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

1. Background on Medicare Payment for Dental Services

Section 1862(a)(12) of the Act generally precludes payment under Medicare Parts A or B for any expenses incurred for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth. (Collectively here, we will refer to "the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth" as "dental services.") That section of the statute also includes an exception to allow payment to be made under Medicare Part A for inpatient hospital services in connection with the provision of such dental services if the individual, because of their underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services. Our regulation at 42 CFR 411.15(i) similarly excludes payment for dental services except for inpatient hospital services in connection with dental services when hospitalization is required because of: (1) the individual's underlying medical condition and clinical status; or (2) the severity of the dental procedure.

However, under our current policy, we make payment under both Medicare Part A and Part B for certain dental services in circumstances where the services are not considered to be in connection with dental services within the meaning of section 1862(a)(12) of the Act or our regulation at § 411.15(i). We make payment when a doctor of dental medicine or dental surgery (hereinafter referred to as a "dentist") furnishes dental services that are an integral part of the covered primary procedure or service furnished by another physician treating the primary medical illness. In these limited circumstances, Medicare payment can be made for dental services such as, but not limited to, the wiring of teeth when done in connection with a reduction of a jaw fracture, the extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease, and/or an oral or dental examination on an inpatient basis performed as part of a comprehensive workup prior to renal transplant surgery. (See Medicare Benefit Policy Manual

(IOM Pub 100-02, Chapter 15, section 150); and Medicare National Coverage Determinations Manual Chapter 1, Part 4 (IOM Pub 100-03, Chapter 1, Part 4, section 260.6)). Medicare Administrative Contractors (MACs) make claim-by-claim determinations as to whether a patient's circumstances do or do not fit within the terms of the preclusion and exception specified in section 1862(a)(12) of the Act and § 411.15(i) of our regulations, and in accordance with the CMS manual provisions.

We have received feedback from interested parties suggesting that our interpretation of section 1862(a)(12) of the Act is unnecessarily restrictive, which may contribute to inequitable distribution of dental services for Medicare beneficiaries. Additionally, a recent report from the National Institutes of Health, "Oral Health in America Advances and Challenges," discusses how unequal distribution of dental services and prohibitive costs, particularly for older adults who are at the highest risk for poor oral health, can lead to and further complicate the treatment of other medical conditions (for more information, see https://directorsblog.nih.gov/2022/06/14/using-science-to-solve-oral-health-inequities/). The interested parties also suggest that there are instances where dental services are directly related to the clinical success of an otherwise covered medical service under Medicare Parts A and B, and that the regulation at § 411.15(i) should be amended to reflect that Medicare payment is available in these circumstances. Recognizing that there may be instances where medical services necessary to diagnose and treat the individual's underlying medical condition and clinical status may require the performance of certain dental services, we believe that there are instances where dental services are so integral to other medically necessary services that they are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth within the meaning of section 1862(a)(12) of the Act. Rather, such dental services are inextricably linked to the clinical success of an otherwise covered medical service, and therefore, are instead substantially related and integral to that primary medical service. We also believe that there are circumstances where the dental services are in direct connection with the care, treatment, filling,

removal, or replacement of teeth or structures directly supporting teeth, and are not inextricably linked to the clinical success of a covered medical service. In these instances, we continue to believe that Medicare payment is precluded by section 1862(a)(12) of the Act except when, due to the patient's underlying medical condition and clinical status, or the severity of the dental procedure, hospitalization is required; and that in those instances, the Medicare Part A exception provided under section 1862(a)(12) of the Act would apply.

To provide greater clarity to our current policies and respond to issues raised by interested parties, as described in section II.L.2 of this proposed rule, we are: (1) proposing to clarify our interpretation of section 1862(a)(12) of the Act and codify certain of our current Medicare FFS payment policies for medically necessary dental services; (2) proposing and seeking comment on payment for other dental services, such as dental examinations, including necessary treatment, performed as part of a comprehensive workup prior to organ transplant surgery, or prior to cardiac valve replacement or valvuloplasty procedures, that are similarly inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services; (3) requesting comments on other types of clinical scenarios where the dental services may be inextricably linked to, and substantially related and integral to the clinical success of, other covered medical services; (4) requesting comments on the potential establishment of a process to identify for our consideration and review submissions of additional dental services that are inextricably linked and substantially related and integral to the clinical success of other covered medical services; (5) requesting comment on other potentially impacted policies; and (6) requesting comment on potential future payment models for dental and oral health care services. We welcome public comments on these areas.

2. Proposals to Clarify the Interpretation of Section 1862(a)(12) of the Act and Codify Current Payment Policies for Certain Dental Services and Request for Comment

a. Proposed Payment for Inpatient Hospital Dental Services and Request for Comment

As explained above, under our interpretation of the statute and our current regulation, and as reflected in our regulation and manuals, items and services furnished in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting the teeth generally are not covered, and no payment may be made for them under either Medicare Part A or Part B. Section 1862(a)(12) of the Act and our regulation at § 411.15(i) includes an exception to allow Medicare Part A payment to be made for inpatient hospital services in connection with the provision of dental services if the individual, because of their underlying medical condition and clinical status or because of the severity of the dental procedure, requires hospitalization in connection with the provision of such services. We believe that there are instances in which a Medicare beneficiary may require dental services that are in direct connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth such that the application of the Medicare Part A payment exception would apply when hospitalization is required because of: (1) a patient's underlying medical condition and clinical status; or (2) the severity of the dental procedure. Under these circumstances, we would continue to apply the exception under section 1862(a)(12) of the Act, and make payment for inpatient hospital services. We are interested in receiving public comments on what professional services, including, but not limited to dental services, may occur during and prior to the patient's hospitalization or procedure requiring hospitalization under this exception. We may consider finalizing, based on our review of public comments, additional payment policies in this area.

b. Proposal to Clarify the Interpretation of Section 1862(a)(12) of the Act and Codify Current Payment Policies for Certain Dental Services

As explained above, Medicare payment can be made for inpatient hospital services associated with dental services that fall within the statutory exception under section 1862(a)(12) of the Act. However, under our current policy, if a dental service and other related services (for example, anesthesia or imaging services) are performed as incident to and as an integral part of a

covered procedure or service performed by a dentist, the total service performed by the dentist is covered, and payment can be made under Medicare Parts A and B as appropriate. This policy is based on the idea that some dental services that would ordinarily be excluded by statute from payment are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services. When that is the case, then we believe those dental services are not in connection with dental services within the meaning of section 1862(a)(12) of the Act, but are instead inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services. As such, we propose to interpret the statute under section 1862(a)(12) of the Act to permit Medicare payment under Parts A and B for dental services where the dental service is inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services and allow payment to be made, regardless of whether the services are furnished in an inpatient or outpatient setting. Under these circumstances, we propose that the exclusion under section 1862(a)(12) of the Act would not apply, because the service is not in connection with the care, treatment, filling, removal, or replacement of the teeth or structures supporting the teeth, but instead is inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services.

As described in section II.L.1. of this proposed rule, in a limited number of circumstances, Medicare Part B currently pays for dental services under the PFS when a dentist furnishes a service(s) that is integral to the covered primary procedure or service rendered when treating the primary medical illness. Our current payment policies for dental services are contained in manual provisions (The Medicare Benefit Policy Manual Chapter 15 (IOM Pub 100-02, Chapter 15, section 150) and Medicare National Coverage Determinations Manual Chapter 1, Part 4 (IOM Pub 100-03, Chapter 1, Part 4, section 260.6)) that reflect the proposed interpretation of section 1862(a)(12) of the Act discussed above.

Our payment policy contained in Medicare National Coverage Determinations Manual Chapter 1, Part 4 (IOM Pub 100-03, Chapter 1, Part 4, section 260.6)[74] (herein "the NCD Manual") provides for payment of an oral or dental examination performed on an inpatient basis as part of a comprehensive workup prior to renal transplant surgery. We believe Medicare payment is permitted under this manual provision for such a dental or oral examination prior to renal transplant surgery, because the examination is inextricably linked to, and substantially related and integral to the clinical success of, the renal transplant procedure. As such, we believe such services are not subject to the payment preclusion under section 1862(a)(12) of the Act. However, we believe that comprehensive workups prior to renal transplant surgery, including related dental examinations, can occur in either the inpatient and outpatient setting. As such, we are proposing to provide Medicare payment for oral or dental examinations performed as part of a comprehensive workup prior to renal transplant surgery when these services occur in either the inpatient or outpatient setting, and revise our regulation at § 411.15(i) accordingly.

The NCD Manual goes on to state that, when performing a dental or oral examination, a dentist is not recognized as a physician under section 1861(r) of the Act. We believe this statement is based on an unnecessarily narrow reading of section 1861(r) of the Act, and is also not consistent with other manual provisions. The statutory definition of physician includes a doctor of dental surgery or of dental medicine in section 1861(r)(2) of the Act, and a similar definition of physician is included in our IOM Pub 100-1, Section 70.2[75] when dental or oral examinations, and specific treatments, are within the State scope of practice for the dentist. As such, we are proposing to amend § 411.15(i) to clarify that Medicare Part B coverage and payment can be made for such a dental or oral examination prior to renal transplant surgery when performed by a doctor of dental surgery or dental medicine as defined in section 1861(r)(2) of the Act.

[74] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS014961.
[75] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS050111.

The Medicare Benefit Policy Manual Chapter 15 (IOM Pub 100-02, Chapter 15, section 150) (herein "the MBP Manual") states that if an otherwise noncovered procedure or service is performed by a dentist as incident to and as an integral part of a covered procedure or service performed by the dentist, the total service performed by the dentist on such an occasion is covered.[76] The MBP Manual continues by providing several specific examples where CMS would pay for dental services:

- The reconstruction of a ridge when it is performed as a result of and at the same time as the surgical removal of a tumor (other than for dental purposes).
- The wiring of teeth when done in connection with the reduction of a jaw fracture.
- The extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease.
- The dental splint when performed in conjunction with treatment that is determined to be a covered medical condition.

Specifically, in the MBP Manual, we describe that the reconstruction of a ridge performed primarily to prepare the mouth for dentures is a noncovered procedure and therefore would not generally be eligible for payment. However, when the reconstruction of a ridge is performed as a result of and at the same time as the surgical removal of a tumor (for other than dental purposes), the totality of surgical procedures is a covered service. In the case of the procedure of ridge reconstruction occurring in conjunction with the surgical removal of a tumor, we believe that the dental services are inextricably linked to, and substantially related and integral to the clinical success of, the other covered medical services, that is, the removal of a tumor; and therefore, Medicare Part A and Part B payment could be made. Additionally, the MBP Manual explains that Medicare makes payment for the wiring of teeth when this is done in connection with the reduction of a jaw fracture. Once again, we believe that the dental services of wiring of the teeth are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services, which in this case is the reduction of a

[76] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS012673.

jaw fracture, and therefore, Medicare Part A and Part B payment could be made. Likewise, the MBP Manual states that the extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease is also currently covered. We continue to believe that in this clinical scenario the dental services related to teeth extraction are inextricably linked to, and substantially related and integral to the clinical success of, the radiation treatment of neoplastic disease; and therefore, Medicare Part A and Part B payment could be made. The Manual also describes a specific situation in which certain dental services may be considered a covered service, depending on whether the underlying medical condition is deemed to be covered. The Manual explains that dental splints used to treat a dental condition are generally excluded from coverage under section 1862(a)(12) of the Act, but if the treatment is determined to be a covered medical condition (that is, dislocated upper/lower jaw joints), then the splint can be covered. We believe that dental splint services could be covered and paid, because the dental services could be inextricably linked to, and substantially related and integral to the clinical success of, a covered medical service, such as treatment of a dislocated jaw. Therefore, we are proposing to clarify and modify the regulations text at § 411.15(i) to include this scenario of dental splints used in the treatment of a covered medical condition. We seek comments on this aspect of the proposal.

Therefore, we are proposing to codify and clarify in the regulation at § 411.15(i) that payment can be made under Medicare Part A and Part B for dental services that are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services, including (1) reconstruction of a ridge when it is performed as a result of and at the same time as the surgical removal of a tumor; (2) the wiring or immobilization of teeth when done in connection with the reduction of a jaw fracture; (3) the extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease; and (4) a dental splint only when used in conjunction with covered treatment of a medical condition. This proposal would constitute a clarification to existing policy, as we are codifying in regulation existing manual provisions.

The MBP Manual states that payment can be made under Medicare Parts A and B for a covered dental procedure regardless of where the service is performed, noting that the hospitalization or non-hospitalization of a patient has no direct bearing on the coverage, payment, or exclusion of a given dental procedure in specific circumstances. As such, dental services that are not excluded from Medicare payment under section 1862(a)(12) of the Act could be appropriately furnished in inpatient or outpatient settings. We propose to clarify in the regulation at § 411.15(i) that payment for dental services that do not fall within the scope of section 1862(a)(12) of the Act, and that are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services, could be made regardless of whether the services are furnished on an inpatient or outpatient basis. We seek comments on whether it is clinically appropriate for these services to be furnished in inpatient or outpatient settings.

The MBP Manual further states that the coverage of services such as the administration of anesthesia, diagnostic x-rays, and other related procedures depends upon whether the primary procedure being performed by the dentist is itself covered. The MBP Manual explains that an x-ray taken in connection with the reduction of a fracture of the jaw or facial bone is covered, while a single x-ray or x-ray survey taken in connection with the care or treatment of teeth or the periodontium is not covered. In order to clarify and codify this current policy, we propose to amend our regulation at § 411.15(i) to provide that payment can be made for dental services provided in conjunction with medical services that are inextricably linked to, and substantially related and integral to the clinical success of, covered medical services, such as X-rays, administration of anesthesia, and use of the operating room.

The MBP Manual also specifies that payment can be made for services and supplies furnished incident to other dental services for which Medicare payment can be made, for example, services furnished incident to the dentist's professional services by a dental technician or registered nurse under the dentist's direct supervision. Medicare payment policy for services

furnished incident to the services of the billing practitioner are contained in § 410.26 of our regulations.

Additionally, the MBP Manual provides that when an excluded service is the primary procedure involved, dental services are not covered, regardless of complexity or difficulty. The MBP Manual describes an example of the extraction of an impacted tooth as not covered, and goes on to state that certain procedures, including an alveoplasty (the surgical improvement of the shape and condition of the alveolar process) and a frenectomy, are excluded from coverage when either of these procedures is performed in connection with an excluded service, for example, the preparation of the mouth for dentures. Additionally, the MBP Manual states that the removal of a *torus palatinus* (a bony protuberance of the hard palate) may be a covered service, but notes that it is often provided in connection with an excluded service (that is, the preparation of the mouth for dentures), and in that event, Medicare does not pay for this procedure.

We are not proposing to modify this policy. No payment is made for dental services when an excluded service is the primary procedure involved. Our interpretation of section 1862(a)(12) of the Act allows for Medicare payment when dental services are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services. Therefore, no payment is made when dental services are related to medical services that are not covered, even if the dental services are inextricably linked to, and substantially related and integral to the clinical success of, the non-covered services. The proposed amendment to § 411.15(i) would specify that, in order for Medicare payment to be made, the dental services must be inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services.

Under our proposal to clarify and codify our current payment policy for dental services, section 1862(a)(12) of the Act does not apply only when dental services are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services, such that the standard of care for that medical service would be compromised or require

the dental services to be performed in conjunction with the covered medical services. When such medically necessary dental services are furnished by a physician or practitioner, including a dentist, Medicare Part A or B payment can be made for the dental services and other services integral or incident to those dental services. Specifically, such services include:

● The wiring of teeth when done in connection with an otherwise covered medical service,

● The reduction of a jaw fracture (such as services described by CPT code sets 21440-21490),

● The extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease (such as services described by Current Dental Terminology (CDT)[77] codes D7140 and D7210 for ICD-10 C41.1 Malignant neoplasm of mandible),

● Dental splints only when used in conjunction with covered treatment of a medical condition (such as dislocated upper/lower jaw joints), or

● An oral or dental examination performed as part of a comprehensive workup prior to renal transplant surgery (such as services described by ICD-10 Z94.0, and codes D0150, D0180, or D0160).

We propose that Medicare Part A and B payment for these dental services can be made, because the services are inextricably linked to, and substantially related and integral to the clinical success of, the other covered medical services. We further seek comment on whether, given current clinical advances, the descriptions of these dental services are clinically accurate and appropriate. For example, we are interested in whether the phrase "wiring of the teeth" is still clinically accurate or if other terminology would be more appropriate.

Given that such dental services would not be subject to the preclusion on payment under section 1862(a)(12) of the Act, Medicare would make payment to the furnishing dentist or another physician or practitioner for the professional dental services. As described in the MBP

[77] https://www.ada.org/publications/cdt.

Manual, payment may also be made for services and supplies furnished incident to those dental services furnished by the dentist or other physician or practitioner, and for other ancillary services integral to the dental services. For example, Medicare payment could be made for services furnished incident to the professional dental services by auxiliary personnel, such as a dental hygienist, dental therapist, or registered nurse who is under the direct supervision of the furnishing dentist or other physician or practitioner, if they meet the requirements for "incident to" services as described in § 410.26 of our regulations. When such dental services are furnished in a facility setting, such as an inpatient acute care hospital or hospital outpatient department, payment for the facility or ancillary services would be made under the applicable payment system.

In summary, we are proposing to amend § 411.15(i) to codify that payment can be made under Medicare Part A and Part B for dental services that are inextricably linked to, and substantially related and integral to the clinical success of, an otherwise covered medical service. We further propose to amend § 411.15(i) to include examples of services for which payment can be made under Medicare Parts A and B on that basis. Specifically, we propose to include as examples the following dental services for which payment is permitted under our current policy: (1) dental or oral examination as part of a comprehensive workup prior to a renal organ transplant surgery; (2) reconstruction of a dental ridge performed as a result of and at the same time as the surgical removal of a tumor; (3) wiring or immobilization of teeth in connection with the reduction of a jaw fracture; (4) extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease; and (5) dental splints only when used in conjunction with medically necessary treatment of a medical condition. We further propose that Medicare payment would be made for these dental services regardless of whether the services are furnished in an inpatient or outpatient setting, and we propose that payment can also be made for services that are ancillary to these dental services, such as x-rays, administration of anesthesia, use of an operating room, other facility services.

We seek comment on all aspects of this proposal. If finalized, we note that we will make conforming changes to the MBP Manual to reflect changes or clarifications, and to remove any text that is no longer applicable. We will also make conforming changes to other Manual provisions or National Coverage Decision policies as necessary.

As discussed, MACs may determine on a claim-by-claim basis whether a patient's circumstances do or do not fit within the terms of the preclusion or exception specified in section 1862(a)(12) of the Act and § 411.15(i). The proposed policies outlined in this section of this proposed rule would not prevent a MAC from making a determination that payment can be made for dental services in other circumstances not specifically addressed within this proposed rule and the proposed amendments to § 411.15(i).

c. Proposed Update to Current Payment Policies for Dental Services

As discussed in section II.L.2 of this proposed rule, we are proposing that payment can be made under Medicare Parts A and B for dental services such as the reconstruction of a dental ridge performed as a result of and at the same time as the surgical removal of a tumor, the wiring or immobilization of the teeth when done in connection with a reduction of a jaw fracture, the extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease, dental splints only when used in conjunction with covered treatment of a medical condition, and an oral or dental examination performed as part of a comprehensive workup prior to renal transplant surgery. We believe, after further review of current medical practice, through consultations with interested parties and our medical officers, that there are additional circumstances that are clinically similar to these examples, and where Medicare payment for the service could be made, because the dental services are inextricably linked to, and substantially related and integral to the clinical success of, the other covered medical service(s).

For example, after further review, we believe that if a patient requiring an organ transplant has an oral infection, the success of that transplant could be compromised if the infection is not properly diagnosed and treated prior to the transplant surgery. Without an oral or

dental examination to identify such an infection, and the necessary treatment, such as restorative dental services, to eradicate it prior to the transplant procedure, the patient's ability to accept the organ transplant could be seriously complicated or compromised. Examples of restorative dental services to eradicate infection could include: extractions (removal of the entire infection, such as pulling of teeth - for example, CDT D7140, D7210), restorations (removal of the infection from tooth/actual structure, such as fillings - for example, CDT D2000-2999), periodontal therapy (removal of the infection that is surrounding the tooth, such as scaling and root planning - for example, CDT D4000-4999, more specifically D4341, D4342, D4335 and D4910), or endodontic therapy (removal of infection from the inside of the tooth and surrounding structures, such as root canal - for example, CDT D3000-3999). If such an infection is not treated prior to transplant, and immunosuppressant therapy is initiated to preserve the transplant, then there is an increased likelihood for morbidity and mortality resulting from spreading of the local infection to sepsis. Similarly, without a dental or oral exam and necessary diagnosis and treatment of any presenting infection of the mouth prior to a cardiac valve replacement[78] or valvuloplasty procedures, an undetected, non-eradicated oral or dental infection could lead to bacteria seeding the valves, seeding surrounding cardiac muscle tissues involved with the surgical site, and conceivably leading to systemic infection or sepsis, all of which increase the likelihood of unnecessary and preventable acute and chronic complications for the patient. Because an oral or dental infection can present substantial risk to the success of these procedures, such that the standard of care would be to not proceed with the procedure when there is a known oral or dental infection present, we believe dental services furnished to identify, diagnose, and treat oral or dental infections prior to organ transplant, cardiac valve replacement, or valvuloplasty procedures are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, but instead are inextricably linked to, and

[78] Knox, K. W., & Hunter, N. (1991). The role of oral bacteria in the pathogenesis of infective endocarditis. Australian dental journal, 36(4), 286–292. https://doi.org/10.1111/j.1834-7819.1991.tb00724.x.

substantially related and integral to the clinical success of, these other covered medical services. We note that, in these circumstances, the necessary treatment to eradicate an infection may not be the totality of recommended dental services for a given patient. For example, if an infected tooth is identified in a patient requiring an organ transplant, cardiac valve replacement, or valvuloplasty procedure, the necessary treatment would be to eradicate the infection, which could result in the tooth being extracted. Additional dental services, such as a dental implant or crown, may not be considered immediately necessary to eliminate or eradicate the infection or its source prior to surgery. Therefore, such additional services would not be inextricably linked to, and substantially related and integral to the clinical success of, the organ transplant, cardiac valve replacement, or valvuloplasty services. As such, no Medicare payment would be made for the additional services that are not immediately necessary prior to surgery to eliminate or eradicate the infection.

As discussed, we believe that there are circumstances where the clinical success of medical or surgical services required for a successful organ transplantation, cardiac valve replacement, and valvuloplasty procedure may require the performance of certain dental services. As such, we propose to amend our regulation at § 411.15(i)(3) to provide that dental services that are inextricably linked to, and substantially related and integral to the clinical success of, a certain covered medical service are not subject to the exclusion under section 1862(a)(12) of the Act; and that payment can be made under Medicare Parts A and B for such dental services. We are proposing to amend § 411.15(i) to include examples of payable services under Medicare Parts A and B, as: (1) the dental or oral examination as part of a comprehensive workup prior to an organ transplant, cardiac valve replacement, or valvuloplasty procedure; and (2) the necessary dental treatments and diagnostics to eliminate the oral or dental infections found during a dental or oral examination as part of a comprehensive workup prior to an organ transplant, cardiac valve replacement, or valvuloplasty procedure. We believe that clinical practice is such that these services can occur within the inpatient hospital or outpatient setting,

and we further propose that Medicare Parts A and B would make payment for these dental services, as applicable, regardless of whether the services are furnished in an inpatient or outpatient setting. Furthermore, we propose that payment under the applicable payment system could also be made for services that are ancillary to these dental services, such as x-rays, administration of anesthesia, and use of the operating room.

We seek comment on this proposed policy and our proposed amendments to § 411.15(i)(3) to specify that payment under Medicare Parts A and B can be made for an oral or dental examination, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection, prior to an organ transplant, cardiac valve replacement, or valvuloplasty procedure. We propose to continue to contractor price the dental services for which payment is made currently, and for the dental services that can be made under the proposed amendments to § 411.15(i)(3) for CY 2023, or until we have further data to establish prospective payment rates. We also seek public comment on the expected utilization of these services.

We solicit comment on these proposals.

i. Other clinical scenarios for dental services integral to other covered medical services

In addition to the examples of dental services for which payment is made under our current policy, and dental services to avoid risk of an oral or dental infection prior to organ transplant, cardiac valve replacement, or valvuloplasty procedures, we believe there may be other clinical scenarios where dental services may not be in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, but instead are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services. These could include certain dental exams and medically necessary diagnostic and treatment services prior to treatments for head and neck cancers, such as radiation therapy with or without chemotherapy, or the initiation of immunosuppressant therapy, such as those used during cancer treatments, where the standard of care is such that it is clinically advisable to eliminate the source of infection prior to proceeding with the necessary

medical care, or the standard of care for the primary medical condition would be significantly materially compromised if the dental services are not performed. As with any assessment of patient health prior to initiating immunosuppressant therapy, it may be necessary to eradicate all sites of infection, including oral infections, prior to suppressing the immune system, regardless of the reason for prescribing an immunosuppressant. We also note some medications may have an immunosuppressant effect, even though they are not prescribed principally to suppress the immune system. We believe, in these circumstances, eradicating oral or dental infection prior to beginning a medication that has been found to have a suppressant effect on that part of the immune system required to eradicate infectious agents could be necessary to the clinical success of the medication therapy.

Similarly, in joint replacement surgery (such as total hip and knee arthroplasty surgery) we believe there may be risks to the outcome of the procedure if an oral infection is not treated. There is evidence that some joint replacement patients have significant dental pathology found before their surgery.[79] Given the incidence of dental pathology in joint replacement patients, there may be some joint replacement patients who would experience a clinically significant benefit from a pre-operative dental exam and medically necessary treatment of oral pathology(ies). As in transplant surgery, patients having joint replacement surgery are at risk for surgical site infection, and there may be an increased risk for those patients with significant dental pathology. The presence of an overlooked oral infection may increase the risk for acute and chronic surgical site infection.[80] [81]

We acknowledge there is other clinical evidence that does not support the need for a dental exam and necessary treatment prior to total joint replacement surgery, specifically total

[79] https://www.aaos.org/aaosnow/2011/feb/clinical/clinical2/.
[80] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4919067/.
[81] https://www.nebh.org/blog/why-its-a-good-idea-to-see-a-dentist-before-your-joint-replacement/.

hip and knee arthroplasty.[82] [83] Rather, there is evidence that further study is needed to determine whether pre-operative dental exams and treatments are necessary and clinically beneficial.[84] Therefore, we are interested in public comment providing systematic clinical evidence as to whether there is an inextricable link between dental service(s) and joint replacement surgery such that the dental services are substantially related and integral to the clinical success of the surgical procedures. We note that if we receive compelling clinical evidence, we may finalize in this final rule additional clinical scenarios, such as dental services prior to joint replacement surgery (for example, total hip and knee arthroplasty surgery), where payment could be made under Medicare Part A or Part B. We are seeking comment on whether there is a significant quality-of-care detriment if certain dental services are not provided prior to joint replacement surgery (such as total hip and knee arthroplasty surgery), and if so, we request a description of that systematic evidence. Specifically, we are looking for medical evidence that the provision of certain dental services leads to improved healing, improved quality of surgery, and the reduced likelihood of readmission and/or surgical revisions, because an infection has interfered with the integration of the implant and interfered with the implant to the skeletal structure. Evidence needs to be clinically meaningful and represent a material difference that results in some level of persistence in the clinical success of the procedure to support that pre-operative dental services are similarly inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services, and therefore in connection with, and substantially related and integral to that primary covered medical service. If commenters are able to provide us with compelling evidence to support that a dental exam and necessary treatment prior to joint replacement procedures such as total hip and knee arthroplasty surgery would result in clinically significant improvements in quality and safety outcomes, for example, fewer revisions, fewer

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[82] Barrere S, Reina N, Peters OA, Rapp L, Vergnes JN, Maret D. Dental assessment prior to orthopedic surgery: A systematic review. Orthop Traumatol Surg Res. 2019 Jun;105(4):761-772. doi: 10.1016/j.otsr.2019.02.024. Epub 2019 May 3. PMID: 31060914.

[83] Young, H., Hirsh, J., Hammerberg, E. M., & Price, C. S. (2014). Dental disease and periprosthetic joint infection. The Journal of bone and joint surgery. American volume, 96(2), 162–168. https://doi.org/10.2106/JBJS.L.01379.

[84] https://www.sciencedirect.com/science/article/pii/S1877056819301318.

readmissions, more rapid healing, quicker discharge, quicker rehabilitation for the patient, then we would consider whether such dental services may be inextricably linked to, and substantially related and integral to the clinical success of, the joint replacement surgery.

We also believe there may be other clinical scenarios involving dental services that we have not yet considered, where certain dental services may be similarly inextricably linked to, and substantially related and integral to the clinical success of, certain otherwise covered medical service such that the exclusion under section 1862(a)12) of the Act would not apply. For example, we are proposing to codify current policy that Medicare payment can be made for the wiring of teeth when done in connection with the reduction of a jaw fracture. We request comment on whether there are other dental services associated with stabilizing and/or repairing the jaw after accidental injury or trauma and similarly that similarly would not be subject to the exclusion under section 1862(a)(12) of the Act, and for which we should consider providing Medicare payment.

We solicit comment on our current approach to payment for dental services that we have already identified under our current and proposed policies as inextricably linked to, and substantially related and integral to the clinical success of, certain covered services, as well as those services we may yet identify, and other operational topics we should consider further. We acknowledge that there may be other clinical circumstances we have not yet identified where dental services may not be in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, and instead are similarly inextricably linked to, and substantially related and integral to the clinical success of, certain other covered medical services. There may be other clinical scenarios involving physiologic or anatomic conditions in which dental services could be a medically critical precondition to the clinical success of other services, such as certain surgical procedures or cancer treatments. For these reasons, we solicit comment on whether there are other clinical scenarios for medical or surgical services where the standard of care is such that the performance of certain dental services (for

example, an exam, and certain diagnostic and treatment services) is considered to be a critical clinical precondition to proceeding with the primary medical procedure and/or treatment, and therefore may be similarly inextricably linked to, and substantially related and integral to the clinical success of, a certain covered service, and therefore, not subject to the exclusion under section 1862(a)(12) of the Act. If we were to finalize our proposed policies as discussed under sections II.L.2.a. and II.L.2.b. of this proposed rule, we may consider finalizing, based on our review of public comments, these additional examples of dental services that may not be subject to the payment exclusion under section 1862(a)(12) of the Act because they are similarly inextricably linked to, and substantially related and integral to the clinical success of, covered medical services. If we were to finalize such additional examples of dental services, we would list those services as examples under the regulation at § 411.15(i)(3), as discussed in section II.L.2.c. of this proposed rule. Lastly, as discussed above, we recognize that the dental services we have identified for which Medicare payment could be made under our proposed policies would occur either prior to, or contemporaneously with, the covered medical service. We are also interested in comments on whether, on the same basis, there are clinical circumstances under which Medicare payment could be made for dental services furnished after the covered medical procedure or treatment.

ii. Establishment of a process to consider additional clinical scenarios for future updates

As discussed, we believe there may be clinical scenarios where dental services are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, and instead are inextricably linked to, and substantially related and integral to the clinical success of, certain covered medical services. We believe there may be additional clinical scenarios we have not yet identified under which Medicare payment could be made for certain dental services on this basis. To ensure we are appropriately considering other potential clinical scenarios that may involve such dental services, we believe it may be appropriate to establish a process whereby interested parties can share recommendations for our

consideration, review and analysis for potential inclusion on the list of dental services for which payment can be made under § 411.15(i)(3) through future rulemaking. If an interested party believes that there is a clinical scenario in which certain dental services are similarly inextricably linked to, and substantially related and integral to the clinical success of, certain covered medical services, we invite interested parties to submit information about the clinical scenario and the medical evidence to support that the standard of care for the medical service is such that one would not proceed with the medical procedure or service without performing the dental services, because the covered medical services would or could be significantly and materially compromised, or where dental services are a clinical prerequisite to proceeding with the primary medical procedure and/or treatment. The interested party should explain why the particular dental services should not be subject to the general preclusion on payment for dental services under section 1862(a)(12) of the Act, because they are inextricably linked to, and substantially related and integral to the clinical success of, covered medical services, and provide the medical evidence to support that conclusion.

To ensure a thorough review can occur, we encourage interested parties to include relevant medical literature, clinical guidelines or generally accepted standards of care, and other supporting documentation to support our review and consideration of the clinical scenario involving dental services. To facilitate our consideration of interested parties' recommendations within an annual rulemaking cycle, we would request that interested parties submit this information by February 10th of that year at MedicarePhysicianFeeSchedule@cms.hhs.gov. Submissions received outside of the public comment period for a PFS proposed rule will be considered for possible inclusion in future notice and comment rulemaking cycles. Recommendations received by February, 10th of a calendar year would be reviewed for consideration and potential inclusion within the PFS proposed rule for the subsequent calendar year. For example, information received by February 10, 2024 would be reviewed for consideration and potential inclusion within the CY 2025 PFS proposed rule. We encourage

interested parties to engage with us and provide medical evidence to support their recommendations for additional clinical scenarios where dental services may not fall within the scope of the payment preclusion under section 1862(a)(12) of the Act.

As discussed previously, we may consider finalizing a change, after reviewing public comments, in the CY 2023 PFS final rule to revise the list of examples of dental services for which Medicare payment can be made. Furthermore, we solicit feedback on: (1) whether there are additional clinical circumstances we should consider where dental services are inextricably linked to, and substantially related and integral to the clinical success of, covered medical services; and (2) the establishment of a process to review additional clinical scenarios identified by the public, which we may consider finalizing, after review of public comments received, in this final rule.

iii. Request for Comment on dental services integral to covered medical services which can result in improved patient outcomes

As described in section II.L.2 of this proposed rule, we believe there are clinical scenarios where the standard of care is such that there is an immediate need for certain dental services as the necessary clinical prerequisite to an otherwise covered medical service. We believe there may be other clinical scenarios, however, where the ongoing disease management of the patient receiving the medically necessary procedure may have an improved outcome or see a clinical benefit from the performance of dental services, but that the dental service may not be inextricably linked to, or substantially related and integral to the clinical success of, the otherwise covered medical service.

For example, we believe there may be certain circumstances where the clinical benefit of medical care or treatment of a diabetic patient could be improved if certain dental services are furnished. We are interested in public feedback on whether certain dental services (for example, a dental exam, necessary treatment of a dental condition such as the extraction of an infected and mobile tooth) should be considered so integral to the standard of care for an otherwise covered

medical service that the preclusion on Medicare payment under section 1862(a)(12) of the Act does not apply.

Additionally, we are interested in comments on whether the success of a given surgery is dependent upon eradication of dental or oral infection. As noted in section II.L.2.c., we believe surgeries dealing with organ transplants, cardiac valve replacement, or valvuloplasty procedures may require a dental exam and treatment prior to the surgery because the services to identify and eradicate dental or oral infection are inextricably linked to, and substantially related and integral to the success of, these otherwise covered medical services. However, we are interested in feedback on whether there are other types of surgery for which certain dental services would meet this threshold. We invite public comment on whether there are other clinical scenarios involving acute or chronic conditions that would have an improved patient outcome if dental services are furnished, and if so, whether we should consider these services as inextricably linked to, and substantially related and integral to the clinical success of, certain covered medical services.

3. Request for Comment on Other Potentially Impacted Policies

As discussed in section II.L.2.a-b of this proposed rule, we are proposing to codify and clarify our current payment policies for dental services. We recognize that under these policies there may be instances where multiple health care providers may need to coordinate the performance of certain medical and dental services based on the patients' chronic conditions and/or serious illnesses. We continue to consider improvements to our payment policies for care management services as health care delivery models evolve. As such, we seek comment on whether our current policies for care management services make clear that time spent by physicians or non-physician practitioners coordinating care with dentists regarding the performance and outcomes of services as proposed under section II.L.2 of this proposed rule, may be counted for purposes of applicable care management codes. We are also interested in whether existing care management codes adequately describe and account for time spent

coordinating with dentists and their clinical staff. We are also interested in comments regarding the impact of changes in how health care is delivered, and whether an increased integration and coordination of care among health care providers should also be taken into account in considering dental services that may be inextricably linked to, and substantially related and integral to the clinical success of, a primary medical service. Additionally, we are interested in whether, and to what extent, the proposed policies as described in section II.L.2 of this proposed rule would address any inequitable distribution of dental services for Medicare beneficiaries.

Finally, we recognize that many Medicare beneficiaries have separate or supplemental dental coverage, such as through a Medigap plan or other plan offering. If we were to finalize in the CY 2023 PFS final rule our proposed policies as described further in section II.L.2 of this proposed rule, we seek comment on how current coordination of dental benefits operates, and where improvements could be provided. Additionally, we seek comment on what aspects of coordinating benefits among supplemental dental providers we should consider if we were to finalize the proposed policies as specified under section II.L.2 of this proposed rule.

4. Request for Comment on Potential Future Payment Models for Dental and Oral Health Care Services

Our waiver authority under section 1115A(d)(1) of the Act provides broad authority for the Secretary to waive such requirements of title XVIII of the Act, which pertain to Medicare, as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act.

In 2014, the Health Care Innovation Awards (HCIA) Round 2, a limited time grant initiative, included awards with the goal to improve the health of populations through activities focused on engaging beneficiaries, prevention, wellness, and comprehensive care that extended beyond the clinical service delivery setting. Several participants used their HCIA Round 2 funds to test models of clinical care that included payment for dental and oral care services. For further

information regarding the success of these awards as applied to dental and oral care services please review the HCIA Round 2 Final Awardee Evaluation Report (2014-2018).[85]

We are seeking comment on additional ways to integrate the payment for dental and oral health care services within existing and future payment models using the Innovation Center's waiver authority in existing or future service delivery models, including models focused on equity, care coordination, total cost of care and specific disease conditions.

[85] https://innovation.cms.gov/data-and-reports/2020/hcia2-fg-finalevalrpt.