Center of CU, LLC nor University Rehab Real Estate, LLC existed on August 15. The companies listed on the certification reflected the new name that the applicants intended to give the county nursing facility once they bought it, but these companies were not created until August 17, 2018.<sup>14</sup>

Clearly, no adverse actions could have been taken against companies that did not actually exist. The new owners deliberately provided the state with false or misleading information.

Nursing home owners also use multiple names in order to conceal their actual ownership of nursing facilities. In 2020, *Barron's* reported that Portopiccolo, a private equity firm started in 2016, operates 100 facilities under various names, such as Accordius, Pelican Health, and Orchid Cove.<sup>15</sup> The name Portopiccolo may not appear on ownership papers or admissions contracts with residents. *The Washington Post* reported in December 2020 that during the coronavirus pandemic, Portopiccolo Group, despite its record of poor care (nearly 70 percent of Portopiccolo facilities had ratings of one or two (of five) on the federal website), short staffing, and coronavirus outbreaks, bought at least 22 nursing facilities, with “scant scrutiny” from state regulators in Maryland and Virginia.<sup>16</sup>

Another example comes from Vermont. *SevenDaysVt* reported in July 2021 that three people were identified on loan documents in the Fall 2020 as wanting to buy three nursing facilities in Vermont that were owned by Genesis HealthCare. When the application for the license was

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<sup>14</sup> Champaign County Health Care Consumers (CCHCC), Champaign County Health Care Consumers (CCHCC), “Research on bidder for Champaign County Nursing Homes” (May 21, 2018), <https://www.healthcareconsumers.org/research-on-bidder-for-champaign-county-nursing-home/>; CCHCC, “Champaign County Nursing Home will not be owned by the companies approved by the County Board” (Oct. 29, 2018), <https://www.healthcareconsumers.org/champaign-county-nursing-home-will-not-be-owned-by-the-companies-approved-by-the-county-board/>; Jim Meadows, “Watchdog Group Says Applicant To Buy County Nursing Home Switched Companies,” *willradio.tv.online* (NPR) (Oct. 29, 2018), <https://will.illinois.edu/news/story/watchdog-group-says-applicant-to-buy-county-nursing-home-switched-companies>.

<sup>15</sup> Eleanor Laise, “As the Pandemic Struck, a Private-Equity Firm Went on a Nursing –Home Buying Spree,” [https://www.barrons.com/articles/as-the-pandemic-struck-a-private-equity-firm-went-on-a-nursing-home-buying-spree-51596723053?mod=hp\\_DAY\\_Theme\\_1\\_1](https://www.barrons.com/articles/as-the-pandemic-struck-a-private-equity-firm-went-on-a-nursing-home-buying-spree-51596723053?mod=hp_DAY_Theme_1_1).

<sup>16</sup> Rebecca Tan and Rachel Chason, “An investment firm snapped up nursing homes during the pandemic. Employees say care suffered,” *The Washington Post* (Dec. 22, 2020), [https://www.washingtonpost.com/local/portopiccolo-nursing-homes-maryland/2020/12/21/a1ffb2a6-292b-11eb-9b14-ad872157ebc9\\_story.html](https://www.washingtonpost.com/local/portopiccolo-nursing-homes-maryland/2020/12/21/a1ffb2a6-292b-11eb-9b14-ad872157ebc9_story.html).

submitted to the state in February 2021, however, the wife of one of the owners, Ephram Lahasky, was substituted for Lahasky because Lahasky had a troubled history with nursing facilities in Pennsylvania.<sup>17</sup> Substituting Lahasky's wife meant that the purchasers were not required to identify the Pennsylvania facilities for Vermont to review.

- abuse of billing privileges, when the provider “has a pattern or practice of submitting claims that fail to meet Medicare requirements.” 42 C.F.R. §424.535(a)(8)(ii). Skilled nursing facilities that have settled False Claims Act cases with the United States for fraudulently billing the Medicare program should be subject to scrutiny under this section and have their certification revoked, even when the nursing facility or nursing facility company does not formally admit responsibility for the fraudulent billing.

g. DMEPOS Payment Denial Based on Violation of Supplier Standard (FR 46236)

The Center agrees with the newly proposed condition of payment to ensure a DMEPOS supplier cannot receive payment unless it is enrolled and has a supplier number. There must, however, be beneficiary protections against a supplier that is not properly enrolled. Notices to beneficiaries must be clear and waivers to guarantee beneficiary responsibility must be required if a beneficiary is to be held financially liable and not be entrapped by such a supplier.

### III. Conclusion

Thank you for the opportunity to submit these comments. For additional information, please contact David Lipschutz, Associate Director at [DLipschutz@medicareadvocacy.org](mailto:DLipschutz@medicareadvocacy.org), or Kata Kertesz, Senior Policy Attorney at [KKertesz@medicareadvocacy.org](mailto:KKertesz@medicareadvocacy.org), both at (202)293-5760. For additional information concerning the medically necessary oral health comments, please contact Wey-Wey Kwok at (860) 456-7790 or [wkwok@medicareadvocacy.org](mailto:wkwok@medicareadvocacy.org).

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<sup>17</sup> Daniel Simmons-Ritchie, “Still Failing the Frail; New Name, Same Nightmare,” Patriot-News (Nov. 15, 2018), <https://www.pennlive.com/news/2018/11/pennlive-special-investigation-still-failing-the-frail.html>.