2024 Medicare Physician Fee Schedule Final Rule Changes Summary

On November 2, 2023, the Centers for Medicare & Medicaid Services (CMS) issued a final rule that announces finalized policy changes for Medicare payments under the Physician Fee Schedule (PFS), and other Medicare Part B issues, effective on or after January 1st for corresponding performance year (CPY) 2024.

Background on the Physician Fee Schedule

Since 1992, Medicare payment has been made under the PFS for the services of physicians and other billing professionals. Physicians' services paid under the PFS are furnished in a variety of settings, including physician offices, hospitals, ambulatory surgical centers (ASCs), skilled nursing facilities and other post-acute care settings, hospices, outpatient dialysis facilities, clinical laboratories, and beneficiaries' homes. Payment is also made to several types of suppliers for technical services, most often in settings for which no institutional payment is made.

For most services furnished in an office setting, Medicare makes payment to physicians and other practitioners at a rate based on the full range of resources involved in furnishing the service. In contrast, PFS rates paid to physicians and other billing practitioners in facility settings, such as a hospital outpatient department (HOPD) or an ASC, reflect only the portion of the resources typically incurred by the practitioner in the course of furnishing the service.

For many diagnostic tests and a limited number of other services under the PFS, separate payment may be made for the professional and technical components of services. The technical component is frequently billed by suppliers, like independent diagnostic testing facilities and radiation treatment centers, while the professional component is billed by the physician or practitioner.

Payments are based on the relative resources typically used to furnish the service. Relative value units (RVUs) are applied to each service for work, practice expense, and malpractice expense. These RVUs become payment rates through the application of a conversion factor. Geographic adjusters (geographic practice cost indexes) are also applied to the total RVUs to account for variation in costs by geographic area. Payment rates are calculated to include an overall payment update specified by statute.

CPY 2024 PFS Rate-Setting and Conversion Factor

By factors specified in law, overall payment rates under the PFS will be reduced by 1.25% in CPY 2024 compared to CPY 2023. CMS is also finalizing significant increases in payment for primary care and other kinds of direct patient care.

The final CPY 2024 PFS conversion factor is $32.74, a decrease of $1.15 (or 3.4%) from the current CPY 2023 conversion factor of $33.89.

Caregiver Training Services

For CPY 2024, CMS is finalizing its proposal to make payment when practitioners train caregivers to support patients with certain diseases or illnesses (e.g., dementia) in carrying out a treatment plan. Medicare will pay for these services when furnished by a physician or a non-physician practitioner (nurse practitioners, clinical nurse specialists, certified nurse-midwives, physician assistants, and clinical psychologists) or therapist (physical therapist, occupational therapist, or speech language pathologist) as part of the patient's individualized treatment plan or therapy plan of care. This action, consistent with the recent Biden-Harris Administration Executive Order on Increasing Access to High Quality Care and Supporting Caregivers, will help support care for persons with Medicare by better training caregivers.

Services Addressing Health-Related Social Needs (Community Health Integration Services, Social Determinants of Health Risk Assessment when done in conjunction with E/M or behavioral health visits, or the Annual Wellness Visit, and Principal Illness Navigation Services)

For CPY 2024, CMS is finalizing coding and payment changes to better account for resources involved in furnishing patient-centered care involving a multidisciplinary team of clinical staff and other auxiliary personnel. These finalized services are aligned with the HHS Social Determinants of Health Action Plan and help implement the Biden-Harris Cancer Moonshot goal of every American with cancer having access to covered patient navigation services. Specifically, CMS is finalizing to pay separately for Community Health Integration, Social Determinants of Health (SDOH) Risk Assessment, and Principal Illness Navigation services to account for resources when clinicians involve certain types of health care support staff such as community health workers, care navigators, and peer support specialists in furnishing medically necessary care. While these types of health care support staff have been able to serve as auxiliary personnel to perform covered services incident to the services of a Medicare-enrolled billing physician or practitioner, the services described by the finalized codes are the first that are specifically designed to describe services involving community health workers, care navigators, and peer support specialists.

Community Health Integration (CHI) and Principal Illness Navigation (PIN) services involve a person-centered assessment to better understand the patient's life story, care coordination, contextualizing health education, building patient self-advocacy skills, health system navigation, facilitating behavioral change, providing social and emotional support, and facilitating access to community-based social services to address unmet social determinations of health (SDOH) needs. Community Health Integration services are to address unmet SDOH needs that affect the diagnosis and treatment of the patient's medical problems. Principal Illness Navigation services are to help people with Medicare who are diagnosed with high-risk conditions (for example, dementia, HIV/AIDS, and cancer) identify and connect with appropriate clinical and support resources. In response to comments, CMS is also finalizing an additional set of Principal Illness Navigation codes to describe services involving auxiliary personnel, such as peer support specialists to better support individuals with behavioral health conditions like severe mental

illness and substance use disorder. CMS is further clarifying that the community health workers, care navigators, peer support specialists, and other such auxiliary personnel providing these services may be employed by community-based organizations (CBOs) as long as there is the requisite supervision by the billing practitioner for these services, similar to other care management services. Access to these services should help contribute to reduced health care disparities in underserved populations with Medicare.

CMS is also finalizing coding and payment for SDOH risk assessments to recognize when practitioners spend time and resources assessing SDOH that may be impacting their ability to treat the patient. CMS is finalizing the addition of the SDOH risk assessment to the annual wellness visit as an optional, additional element with an additional payment and no patient coinsurance nor deductible (when provided with the annual wellness visit). CMS is also finalizing codes and payment for SDOH risk assessments furnished with an evaluation and management or behavioral health visit.

Evaluation and Management (E/M) Visits

Beginning January 1, 2024, CMS is finalizing implementation of a separate add-on payment for healthcare common procedure coding system (HCPCS) code G2211. This add-on code will better recognize the resource costs associated with evaluation and management visits for primary care and longitudinal care. Generally, it will be applicable for outpatient and office visits as an additional payment, recognizing the inherent costs involved when clinicians are the continuing focal point for all needed services, or are part of ongoing care related to a patient's single, serious condition or a complex condition.

For example, a primary care clinician, as the continuing focal point for all needed health care services for a patient, often bears the cognitive load, responsibility, and an accountability for building the most effective, trusting relationship possible amidst evaluating and managing other health care problems during a visit. Building an effective longitudinal relationship, in and of itself, is a key aspect of providing reasonable and necessary medical care and will make the patient more likely to comply with treatment recommendations after the visit and during future visits. It's the work building this important relationship between the practitioner and patient for primary and longitudinal care that has been previously unrecognized and unaccounted for during evaluation and management visits. In the rule, CMS provided greater detail on how clinicians can utilize the code, as requested by commenters, and may produce educational materials as is necessary.

Implementing payment for this add-on code has redistributive impacts for all other CPY 2024 payments under the Medicare Physician Fee Schedule, due to statutory budget neutrality requirements.

However, these redistributive impacts are comparatively less than what CMS initially estimated for this policy in CPY 2021 when CMS originally finalized this policy in the CPY 2021 Medicare Physician Fee Schedule final rule. At that time, Congress suspended the use of the add-on code by prohibiting CMS from making additional payment under the PFS for these inherently

complex E/M visits before January 1, 2024. Since this policy will improve the accuracy of payment for primary and longitudinal care, CMS is finalizing implementation of the policy with certain modifications for 2024.

CMS is finalizing refinements to the 2021 policy after considering information from interested parties who shared feedback in earlier rulemaking about their utilization assumptions and the estimated redistributive impact of the code on PFS payments. These changes have reduced the estimated redistributive impacts of this policy. Specifically, CMS is finalizing that the add-on code cannot be billed with an office or outpatient evaluation and management visit that is itself focused on a procedure or other service instead of being focused on longitudinal care for all needed healthcare services, or a single, serious or complex condition. Further, in response to public feedback, CMS will also consider refinements to this prohibition and monitor how the service is furnished. Second, CMS has refined their utilization estimates for HCPCS code G2211 in response to public feedback. Together, these modifications reduce the redistributive impact to the CPY 2024 conversion factor by nearly one third from the estimated impact described in the CPY 2021 Medicare Physician Fee Schedule final rule.

Split (or Shared) Evaluation and Management (E/M) visits

Split (or shared) E/M visits refer to visits provided in part by physicians and in part by other nonphysician practitioners in hospitals and other institutional settings. For CPY 2024, CMS is finalizing a revision to their definition of "substantive portion" of a split (or shared) visit to include the revisions to the Current Procedural Terminology (CPT) guidelines, such that for Medicare billing purposes, the "substantive portion" means more than half of the total time spent by the physician or nonphysician practitioner performing the split (or shared) visit, or a substantive part of the medical decision making. This responds to public comments asking that CMS allows either time or medical decision making to serve as the substantive portion of a split (or shared) visit.

Telehealth Services under the PFS

For CPY 2024, CMS is finalizing their proposal to add health and well-being coaching services to the Medicare Telehealth Services List on a temporary basis for CPY 2024, and Social Determinants of Health Risk Assessments on a permanent basis.

CMS is also finalizing refinements to their process to analyze requests received for the addition of services to the Medicare Telehealth Services List, including a determination on whether the requested services should be added permanently or provisionally.

CMS is also finalizing implementation of several telehealth-related provisions of the Consolidated Appropriations Act, 2023 (CAA, 2023), including the temporary expansion of the scope of telehealth originating sites for services furnished via telehealth to include any site in the United States where the beneficiary is located at the time of the telehealth service, including an individual's home; the expansion of the definition of telehealth practitioners to include qualified occupational therapists, qualified physical therapists, qualified speech-

language pathologists, and qualified audiologists; the continued payment for telehealth services furnished by RHCs and FQHCs using the methodology established for those telehealth services during the COVID-19 PHE; delaying the requirement for an in-person visit with the physician or practitioner within six months prior to initiating mental health telehealth services, and again at subsequent intervals as the Secretary determines appropriate, as well as similar requirements for RHCs and FQHCs; and the continued coverage and payment of telehealth services included on the Medicare Telehealth Services List (as of March 15, 2020) until December 31, 2024.

CMS is finalizing that, beginning in CPY 2024, telehealth services furnished to people in their homes will be paid at the non-facility PFS rate to protect access to mental health and other telehealth services by aligning with telehealth-related flexibilities that were extended via the CAA, 2023.

CMS is finalizing that they will continue to define direct supervision to permit the presence and immediate availability of the supervising practitioner through real-time audio and video interactive telecommunications through December 31, 2024. They believe that extending this definition of direct supervision through December 31, 2024, aligns the timeframe of this policy with many of the previously discussed PHE-related telehealth policies that were extended under provisions of the CAA, 2023.

Collectively, these policies will continue many of the flexibilities put in place during the COVID-19 PHE for Medicare telehealth services at least until the end of 2024. Telehealth services, both audiovisual and audio-only, have enabled individuals in rural and underserved areas to have improved access to care.

Telehealth Services Furnished in Teaching Settings

In the CPY 2021 PFS final rule, CMS established a policy that, after the end of the COVID-19 PHE , teaching physicians must have a physical presence to bill for their services involving residents, including Medicare telehealth services. CMS finalized an exception for residency training sites located outside of a metropolitan statistical area (MSA), in which case the teaching physician could be present through audio/video real-time communications technology.

To be consistent with the telehealth policies that were extended under the CAA, 2023, CMS exercised enforcement discretion through the end of CPY 2023 and are finalizing a policy to continue to allow teaching physicians to use audio/video real-time communications technology to be present when the resident furnishes Medicare telehealth services in all residency training locations through the end of CPY 2024. This virtual presence will meet the requirement that the teaching physician be present for the key portion of the service.

Medicare Part B Payment for Preventive Vaccine Administration Services

In June 2021, CMS announced an additional payment for in-home COVID-19 vaccine administration, which was established on a preliminary basis during the PHE. Based on resource

costs and data showing that this payment has helped improve healthcare access to vaccines for underserved Medicare populations, CMS is finalizing their proposal to maintain this additional payment for the administration of a COVID-19 vaccine in the home, and to extend this in-home additional payment to the administration of the other three preventive vaccines included in the Part B preventive vaccine benefit — the pneumococcal, influenza, and hepatitis B vaccines — when provided in the home.

Effective January 1, 2024, the payment amount for the in-home administration of all four vaccines will be identical, that is, Medicare Part B will pay the same additional payment amount to providers and suppliers that administer a pneumococcal, influenza, hepatitis B, or COVID-19 vaccine in the home. This additional payment amount will be annually updated using the percentage increase in the Medicare Economic Index and adjusted to reflect geographic cost variations. CMS is also finalizing their proposal to limit the additional payment to one payment per home visit, even if multiple vaccines are administered during the same home visit. Every vaccine dose that is furnished during a home visit will still receive its own unique vaccine administration payment.

Behavioral Health Services

For CPY 2024, CMS is implementing Section 4121 of the CAA, 2023, which provides for Medicare Part B coverage and payment under the Medicare Physician Fee Schedule for the services of marriage and family therapists (MFTs) and mental health counselors (MHCs) when billed by these professionals. Additionally, CMS is finalizing their proposal to allow addiction counselors or drug and alcohol counselors who meet the applicable requirements to be an MHC to enroll in Medicare as MHCs. MFTs and MHCs will be able to begin submitting Medicare enrollment applications after the CPY 2024 Physician Fee Schedule final rule is issued, and they will be able to bill Medicare for services starting January 1, 2024, consistent with statute. (See link here for enrollment information). CMS is also making corresponding changes to Behavioral Health Integration codes to allow MFTs and MHCs to bill for these services.

CMS is also implementing Section 4123 of the CAA, 2023, which requires the Secretary to establish new HCPCS codes under the PFS for psychotherapy for crisis services that are furnished in an applicable site of service (any place of service at which the non-facility rate for psychotherapy for crisis services applies, other than the office setting, including the home or a mobile unit) furnished on or after January 1, 2024. Section 4123 of the CAA, 2023 specifies that the payment amount for psychotherapy for crisis services shall be equal to 150% of the fee schedule amount for non-facility sites of service for each year for the services identified (as of January 1, 2022) by HCPCS codes 90839 (*Psychotherapy for crisis; first 60 minutes*) and 90840 (*Psychotherapy for crisis; each additional 30 minutes — List separately in addition to code for primary service*), and any succeeding codes.

Additionally, CMS is finalizing their proposal to allow the Health Behavior Assessment and Intervention (HBAI) services described by CPT codes 96156, 96158, 96159, 96164, 96165, 96167, and 96168, and any successor codes, to be billed by clinical social workers, MFTs, and MHCs, in addition to clinical psychologists. Health Behavior Assessment and Intervention codes

are used to identify the psychological, behavioral, emotional, cognitive, and social factors included in the treatment of physical health problems. Allowing a wider range of practitioner types to furnish these services will allow for better integration of physical and behavioral health care, particularly given that there are so many behavioral health ramifications of physical health illness.

CMS is also finalizing an increase in the valuation for timed behavioral health services under the PFS. Specifically, CMS is finalizing their proposal to apply an adjustment to the work RVUs for psychotherapy codes payable under the PFS, which CMS is implementing over a four-year transition. In response to public comments, CMS is also finalizing the application of this adjustment to psychotherapy codes that are billed with an E/M visit and to the HBAI codes. CMS believes that these finalized changes will begin to address distortions that have occurred in valuing time-based behavioral health services over many years.

Section 4121(b) of the CAA, 2023 also established that the hospice interdisciplinary group is required to include at least one social worker, MFT, or MHC. Therefore, CMS is finalizing its proposal to modify the requirements for the hospice Conditions of Participation (CoPs) to allow social workers, MHCs or MFTs to serve as members of the interdisciplinary group (IDG) and removing the proposed language requiring that the determination regarding whether a social worker, MFT or MHC serve as a member of the IDG *depending on the preferences and needs of the patient.*

Additionally, Section 4121(b) of the CAA 2023 allows MFTs and MHCs to furnish services in Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs). CMS is finalizing the requirements for the RHC and FQHC Conditions for Certification and Conditions for Coverage (CfCs) to allow MFTs and MHCs to provide additional behavioral health services in these facilities. CMS is also finalizing, as proposed, revising the definitions of several health care professionals who are already eligible to provide services at RHCs and FQHCs, including nurse practitioners. The revised definition for nurse practitioners includes the removal of the requirement that they be certified in primary care to provide care in these facilities. CMS believes that removing this requirement will aid in addressing staffing shortages that healthcare facilities are experiencing in underserved and rural communities by increasing the number of nurse practitioners eligible to provide care in RHCs and FQHCs.

In the proposed rule, CMS also sought comment on ways they can continue to expand access to behavioral health services and requested information on digital therapies, including digital cognitive behavioral therapy, which CMS may consider for future rulemaking.

Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

CMS is finalizing conforming regulatory text changes to implement Sections 4113 and 4121 of the CAA, 2023, specifically, extending payment for telehealth services furnished in RHCs and FQHCs through December 31, 2024, delaying the in-person requirements under Medicare for mental health visits furnished by RHCs and FQHCs, and including marriage and family therapists (MFTs) and mental health counselors (MHCs) as eligible for payment.

In addition, CMS is aligning enrollment policies so that addiction, drug, or alcohol counselors who meet all of the requirements of MHCs to enroll with Medicare as MHCs will also apply for RHCs and FQHCs.

CMS also notes that Section 4124 of Division FF of the CAA, 2023 established Medicare coverage and payment for intensive outpatient program (IOP) services furnished by an RHC or FQHC. CMS' finalized proposals are described in the CPY 2024 Outpatient Prospective Payment System rule.

CMS is finalizing their proposal to extend the definition of direct supervision to permit virtual presence in RHCs and FQHCs through December 31, 2024.

CMS is also finalizing their proposal to change the required level of supervision for behavioral health services furnished "incident to" a physician or NPP's services in RHCs and FQHCs to allow general supervision, rather than direct supervision, consistent with the policies finalized under the PFS during last year's rulemaking for other settings.

CMS is finalizing their proposal to include Remote Physiologic Monitoring and Remote Therapeutic Monitoring in the general care management HCPCS code G0511 when these services are furnished by RHCs and FQHCs.

In addition, CMS is finalizing their proposal to include Community Health Integration (CHI) and Principal Illness Navigation (PIN) services in the general care management HCPCS code G0511 when these services are provided by RHCs and FQHCs. RHCs and FQHCs that furnish CHI and PIN services will be able to bill these services using HCPCS code G0511, either alone or with other payable services on an RHC or FQHC claim, for dates of service on or after January 1, 2024.

CMS is also finalizing a change in the methodology to calculate the payment rate for the general care management HCPCS code G0511 that takes into account how frequently the various services are utilized.

Finally, CMS is clarifying that obtaining beneficiary consent for chronic care management and virtual communications services is required, but the mode of obtaining the consent can vary and direct supervision is not needed.

Opioid Treatment Programs (OTPs)

CMS is finalizing its proposal to extend current flexibilities for periodic assessments that are furnished via audio-only telecommunications through the end of CPY 2024. CMS will allow OTPs to bill Medicare under the Part B OTP benefit for furnishing periodic assessments via audio-only telecommunications when video is not available to the beneficiary, to the extent that use of audio-only communications technology is permitted under the applicable SAMHSA and DEA requirements at the time the service is furnished, and all other applicable requirements are met. CMS believes extending this flexibility by an additional year (through CPY 2024) may

promote continued beneficiary access to these services by minimizing potential disruptions to services following the end of the COVID-19 PHE. This extension will also better align telehealth flexibilities for OTPs with telehealth flexibilities authorized for certain other settings under the CAA, 2023.

Supervision Policy for Physical and Occupational Therapists in Private Practice

Since 2005, CMS has required PTs and OTs in private practices (PTPPs and OTPPs, respectively) to provide direct supervision of their therapy assistants. CMS is finalizing a regulatory change to allow for general supervision of therapy assistants by PTPPs and OTPPs for remote therapeutic monitoring (RTM) services. This will align with the RTM general supervision policy that CMS finalized in their CPY 2023 rulemaking.

In the proposed rule, CMS solicited comments on whether to revise the current direct supervision policy for therapy assistants working with PTPPs and OTPPs to require general supervision for all therapy services, not just for RTM services. In particular, CMS sought feedback and any available supporting data on the potential effects of implementing such a policy, including but not limited to patient quality of care, patient safety, and changes in utilization. CMS received feedback in response to all of their questions and will take it into consideration for future rulemaking.

Payment for Outpatient Therapy Services, Diabetes Self-Management Training (DSMT), and Medical Nutrition Therapy (MNT) when Furnished by Institutional Staff to Beneficiaries in Their Homes Through Communication Technology

As discussed in Frequently Asked Questions on CMS waivers, flexibilities, and the end of the COVID-19 public health emergency (PHE), institutional providers are able to continue to bill for physical therapy, occupational therapy, speech-language pathology, DSMT and MNT services on the telehealth list furnished remotely the same way that they could during the PHE through the end of CPY 2023. CMS is finalizing the proposed policy that — with the addition of a requirement to use the 95 modifier on all claims, except Method II critical access hospitals (CAHs), and — to note specifically for outpatient hospitals that patients' homes no longer need to be designated as provider-based entities — continues to allow institutional providers to bill for outpatient therapy, DSMT, and MNT services furnished remotely at least through the end of CPY 2024.

In the proposed rule, CMS sought comment on the effectiveness of these services when furnished remotely, compared to in person, and may consider this feedback for future rulemaking.

Diabetes Self-Management Training (DSMT) Services Furnished by Registered Dietitians (RDs) and Nutrition Professionals

CMS is finalizing an amendment to the regulatory provision at § 410.72(d), that CMS established during CPY 2022 PFS rulemaking, that clarifies that an RD or nutrition professional

must personally perform MNT services, but the enrolled RD or nutrition professional, when acting as the DSMT certified provider, may bill for, or on behalf of, the entire DSMT entity, regardless of which professional personally delivers each aspect of the services. This finalized policy builds on recent policy changes designed to improve access to DSMT services.

Telehealth Proposals for DSMT Services

Currently, CMS's manual instruction for DSMT payment in the Medicare Claims Processing Manual, Pub. 100-04, chapter 12, Section 190.3.6, requires one hour of the 10-hour DSMT benefit's initial training and one hour of the two-hour follow-up annual training to be furnished in-person to allow for effective injection training when injection training is applicable for insulin-dependent beneficiaries. However, with the expansion of the use of telehealth during the PHE for COVID-19, CMS believes that there have been significant changes in clinical standards, guidelines, and best practices regarding services furnished using interactive telecommunications technology, including for injection training for insulin-dependent patients. Because CMS does not want their policies to prevent injection training via telehealth when clinically appropriate, CMS is finalizing the proposal to allow the entirety of DSMT services to be furnished via telehealth. CMS is also finalizing a policy that will better align billing rules for DSMT furnished in-person and via telehealth. These policies are expected to promote access to historically underutilized DSMT services that have been shown to improve care for individuals with diabetes.

Expanded Diabetes Screening

CMS is finalizing their proposal to expand coverage of diabetes screening to include the Hemoglobin A1c (HbA1c) test. CMS is also finalizing their proposal to simplify and expand diabetes screening frequency limitations and to remove the specific clinical test criteria from the codified definition of "diabetes" for screening, MNT and DSMT regulations. CMS's final rule will remove barriers, reduce provider and patient burden and confusion, and allow for greater person-centered care.

Dental and Oral Health Services

Historically, Medicare has paid for dental services in some clinical circumstances when dental services are inextricably linked to the clinical success of specific covered medical services. In last year's PFS final rule, CMS codified that Medicare payment under Parts A and B could be made when dental services are furnished in either the inpatient or outpatient setting under particular kinds of circumstances.

Specifically, in CPY 2023, CMS finalized:

1) CMS's proposal to clarify and codify certain aspects of previous Medicare FFS payment policies for dental services.

2) Payment for dental services that are inextricably linked to other covered medical services, such as dental exams and necessary treatments prior to organ transplants (including stem cell and bone marrow transplants), cardiac valve replacements, and valvuloplasty procedures.

3) A process to review and consider public submissions for potentially analogous clinical scenarios under which Medicare payment could be made for dental services.

4) Medicare payment, beginning in CPY 2024, for dental exams and necessary treatments prior to the treatment for head and neck cancers.

For CPY 2024, CMS is building up on their efforts in the CPY 24 PFS final rule and are finalizing:

1. A codification of the previously finalized payment policy for dental services for head and neck cancer treatments, whether primary or metastatic.

2. The codification to permit Medicare Part A and Part B payment for dental or oral examination performed as part of a comprehensive workup prior to medically necessary diagnostic and treatment services, to eliminate an oral or dental infection prior to, or contemporaneously with, those treatment services, and to address dental or oral complications after radiation, chemotherapy, and/or surgery when used in the treatment of head and neck cancer.

3. CMS's proposal to permit payment for certain dental services inextricably linked to other covered services used to treat cancer prior to, or during:

    1. Chemotherapy services.

    2. Chimeric Antigen Receptor T- (CAR-T) Cell therapy.

    3. The use of high-dose bone modifying agents (antiresorptive therapy).

These final policies are consistent with the Agency for Healthcare Research and Quality's July 2023 report, "Efficacy of Dental Services for Reducing Adverse Events in Those Receiving Chemotherapy for Cancer," on dental services in these contexts[1]. These policies will improve the success of these cancer-related treatments and improve access to certain dental care in these circumstances. In the proposed rule, CMS also sought comment on additional circumstances where evidence supports dental services being integral to the clinical success of covered medical services, which CMS may consider for future rulemaking.

In February 2024, CMS will accept and consider public submissions for potentially analogous clinical scenarios under which Medicare payment could be made for dental services. These submissions will help inform future rulemaking. As part of this process, CMS encourages members of the public to review the ARHQ's July 2023 report, "Efficacy of Dental Services for Reducing Adverse Events in Those Receiving Chemotherapy," as an example of the clinical analyses CMS solicits to inform future rulemaking on dental services and care inextricably linked to medical need in the Medicare population.

Provisions from the Inflation Reduction Act Relating to Drugs and Biologicals Payable Under Medicare Part B

The Inflation Reduction Act (Pub. L. 117-169, August 16, 2022) contains several provisions that affect payment limits for beneficiary out-of-pocket costs for certain drugs payable under Part B. In this final rule, CMS address the following:

- Section 11402 amends the payment limit for new biosimilars furnished on or after July 1, 2024, during the initial period when ASP data is not available. CMS is finalizing the codification of this provision in regulation.

- Section 11403 makes changes to the payment limit for certain biosimilars with an ASP that is not more than the ASP of the reference biological for a period of five years. CMS implemented Section 11403 of the IRA under program instruction, as permitted under Section 1847A(c)(5)(C) of the Act. CMS is finalizing conforming changes to regulatory text to reflect these provisions.

- Section 11101 requires that beneficiary coinsurance for a Part B rebatable drug is to be based on the inflation-adjusted payment amount if the Medicare payment amount for a calendar quarter exceeds the inflation-adjusted payment amount, beginning on April 1, 2023. CMS issued initial guidance implementing this provision, as permitted under Section 1847A(c)(5)(C) of the Act, on February 9, 2023. CMS is finalizing conforming changes to regulatory text.

- Section 11407 provides that for insulin furnished through an item of DME on or after July 1, 2023, the deductible is waived and coinsurance is limited to $35 for a month's supply of insulin furnished through a covered item of DME. CMS has implemented this provision under program instruction for 2023, as required under Section 11407(c) of the IRA. CMS is finalizing the codification of this provision for 2024 and future years in a manner that is consistent with the program instruction.

Drugs and Biologicals that are Not Usually Self-Administered by the Patient, and Complex Drug Administration Coding

In the proposed rule, CMS solicited comments regarding their policies on the exclusion of coverage for certain drugs under Part B that are usually self-administered by the patient. In addition, CMS sought comment on coding and payment policies for complex non-chemotherapeutic drugs, in an effort to promote coding and payment consistency and patient access to infusion services. CMS will consider these comments for potential future rulemaking.

Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs to Provide Refunds with Respect to Discarded Amounts

In the CPY 2023 PFS final rule, CMS adopted many policies to implement Section 90004 of the Infrastructure Investment and Jobs Act. Among them, CMS finalized: a definition of "refundable

single-dose container or single-use package drug," which also specifies certain exclusions; reporting requirements for use of the JW modifier to report discarded amounts of drugs from single-dose containers and the use of the JZ modifier for such drugs with no discarded amounts; an increased applicable percentage of 35% for a category of drugs with unique circumstances; and a dispute resolution process.

In the CPY 2024 PFS final rule, CMS is finalizing additional policies to implement this provision, including: timelines for the initial and subsequent discarded drug refund reports to manufacturers, the method of calculating refunds for discarded amounts from lagged claims data, the method of calculating refunds when there are multiple manufacturers for a refundable drug, increased applicable percentages for certain drugs with unique circumstances (e.g., drugs with small volume doses and rarely utilized orphan drugs), and an application process by which manufacturers may request an increased applicable percentage for a drug with unique circumstances. CMS is also finalizing a modification to the JW and JZ modifier policy for drugs payable under Part B from single-dose containers that are furnished by a supplier who does not administer the drug.

Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-In of Payment Reductions

In accordance with Section 4114 of the CAA, 2023, CMS is finalizing their proposal to make certain conforming changes to the data reporting and payment requirements for clinical diagnostic laboratory tests (CDLTs). Specifically, CMS is updating the regulatory definition of both the "data collection period" and "data reporting period," specifying that for the data reporting period of January 1, 2024, through March 31, 2024, the data collection period for CDLTs that are not advanced diagnostic laboratory tests (ADLTs) is January 1, 2019 through June 30, 2019. CMS is also finalizing revisions to indicate that initially, data reporting begins January 1, 2017, and is required every three years beginning January 2024. In addition, CMS is finalizing conforming changes to their requirements for the phase-in of payment reductions to reflect the amendments in Section 4114(a) of the CAA, 2023. Specifically, CMS is revising the regulations to indicate that for CPY 2023, payment for a CDLT that is not an ADLT may not be reduced compared to the payment amount established for that test in CPY 2022, and for CPYs 2024 through 2026, payment may not be reduced by more than 15% as compared to the payment amount established for that test for the preceding year.

Ambulance Fee Schedule (AFS): Ambulance Extenders Provisions

Section 4103 of the CAA, 2023 extended three existing temporary add-on payments to the ground ambulance base and mileage rates under the AFS through December 31, 2024. Accordingly, CMS is finalizing their proposal to revise their regulations at 42 CFR §414.610(c)(1)(ii) and 414.610(c)(5)(ii) in this final rule to align with existing law.

Medicare Ground Ambulance Data Collection System (GADCS)

Section 50203(b) of the Bipartisan Budget Act of 2018 required CMS to finalize regulations for a ground ambulance data collection system by December 31, 2019. This legislation also required CMS to identify the providers and suppliers required to submit information each year through 2024 and no less than once every three years after 2024. The GADCS is required to collect cost, revenue, utilization, and other information with respect to providers and suppliers of ground ambulance services in order to evaluate the extent to which reported costs relate to payment rates. The GADCS portal went live on January 1, 2023 and, for the first time, CMS will collect this information and provide the data to MedPAC for its report to Congress. CMS identified opportunities to improve the GADCS instrument through stakeholder engagement. Accordingly, CMS is finalizing their proposals for the following changes to the GADCS instrument in this final rule: Adding the ability to address partial year responses from ground ambulance organizations, introducing a minor edit to improve the reporting consistency of hospital-based ambulance organizations, and four technical corrections to typos.

Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Program

CMS is finalizing the proposal to pause efforts to implement the Appropriate Use Criteria (AUC) program. CMS is rescinding the current AUC program regulations at 42 CFR 414.94. CMS will continue efforts to identify a workable implementation approach, and any such approach would be proposed through subsequent rulemaking.

Request for Information (RFI) on the Histopathology, Cytology, and Clinical Cytogenetics Regulations under the Clinical Laboratory Improvement Amendments (CLIA) of 1988

CMS solicited comments in the following areas of CLIA: Histopathology, Cytology, and Clinical Cytogenetics. CMS received 52 comments. Commentors were in favor of updating the CLIA ’88 regulations in Histopathology, Cytology, and Clinical Cytogenetics to reflect advancements in technology and current laboratory practices. CMS will consider the input received as they continue to evaluate possible future changes to the CLIA regulations.

Medicare Diabetes Prevention Program (MDPP) Expanded Model

CMS finalized changes to extend the MDPP Expanded Model’s Public Health Emergency Flexibilities for four years, which will allow all MDPP suppliers to continue to offer MDPP services virtually through December 31, 2027, if suppliers maintain an in-person Centers for Disease Control and Prevention (CDC) Diabetes Prevention Recognition Program (DPRP) and utilize a new HCPCS G-Code for distance learning. CMS also finalized changes to simplify MDPP’s current performance-based payment structure by allowing fee-for-service payments for beneficiary attendance.

Medicare and Medicaid Provider and Supplier Enrollment

CMS is finalizing several regulatory provisions regarding Medicare and Medicaid provider enrollment. These include, but are not limited to, the following:

- Creation of a new Medicare provider enrollment action labeled a "stay of enrollment," which CMS believes will ease the burden on providers and suppliers while strengthening Medicare program integrity. (The final provisions include several modifications suggested by commenters.)

- Requiring all Medicare provider and supplier types to report additions, deletions, or changes in their practice locations within 30 days.

- Establishing several new and revised Medicare denial and revocation authorities.

- Clarifying the length of time for which a Medicaid provider will remain in the Medicaid termination database.

Requirement for Electronic Prescribing for Controlled Substances (EPCS) for a Covered Part D Drug under a Prescription Drug Plan or an MA-PD Plan

CMS is finalizing the provision as proposed to continue the practice of issuing a prescriber notice of non-compliance as the non-compliance action for subsequent measurement years.

CMS may consider a prescriber's non-compliance under the CMS EPCS program in their processes for assessing potential fraud, waste, and abuse, which, in some instances, could result in a referral to law enforcement or revocation of billing privileges, in the event that evidence of fraud, waste, or abuse is present.

CMS is also finalizing the provisions as proposed to:

- Remove the same entity exception.

- Determine compliance by counting unique prescriptions in the measurement year by prescription number assigned by the pharmacy and included in the Part D claims data. This would exclude refills (which are not separately transmitted) from the compliance calculations and include renewals, which are assigned a new prescription number by the pharmacy.

- Update the exception for emergencies to allow CMS to identify which emergencies qualify for the exception and establishing that, as a default, prescribers impacted by the recognized emergency exception would be excepted for the entire measurement year.

- Updates to extraordinary circumstances waivers to further clarify the process for applying for a waiver, and the circumstances in which CMS can grant a waiver, and establishing that approved waivers would apply to the entire measurement year.

CMS is also affirming that, as discussed in the proposed rule and under the existing regulation at § 423.160(a)(5), the CMS EPCS Program will continue to align with Part D e-prescribing standards.