Issue Brief

FEDERAL ISSUE BRIEF

Analysis provided for MHA by Larry Goldberg, Goldberg Consulting

November 9, 2023

Final CY 2024 Revisions to Payment Policies under the Medicare Physician Fee Schedule and Other Part B Payment and Coverage Policies Released

The Centers for Medicare & Medicaid Services (CMS) have issued a final rule to update the Medicare Physician Fee Schedule (MPFS) for CY 2024.

A copy of this 2,709-page rule is at the ***Federal Register*** office, and a copy is currently available at: https://public-inspection.federalregister.gov/2023-24184.pdf. The rule is scheduled for publication on November 16.

Comment

As usual, this MPFS regulation is a long and complex document. Given CMS' propensity for rules without a table of contents it is not surprising that such is totally missing. This is not only shameful but is inexcusable.

Addenda Available Only Through the Internet on the CMS Website:

The PFS Addenda along with other supporting documents and tables referenced in this final rule are available on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.

Click on the link on the left side of the screen titled, "PFS Federal Regulations Notices" for a chronological list of PFS ***Federal Register*** and other related documents. For the CY 2024 PFS final rule, refer to item CMS-1784-F. Readers with questions related to accessing any of the Addenda or other supporting documents referenced in this final rule and posted on the CMS website identified above should contact MedicarePhysicianFeeSchedule@cms.hhs.gov. The material on the website has grown more complex and more difficult to find specific items. For example, CMS says a number of items can be found in Addendum A and B. However, there does not appear to be a direct link to these tables.

Specifically, the rule says it includes discussions regarding the following items. We have added page numbers (in red) and have used such as a surrogate table of contents.

II. Provisions of the Final Rule for the PFS

Questions? Contact Andrew Wheeler, MHA's Vice President of Federal Finance, at 573-893-3700 | ext. 1336 or awheeler@mhanet.com.

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• Updates to the Definitions of Certified Electronic Health Record Technology (section III.R.) (Page 1,497)
• A Social Determinants of Health Risk Assessment in the Annual Wellness Visit (section III.S.) (Page 1,511)
• Updates to the Quality Payment Program (section IV.) (Page 1,527)
• Collection of Information Requirements (section V.) (Page 1,833)
• Response to Comments (section VI.) The proposed rule contained this item. It is not in the final.
• Regulatory Impact Analysis (section VII.) (Page 1,934)

Accounting Statement: Classification of Estimated Expenditures (Page 2,065)

Category	Transfers
CY 2024 Annualized Monetized Transfers	Estimated decrease in expenditures of $2.4 billion for PFS CF update.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.

Bottom line is the rate of increase to physicians under the MPFS for CY 2024 will be a **negative $2.4 billion.**

Accounting Statement for Provision for the Medicare Shared Savings Program (CY Years 2024-2033) (Page 2,066)

Category	PrimaryEstimate	Minimum Estimate	MaximumEstimate	Source Citation
Transfers From the Federal Government to ACOs				
Annualized monetized:Discount rate: 7%	-15 million	-171 million	174 million	Tables 120 through 123
Annualized monetized:Discount rate: 3%	-25 million	-189 million	172 million	

The material that follows, with the exception of the conversion factors, basically follows the organization of the rule. Note, not all items are addressed

PAYMENT PROVISIONS OF THE CY 2024 PFS RULE

Payment Updates and Conversion Factors (CF) (Page 1,948)

CMS estimates the CY 2024 PFS CF to be **32.7442** which reflects a -2.18 percent budget neutrality adjustment under section 1848(c)(2)(B)(ii)(II) of the Act, the 0.00 percent update adjustment factor specified under section 1848(d)(19) of the Act, and the 1.25 percent payment increase for services furnished in CY 2024, as provided in the **Consolidated Appropriations Act** (CAA), 2023.

CMS estimates the CY 2024 anesthesia CF to be 20.4349, reflecting the same overall PFS adjustments with the addition of anesthesia-specific PE and MP adjustments.

Table 116: Calculation of the CY 2023 PFS Conversion Factor

CY 2023 Conversion Factor		33.8872
Conversion Factor without the CAA, 2023 (2.5 Percent Increase for CY 2023)		33.0607
CY 2024 RVU Budget Neutrality Adjustment	-2.20 percent (0.9780)	
CY 2024 1.25 Percent Increase Provided by the CAA, 2023	1.25 percent (1.0125)	
CY 2024 Conversion Factor		**32.7375**

CMS estimates the CY 2024 anesthesia CF to be 20.4370 which reflects the same overall PFS adjustments with the addition of anesthesia-specific PE and MP adjustments.

Calculation of the CY 2024 Anesthesia Conversion Factor

CY 2023 National Average Anesthesia Conversion Factor		21.1249
Conversion Factor without the CAA, 2023 (2.5 Percent Increase for CY 2023)		20.6097
CY 2024 RVU Budget Neutrality Adjustment	-2.18 percent (0.9782)	
CY 2024 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment	0.11 percent (1.0011)	
CY 2024 1.25 Percent Increase Provided by the CAA, 2023	1.25 percent (1.0125)	
CY 2024 Conversion Factor		**20.4349**

Comment

The calculations in PFS tables above are correct. That is, for the PFS factor the table factor of 32.7375 is correct. Same for the anesthesia factor. However, both do not agree with the narrative citations. This is a serious issue inasmuch as the conversion factors play a major role in determining every payment amount. Which are the correct factors?

Impact

The table below shows the payment impact by specialty of the policies contained in the rule. (Page 1,283)

CY 2024 PFS Estimated Impact on Total Allowed Charges by Specialty

(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
ALLERGY/ IMMUNOLOGY	$217	0%	-1%	0%	-1%
ANESTHESIOLOGY	$1,650	-2%	-1%	0%	-2%
AUDIOLOGIST	$69	-1%	-1%	0%	-2%
CARDIAC SURGERY	$175	-1%	-1%	0%	-2%
CARDIOLOGY	$6,015	0%	0%	0%	0%

(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
CHIROPRACTIC	$649	-1%	-1%	0%	-2%
CLINICAL PSYCHOLOGIST	$717	1%	0%	0%	2%
CLINICAL SOCIAL WORKER	$801	2%	0%	0%	2%
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%	1%	0%	3%
FAMILY PRACTICE	$5,538	2%	2%	0%	3%
GASTROENTEROLOGY	$1,476	0%	0%	0%	0%
GENERAL PRACTICE	$368	1%	1%	0%	2%
GENERAL SURGERY	$1,625	-1%	-1%	0%	-1%
GERIATRICS	$184	0%	1%	0%	1%
HAND SURGERY	$252	-1%	0%	0%	-1%
HEMATOLOGY/ONCOLOGY	$1,595	1%	0%	0%	2%
INDEPENDENT LABORATORY	$551	-1%	-1%	0%	-1%
INFECTIOUS DISEASE	$576	-1%	0%	0%	-1%
INTERNAL MEDICINE	$9,683	0%	1%	0%	1%
INTERVENTIONAL PAIN MGMT	$853	0%	0%	0%	0%
INTERVENTIONAL RADIOLOGY	$458	-1%	-3%	0%	-4%
MULTISPECIALTY CLINIC/OTHER PHYS	$147	0%	0%	0%	0%
NEPHROLOGY	$1,813	-1%	0%	0%	-1%
NEUROLOGY	$1,330	0%	0%	0%	1%
NEUROSURGERY	$699	-1%	0%	0%	-1%
NUCLEAR MEDICINE	$51	-1%	-2%	0%	-3%
NURSE ANES / ANES ASST	$1,081	-2%	0%	0%	-2%
NURSE PRACTITIONER	$6,297	1%	1%	0%	2%
OBSTETRICS/GYNECOLOGY	$560	0%	1%	0%	1%
OPHTHALMOLOGY	$4,647	0%	0%	0%	-1%
OPTOMETRY	$1,299	-1%	-1%	0%	-2%
ORAL/MAXILLOFACIAL SURGERY	$63	-1%	-1%	0%	-2%
ORTHOPEDIC SURGERY	$3,369	-1%	0%	0%	-1%
OTHER	$56	0%	0%	0%	0%
OTOLARYNGOLOGY	$1,115	0%	0%	0%	0%
PATHOLOGY	$1,142	-1%	-1%	0%	-2%
PEDIATRICS	$56	0%	0%	0%	1%
PHYSICAL MEDICINE	$1,093	0%	0%	0%	-1%
PHYSICAL/OCCUPATIONAL THERAPY	$5,281	-1%	-2%	0%	-3%
PHYSICIAN ASSISTANT	$3,377	1%	1%	0%	2%

(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
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 RADIATION THERAPY CENTERS	$1,556	0%	-2%	0%	-2%
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%

II. PROVISIONS OF THE FINAL RULE

DETERMINATION OF PE RVUS (SECTION II.B.) (Page 11)

Practice expense (PE) is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding malpractice (MP) expenses. As required by section 1848(c)(2)(C)(ii) of the Act, CMS uses a resource-based system for determining PE RVUs for each physicians' service. CMS develops PE RVUs by considering the direct and indirect practice resources involved in furnishing each service.

This section explains how CMS develops PE RVUs by considering the direct and indirect practice resources involved in furnishing each service.

POTENTIALLY MISVALUED SERVICES UNDER THE PFS (SECTION II.C.) (Page 71)

Section 1848(c)(2)(K) of the Act requires the Secretary to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the relative values for those services.

CMS says it received 10 nominations concerning various codes –

1) CPT code 59200 (Insertion cervical dilator (e.g., laminaria, prostaglandin)) (000 zero-day global code). CMS now says this code is misvalued. (Page 77)

2) CPT code 27279 (Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device) (090-day global code). CMS is not considering CPT code 27279 as misvalued and welcomes comments for future consideration as potentially misvalued. (Page 80)

3) CPT codes 99221, 99222, and 99223. After consideration of this nomination and their requests for higher work RVUs for CPT codes 99221, 99222, and 99223, CMS does not consider these code to be misvalued and will maintain the values that were finalized for these codes in the CY 2023 PFS final rule. (Page 83)

4) CPT codes 36514, 36516, 36522. CMS is finalizing CPT codes 36514, 36516, and 36522 as potentially misvalued.

5) CPT codes 44205 and 44204. CMS says it is not inclined to agree that CPT code 44205 is potentially misvalued when compared to CPT code 44204, or to modify this payment differential by paying a higher amount for CPT code 44205. CMS is not nominating this service as potentially misvalued. (Page 87)

6) CPT codes 93655 and 93657. CMS is not nominating these codes as potentially misvalued for CY 2024. (Page 88)

7) CPT code 94762 and 95800. CMS is not finalizing CPT codes 94762 and 95800 as potentially misvalued. (Page 89)

8) CPT codes 0596T and 0597T. CMS not finalizing CPT codes 0596T and 0597T as potentially misvalued. (Page 92)

9) CPT code 93000. CMS is not finalizing CPT code 93000 as potentially misvalued for CY 2024. (Page 94)

10) 19 therapy codes. CMS recommends the nomination of 19 codes as potentially misvalued for CY 2024. (Page 94)

The 19 therapy codes are listed in the rule on page 96

PAYMENT FOR MEDICARE TELEHEALTH SERVICES UNDER SECTION 1834(M) OF THE ACT (SECTION II.D.) (Page 97)

CMS says it received several requests to permanently add various services to the Medicare Telehealth Services List effective for CY 2024. CMS is providing a summary of the reasons why it did not propose to add these services to the Medicare Telehealth Services List on a Category 1 basis:

- Cardiovascular Procedures - CPT code 93793. CMS says that because CPT code 93793 does not describe an inherently face-to-face service, it would not be appropriate to consider or recognize it as a telehealth service. (Page 103)

- Cardiovascular and Pulmonary Rehab – CPT codes 93797 and CPT code 94624. CMS says in the absence of further Congressional action these codes cannot be furnished via telehealth to a beneficiary in the home beginning January 1, 2025. CMS will continue to include these services on the Medicare Telehealth Services List through CY 2024. CMS would then remove CPT codes 93797 and 94626 from the Medicare Telehealth Services List for CY 2025. (Page (104)

- Deep Brain Stimulation - CPT codes 95970, 95983, and 95984. CMS says more time for further study would be appropriate, and that adding these services to the Medicare Telehealth Services List on a permanent basis beginning in CY 2024 would be premature. CMS will keep these services on the Medicare Telehealth Services List for CY 2024. (Page 106)

- Therapy - Therapy Procedures: CPT codes 97110, 97112, 97116; Physical Therapy Evaluations: CPT codes 97161-97164; Therapy Personal Care services: CPT code 97530; and Therapy Tests and Measurements services: CPT codes 97750, 97763 and Biofeedback: 90901. CMS says it continues to have questions and is not finalizing to add these services to the Medicare Telehealth Services List on a Category 1 or 2 basis.

  CMS will keep these therapy services on the Medicare Telehealth Services List until the end of CY 2024, and will consider any further action with regard to these codes in future rulemaking. (Page 108)

- Hospital Care, Emergency Department and Hospital – CPT codes 99221, 99222, 99223, 99234, 99235, 99236, 99238, 99239, 99281, 99282 and 99284.

  CMS is not adding these services to the list on a permanent basis at this time, but that they will remain available on the Medicare Telehealth Services List through CY 2024. CMS notes that CPT codes 99231 through 99233 are codes that describe subsequent services and are part of the same Hospital or Observation Care code family (CPT codes 99218-99236), and have permanent status on the Medicare Telehealth Services List. CMS says it continues to believe that new patients should be seen in person when the temporary telehealth flexibilities end, and as a result CMS is not changing determinations of the status of any of these codes. (Page 111)

- Health and Well-being Coaching – Codes 0591T, 0592T, 0593T.

  CMS is not adding these health and well-being coaching services to the Medicare Telehealth Services List on a permanent basis, but is continuing to add them to the list on a temporary basis for CY 2024. (Page 118)

CMS Proposals to Add New Codes to the List

CMS is finalizing, as proposed, and assigning HCPCS code G0136 (Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment tool, 5-15 minutes) permanent status on the Medicare Telehealth List, beginning in CY 2024. (Page 120)

CMS proposed to redesignate any services that are currently on the Medicare Telehealth Services List on a Category 1 or 2 basis and would be on the list for CY 2024 to a proposed new "permanent" category while any services currently added on a "temporary Category 2" or Category 3 basis would be assigned to a "provisional" category. (Page 137) The rule's Table 11 lists codes CMS is finalizing for the Medicare Telehealth Services List and includes the simplified categorization of each service as either provisional or permanent. *This list is four pages long.* (Page 138)

This rule clarifies that certain telehealth flexibilities that were previously extended until 151 days after the end of the public health emergency (PHE), by the CAA, 2022, have been extended until December 31, 2024, in accordance with the amendments made by provisions of the CAA, 2023. (Page 147)

CMS is finalizing, as proposed, its policy to delay in-person requirements for telehealth behavioral health services until January 1, 2025. (Page 149)

CMS is finalizing, as proposed, that beginning in CY 2024, claims for telehealth services billed with POS 10 will be paid at the non-facility PFS rate. Claims billed with POS 02 will continue to be paid at the facility rate. In addition, modifier "95" should be used when the clinician is in the hospital and the patient is in the home, as well as for outpatient therapy services furnished via telehealth by PT, OT, or SLP. (Page 160)

CMS is finalizing, as proposed, its proposal for CY 2024 to continue the removal of Medicare telehealth services frequency limitations for Subsequent Inpatient Visit, Subsequent Nursing Facility Visit, and Critical Care Consultation Services. (Page 165)

Comment

The telehealth provisions material extends some 100 pages. There are numerous codes being addressed. Perhaps the following offers a succinct snapshot.

CMS is 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.

VALUATION OF SPECIFIC CODES (SECTION II.E.) (Page 196)

On an annual basis, the Relative Value Scale Update Committee (RUC) provides CMS with recommendations regarding PE inputs for new, revised, and potentially misvalued codes.

CMS explains changes to the specific CPT codes identified below.

In red, is the rule's display copy page number on which the code(s) discussions begin.

1	Dorsal Sacroiliac Joint Arthrodesis (CPT code 27278) (Page 217)
2	Vertebral Body Tethering (CPT codes 22836, 22837, and 22838) (Page 219)
3	Total Disc Arthroplasty (CPT codes 22857 and 22860) (Page 220)
4	Phrenic Nerve Stimulation System (CPT codes 33276, 33277, 33278, 33279, 33280, 33281, 33287, 33288, 93150, 93151, 93152, and 93153) (Page 222)
5	Posterior Nasal Nerve Ablation (CPT codes 30117, 30118, 31242, and 31243) (Page224)
6	Cystourethroscopy with Urethral Therapeutic Drug Delivery (CPT code 52284) (Page 230)
7	Transcervical RF Ablation of Uterine Fibroids (CPT code 58580) (Page 231)
8	Suprachoroidal Injection (CPT code 67516) (Page 234
9	Skull Mounted Cranial Neurostimulator (CPT codes 61889, 61891, and 61892) (Page 235)
10	Spinal Neurostimulator Services (CPT codes 63685, 63688, 64596, 64597, and 64598) (Page 236)
11	Neurostimulator Services-Bladder Dysfunction (CPT codes 64590 and 64595) (Page 237)
12	Ocular Surface Amniotic Membrane Placement/Reconstruction (CPT codes 65778, 65779, and 65780) (Page 238)
13	Fractional Flow Reserve with CT (CPT code 75580) (Page 241)
14	Ultrasound Guidance for Vascular Access (CPT code 76937) (Page 245)
15	Neuromuscular Ultrasound (CPT codes 76881, 76882, and 76883) (Page 246)
16	Intraoperative Ultrasound Services (CPT codes 76998, 76984, 76987, 76988, and 76989) (Page 251)
17	Percutaneous Coronary Interventions (CPT code 92972) (Page 264)
18	Auditory Osseo integrated Device Services (CPT codes 92622 and 92623) (Page 265)
19	Venography Services (CPT codes 93584, 93585, 93586, 93587, and 93588) (Page 266)
20	Post Operative Low-Level Laser Therapy (CPT code 97037) (Page 269)
21	General Behavioral Health Integration Care Management (CPT code 99484, and HCPCS code G0323) (Page 270)
22	Advance Care Planning (CPT codes 99497 and 99498) (Page 274)
23	Pelvic Exam (CPT code 99459) (Page 275)
24	Hyperthermic Intraperitoneal Chemotherapy (HIPEC) (CPT codes 96547 and 96548) (Page 276)
25	Hyperbaric Oxygen Under Pressure (HCPCS code G0277) (Page 277)
26	Remote Interrogation Device Evaluation – Cardiovascular (HCPCS code G2066, and CPT codes 93297, and 93298)) (Page 281)
27	Payment for Caregiver Training Services (Page 284)
28	Services Addressing Health-Related Social Needs (Community Health Integration services, Social Determinants of Health Risk Assessment, and Principal Illness Navigation Services) (Page 303)
29	Maternity Services (CPT codes 59400, 59410, 59425, 59426, 59430, 59510, 59515, 59610, 59614, 59618, 59622) (Page 402)

Comment

Items 27, 28 and 29 above extend more than 150 pages.

Tables

The rule's Table 14 contains the CY 2024 Work RVUs for New, Revised, and Potentially Misvalued Codes (Page 404)
The rule's Table 15 contains the CY 2024 Direct PE Refinements – Equipment Refinements Conforming to Changes in Clinical Labor Time (Page 414)

The rule's Table 19 contains the list of no PE Refinements. (Page 420)

EVALUATION AND MANAGEMENT (E/M) VISITS (SECTION II.F.) (Page 422)

E/M visits comprise approximately 40 percent of all allowed charges under the PFS.

CMS says this section of the rule addresses two outstanding issues in E/M visit payment: implementing separate payment for the office/outpatient (O/O) E/M visit complexity add-on code for separate payment, and CMS' definitions of split (or shared) visits, which was delayed from last year.(Page 422)

Beginning January 1, 2024, CMS is finalizing implementation of a separate add-on payment for healthcare common procedure coding system (HCPCS) code G2211.

CMS says "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."

CMS says it does not expect HCPCS add-on code G2211 to be reported when the O/O E/M service is reported with a payment modifier, such as modifier -25, which denotes a separately billable E/M service by the same practitioner furnished on the same day of a procedure or other service. (Page 431)

Split (or Shared) Visits (Page 468)

A split (or shared) visit refers to an E/M visit performed by both a physician and an NPP in the same group practice.

For CY 2024, CMS is finalizing a policy that reflects a revised definition of "substantive portion" of a split (or shared) visit to reflect the revisions to the CPT E/M guidelines, such that for Medicare billing purposes, the "substantive portion" means more than half of the total time spent by the physician and nonphysician practitioner *(*NPP) performing the split (or shared) visit, or a substantive part of the medical decision making except concerning critical care visits which do not use medical decision making (MDM) and only use time, the "substantive portion" continues to mean more than half of the total time spent by the physician and NPP performing the split (or shared) visit. CMS will revise its regulations at 42 CFR 415.140 to reflect this change for split (or shared) visits. CMS notes that it is finalizing this policy for CY 2024, in part, to avoid the administrative burden, as described by commenters, that would otherwise be present for facilities and practices that spend time and resources preparing for potential policy changes that are delayed year after year. If warranted, CMS will address any subsequent change in policy through notice and comment rulemaking. (Page 476)

GEOGRAPHIC PRACTICE COST INDICES (GPCIS) (SECTION II G.) (Page 477)

Section 1848(e)(1)(E) of the Act provides for a 1.0 floor for the work GPCIs for the purposes of payment for services furnished on or after January 1, 2004, and before January 1, 2024. Therefore, the CY 2024 work GPCIs and summarized GAFs do not reflect the 1.0 work floor.

Addenda D and E contain the CY 2024 GPCIs and summarized GAFs. These Addenda are available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.

PAYMENT FOR SKIN SUBSTITUTES (SECTION II.H.) (Page 485)

"The CY 2024 PFS proposed rule includes no proposals for skin substitute polices. Instead, CMS solicited comments from interested parties to help "us" consider an approach to pricing these products as supplies."

SUPERVISION OF OUTPATIENT THERAPY SERVICES, KX MODIFIER THRESHOLDS, DIABETES SELF-MANAGEMENT TRAINING (DSMT) SERVICES BY REGISTERED DIETITIANS AND NUTRITION PROFESSIONALS, AND DSMT TELEHEALTH SERVICES (SECTION II.I.) (Page 494)

In the CY 2023 PFS final rule, CMS finalized new policies that would allow Medicare payment for remote therapeutic monitoring (RTM) services, including allowing any RTM service to be furnished under general supervision requirements.

Current regulations at §§ 410.59(a)(3)(ii) and 410.60(a)(3)(ii) specify that all occupational and physical therapy services are performed by, or under the direct supervision of, the occupational or physical therapist, respectively, in private practice.

CMS is finalizing its proposal for RTM services to allow general supervision of OTAs and PTAs by OTs and PTs in private practice; and is finalizing its proposal to continue the requirement for direct supervision of unenrolled PTs and OTs, including for RTM services. (Page 496)

KX Modifier Thresholds (Page 503)

CMS is finalizing the CY 2024 KX modifier threshold amounts of $2,330 for physical therapy and speech-language pathology services combined and $2,330 for occupational therapy services, as proposed.

The medical review (MR) threshold is $3,000 for physical therapy and speech-language pathology services combined and $3,000 for occupational therapy services.

Diabetes Self-Management Training (DSMT) Services Furnished by Registered Dietitians (RDs) and Nutrition Professionals (Page 506)

CMS is finalizing its proposal to revise §410.72(d) to clarify that RDs and nutrition professionals can bill as or on behalf of a DSMT entity regardless of which professional furnished the actual services, but that they must directly provide the MNT services they bill for. (Page 509)

DSMT Telehealth Issues (Page 509)

CMS is codifying its billing rules for DSMT services furnished as Medicare telehealth services at § 410.78(b)(2)(x) to allow distant site practitioners who can appropriately report DSMT services furnished in person by the DSMT entity, such as RDs and nutrition professionals, physicians, nurse practitioners (NPs), physician assistants (PAs), and clinical nurse specialists (CNSs), to also report DSMT services

furnished via telehealth by the DSMT entity, including when the services are performed by others as part of the DSMT entity.

Telehealth Injection Training for Insulin-Dependent Beneficiaries (Page 510)

CMS is finalizing its proposal on insulin injection-training that will allow the full initial 10-hours, or annual 2 hours, of DSMT services for insulin-dependent diabetics, via telehealth, when clinically appropriate.

ADVANCING ACCESS TO BEHAVIORAL HEALTH (SECTION II.J.)(Page 514)

CMS is finalizing its proposals to implement section 4121 of the CAA, with some clarifications and modifications. CMS is clarifying that to the extent that addiction counselors and alcohol and drug counselors who furnish services for the diagnosis and treatment of mental illnesses, including substance use disorders, can meet all the statutory and regulatory requirements regarding education, clinical supervised experience, and State licensure for mental health counselors (MHCs), such counselors can enroll in Medicare as MHCs. CMS is also finalizing a clarification that individuals who meet the statutory and regulatory requirements for education and clinical supervised experience for MHCs but are licensed to furnish mental health counseling in their State under a title other than mental health counselor, clinical professional counselor, or professional counselor, are eligible to enroll in Medicare as MHCs. (Page 536)

Section 4123(a)(1) of the CAA, 2023, amended section 1848 of the Act by adding a new paragraph (b)(12) regarding payment for psychotherapy for crisis services furnished in an applicable site of service.

Specifically, CMS is finalizing two new G-codes to describe psychotherapy for crisis 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) and establishing a fee schedule amount for these two new G-codes that is 150 percent of the current PFS non-facility RVUs for CPT 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)), respectively.

The new G-codes and their descriptors are:

- G0017 (Psychotherapy for crisis 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); first 60 minutes); and
- G0018 (Psychotherapy for crisis 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); each additional 30 minutes (List separately in addition to code for primary service)). (Page 545)

CMS is finalizing its proposal to allow Health and 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 CSWs, MFTs, and MHCs, in addition to clinical psychologists (CPs). (Page 548)

CMS is finalizing its proposal to apply an upward adjustment of 19.1 percent to the work RVUs for the standalone psychotherapy services, in addition to the psychotherapy codes that are billed as an add-on to an E/M visit (CPT codes 90833, 90836, and 90838) and the codes describing HBAI services (CPT codes 96156, 96158, 96159, 96164, 96165, 96167, and 96168), and is implementing this adjustment over a 4-year transition. (Page 562)

Updates to the Payment Rate for the PFS Substance Use Disorder (SUD) bundle (HCPCS codes G2086-G2088) (Page 562)

CMS is finalizing, as proposed, to increase the payment rate for HCPCS codes G2086 and G2087 to reflect two individual psychotherapy sessions per month, based on a crosswalk to the work RVUs assigned to CPT code 90834 (Psychotherapy, 45 minutes with patient), rather than CPT code 90832 (Psychotherapy, 30 minutes with patient). (Page 564)

POLICIES ON MEDICARE PARTS A AND B PAYMENT FOR DENTAL SERVICES INEXTRICABLY LINKED TO SPECIFIC COVERED SERVICES (Section II.K.) (Page 574)

In general, the statute precludes payment under Medicare Parts A or B for any expenses incurred for coverage, items, and services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth.

For CY 2024, CMS is (1) codifying dental services prior to, or during, head and neck cancer treatments, whether primary or metastatic; (2) permitting 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) permitting payment for certain dental services inextricably linked to other covered services used to treat cancer prior to, or during:

- Chemotherapy services.
- Chimeric Antigen Receptor T- (CAR-T) Cell therapy.
- The use of high-dose bone modifying agents (antiresorptive therapy).

III. OTHER PROVISIONS OF THE RULE (Page 659)

DRUGS AND BIOLOGICAL PRODUCTS PAID UNDER MEDICARE PART B (SECTION III.A.)

*Provisions from the **Inflation Reduction*** (Act) *Relating to Drugs and Biologicals Payable Under Medicare Part B (§§ 410.152, 414.902, 414.904, 489.30)*

a. Payment for Drugs under Medicare Part B During an Initial Period (Page 660)

Section 11402 of the IRA amends the payment limit for new biosimilars furnished on or after July 1, 2024. When ASP data is not sufficiently available, the payment limit for the biosimilar is 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 in effect on November 1, 2003, or (2) 106 percent of the

lesser of the WAC or Average Sales Price (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. (Page 661)

b. Temporary Increase in Medicare Part B Payment for Certain Biosimilar Biological Products (Page 665)

Section 11403 of the IRA amended section 1847A(b)(8) of the Act by establishing a temporary payment limit increase for qualifying biosimilar biological products furnished during the applicable 5-year period. Section 1847A(b)(8)(B)(iii) of the Act defines a "qualifying biosimilar biological product" (hereinafter referred to as a "qualifying biosimilar") as a biosimilar biological with an ASP less than the ASP of the reference biological for a calendar quarter during the applicable 5-year period. Section 11403 of the IRA requires that a qualifying biosimilar be paid at ASP plus 8 percent of the reference biological's ASP rather than 6 percent during the applicable 5-year period.

c. Inflation-adjusted Beneficiary Coinsurance and Medicare Payment for Medicare Part B Rebatable Drugs (Page 668)

Section 11101(a) of the IRA amended section 1847A of the Act by adding a new subsection (i), which 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. The provisions of section 11101 of the IRA are currently being implemented through program instruction, as directed under section 1847A(c)(5)(C) of the Act.

CMS is finalizing the codification of the coinsurance amount and the Medicare payment for Part B rebatable drugs at § 489.30 and § 410.152, respectively, as proposed. (Page 670)

2. Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs to Provide Refunds With Respect to Discarded Amounts (§§ 414.902 and 414.940) (Page 680)

Section 90004 of the IRA requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug (hereafter referred to as "refundable drug"). The refund amount is the amount of discarded drug that exceeds an applicable percentage, which is required to be at least 10 percent, of total charges for the drug in a given calendar quarter.

In the CY 2023 PFS final rule, CMS adopted many policies to implement section 90004 of the IRA. CMS finalized the requirement that billing providers and suppliers report the JW modifier for all separately payable drugs with discarded drug amounts from single use vials or single use packages payable under Part B, beginning January 1, 2023. CMS also finalized the requirement that billing providers and suppliers report the JZ modifier for all such drugs with no discarded amounts beginning no later than July 1, 2023, and CMS stated that it would begin claims edits for both the JW and JZ modifiers beginning October 1, 2023

Comment

CMS provides much information on the timing of reports, use of the JW and JZ modifiers, and the amounts and manner of refunds. The material is obviously aimed at drug manufacturers.

RURAL HEALTH CLINICS (RHCS) AND FEDERALLY QUALIFIED HEALTH CENTERS (FQHCS) (SECTION III.B.) (Page 737)

Sections 4113 and 4121 of the CAA, 2023, specifically, extend payment for telehealth services furnished in RHCs and FQHCs through December 31, 2024, and 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) until January 1, 2025. (Page 745)

CMS is finalizing its proposal, as proposed, to codify payment provisions for MFTs and MHCs under 42 CFR part 405, subpart X beginning January 1, 2024. That is, RHC and FQHCs will be paid under the RHC All Inclusive Rate and FQHC PPS, respectively, when MFTs and MHCs furnish RHC and FQHC services defined in §§ 405.2411 and 405.2446. As eligible RHC and FQHC practitioners, MFTs and MHCs should follow the same policies and supervision requirements as a PA, NP, CNM, CP, and CSW. (Page 754)

Effective January 1, 2024, CMS is finalizing the clarification that when MFTs and MHCs provide the services described in HCPCS code G0323 in an RHC or FQHC, the RHC or FQHC can bill HCPCS code G0511.

Section 4124 of Division FF of the CAA, 2023 establishes coverage and payment under Medicare for the Intensive Outpatient Program (IOP) benefit, effective January 1, 2024. IOP may be furnished by hospitals, Community Mental Health Centers (CMHCs), FQHCs and RHCs. Payment for IOP services furnished by RHCs and FQHCs is to be made at the same payment rate as if it were furnished by a hospital. (Page 755)

Currently, behavioral health services furnished in the RHC and FQHC settings require direct supervision. CMS is finalizing its proposal to revise the regulations at §§405.2413 and 405.2415 to reflect that behavioral health services can be furnished under general supervision of the physician (or other practitioner) when these services or supplies are provided by auxiliary personnel incident to the services of a physician (or another practitioner), as proposed. (Page 757)

CMS is finalizing, as proposed, to add the suite of services that comprise Remote Physiologic Monitoring (RPM) and Remote Therapeutic Monitoring (RTM) Services Furnished in RHCs and FQHCs to the general care management code G0511 beginning January 1, 2024, as the requirements for RPM and RTM services are similar to the non-face-to-face requirements for the general care management services furnished in RHCs and FQHCs. (Page 765)

CMS is finalizing, as proposed, 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.

RURAL HEALTH CLINICS (RHCS) AND FEDERALLY QUALIFIED HEALTH CENTERS (FQHCS) CONDITIONS FOR CERTIFICATION OR COVERAGE (CFCs) (SECTION III.C.) (Page 788)

Section III.C. outlines changes to the RHC and FQHC CfCs as required in section 4121 of division FF of the ***Consolidated Appropriations Act*** (CAA 2023). Specifically, CMS must implement provisions that would modify the existing RHC and FQHC CfCs at § 491.8(a)(3) to include marriage and family

therapists (MFTs) and mental health counselors (MHCs) as part of the collaborative team approach to provide services under Medicare Part B.

CMS is also finalizing the requirement that Nurse Practitioners s must be certified by a recognized certifying body and possess a master's or doctoral degree in nursing.

CLINICAL LABORATORY FEE SCHEDULE: REVISED DATA REPORTING PERIOD AND PHASE-IN OF PAYMENT REDUCTIONS (SECTION III.D.) (Page 795)

Section 4114(b) of the CAA, 2023 amended the data reporting requirements in section 1834A(a)(1)(B) of the Act to delay the next data reporting period for clinical diagnostic laboratory tests (CDLTs) that are not advanced diagnostic laboratory tests (ADLT) by 1 year, so that data reporting would be required during the period of January 1, 2024, through March 31, 2024, instead of the data reporting period of January 1, 2023, through March 31, 2023. (Page 802)

Section 4114(a) of the CAA, 2023 further amends section 1834A(b)(3)(B)(iii) of the Act to state that the applicable percent of 15 percent will apply for CYs 2024 through 2026. (Page 803)

PULMONARY REHABILITATION, CARDIAC REHABILITATION AND INTENSIVE CARDIAC REHABILITATION EXPANSION OF SUPERVISING PRACTITIONERS (SECTION III.E.) (Page 808)

Section 51008 of the ***Bipartisan Budget Act*** (BBA) of 2018, entitled "Allowing Physician Assistants, Nurse Practitioners, and Clinical Nurse Specialists to Supervise Cardiac, Intensive Cardiac and Pulmonary Rehabilitation Programs," amended sections 1861(eee) and (fff) of the Act, effective January 1, 2024. The amendment directs CMS to add to the types of practitioners who may supervise PR, CR and ICR programs to also include a physician assistant (PA), nurse practitioner (NP), or clinical nurse specialist (CNS).

CMS is finalizing these additions and revisions, as proposed. All other provisions of these regulations remain unchanged. (Page 812)

MODIFICATIONS RELATED TO MEDICARE COVERAGE FOR OPIOID USE DISORDER (OUD) TREATMENT SERVICES FURNISHED BY OPIOID TREATMENT PROGRAMS (OTPs) (SECTION III.F.) (Page 815)

CMS is finalizing its proposal to revise paragraph (vii) of the definition of "Opioid use disorder treatment service" at § 410.67(b) to state that through the end of CY 2024, in cases where a beneficiary does not have access to two-way audio-video communications technology, periodic assessments can be furnished using audio-only telephone calls if all other applicable requirements are met.

MEDICARE SHARED SAVINGS PROGRAM (SECTION III.G.) (Page 828)

This is one of the longer sections of this proposal, extending more than 400 pages. CMS has issued a separate fact sheet describing major changes. The fact sheet is available at: https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2024-medicare-physician-fee-schedule-final-rule-medicare-shared-savings-program.

For performance year 2024 and subsequent performance years, CMS is establishing the Medicare CQMs for Accountable Care Organizations as a new collection type for Shared Savings Program ACOs under the Alternative Payment Model (APM) Performance Pathway (APP).

As a general summary, CMS is finalizing the following changes to Shared Savings Program policies to:

- Revise the quality reporting and the quality performance requirements (section III.G.2. of this final rule), including the following: (Page 835)

  - Allow Shared Savings Program ACOs the option to report quality measures under the APP on only their Medicare beneficiaries through Medicare CQMs (Page 840)
  - Update the APP measure set for Shared Savings Program ACOs (Page 890)
  - Revise the calculation of the health equity adjustment underserved multiplier (Page 894)
  - Use historical data to establish the 40th percentile MIPS Quality performance category score used for the quality performance standard ((Page 903)
  - Apply a Shared Savings Program scoring policy for excluded APP measures and APP measures that lack a benchmark (Page 917)
  - Require Spanish language administration of the CAHPS for MIPS survey (Page 923)
  - Align CEHRT requirements for Shared Savings Program ACOs with MIPS (Page 924)
  - MIPS Value Pathway (MVP) Reporting for Specialists in Shared Savings Program ACOs -Request for Information (RFI) (Page 948)
  - Revise the requirement to meet the case minimum requirement for quality performance standard determinations (Page 952)

- Revise the policies for determining beneficiary assignment (section III.G.3).

  - Modify the step-wise beneficiary assignment methodology and approach to identifying the assignable beneficiary population (Page 960)
  - Update the definition of primary care services used in beneficiary assignment at § 425.400(c) (Page 974)

- Revise the policies on the Shared Savings Program's benchmarking methodology (section III.G.4.).

  - Modify the calculation of the regional update factor used to update the historical benchmark between benchmark year (BY) 3 and the performance year by capping an ACO's regional service area risk score growth through use of an adjustment factor to provide more equitable treatment for ACOs and for symmetry with the cap on ACO risk score growth. (Page 1,072)
  - Further mitigate the impact of the negative regional adjustment on the benchmark to encourage participation by ACOs caring for medically complex, high-cost beneficiaries. (Page 1,103)
  - Specify the circumstances in which CMS will recalculate the prior savings adjustment for changes in values used in benchmark calculations due to compliance action taken to address avoidance of at-risk beneficiaries, or as a result of the issuance of a revised initial determination of financial performance for a previous performance year. (Page 1,130)

- Specify use of the CMS-HCC risk adjustment methodology applicable to the calendar year corresponding to the performance year in calculating prospective HCC risk scores for Medicare FFS beneficiaries for the performance year, and for each benchmark year of the ACO's agreement period. (Page 1,145)

- Refine AIP policies, including the following (section III.G.5):

- Modify advance investment payments (AIP) eligibility requirements to allow an ACO to elect to advance to a two-sided model level of the BASIC track's glide path beginning with the third performance year of the 5-year agreement period in which the ACO receives advance investment payments. (Page 1,170)
- Modify AIP recoupment and recovery polices to forgo immediate collection of advance investment payments from an ACO that terminates its participation agreement early in order to early renew under a new participation agreement to continue its participation in the Shared Savings Program. (Page 1,186)
- Modify termination policies to specify that CMS will immediately terminate advance investment payments to an ACO for future quarters if the ACO voluntarily terminates its participation agreement. (Page 1,191)
- Modify ACO reporting requirements to require ACOs to submit spend plan updates and actual spend information to CMS in addition to publicly reporting such information.
- Modify AIP requirements to permit ACOs to seek reconsideration review of all quarterly payment calculations. (Page 1,196)

- Update Shared Savings Program eligibility requirements, including the following (section III.G.6):

- Remove the option for ACOs to request an exception to the shared governance requirement that 75 percent control of an ACO's governing body must be held by ACO participants.
- Codify the existing Shared Savings Program operational approach to specify that CMS determines that an ACO participant TIN participated in a performance-based risk Medicare ACO initiative if it was or will be included on a participant list used in financial reconciliation for a performance year under performance-based risk during the five most recent performance years. (Page 1,198)

- Make technical changes to references in Shared Savings Program regulations (section III.G.7.), including to update assignment selection references to either § 425.226(a)(1) or § 425.400(a)(4)(ii) in subpart G of the regulations, correct typographical errors in the definitions in § 425.20, and update certain terminology used in § 425.702. (Page 1,203)

MEDICARE PART B PAYMENT FOR PREVENTIVE VACCINE ADMINISTRATION SERVICES (SECTION III.H.) (Page 1,249)

CMS provides the following tables regarding payments for vaccines.

CY 2024 Part B Payments for Preventive Vaccine Administration if the Emergency Use Authorization Declaration for Drugs and Biologicals with Respect to COVID-19 Continues into CY 2024

Category of Part B Product Administration	Part B Payment Amount (Unadjusted)	Annual Update	Geographic Adjustment
Influenza, Pneumococcal, Hepatitis B1,4	$32.57	Medicare Economic Index	GAF
COVID-19 Vaccine	$43.43	MEI	GAF
In-Home Additional Payment for Part B Vaccine Administration (M0201)	$38.55	MEI	GAF

Part B Payments for Preventive Vaccine Administration Beginning January 1, 2024, if the EUA Declaration for Drugs and Biologicals with Respect to COVID 19 is Terminated on or Before December 31, 2023

Category of Part B Product Administration	Part B Payment Amount (Unadjusted)	Annual Update	Geographic Adjustment
Influenza, Pneumococcal, Hepatitis B1,4	$32.57	MEI	GAF
COVID-192,4	$32.57	MEI	GAF
In-Home Additional Payment for Part B Vaccine Administration (M0201)	$38.55	MEI	GAF

MEDICARE DIABETES PREVENTION PROGRAM (MDPP)(SECTION III.I) (Page 1,273)

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.

APPROPRIATE USE CRITERIA FOR ADVANCED DIAGNOSTIC IMAGING (SECTION III.I.)
(Page 1,319)

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.

MEDICARE AND MEDICAID PROVIDER AND SUPPLIER ENROLLMENT (SECTION III.K.)
(Page 1,349)

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

- Creating 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.

EXPAND DIABETES SCREENING AND DIABETES DEFINITIONS (SECTION III.L.) (Page 1,401)

CMS is finalizing the proposals made in the CY 2024 PFS proposed rule to (1) expand coverage of diabetes screening tests to include the Hemoglobin A1C test (HbA1c) test; (2) expand and simplify the frequency limitations for diabetes screening; and (3) simplify the regulatory definition of "diabetes" for diabetes screening (§ 410.18(a)), Medical Nutrition Therapy (MNT) (§ 410.130) and Diabetes Outpatient Self-Management Training Services (DSMT) (§ 410.140). (Page 1,415)

REQUIREMENT FOR ELECTRONIC PRESCRIBING FOR CONTROLLED SUBSTANCES (EPCS) FOR A COVERED PART D DRUG UNDER A PRESCRIPTION DRUG PLAN OR AN MA-PD PLAN (SECTION 2003 OF THE SUPPORT ACT) (SECTION III.M.) (Page 1,418)

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 says it may consider a prescriber's non-compliance under the CMS EPCS program in its 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.

CHANGES TO THE REGULATIONS ASSOCIATED WITH THE AMBULANCE FEE SCHEDULE AND THE MEDICARE GROUND AMBULANCE DATA COLLECTION SYSTEM (GADCS) (SECTION III.N.) (Page 1,443)

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.

CMS is finalizing its 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.

HOSPICE: CHANGES TO THE HOSPICE CONDITIONS OF PARTICIPATION (SECTION III.O.) (Page 1,456)

CMS says that all the hospice CoP information and requirements related to marriage and family therapist (MFT) services and mental health counselor (MHC) services are published in this final rule, and there are no plans to republish this information in a separate hospice rule. (Page 1,459)

The hospice IDG will only be required to include one SW (Social Worker), one MFT, or one MHC. The hospice is not required to include all three of these professions as members of the Interdisciplinary group (IDG).

The statutory language of division FF, section 4121 of the CAA 2023 states that section 1861(dd)(2)(B)(i)(III) of the Act (42 U.S.C. 1395x(dd)(2)(B)(i)(III)) is amended by inserting, marriage and family therapist, or mental health counselor' after social worker, and that, "The amendments made by this section shall apply with respect to services furnished on or after January 1, 2024." This language clarifies that hospices have the ability to discern which professional to choose to serve as a member of the IDG. (Page 1,468)

CMS is finalizing the proposed requirements with modification at § 418.56 by removing the phrase "depending on the preferences and needs of the patient."

RFI: HISTOPATHOLOGY, CYTOLOGY, AND CLINICAL CYTOGENETICS REGULATIONS UNDER THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) OF 1988 (SECTION III.P.) (Page 1,473)

CMS solicited comments in the following areas of CLIA: Histopathology, Cytology, and Clinical cytogenetics. 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 says it will consider the input received as it continues to evaluate possible future changes to the CLIA regulations.

CHANGES TO THE BASIC HEALTH PROGRAM REGULATIONS (SECTION III.Q.) (Page 1,481)

States have an option to operate a Basic Health Program (BHP). In the States that elect to operate a BHP, the State's BHP makes affordable health benefits coverage available for lawfully present individuals under age 65 with household incomes between 133 and 200 percent of the Federal poverty level.

States wishing to suspend their BHP must submit an application to HHS. As of the date of this rule, only New York and Minnesota have implemented a BHP.

UPDATES TO THE DEFINITIONS OF CERTIFIED ELECTRONIC HEALTH RECORD TECHNOLOGY (SECTION III.R.) (Page 1,497)

CMS is finalizing revisions to the CEHRT definitions in the Medicare Promoting Interoperability Program and the Quality Payment Program (on which the Shared Savings Program's definition of CEHRT at § 425.20 also relies) to support the proposed transition from the historical state of year themed "editions" to the "edition-less state" in the ONC HTI-1 proposed rule.

A SOCIAL DETERMINANTS OF HEALTH RISK ASSESSMENT IN THE ANNUAL WELLNESS VISIT (SECTION III.S.) (Page 1,511)

CMS is finalizing its proposal made in the CY 2024 PFS proposed rule to exercise its authority in section 1861(hhh)(2)(I) of the Act to add elements to the AWV by adding a new SDOH Risk Assessment as an optional, additional element of the AWV with an additional payment and no applicable beneficiary cost sharing.

UPDATES TO THE QUALITY PAYMENT PROGRAM (SECTION IV.) (Page 1,527)

CMS says "it continues to move the Quality Payment Program forward, including focusing more on measurement efforts and refining how clinicians would be able to participate in a more meaningful way, to achieve continuous improvement in the quality of health care services provided to Medicare beneficiaries and other patients through the Quality Payment Program's Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs) for the CY 2024 performance period/2026 MIPS payment year."

CMS is finalizing 5 new MIPS Valued Pathways (MVPs).

They are:

1) Focusing on Women's Health
2) Quality Care for the Treatment of Ear, Nose, and Throat Disorders
3) Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV
4) Quality Care in Mental Health and Substance Use Disorders
5) Rehabilitative Support for Musculoskeletal Care.

The preamble's quality discussion extends more than 300 pages. Once again, CMS has released a 60-page fact sheet on the CY 2024 Quality material at: https://qpp-cm-prod-content.s3.amazonaws.com/uploads/2481/2024%20QPP%20Proposed%20Rule%20Fact%20Sheet%20and%20Policy%20Comparison%20Table%20(2).pdf.

Please refer to this site for specific changes. Also, see the Appendices below for additional material.

REGULATORY IMPACT ANALYSIS (Section VII) (Page 1,934)

Do not overlook the regulatory impact analysis section. It contains much additional and helpful information

APPENDICES (Page 2,200)

Appendix 1: MIPS Quality Measures

- Table Group A: New Quality Measures Finalized and Not Finalized for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years (Page 2,200)
- Table Group B: Modifications to Previously Finalized Specialty Measures Sets Finalized for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years (Page 2,234)
- Table Group C: Previously Finalized Quality Measures Finalized and Not Finalized for Removal in the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years (Page 2,530)
- Table Group CC: Finalized Partial Removal of Three Previously Finalized Quality Measures as Component Measures in Traditional MIPS and Finalized Retention of These Three Measures for Use in Relevant MVPs for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years (Page 2,543)
- Table Group D: Previously Finalized Quality Measures with Substantive Changes Finalized for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years (Page 2,549)
- Table Group DD: Previously Finalized Quality Measures with Substantive Changes Finalized for Partial Removal as Component Measures in Traditional MIPS and Finalized for Retention for Use in Relevant MVPs for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years (Page 2,615)
- Table Group E: Previously Finalized CMS Web Interface Quality Measures with Substantive Changes Finalized for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years (Page 2,618)

Appendix 2: Improvement Activities (Page 2,629)

- Table A: New Improvement Activities for the CY 2024 Performance Period/2026 MIPS Payment Year and for Future Years (Page 2,629)
- Table B: Changes to Previously Adopted Improvement Activities for the CY 2024 Performance Period/2026 MIPS Payment Year and for Future Years (Page 2,638)

- Table C: Improvement Activities Proposed for Removal for the CY 2024 Performance Period/2026 MIPS Payment Year and for Future Years (Page 2,639)

Appendix 3: MVP Inventory (Page 2,641)

This appendix contains two groups of MVP tables: Group A, which includes five new MVPs and Group B, which includes modifications to 12 previously finalized MVPs. We received comments on all Group A and Group B MVPs with the comment summaries and responses embedded in each MVP table. (Page 2,641)

- Group A: New MVPs for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years (Page 2,644)

  - A.1 Focusing on Women's Health MVP
  - A.2 Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP.
  - A.3 Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP
  - A.4 Quality Care in Mental Health and Substance Use Disorders MVP
  - A.5 Rehabilitative Support for Musculoskeletal Care MVP

- Group B: Modifications to Previously Finalized MVPs for the CY 2023 Performance Period/2025 MIPS Payment Year and Future Years (Page 2,670)

  - B.1: Advancing Cancer Care MVP
  - B.2: Optimal Care for Kidney Health MVP
  - B.3: Optimal Care for Patients with Episodic Neurological Conditions MVP
  - B.4: Supportive Care for Neurodegenerative Conditions MVP
  - B.5: Advancing Care for Heart Disease MVP
  - B.6: Advancing Rheumatology Patient Care MVP
  - B.7: Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP

Final Thoughts

At over 2,700 pages, this rule is extremely difficult to comprehend and navigate. It contains much, too much, unneeded history about origins of the issues being addressed. As we have stated before, the issue at hand is discussing changes from CY 2023 to CY 2024. Why discuss items from 20 years ago?

Our intent in this analysis is to provide the reader with the issues, and more importantly where with-in the document information is presented.

With the preamble and appendix items, quality extends more than 800 pages. As we have noted in the past, with constant changes and revisions, the basic question remains. Is CMS achieving any real quality changes or just collecting statistics for payment reduction purposes? It is understandable why commenters/ stakeholders and others say the quality material is both burdensome and confusing.

CMS has listed more than 575 footnotes. It is obvious those working in this area are trying to understand physician and related provider services. However, most of the material is from papers, essays and studies. One would expect more to be from those actually providing the services.

We find the rule deficient in that rule does not have clear and concise final action/ decision sections. CMS has created such sections in many of its other rule's. Many final items are revealed in "after consideration" notations, but not all. Not having such makes it much more difficult for the reader to focus on the changes being made or perhaps not made.

CMS' favorite replies to most commenters responses that agree with the agency's decisions is to congratulate with phrases "We appreciate the support; We appreciate commenters' feedback; We thank commenters; we agree with commenters" and so forth. To a large extent these phrases extend a bias in CMS' replies to such comments. For example, CMS has stated "we appreciate" 428 times. CMS has never revealed the number of positive versus negative commenter responses. Perhaps CMS should.

We have referred to CMS fact sheets for additional information. At present, when one goes to CMS.gov and selects newsroom in the top heading, the latest fact sheets do not always appear. If such happens, please hit the reload page symbol which should reveal the latest fact sheets.