CY 2024 Medicare Physician Fee Schedule Final Rule Summary

On November 2, the Centers for Medicare & Medicaid Services (CMS) released the Medicare Physician Fee Schedule (MPFS) final rule for CY 2024 (CMS-1784-F). The rule updates payment policies and payment rates for Part B services furnished under the MPFS, and makes changes to the Quality Payment Program (QPP). The rule in its entirety and the addenda, including Addendum B, which lists the final RVUs for each CPT® code can be found here.

CMS finalized several significant policy changes, including the implementation of HCPCS G2211, an add-on for services associated with complex patient care; reimbursement for health-related social needs services; and the maintenance of several telehealth payment policies until the end of 2024. The following summarizes the major policies of the rule. Note that the page numbers listed in this document refer to the <u>display copy</u> of the final rule.

Regulatory Impact Analysis

Highlight: Conversion factor set for a decrease again for CY 2024

Conversion Factor for 2024

The conversion factor for 2024 is set to decrease by approximately **3.37% from \$33.8872 to \$32.7442**. This 2024 conversion factor is derived from a statutory 0% update, a negative 2.18% RVU budget neutrality adjustment, and the expiration of 1.25% of the payment increase as provided by the Consolidated Appropriations Act (CAA) of 2023. Without Congressional action, CMS cannot implement policy to avert the cut to the conversion factor.

Specialty Level Impact of the Final Rule – p. 1,950

The impact on group practices and individual physicians varies based on practice type and the mix of patients and services provided to those patients. The following table outlines estimated specialty level impacts from Table 118 of the rule, also shown in Appendix D of this document and includes some specialties with the greatest impact, both positive and negative for comparison purposes. The impact table estimates include the effects of the implementation of G2211 and other policy changes in the fee schedule and does not include the expiration of the 1.25% payment increase implemented in the CAA of 2023.

Table 1: CY 2024 Estimated Impact Total Allowed Charges by Specialty for Selected Specialties

	Medicare Allowed	Work RVU	PE RVU	MP RVU	Overall
Specialty	Charges (millions)	Impact	Impact	Impact	Impact
Endocrinology	\$507	1%	1%	0%	3%
Hematology/Oncology	\$1,591	1%	0%	0%	2%
Rheumatology	\$509	1%	1%	0%	2%
Internal Medicine	\$9,618	0%	1%	0%	1%
Gastroenterology	\$1,474	0%	0%	0%	0%
Allergy/Immunology	\$216	0%	-1%	0%	-1%
Infectious Diseases	\$573	-1%	0%	0%	-1%
Vascular Surgery	\$1,009	0%	-3%	0%	-3%
Interventional Radiology	\$457	-1%	-3%	0%	-4%

Determination of Practice Expense RVUs - p. 34

Highlight: No change in the MEI methodology while CMS waits for updated practice expense data from the AMA.

Last year, CMS finalized policy to rebase and revise the Medicare Economic Index (MEI) to reflect current market conditions in the delivery of physician services. However, after receiving comments on this issue, and considering the American Medical Association's (AMA) ongoing project of updating and collecting new data through the Physician Practice Information Survey, CMS delayed using rebased and revised MEI data for 2024 rate setting. ASH and other medical specialty societies will join a call organized by the AMA with CMS in early December to discuss the current payment policy changes. ASH will provide relevant updates to members.

Review of Potentially Misvalued Services: CPT codes 36514, 36516, 36522 - p. 85

CPT codes 36514 (Therapeutic apheresis; for plasma pheresis), 36516 (Therapeutic apheresis; with extracorporeal immunoadsorption, selective adsorption or selective filtration and plasma reinfusion), and 36522 (Photopheresis, extracorporeal) were nominated as potentially misvalued in the proposed rule. The nominator stated that the direct practice expense input for clinical labor L042A, "RN/LPN" (for labor rate of \$0.525 per minute) is incorrect and should be changed to a more specific clinical labor type.

CMS agrees with nominator and commenters that the practice expense inputs for clinical labor for these services may be misvalued. The agency has labeled the codes as potentially misvalued, and therefore, the services will be reviewed by the AMA Relative Value Service (RVS) Update Committee (RUC) at the January 2024 meeting.

Payment for Medicare Telehealth Services Under Section 1834(m) of the Act – p. 97

Highlight: CMS updates telehealth regulations to be consistent with Consolidated Appropriations Act (CAA) 2023 extensions and will continue to pay for telehealth services at the non-facility rate if the place of service (POS) code indicates the originating site is the patient's home.

CMS Adds New Code for Assessing Social Determinants of Health (SDOH) to the Telehealth List

CMS finalized the addition of HCPCS code G0136 (Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment tool, 5-15 minutes) to the telehealth list on permanent basis. This service requires a face-to-face encounter between a clinician and beneficiary during which the practitioner uses their clinical judgement to determine whether to complete the SDOH screening with or without direct patient interaction. The service must be delivered on the same day as an evaluation and management (E/M) service, which can be delivered via telehealth.

Implementation of Provisions of the Consolidated Appropriations Act, 2023

The CAA 2023 extended certain telehealth policies through December 31, 2024. CMS seeks to update its regulations to reflect this extension for the following flexibilities: (1) waiver of in-person requirements for mental health telehealth; 2) the waiver of originating site requirements; (3) the expansion of telehealth practitioners to include occupational therapists, physical therapists, speech-language pathologists, and audiologists as well as marriage and family therapists and mental health counselors as of January 1, 2025; and (4) audio-only services.

In the CY 2023 final rule, CMS established Point of Service (POS) 10 for telehealth provided in the patient's home. The agency finalized that claims billed with POS 10 will be paid at the non-facility rate beginning in CY 2024 in recognition that practitioners will need to maintain an in-person practice setting in addition to providing telehealth services. Claims billed with POS 02 (Telehealth Provided Other than in Patient's Home) will continue to be paid at the facility rate beginning on January 1, 2024. CMS believes, for these non-home originating sites, such as physician's offices and hospitals, the facility rate more accurately reflects the PE of these telehealth services. Through this policy, the agency seeks to protect access to mental health and other telehealth services by aligning with the telehealth-related flexibilities that were extended via the CAA, 2023.

Other Non-Face-to-Face Services Involving Communications Technology under the PFS

Direct Supervision

With the end of the public health emergency, CMS was concerned about the expiration of policy that allowed direct supervision via a virtual presence Therefore, the agency finalized that direct supervision may be defined as presence and "immediate availability" of the supervising practitioner through real-time audio and visual interactive telecommunications through December 31, 2024, to align with the extension of other telehealth flexibilities through that date.

Supervision of Residents in Teaching Settings

In the CY 2021 final rule, CMS included a policy to allow teaching physicians to supervise residents virtually for services delivered in residency training sites that are located outside of an Office of Management and Budget-defined metropolitan statistical area (MSA) after the end of the public health emergency and now seeks to align this policy with other telehealth policies. The agency has finalized that it is permissible for the teaching physician to have a virtual presence in all teaching settings for services provided virtually through December 31, 2024. The virtual presence policy would continue to require real-time observation by the teaching physician and would exclude audio-only technology. The documentation must include whether the physician was physically present or present virtually at the time of the telehealth service. CMS is exercising enforcement discretion to allow teaching physicians in all residency training sites to be present virtually for services furnished involving residents through December 31, 2023.

Clarifications for Remote Monitoring Services

Under current policy, remote physiologic monitoring (RPM) services may only be delivered to established patients now that the public health emergency has expired. Patients who received initial remote monitoring services during the public health emergency are now considered established patients for the purpose of this policy.

The agency is not extending its interim policy to permit billing for remote monitoring codes when less than 16 days of data are collected within a given 30-day period. This 16-day monitoring requirement was reinstated when the public health emergency expired and applies to RPM and remote therapeutic monitoring (RTM) services. This requirement applies to the following CPT codes: 98976, 98977, 98978, 98980, and 98981.

Use of RPM, RTM, in conjunction with other services

Either RPM or RTM, but not both, may be billed concurrently with the following care management services: Chronic Care Management (CCM), Transitional Care Management (TCM), Behavioral Health Integration (BHI), Principal Care Management (PCM), and Chronic Pain Management (CPM). CMS intends to provide maximum flexibility for practitioners to select the appropriate mix of care management services without creating program integrity concerns.

Other Clarifications for Appropriate Billing

CMS has received inquiries regarding the use of remote monitoring during surgical global periods and proposes to clarify that RPM or RTM services may be furnished and paid separately from the global period if the requirements for the global and remote monitoring service are both met.

Telephone Evaluation and Management Services

Since the start of the public health emergency, CMS has separately paid for CPT codes 99441 through 99443 and 98966 and 98968, which describe E/M and assessment and management services delivered via telephone. The agency will continue to assign an active payment status for these services through CY 2024 to align with the telehealth flexibilities extended through 2024.

Telehealth Originating Site Facility Fee Payment Amount Update

For CY 2024, CMS finalized a payment amount \$29.96 for HCPCS code Q3014 (Telehealth originating site facility fee).

Payment for Caregiver Training Services (CTS) - p. 285

Highlight: Caregiver training seen as key to success in patient outcomes.

In recent years, CMS has been exploring policies to increase support and training needed when caring for patients that have certain illnesses and diseases. Beginning in 2024, and in alignment with the White House executive order to increase access to high quality care and increase support for caregivers, CMS will make payment for CTS by establishing an active payment status for CPT codes 96202 (Multiple-family group behavior management/modification training for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of parent(s)/guardian(s)/caregiver(s); initial 60 minutes) and 96203 (each additional 15 minutes). Payment for caregiver training services will go into effect January 1, 2024.

Additionally, the agency finalized payment for new codes 97550 (Caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (e.g., activities of daily living [ADLs], instrumental ADLs [IADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face-to-face; initial 30 minutes), 97551 (;each additional 15 minutes), and 97552 Group caregiver training in strategies and techniques to facilitate the patient's functional performance in the home or community (e.g., activities of daily living [ADLs], instrumental ADLs [IADLs], transfers, mobility, communication, swallowing, feeding, problem solving, safety practices) (without the patient present), face-to-face with multiple sets of caregivers).

After considering public comments, the agency revised the definition of caregiver in the final rule, which now reads as a caregiver is "an adult family member or other individual who has a significant relationship with, and who provides a broad range of assistance to, an individual with a chronic or other health condition, disability, or functional limitation" and "a family member, friend, or neighbor who provides unpaid assistance to a person with a chronic illness or disabling condition."

Evaluation and Management (E/M) Visits - p. 422

Highlight: Amid controversy and after a three-year delay, CMS finalizes implementation of G2211, which is a code that will be used to pay for complex care services delivered by a provider with an ongoing relationship with the patient.

Office/Outpatient (O/O) E/M Visit Complexity Add-on Implementation

Background: In CY 2021, CMS finalized the O/O E/M visit complexity add-on code G2211 to describe intensity and complexity inherent to O/O E/M visits for medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex condition. The agency planned for the add-on code to be reported with all O/O E/M service levels. However, Congress delayed the code's implementation until January 1, 2024.

Since the delay of the code's implementation and during the comment period for the CY 2024 MPFS rule, CMS received feedback from stakeholders on several issues: when it would be appropriate to report G2211, the redistributive impact of its implementation, the overlap of services between G2211 and other E/M codes, the definition of "complex and serious," cost sharing implications for beneficiaries, and administrative burden of reporting the code, among many other issues.

CMS addressed some comments in the final rule, but of note, the agency believes that this new G code will address "longstanding issues with coding and valuation of O/O E/M services that do not fully distinguish and account for resource costs for primary care and other longitudinal care for complex patients, but specifically for visits associated with longitudinal, non-procedural care when compared to work RVUs for procedural services and visits furnished in association with procedural-based care." The agency also believes that the work and expertise of those who primarily bill E/M codes for their services are "left relatively underrecognized within the previous and current E/M coding and valuation structure."

Despite the concerns from some stakeholders, the agency has finalized the implementation of G2211, as an add-on code to office visit E/M services, effective January 1, 2024. G2211 will have a work RVU of 0.33 and will have a payment of approximately \$16.00. The code is not payable when the office visit is reported with payment modifier - 25, meaning G2211 cannot be billed when an office visit is billed on the same day as a procedure or other service delivered by the same practitioner.

The agency also maintained the proposed utilization assumptions that G2211 will be billed with 38% of all office visit E/M visits, at least initially.

Finally, to provide clarity as to when G2211 should be billed, the agency has explained that the single most important factor when deciding to bill for services associated with the code is the *relationship* between the patient and the practitioner. When the practitioner is "the continuing focal point for all health care services that the patient needs," that is how it should be decided to bill for the service or not. For example, if a patient reports to the office with a sinus infection, and the practitioner is the focal point for all health care services and needs of this patient, then it would be appropriate to report the complex add-on code with the E/M service. As the agency has described it, it is the "cognitive load of the continued responsibility of being the focal point for all needed services for this patient" that determines if the complex care add-on code is appropriate.

Request for Comment About Evaluating E/M Services More Regularly and Comprehensively

CMS requested comment about the range of approaches that the agency could take to improve the accuracy of valuing services and was particularly interested in how E/M services might be evaluated with greater specificity, more regularly and comprehensively.

CMS received comments that provided the agency with opinions and options about how to best value services under the MPFS. As expected, the comments were divided in support of the AMA RUC process, and those that would welcome another approach such as an expert panel that would fall under CMS's purview. Others recommended that CMS use real-world data to value physician services, and not data that is derived from physician surveys.

The agency welcomed all the comments and thoughtful responses and noted that they will consider all comments to inform future rulemaking.

Split/Shared Visits – p. 468

A split/shared visit is an E/M service performed by a physician and a nonphysician practitioner (NPP) in the same group practice in the facility setting where the "incident to" policy does not apply. CMS proposed, and delayed multiple times, that the "substantive portion of the service" which determines the practitioner that bills for the service—the physician or the NPP—would be defined by the practitioner that provides more than half the service using time as the deciding factor. After review of comments, and in consideration of the revision to coding guidance in the 2024 CPT coding manual, the agency has finally defined the substantive portion to mean "more than half of the total time spent by the physician and NPP performing the split (or shared) visit, or a substantive part of the medical decision making as defined by CPT." The revised definition and hence payment policy will become effective January 1, 2024.

Services Addressing Health-Related Social Needs (Community Health Integration Services, Social Determinants of Health Risk Assessment, and Principal Illness Navigation Services)

Highlight: The agency will pay for new services to provide greater access to care that includes payment for community health worker (CHW) services.

Community Health Integration Services (CHI) – p. 307

The agency has taken steps to recognize the valuable services that CHWs provide when assisting Medicare beneficiaries with services not typically reimbursed on the MPFS. Therefore, CMS finalized the creation of two new

HCPCS codes to describe services performed by "certified or trained auxiliary personnel, which may include a CHW, incident to the professional services and under the general supervision of the billing practitioner."

The services described by the new codes are expected to be provided monthly after an E/M visit (CHI initiating visit) in which the provider identifies the need for CHI based on the presence of certain social determinants of health (SDOH) factors. The framework for the provision of these services is like that for care management services. The first visit, the CHI initiating visit would "serve as the pre-requisite for billing CHI services by the billing practitioner" whereby they would identify and assess the SDOH needs of the patient that limit the practitioner's ability to diagnose and treat the patient's medical condition. Any of the follow-up CHI performed by the CHW or other authorized personnel may bill incident to the professional services of the practitioner who billed the initiating visit. For the code descriptors, see page 317 of the display copy of the final rule.

Social Determinants of Health – Establishment of a HCPCS G Code – p. 343

One of the pillars of the Biden administration has been the development of policies and regulations that address health equity and fair access to government funded programs. As a part of this initiative, the agency has finalized the creation and payment for HCPCS code G0136 - Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment, 5-15 minutes, not more often than every 6 months.

The code was developed to account for time and other resources required when providers are assessing their patient's SDOH, as those factors usually affect the outcome of treatment. After consideration of comments, CMS will **NOT** require that the risk assessment be performed on the same day as an E/M service. The required elements of the assessment however, remained unchanged from the proposed rule and must include "administration of a standardized, evidence-based SDOH risk assessment tool that has been evaluated and validated through research, and includes the domains of food insecurity, housing insecurity, transportation needs, and utility difficulties."

When SDOH needs are identified through the risk assessment, those needs must be documented in the medical record. While not required, the agency is encouraging the use of ICD-10-CM Z codes (Z55-Z65) to document findings of the assessment within the patient's medical record. CMS finalized adding SDOH Risk Assessment as an optional, additional element of the annual wellness visit that would include additional payment for the provision of this service. There would be no cost-sharing for the beneficiary.

Finally, the agency was appreciative of the thoughtful and thorough comments on the frequency and limitations of the use of the SDOH G code. After review of comments, the agency has finalized a limitation on payment for the SDOH risk assessment service of once every six months per practitioner per beneficiary.

Principal Illness Navigation – p. 361

Included in this final rule and conforming with other finalized policies that expand care for many different types of populations, CMS finalized HCPCS codes and payment to describe services associated with the care of patients with a "serious, high-risk disease expected to last at least 3 months, that places the patient at significant risk of hospitalization or nursing home placement, acute exacerbation/decompensation, functional decline, or death, and the condition requires development, monitoring, or revision of a disease-specific care plan, and may require frequent adjustment in the medication or treatment regimen, or substantial assistance from a caregiver."

The new services, Principal Illness Navigation (PIN), are like CHI services, but the patient may not necessarily have SDOH that affect their care and as such may involve "service elements to describe identifying or referring the patient to appropriate supportive services, providing information/resources to consider participation in clinical research/clinical trials, and inclusion of lived experience or training in the specific condition being addressed." The services may be billed incident to physician services and may be provided under general supervision. The code descriptions can be found on page 373 of the final rule. The service described by code G0023 is billed 60 minutes per calendar month, and the second code, G0024 is billed each additional 30 minutes per calendar month.

Medicare Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Medical Services – p. 574

Highlight: CMS continues to recognize the importance of dental care in the overall health of Medicare beneficiaries. However, decides to not include SCD as a covered indication for dental services.

Medicare Payment for Dental Services

In the CY 2023 MPFS final rule, the agency identified certain clinical scenarios where payment is permitted under Parts A and B for certain dental services that are not services in conjunction with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, defined in the proposed rule as "dental services." This includes dental services that are inextricably linked to, and substantially related to the clinical success of, certain other covered services. CMS also created an annual public process where stakeholders can submit recommendations for other scenarios to include on the list of dental services that may be covered under the statute.

The agency finalized the proposal to add several other cases where dental services are inextricably linked to other covered services. These include:

- Chemotherapy, when used in the treatment of cancer;
- CAR T-Cell therapy, when used in the treatment of cancer;
- Administration of high-dose bone-modifying agents (antiresorptive therapy), when used in the treatment of cancer.

CMS will allow payment under Parts A and B for the following:

- Dental or oral examination performed as part of a comprehensive workup prior to the following Medicare-covered services: chemotherapy when used in the treatment of cancer, CAR T-Cell therapy when used in the treatment of cancer, the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer, and after radiation, chemotherapy and/or surgery when used in the treatment of head and neck cancer; and
- Medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with chemotherapy when used in the treatment of cancer, CAR T-Cell therapy when used in the treatment of cancer, the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer, and after radiation, chemotherapy and/or surgery when used in the treatment of head and neck cancer.

Request for Information on Dental Services Integral to Specific Covered Services to Treat Sickle Cell Disease (SCD) and Hemophilia Stakeholders encouraged CMS to provide payment for dental services for individuals living with sickle cell disease (SCD) and hemophilia. The agency sought comments on whether certain dental services are inextricably linked to other covered services used in the treatment of SCD, such as hydroxyurea therapy. The agency also sought comments to identify any covered services for hemophilia that are inextricably linked to dental services, and whether dental services such as prophylaxis are a standard of care in the management of hemophilia.

After reviewing the comments, CMS is not expanding policy to include the coverage of dental services for SCD, or hemophilia inextricably linked to other covered services. The agency found that the information provided did not support the coverage of dental services as inextricably linked to an existing covered medical service for SCD or that the standard of care would be compromised if dental services were not covered. To support the decision, CMS noted that one of the articles submitted stated that appropriate oral care might be just as important for diabetes as it is for those with SCD, and that the article stated more research is needed. Additionally, the agency is not striving to cover dental services for a condition or disease state but is considering coverage for dental services when needed prior to or in conjunction with therapies whereby good oral health is an important factor in the outcome of said treatment. CMS will accept future considerations and additional evidence for dental services inextricably linked to other covered services. Evidence to support this includes:

- (1) Relevant peer-reviewed medical literature and research/studies regarding the medical scenarios requiring medically necessary dental care;
- (2) Evidence of clinical guidelines or generally accepted standards of care for the suggested clinical scenario; and/or
- (3) Other supporting documentation to justify the inclusion of the proposed medical clinical scenario requiring dental services.

Requests for consideration in the 2025 MPFS are due February 10, 2024.

Request for Information on Implementation of Payment for Dental Services Inextricably Linked to Other Specific Covered Services In the proposed rule, CMS sought comments on several policies related to the implementation of payment for dental services. In the CY 2023 MPFS final rule, the agency codified the policy on payment for dental services and added examples of circumstances where payments can be made for certain dental services, including a dental exam and services to diagnose and eliminate an oral or dental infection prior to organ transplant, cardiac valve replacement, or valvuloplasty procedure.

The agency provided examples of dental services that could be furnished to eradicate infection, such as diagnostic services, evaluations and exams, extractions, restorations, periodontal therapy, or endodontic therapy. The agency maintains that additional dental services, such as a dental implant or crown, may not be immediately necessary to eliminate or eradicate the infection. Therefore, no Medicare payment is available for additional services that are not immediately necessary to eliminate or eradicate the infection. The agency also clarified that they will not cover services for the preparation or placement of dentures.

The agency appreciated the comments on implementation of the dental policies and will work with the MACs and other interested parties to address issues raised in the comments. CMS plans to provide guidance and further rulemaking as necessary as the policy is implemented. The agency will also monitor service utilization to identify any concerns about consistency of claims processing and adequacy of access.

In order to be considered for CY 2025 rulemaking, submissions through the public process for recommendations on payment for dental services must be received by February 10, 2024 to MedicarePhysicianFeeSchedule@cms.hhs.gov, with the subject line "dental recommendations for CY 2025 review".

<u>Drugs and Biological Products Paid Under Medicare Part B – p. 659</u> *Highlight: Policies related to the Inflation Reduction Act are codified.*

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

The Inflation Reduction Act (IRA) included several provisions that impact payment limits or beneficiary out-of-pocket costs for certain drugs payable under Part B. The agency finalized the proposal to codify these provisions in regulation. Two provisions that affect payment limits for biosimilar biological products ("biosimilars") are as follows:

- Section 11402 amends the payment limit for new biosimilars furnished on or after July 1, 2024, during the initial period when average sales price (ASP) data is not available
- Section 11403 revises the payment limit for certain biosimilars with an ASP that is not more than the ASP of the reference biological for a period of 5 years (CMS implemented this section with program instructions)

Two provisions make statutory changes that affect beneficiary out-of-pocket costs for certain Part B drugs are as follows:

• Section 11101 of the IRA requires that beneficiary coinsurance for a Part B rebatable drug be based on the inflation-adjusted payment amount if the Medicare payment amount for a calendar quarter exceeds the inflation-adjusted payment amount, starting on April 1, 2023 (CMS issued initial guidance to implement this provision)

• Section 11407 of the IRA provides that for insulin furnished through an item of durable medical equipment (DME) on or after July 1, 2023, the deductible is waived, and the coinsurance is limited to \$35 for a month's supply of insulin furnished through a covered DME (CMS implemented this section with program instructions)

Payment for Drugs Under Medicare Part B During an Initial Period

Section 11402 of the IRA required that for new biosimilars furnished on or after July 1, 2024, during the initial period when ASP data is not available, the payment limit for the biosimilar will be the lesser of: 1) an amount not to exceed 103 percent of the Wholesale Acquisition Cost (WAC) of the biosimilar or the Medicare Part B drug payment methodology, or 2) 106 percent of the lesser of the WAC or ASP of the reference biological, or in the case of a selected drug during a price applicability period, 106 percent of the maximum fair price of the reference biological. CMS finalized the proposal to codify these changes in regulation.

Inflation-adjusted Beneficiary Coinsurance and Medicare Payment for Medicare Part B Rebatable Drugs

Section 11101 of the IRA requires the payment of rebates into the Supplementary Medical Insurance Trust Fund for Part B rebatable drugs if the payment limit amount exceeds the inflation-adjusted payment amount. CMS previously issued final guidance for computing the inflation-adjusted beneficiary coinsurance. Additional information on implementation of this section can be found <u>here</u>.

For Part B rebatable drugs furnished on or after April 1, 2023, in quarters where the amount specified in the statute exceeds the inflation-adjusted payment amount, the coinsurance will be 20 percent of the inflation-adjusted payment amount for that quarter. The agency finalized the proposal to codify the coinsurance amount for Part B rebatable drugs.

The section also requires that if the inflation-adjusted payment amount of a Part B rebatable drug exceeds the payment amount described in the statute, then the Part B payment will equal the difference between the payment amount and the inflation-adjusted coinsurance amount. CMS finalized the proposal to codify the Medicare payment for Part B rebatable drugs.

Request for Information: Drugs and Biologicals which are not Usually Self-Administered by the Patient, and Complex Drug Administration Coding

Medicare is allowed to pay for services and supplies, including drugs and biologicals, which are not usually self-administered by the patient and that are furnished as "incident to" a physician's professional service. CMS has provided definitions and guidance to the MACs about determining if a drug is usually self-administered and publishing this information on their websites as the self-administered drug (SAD) list. Stakeholders have requested that CMS update and clarify the SAD list guidance and have also raised concerns that non-chemotherapeutic complex drug administration payments are inadequate and do not reflect the resources used to furnish infusion services.

CMS will consider the comments received on this topic from the MPFS comments for future rulemaking and guidance.

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

Section 90004 of the Infrastructure Investment and Jobs Act ("the Infrastructure Act") added a new requirement for manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug, referred to as a "refundable drug." The refundable amount is the amount of discarded drug that exceeds an applicable percentage of total charges for the drug in each calendar quarter; the applicable percentage is required to be at least 10 percent.

CMS previously finalized several policies to implement this new requirement in the CY 2023 MPFS final rule. The agency finalized several more policies in this final rule:

- The date of the initial report to manufacturers;
- The date for subsequent reports to manufacturers;
- The method for calculating refunds for discarded amounts in lagged claims data;
- The method for calculating refunds when there are multiple manufacturers for a refundable drug;
- Increased applicable percentages for certain drugs with unique circumstances; and
- A future application process for manufacturers to apply for an increased applicable percentage for a drug

Medicare Part B Payment for Preventive Vaccine Administration Services - p. 1,249

Highlight: Vaccine payment rates stay the course

As finalized in 2023, the agency will continue to update payment rates for preventative vaccines using the percentage increase in the MEI. Those base payments will then be adjusted by a geographic locality adjustment to account for differences in costs across the US. There is one payment amount per home visit for the administration of the four covered preventative vaccines (pneumococcal, influenza, hepatitis B, and COVID-19 vaccine).

Major APM Provisions - p. 1538

Highlight: CMS finalized requirements for APMs to use CEHRT to be an Advanced APM; and QP thresholds are scheduled to increase, consistent with the CAA, 2023.

Advanced APMs

CMS' current regulations state that 75% of eligible clinicians in each participating APM Entity (for example, an ACO) must be required under the terms of the APM to use CEHRT for the APM to be an Advanced APM. CMS will retain the 75% threshold in CY 2024 and plans to remove the threshold effective beginning CY 2025. CMS is finalizing its proposal to specify that, to be an Advanced APM, the APM must require the use of certified EHR technology.

APM Incentive

CMS did not finalize its proposal to calculate the qualifying APM participant (QP) determinations at the individual eligible clinician level only, instead of the APM Entity level. Consistent with the CAA, 2023, the QP and Partial QP threshold percentages for the Medicare Option and All-Payer Option will remain unchanged in 2023/2025, as per last year's values. Under current statute, the QP threshold percentages will increase beginning with the 2024 performance year/2026 payment year.

- Medicare payments:
 - o QP threshold increasing from 50% to 75%
 - o Partial QP threshold increasing from 40% to 50%
- Medicare patients:
 - O QP threshold increasing from 35% to 50%
 - o Partial QP threshold increasing from 25% to 35%

Under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), clinicians participating in advanced APMs were to receive a 5% incentive payment until the 2022 performance year /2024 payment year. The CAA, 2023, extended the APM Incentive Payment for one year allowing eligible clinicians to receive a 3.5% incentive payment in the 2023 performance year/2025 payment year. After the 2023 performance year/2025 payment year, the APM Incentive Payment will end. As directed under MACRA, beginning for the 2024 performance year/2026 payment year, QPs will receive a higher MPFS update of 0.75% compared to non-QPs, who will receive a 0.25% MPFS update, which will result in a differentially higher PFS payment rate for eligible clinicians who are QPs. Eligible clinicians who are QPs for a year will continue to be excluded from MIPS reporting and payment adjustments for the year.

TABLE 118: CY 2024 PFS Estimated Impact on Total Allowed Charges by Specialty

ALLERGY/IMMUNOLOGY	(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
ANESTHESIOLOGY	ALLERGY/IMMUNOLOGY	\$217	0%	-1%	0%	-1%
AUDIOLOGIST S69		\$1,650	-2%	-1%	0%	-2%
CARDIAC SURGERY S175						
CARDIOLOGY						
CHIROPRACTIC \$649						
CLINICAL PSYCHOLOGIST S717 19% 09% 09% 29% CLINICAL SOCIAL WORKER S801 29% 09% 09% 29% 29% 09% 09% 2						
CLINICAL SOCIAL WORKER						
COLON AND RECTAL SURGERY \$147 -1% -1% 0% -2% CRITICAL CARE \$333 -1% 0% 0% -2% DERMATOLOGY \$3,717 0% 0% 0% -1% DIAGNOSTIC TESTING FACILITY \$833 0% -1% 0% -2% EMERGENCY MEDICINE \$2,473 -2% -1% 0% -2% ENDOCRINOLOGY \$509 1% 0% 0% 3% FAMILY PRACTICE \$5,538 2% 2% 0% 3% GASTROENTEROLOGY \$1,476 0% 0% 0% 0% GENERAL SURGERY \$1,625 -1% 0% 0% 0% GERIATRICS \$184 0% 1% 0% 0% 2% GERIATRICS \$184 0% 1% 0% 0% -1% HEMATOLOGY/ONCOLOGY \$1,595 1% 0% 0% -1% INDEPENDENT LABORATORY \$551 -1% 0%						
CRITICAL CARE						
DERMATOLOGY						
DIAGNOSTIC TESTING FACILITY						
EMERGENCY MEDICINE						
ENDOCRINOLOGY						
FAMILY PRACTICE						
GASTROENTEROLOGY		44.47				
GENERAL PRACTICE						
GENERAL SURGERY \$1,625 -1% -1% 0% -1% GERIATRICS \$184 0% 1% 0% 1% HAND SURGERY \$252 -1% 0% 0% 0% -1% HEMATOLOGY/ONCOLOGY \$1,595 1% 0% 0% 0% -2% INDEPENDENT LABORATORY \$551 -1% -1% 0% 0% -1% INFECTIOUS DISEASE \$576 -1% 0% 0% 0% -1% INFECTIOUS DISEASE \$576 -1% 0% 0% 0% 1% INTERNAL MEDICINE \$9,683 0% 1% 0% 0% 1% INTERVENTIONAL PAIN MGMT \$853 0% 0% 0% 0% 0% INTERVENTIONAL RADIOLOGY \$458 -1% -3% 0% 0% 0% MULTISPECIALTY CLINIC/OTHER \$147 0% 0% 0% 0% 0% MULTISPECIALTY CLINIC/OTHER \$147 0% 0% 0% 0% 0% NEUROLOGY \$1,813 -1% 0% 0% 0% -1% NEUROSURGERY \$699 -1% 0% 0% 0% -1% NUCLEAR MEDICINE \$51 -1% -2% 0% 0% -2% NURSE ANES / ANES ASST \$1,081 -2% 0% 0% -2% NURSE PRACTITIONER \$6,297 1% 1% 0% 0% -2% OBSTETRICS/GYNECOLOGY \$5,60 0% 0% 0% -1% OPTOMETRY \$1,299 -1% -1% 0% 0% -2% ORAL/MAXILLOFACIAL SURGERY \$63 -1% -1% 0% 0% -2% ORTHOPEDIC SURGERY \$3,369 -1% 0% 0% 0% 0% OTOLARYNGOLOGY \$1,115 0% 0% 0% 0% 0% OTOLARYNGOLOGY \$1,115 0% 0% 0% 0% 0% PATHOLOGY \$1,142 -1% -1% 0% 0% 0% PHYSICAL MEDICINE \$1,093 0% 0% 0% 0% -1% PHYSICAL MEDICINE \$1,093 0% 0% 0% 0% -3%						
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INDEPENDENT LABORATORY						
INFECTIOUS DISEASE \$576						
INTERNAL MEDICINE						
INTERVENTIONAL PAIN MGMT						
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	THERAPY	\$5,281	-170	-2%	0%	-3%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
PHYSICIAN ASSISTANT	\$3,377	1%	1%	0%	2%
PLASTIC SURGERY	\$303	-1%	-1%	0%	-1%
PODIATRY	\$1,910	0%	0%	0%	0%
PORTABLE X-RAY SUPPLIER	\$76	0%	0%	0%	-1%
PSYCHIATRY	\$907	1%	1%	0%	2%
PULMONARY DISEASE	\$1,295	0%	0%	0%	0%
RADIATION ONCOLOGY AND	\$1,556	0%	-2%	0%	-2%
RADIATION THERAPY CENTERS					
RADIOLOGY	\$4,536	-1%	-2%	0%	-3%
RHEUMATOLOGY	\$510	1%	1%	0%	2%
THORACIC SURGERY	\$293	-1%	-1%	0%	-2%
UROLOGY	\$1,630	0%	0%	0%	1%
VASCULAR SURGERY	\$1,011	-1%	-3%	0%	-3%
TOTAL	\$88,967	0%	0%	0%	0%

^{*} Column F may not equal the sum of columns C, D, and E due to rounding.