Issue Brief

FEDERAL ISSUE BRIEF

Analysis provided for MHA by Larry Goldberg, Goldberg Consulting

July 18, 2023

Proposed CY 2024 Revisions to Payment Policies under the Medicare Physician Fee Schedule Released

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

A copy of this 2,033-page rule is at the ***Federal Register*** office, and a copy is currently available at: https://public-inspection.federalregister.gov/2023-14624.pdf. The rule is scheduled for publication on August 7. A 60-day comment period ending September 11 is provided.

Comment

This MPFS regulation is long and complex. Given CMS' propensity for rules without a table of contents it is not surprising that such is totally missing, here.

Specifically, the rule says it includes discussions regarding the following items below. We have added page numbers to allow access to the material, and have used such as a surrogate table of contents. Referenced page numbers in red are based on the Adobe page count of the regulation.

Specifically, this proposed rule addresses:

- Determination of PE RVUs (section II.B.) (Page 13)
- Potentially Misvalued Services Under the PFS (section II.C.) (Page 59)
- Payment for Medicare Telehealth Services Under Section 1834(m) of the Social Security Act (the Act) (section II.D.) (Page 82)
- Valuation of Specific Codes (section II.E.) (Page 158)
- Evaluation and Management (E/M) Visits (section II.F.) (Page 290)
- Geographic Practice Cost Indices (GPCI) (section II.G.) (Page 307)
- Payment for Skin Substitutes (section II.H.) (Page 312)
- Supervision of Outpatient Therapy Services, KX Modifier Thresholds, Diabetes Self-Management Training (DSMT) Services by Registered Dietitians and Nutrition Professional, and DSMT Telehealth Services (section II.I.) (Page 316)
- Advancing Access to Behavioral Health (section II.J.) (Page 328)
- Proposals on Medicare Parts A and B Payment for Dental Services Inextricably Linked to Specific Covered Medical Services (section II.K.) (Page 361)
- Drugs and Biological Products Paid Under Medicare Part B (section III.A.) (Page 406)
- Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (section III.B.) (Page 443)
- Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) Conditions for Certification or Coverage (CfCs) (section III.C.) (Page 479)
- Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-in of Payment Reductions (section III.D.) (Page 487)

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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- Pulmonary Rehabilitation, Cardiac Rehabilitation and Intensive Cardiac Rehabilitation Expansion of Supervising Practitioners (section III.E.) (Page 497)
- Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs) (section III.F.) (Page 500)
- Medicare Shared Savings Program (section III.G.) (Page 508)
- Medicare Part B Payment for Preventive Vaccine Administration Services (section III.H.)
- (Page 757)
- Medicare Diabetes Prevention Program Expanded Model (section III.I.) (Page 771)
- Appropriate Use Criteria for Advanced Diagnostic Imaging (section III.J.) (Page 797)
- Medicare and Medicaid Provider and Supplier Enrollment (section III.K.) (Page 817)
- Expand Diabetes Screening and Diabetes Definitions (section III.L.) (Page 859)
- Requirement for Electronic Prescribing for Controlled Substances 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 873)
- Proposed Changes to the Regulations Associated with the Ambulance Fee Schedule and the Medicare Ground Ambulance Data Collection System (GADCS) (section III.N.) (Page 889)
- Hospice: Changes to the Hospice Conditions of Participation (section III.O.) (Page 900)
- RFI: Histopathology, Cytology, and Clinical Cytogenetics Regulations under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 (section III.P.) (Page 904)
- Changes to the Basic Health Program Regulations (section III.Q.) (Page 911)
- Updates to the Definitions of Certified Electronic Health Record Technology (section III.R.)
- (Page 925)
- A Social Determinants of Health Risk Assessment in the Annual Wellness Visit (section III.S.) (Page 933)
- Updates to the Quality Payment Program (section IV.) (Page 946)
- Collection of Information Requirements (section V.) (Page 1,172)
- Response to Comments (section VI.) (Page 1,266)
- Regulatory Impact Analysis (section VII.) (Page 1,266)

Hopefully, the above page numbering can assist in determining the size (by pages) of the issue being addressed.

Not all items in the proposal are addressed in the analysis that follows

Accounting Statement: Classification of Estimated Expenditures (Page 1,397)

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 1,397)

Category	Primary Estimate	Minimum Estimate	Maximum Estimate	Source Citation
Transfers From the Federal Government to ACOs				
Annualized monetized: Discount rate: 7%	-15 million	-171 million	174 million	Tables 109 through 112
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.

Please note the ***Federal Register*** Office originally posted this rule indicating it was 1,963 pages. Checking again, the rule is now 2,033 pages. Our analysis is based on the 2,033-page version.

PAYMENT PROVISIONS OF THE CY 2024 PFS RULE

Payment Updates and Conversion Factors (CF) (Page 1,281)

CMS estimates the CY 2024 PFS CF to be 32.7476 which reflects a -2.17 percent budget neutrality adjustment under section 1848(c)(2)(B)(ii)(II) of the Act, a 0.00 percent update adjustment factor specified under section 1848(d)(19) of the Act, and a 1.25 percent payment increase for services furnished in CY 2024, as provided in the ***Consolidated Appropriations Act*** (CAA), 2023.

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	-2.17 percent (0.9783)	
CY 2024 1.25 Percent Increase Provided by the CAA, 2023	1.25 percent (1.0125)	
CY 2024 Conversion Factor		**32.7476**

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	-2.17 percent (0.9783)	
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		20.4370

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	$216	0%	-1%	0%	-1%
ANESTHESIOLOGY	$1,647	-2%	-1%	0%	-2%
AUDIOLOGIST	$69	-1%	-1%	0%	-2%
CARDIAC SURGERY	$174	-1%	-1%	0%	-2%
CARDIOLOGY	$5,989	0%	0%	0%	0%
CHIROPRACTIC	$644	-1%	-1%	0%	-2%
CLINICAL PSYCHOLOGIST	$711	1%	0%	0%	2%
CLINICAL SOCIAL WORKER	$795	2%	0%	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
COLON AND RECTAL SURGERY	$147	-1%	-1%	0%	-2%
CRITICAL CARE	$331	-1%	0%	0%	-1%
DERMATOLOGY	$3,713	0%	0%	0%	-1%
DIAGNOSTIC TESTING FACILITY	$828	0%	-2%	0%	-2%
EMERGENCY MEDICINE	$2,460	-2%	-1%	0%	-2%
ENDOCRINOLOGY	$507	1%	1%	0%	3%
FAMILY PRACTICE	$5,504	2%	2%	0%	3%
GASTROENTEROLOGY	$1,474	0%	0%	0%	0%
GENERAL PRACTICE	$361	1%	1%	0%	2%
GENERAL SURGERY	$1,614	-1%	-1%	0%	-1%
GERIATRICS	$180	0%	1%	0%	1%
HAND SURGERY	$251	-1%	0%	0%	-1%
HEMATOLOGY/ONCOLOGY	$1,591	1%	0%	0%	2%
INDEPENDENT LABORATORY	$546	-1%	-1%	0%	-1%
INFECTIOUS DISEASE	$573	-1%	0%	0%	-1%
INTERNAL MEDICINE	$9,618	0%	1%	0%	1%
INTERVENTIONAL PAIN MGMT	$849	0%	0%	0%	0%
INTERVENTIONAL RADIOLOGY	$457	-1%	-3%	0%	-4%
MULTISPECIALTY CLINIC/OTHERPHYS	$146	0%	0%	0%	0%
NEPHROLOGY	$1,803	-1%	0%	0%	-1%
NEUROLOGY	$1,323	0%	0%	0%	1%
NEUROSURGERY	$694	-1%	0%	0%	-1%

(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
NUCLEAR MEDICINE	$51	-1%	-2%	0%	-3%
NURSE ANES / ANES ASST	$1,081	-2%	0%	0%	-2%
NURSE PRACTITIONER	$6,260	1%	1%	0%	2%
OBSTETRICS/GYNECOLOGY	$558	0%	1%	0%	1%
OPHTHALMOLOGY	$4,647	0%	0%	0%	-1%
OPTOMETRY	$1,292	-1%	-1%	0%	-2%
ORAL/MAXILLOFACIAL SURGERY	$62	-1%	-1%	0%	-2%
ORTHOPEDIC SURGERY	$3,358	-1%	0%	0%	-1%
OTHER	$55	0%	-1%	0%	0%
OTOLARYNGOLOGY	$1,112	0%	0%	0%	0%
PATHOLOGY	$1,136	-1%	-1%	0%	-2%
PEDIATRICS	$55	0%	1%	0%	1%
PHYSICAL MEDICINE	$1,087	0%	0%	0%	-1%
PHYSICAL/OCCUPATIONAL THERAPY	$5,257	-1%	-2%	0%	-2%
PHYSICIAN ASSISTANT	$3,366	1%	1%	0%	2%
PLASTIC SURGERY	$300	-1%	-1%	0%	-1%
PODIATRY	$1,890	0%	0%	0%	0%
PORTABLE X-RAY SUPPLIER	$75	0%	0%	0%	-1%
PSYCHIATRY	$897	1%	1%	0%	2%
PULMONARY DISEASE	$1,290	0%	0%	0%	0%
RADIATION ONCOLOGY AND RADIATION THERAPY CENTERS	$1,552	0%	-2%	0%	-2%
RADIOLOGY	$4,517	-1%	-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
RHEUMATOLOGY	$509	1%	1%	0%	2%
THORACIC SURGERY	$292	-1%	-1%	0%	-2%
UROLOGY	$1,623	0%	0%	0%	1%
VASCULAR SURGERY	$1,009	0%	-3%	0%	-3%
TOTAL	$88,549	0%	0%	0%	0%

II. PROVISIONS OF THE PROPOSED RULE FOR THE PFS

DETERMINATION OF PE RVUS (SECTION II.B.) (Page 14)

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.

POTENTIALLY MISVALUED SERVICES UNDER THE PFS (SECTION II.C.) (Page 59)

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.

"In each proposed rule, we seek nominations from the public and from interested parties of codes that they believe we should consider as potentially misvalued." (Page 67)

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 does not agree that CPT code 59200 is potentially misvalued. (Page 68)
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 welcomes comments on the nomination of CPT code 27279 for consideration as potentially misvalued. (Page 70)

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 is proposing to maintain the values that were finalized for these codes in the CY 2023 PFS final rule. (Page 72)
4) CPT codes 36514, 36516, 36522. CMS welcomes comments on the nomination of these codes as potentially misvalued, or not. (Page 73)
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 soliciting feedback regarding the nomination of CPT code 44205 as potentially misvalued. (Page 74)
6) CPT codes 93655 and 93657. CMS is not proposing to nominate these codes as potentially misvalued for CY 2024. (Page 75)
7) CPT code 94762 and 95800. CMS welcomes comments as to whether or not these codes are potentially misvalued. (Page 78)
8) CPT codes 0596T and 0597T. CMS welcomes comments as to whether or not these two temporary category II CPT codes, are potentially misvalued, and whether these codes should remain contractor priced or not. (Page 79)
9) CPT code 93000. CMS is not proposing to nominate CPT code 93000 as potentially misvalued for CY 2024. (Page 80)
10) 19 therapy codes. CMS recommends nomination of these 19 codes as potentially misvalued for CY 2024, and welcomes comments on this nomination. (Page 81)

PAYMENT FOR MEDICARE TELEHEALTH SERVICES UNDER SECTION 1834(M) OF THE ACT (SECTION II.D.) (Page 82) (Page 1,311)

Requests to Add Services to the Medicare Telehealth Services List for CY **2024** *(Page 86)*

CMS says it received several requests to permanently add various services to the Medicare Telehealth Services List effective for CY 2024. CMS found that none of the requests were received by the February 10 submission deadline criteria for permanent addition to the Medicare Telehealth Services List. (Page 87)

Refer the rule's table 9 for a list of the proposals with details, and which are listed as follow: (Page 88)

- Cardiovascular Procedures - CPT code 93793. CMS is not proposing to add this service to the Medicare Telehealth Services List on a Category 1 basis. (Page 91)
- Cardiovascular and Pulmonary Rehab – CPT codes 93797 and CPT code 94624. (Page 92)

  CMS is not proposing to include these services permanently on the Medicare Telehealth Services List on a Category 1 basis. Instead CMS is proposing to 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 92)

- Deep Brain Stimulation - CPT codes 95970, 95983, and 95984.

  CMS is proposing to keep these services on the Medicare Telehealth Services List for CY 2024. (Page 94)

- 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 proposing to add these services to the Medicare Telehealth Services List on a Category 1 or 2 basis.

  CMS is proposing to 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 98)

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

  CMS is not proposing to add these services to the list on a permanent basis at this time, but is proposing that they would remain available on the Medicare Telehealth Services List through CY 2024. (Page 101)

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

  CMS is not proposing to add these health and well-being coaching services to the Medicare Telehealth Services List on a permanent basis, but is proposing to add them to the list on a temporary basis for CY 2024. (Page 102)

CMS Proposal to Add New Codes to the List – CMS is proposing to add HCPCS code GXXX5 (Administration of a standardized, evidence-based Social Determinants of Health Risk Assessment tool, 5-15 minutes) to the Medicare Telehealth Services List. (Page 103)

CMS is soliciting comments on procedures for additions to, removals from, or changes in status for services on the Medicare Telehealth Services List. (Page 104)

CMS is proposing 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 121)

CMS is proposing that, beginning in CY 2024, claims billed with POS 10 (Telehealth Provided in Patient's Home) be paid at the non-facility PFS rate. (Page 131)

Claims billed with POS 02 (Telehealth Provided Other than in Patient's Home) will continue to be paid at the PFS facility rate beginning on January 1, 2024. (Page 132)

CMS is proposing to remove the telehealth frequency limitations for the following codes: (Page 132)

99231, 99232, 99233, 99307, 99308, 99309, 99310, G0508, G0508.

VALUATION OF SPECIFIC CODES (SECTION II.E.) (Page 158)

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 it is making, and in many cases not making, 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 2X000) (Page 177)
2	Vertebral Body Tethering (CPT codes 2X002, 2X003, and 2X004) (Page 178)
3	Total Disc Arthroplasty (CPT codes 22857 and 22860) (Page 178)
4	Phrenic Nerve Stimulation System (CPT codes 3X008, 3X009, 3X010, 3X011, 3X012, 3X013, 3X014, 3X015, 9X045, 9X046, 9X047, and 9X048) (Page 180)
5	Posterior Nasal Nerve Ablation (CPT codes 30117, 30118, 3X016, and 3X017) (Page182)
6	Cystourethroscopy with Urethral Therapeutic Drug Delivery (CPT code 5X000) (Page 186)
7	Transcervical RF Ablation of Uterine Fibroids (CPT code 5X005) (Page 187)
8	Suprachoroidal Injection (CPT code 6X000) (Page 188)
9	Skull Mounted Cranial Neurostimulator (CPT codes 619X1, 619X2, and 619X3) (Page 189)
10	Spinal Neurostimulator Services (CPT codes 63685, 63688, 64XX2, 64XX3, and 64XX4) (Page 190)
11	Neurostimulator Services-Bladder Dysfunction (CPT codes 64590 and 64595) (Page 190)
12	Ocular Surface Amniotic Membrane Placement/Reconstruction (CPT codes 65778, 65779, and 65780) (Page 191)
13	Fractional Flow Reserve with CT (CPT code 7X005) (Page 192)
14	Ultrasound Guidance for Vascular Access (CPT code 76937) (Page 195)
15	Neuromuscular Ultrasound (CPT codes 76881, 76882, and 76883) (Page 195)
16	Intraoperative Ultrasound Services (CPT codes 76998, 7X000, 7X001, 7X002, and 7X003) (Page 198)
17	Percutaneous Coronary Interventions (CPT code 9X070) (Page 206)
18	Auditory Osseo integrated Device Services (CPT codes 926X1 and 926X2) (Page 206)

19	Venography Services (CPT codes 9X000, 9X002, 9X003, 9X004, and 9X005) (Page 207)
20	General Behavioral Health Integration Care Management (CPT code 99484, and HCPCS code G0323) (Page 210)
21	Advance Care Planning (CPT codes 99497 and 99498) (Page 212)
22	Pelvic Exam (CPT code 9X036) (Page 213)
23	Hyperthermic Intraperitoneal Chemotherapy (HIPEC) (CPT codes 9X034 and 9X035)) (Page 213)
24	Hyperbaric Oxygen Under Pressure (HCPCS code G0277) (Page 214)
25	Remote Interrogation Device Evaluation – Cardiovascular (HCPCS code G2066, and CPT codes 93297, and 93298)) (Page 216)
26	Payment for Caregiver Training Services (Page 218)
27	Services Addressing Health-Related Social Needs (Community Health Integration services, Social Determinants of Health Risk Assessment, and Principal Illness Navigation Services) (Page 231)
28	Maternity Services (CPT codes 59400, 59410, 59425, 59426, 59430, 59510, 59515, 59610, 59614, 59618, 59622) (Page 273)

The rule's Table 12 contains the CY 2024 Work RVUs for New, Revised, and Potentially Misvalued Codes (Page 273)

The rule's Table 13 contains a list of codes and descriptors for which CMS is proposing work RVUs for CY 2024; this includes all codes for which CMS received RUC recommendations by February 10, 2023.

The proposed work RVUs, work time and other payment information for all CY 2024 payable codes are available on the CMS website for the CY 2024 PFS proposed rule at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html. (Page 282)

The rule's Table 14 contains the CY 2024 Direct PE Refinements – Equipment Refinements Conforming to Changes in Clinical Labor Time (Page 285)

The rule's Table 17 contains the list of no PE Refinements. (Page 289)

EVALUATION AND MANAGEMENT (E/M) VISITS (SECTION II.F.) (Page 290) (Page 1,314)

In the CAA of 2021, Congress imposed a statutory moratorium on Medicare payment for the office/outpatient (O/O) E/M visit inherent complexity add-on code until January 1, 2024.

CMS is proposing to change the status of HCPCS code G2211 to make it separately payable by assigning the "active" status indicator, effective January 1, 2024. (Page 299)

CMS is proposing that the O/O E/M visit complexity add-on code, HCPCS code G2211, would not be payable when the O/O E/M visit is reported with payment modifier-25.

Split (or Shared) Visits (Page 304)

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

CMS is proposing to maintain the current definition of substantive portion for CY 2024 that allows for use of either one of the three key components (history, exam, or medical decision making *(*MDM)) or more than half of the total time spent to determine who bills the visit. "This proposed additional delay allows interested parties to have another opportunity to comment on this policy, and gives CMS time to consider more recent feedback and evaluate whether there is a need for additional rulemaking on this aspect of our policy."

GEOGRAPHIC PRACTICE COST INDICES (GPCIS) (SECTION II G.) (Page 307)

Congress recently extended the 1.0 work GPCI floor only through December 31, 2023, in division CC, section 101 of the **Consolidated Appropriations Act**, 2021. 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 312)

CMS seeks comments on various cost-gathering that could inform how to establish direct PE inputs for skin substitute products and appropriately develop payment rates for physician services that involve furnishing skin substitute products.

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 316)

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

CMS did not propose revisions to §§ 410.59 and 410.60 last year for occupational therapists in private practice (OTPPs) and physical therapists in private practice (PTPPs).

CMS is now proposing to establish (RTM) specific general supervision policy at §§ 410.59(a)(3)(ii) and (c)(2) and 410.60(a)(3)(ii) and (c)(2) to allow OTPPs and PTPPs to provide general supervision only for RTM services furnished by their OTAs and PTAs, respectively.

KX Modifier Thresholds (Page 322)

CMS proposes to increase the CY 2023 KX modifier threshold amount by the most recent forecast of the 2017-based MEI. For CY 2024, the proposed growth rate of the 2017-based MEI is estimated to be 4.5 percent, based on the IHS Global, Inc. (IGI) first quarter 2023 forecast with historical data through the fourth quarter of 2022. Multiplying the CY 2023 KX modifier threshold amount of $2,230 by the proposed CY 2024 percentage increase in the MEI of 4.5 percent ($2,230 x 1.045), and rounding to the nearest $10.00, results in a proposed CY 2024 KX modifier threshold amount of $2,330 for physical therapy and speech-language pathology services combined and $2,330 for occupational therapy services.

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 324)

CMS proposes to amend the regulation at § 410.72(d) to clarify that a RD or nutrition professional must personally perform Medical Nutrition Therapy (MNT) services. Additionally, CMS proposes to clarify that a RD or nutrition professional may bill for, or on behalf of, the entire DSMT entity as the DSMT certified provider regardless of which professional furnishes the actual education services. CMS proposes to clarify § 410.72(d) to provide that, except for DSMT services furnished as, or on behalf of, an accredited DSMT entity, registered dietitians and nutrition professionals can be paid for their professional MNT services only when the services have been directly performed by them.

CMS is proposing to continue to allow institutional providers to bill for outpatient therapy, DSMT, and MNT services until the end of CY 2024.

DSMT Telehealth Issues (Page 326)

CMS is proposing to codify 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 328)

CMS is proposing to revise its policy at 410.78(e) to allow a 1 hour of in-person training (for initial and/or follow-up training), when required for insulin-dependent beneficiaries, to be provided via telehealth.

ADVANCING ACCESS TO BEHAVIORAL HEALTH (SECTION II.J.)(Page 328)

CMS is proposing to create two new regulation sections at § 410.53 and § 410.54 to codify the coverage provisions for marriage and family therapists (MFTs) and mental health counselors (MHCs), respectively. These new regulations define in detail the requirements each group must have.

CMS is proposing to add MFTs and MHCs to the list of practitioners who are eligible to furnish Medicare telehealth services at the distant site.

Consistent with the requirements described in new paragraph (12) of section 1848(b) of the Act, CMS is proposing to create two new G-codes describing psychotherapy for crisis services furnished in any place of service at which the non-facility rate for psychotherapy for crisis services applies, other than the office setting: HCPCS codes GPFC1 and GPFC2. (Page 339)

The proposed new G-codes and their descriptors are:

- GPFC1 (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
- GPFC2 (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)).

CMS is proposing to allow the 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 CPs. (Page 344)

CMS is also proposing an increase in the valuation for timed behavioral health services under the PFS. Specifically, CMS is proposing to apply an adjustment to the work RVUs for psychotherapy codes payable under the PFS, and proposing to implement such over a four-year transition.

This would result in an approximate upward adjustment of 19.1 percent for work RVUs for these services, comparable to the relative difference in office/outpatient visits. (Page 351)

Updates to the Payment Rate for the PFS Substance Use Disorder (SUD) bundle (HCPCS codes G2086-G2088) (Page 354)

In order to update the valuation for HCPCS codes G2086 and G2087, CMS is proposing to increase the current payment rate 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). The current work RVU assigned to CPT code 90834 is 2.24, compared to the work RVU assigned to CPT code 90832, which is 1.70, which results in a difference of 0.54 work RVUs. Because the bundled payments described by HCPCS codes G2086 and G2087 include two individual psychotherapy sessions per month, CMS is proposing to add 1.08 RVUs to the work value assigned to HCPCS codes G2086 and G2087, which results in a new work RVU of 8.14 for HCPCS code G2086 and 7.97 for HCPCS code G2087.

PROPOSALS ON MEDICARE PARTS A AND B PAYMENT FOR DENTAL SERVICES INEXTRICABLY LINKED TO SPECIFIC COVERED SERVICES (Section II.K.) (Page 361)

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.

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

For CY 2024, CMS is proposing to codify dental services prior to, or during, head and neck cancer treatments, whether primary or metastatic. Additionally, CMS is proposing to permit payment for certain dental services inextricably linked to other covered services used to treat cancer — chemotherapy services, Chimeric Antigen Receptor T- (CAR-T) Cell therapy, and the use of high-dose bone modifying agents (antiresorptive therapy).

III. OTHER PROVISIONS OF THE PROPOSED RULE (Page 406)

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

Section 11402 of the **Inflation Reduction Act** (IRA) limits the payment amount for biosimilars. The provision requires that for new biosimilars furnished on or after July 1, 2024, during the initial period 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 409)

Inflation-adjusted Beneficiary Coinsurance and Medicare Payment for Medicare Part B Rebatable Drugs (Page 410)

Section 11101 requires that beneficiary coinsurance for a Part B rebatable drug is to be based on the inflation-adjusted payment amount if the Medicare payment amount for a calendar quarter exceeds the inflation-adjusted payment amount, beginning on April 1, 2023. CMS issued initial guidance implementing this provision, as permitted under section 1847A(c)(5)(C) of the Act, on February 9, 2023. CMS is now proposing conforming changes to regulatory text. The coinsurance will be 20 percent of the inflation-adjusted payment amount for such quarter (hereafter, the inflation-adjusted coinsurance amount).

Section 11407 of the IRA made three changes to the manner in which beneficiaries pay for insulin furnished through covered DME. First, the Part B deductible is waived for insulin furnished through covered DME on or after July 1, 2023. Second, beneficiary coinsurance responsibility, which is limited to $35 for a month's supply of insulin, could equal less than 20 percent if the Part B payment amount of a month's supply of insulin is greater than $175. Third, the Act requires the Secretary to increase the Medicare Part B payment to above 80 percent in the case the coinsurance amount for insulin furnished through covered DME equals less than 20 percent of the payment amount to pay for the full difference between the payment amount and coinsurance. (Page 413)

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 417)

Section 90004 of the ***Infrastructure Investment and Jobs Act*** (hereinafter is referred to as "the Infrastructure Act") 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").

In the CY 2023 PFS final rule, CMS adopted many policies to implement section 90004 of the ***Infrastructure Act***. 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

To implement the discarded drug refund, CMS proposes to issue the initial refund report to manufacturers, to include all calendar quarters for 2023, no later than December 31, 2024. (Page 420)

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 aimed at drug manufacturers.

RURAL HEALTH CLINICS (RHCS) AND FEDERALLY QUALIFIED HEALTH CENTERS (FQHCS) (SECTION III.B.) (Page 443)

CMS is proposing conforming regulatory text changes to implement Sections 4113 and 4121 of the CAA, 2023, specifically, extending payment for telehealth services furnished in RHCs and FQHCs through December 31, 2024, 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.

CMS is proposing to revise the code descriptor for HCPCS code G0323 in order to allow MFTs and MHCs, as well as CPs and CSWs, to be able to bill for this monthly care integration service. Since MFTs and MHCs are statutorily authorized to furnish services in RHCs and FQHCs effective January 1, 2024, CMS is proposing to clarify 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. (Page 452)

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 453)

Currently, behavioral health services furnished in the RHC and FQHC settings require direct supervision. CMS is proposing to change the required level of supervision for behavioral health services furnished "incident to" a physician or NPP's services at RHCs and FQHCs to allow general supervision, rather than direct supervision, consistent with the policies finalized under the PFS for CY 2023. (Page 454)

CMS proposes that RHCs and FQHCs that furnish RPM and RTM services would be able to bill these services using HCPCS code G0511, either alone or with other payable services on an RHC or FQHC claim for dates of service on or after January 1, 2024. (Page 461)

CMS is proposing 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.

CMS is also proposing a change in the methodology to calculate the payment rate for HCPCS code G0511 that takes into account how frequently the various services are utilized, i.e. weighting.

CMS is clarifying that for beneficiary consent for Chronic Care Management and virtual communications services, that the sequencing and mode of consent can take various forms and direct supervision is not needed.

RURAL HEALTH CLINICS (RHCS) AND FEDERALLY QUALIFIED HEALTH CENTERS (FQHCS) CONDITIONS FOR CERTIFICATION OR COVERAGE (CFCs) (SECTION III.C.) (Page 479)

Section III.C. of this proposed rule 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 also proposes to include definitions of other healthcare professionals who are already eligible to provide services at RHCs and FQHCs.

CLINICAL LABORATORY FEE SCHEDULE: REVISED DATA REPORTING PERIOD AND PHASE-IN OF PAYMENT REDUCTIONS (SECTION III.D.) (Page 487)

CMS is proposing to make certain conforming changes to the data reporting and payment requirements for clinical diagnostic laboratory tests (CDLTs). Specifically, CMS is proposing to update the regulatory definition of both the "data collection period" and "data reporting period," specifying that for the data reporting period of January 1, 2024 through March 31, 2024, the data collection period is January 1, 2019 through June 30, 2019. CMS is also proposing revisions to indicate that initially, data reporting begins January 1, 2017 and is required every three years beginning January 2024. In addition, CMS is proposing to make conforming changes to its requirements for the phase-in of payment reductions to reflect the amendments in section 4114(a) of the CAA, 2023. Specifically, CMS is proposing to revise the regulations to indicate that for CY 2023, payment for an applicable CDLTs may not be reduced compared to the payment amount established for that test in CY 2022, and for CYs 2024 through 2026, payment may not be reduced by more than 15 percent as compared to the payment amount established for that test for the preceding year.

PULMONARY REHABILITATION, CARDIAC REHABILITATION AND INTENSIVE CARDIAC REHABILITATION EXPANSION OF SUPERVISING PRACTITIONERS (SECTION III.E.) (Page 497)

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).

MODIFICATIONS RELATED TO MEDICARE COVERAGE FOR OPIOID USE DISORDER (OUD) TREATMENT SERVICES FURNISHED BY OPIOID TREATMENT PROGRAMS (OTPs) (SECTION III.F.) (Page 500)

CMS would allow periodic assessments to be furnished audio-only when video is not available to the extent that use of audio-only communications technology is permitted under the applicable SAMHSA and DEA requirements at the time the service is furnished and all other applicable requirements are met. (Page 506)

MEDICARE SHARED SAVINGS PROGRAM (SECTION III.G.) (Page 508)

This is one of the longer sections of this proposal, extending some 250 pages. In fact, CMS has issued a separate fact sheet describing major changes. The fact sheet is at: https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2024-medicare-physician-fee-schedule-proposed-rule-medicare-shared-savings-program.

Eligible groups of providers and suppliers, including physicians, hospitals, and other healthcare providers, may participate in the Medicare Shared Savings Program (Shared Savings Program) by forming or joining an accountable care organization (ACO) and in so doing agree to become accountable for the total cost and quality of care provided under Traditional Medicare to an assigned population of Medicare fee-for-service (FFS) beneficiaries. Under the Shared Savings Program, providers and suppliers that participate in an ACO continue to receive traditional Medicare FFS payments under Parts A and B, and the ACO may be eligible to receive a shared savings payment if it meets specified quality and savings requirements, and in some instances may be required to share in losses if it increases health care spending. (Page 508)

CMS proposes changes to the quality performance standard and reporting requirements under the Alternative Payment Model (APM) Performance Pathway (APP) within the Quality Payment Program QPP) that would continue to move ACOs toward digital measurement of quality and align with the QPP. Further, the policy proposals would add a third step to the step-wise beneficiary assignment methodology under which CMS would use an expanded period of time to identify whether a beneficiary has met the requirement for having received a primary care service from a physician who is an ACO professional in the ACO to allow additional beneficiaries to be eligible for assignment, as well as to propose related changes to how CMS identify assignable beneficiaries used in certain Shared Savings Program calculations. (Page 509)

As a general summary, CMS is proposing the following changes to Shared Savings Program policies to: (Page 516) Note: We have included page numbers (in red) corresponding to the section discussions.

- Revise the quality reporting and the quality performance requirements), including the following: (520)
  - Allow Shared Savings Program ACOs the option to report quality measures under the Alternative Payment Model (APM) Performance Pathway (APP) on only their Medicare beneficiaries through Medicare CQMs. (section III.G.2.b.) (521)
  - Update the APP measure set for Shared Savings Program ACOs. (section III.G.2.c.) (537)
  - Revise the calculation of the health equity adjustment underserved multiplier. (section III.G.2.d.) (541)
  - Use historical data to establish the 40th percentile MIPS Quality performance category score used for the quality performance standard. (section III.G.2.e.) (546)
  - Apply a Shared Savings Program scoring policy for suppressed APP measures. (section III.G.2.f.) (552)
  - Require Spanish language administration of the CAHPS for MIPS survey. (section III.G.2.g.) (555)
  - Align CEHRT requirements for Shared Savings Program ACOs with MIPS. (section III.G.2.h.) (556)

    - Solicit comments on MIPS Value Pathway reporting for specialists in Shared Savings Program ACOs. (section III.G.2.i.) (568)
    - Revise the requirement to meet the case minimum requirement for quality performance standard determinations. (section III.G.2.j.) (573)
- Revise the policies for determining beneficiary assignment (section III.G.3.) (578)
    - Modify the step-wise beneficiary assignment methodology and approach to identifying the assignable beneficiary population (section III.G.3.a.) (578)
    - Update the definition of primary care services used in beneficiary assignment at § 425.400(c) (section III.G.3.b.) (610)
- Revise the policies on the Shared Savings Program's benchmarking methodology (section III.G.4) (633)
    - 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 (section III.G.4.b.) (634)
    - Further mitigate the impact of the negative regional adjustment on the benchmark to encourage participation by ACOs caring for medically complex, high-cost beneficiaries (section III.G.4.c.). (658)
    - Specify the circumstances in which CMS would 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 (section III.G.4.d). (676)
    - 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 (section III.G.4.e.) (690)
- Refine AIP policies, including the following (section III.G.5): (710)
    - Modify 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. (711)
    - 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 their participation in the Shared Savings Program. (717)
    - Modify termination policies to specify that CMS would immediately terminate advance investment payments to an ACO for future quarters if the ACO voluntarily terminates from the Shared Savings Program. (719)
    - Modify ACO reporting requirements to require ACOs to submit spend plan updates to CMS in addition to publicly reporting spend plan updates. (721)
    - Modify AIP requirements to permit ACOs to seek reconsideration review of all quarterly payment calculations. (722)

- Update Shared Savings Program eligibility requirements, including the following (section III.G.6): (723)
  - 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. (710)
  - 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 included on a participant list used in financial reconciliation for a performance year under performance-based risk during the five most recent performance years. (710)

- 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. (731)

MEDICARE PART B PAYMENT FOR PREVENTIVE VACCINE ADMINISTRATION SERVICES (SECTION III.H.) (Page 757)

Effective January 1, 2024, the payment amount for administration of four vaccines would be identical, that is, Medicare Part B will pay the same additional payment amount to providers and suppliers that administer a pneumococcal, influenza, hepatitis B, or COVID-19 vaccine in the home. This additional payment amount will be annually updated using the percentage increase in the Medicare Economic Index and adjusted to reflect geographic cost variations.

MEDICARE DIABETES PREVENTION PROGRAM (MDPP)(SECTION III.I) (Page 771)

CMS is proposing to extend the MDPP Expanded Model's Public Health Emergency Flexibilities for four years, which would allow all MDPP suppliers to continue to offer MDPP services virtually using distance learning delivery through December 31, 2027, if they maintain an in-person Centers for Disease Control and Prevention organization code. CMS also proposes 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 797)

Section 218(b) of the ***Protecting Access to Medicare Act*** of 2014 established a program that would require a practitioner who orders an advanced diagnostic imaging service for a Medicare beneficiary to consult with a Clinical Decision Support Mechanism (CDSM). CDSMs are electronic portals through which an Appropriate Use Criteria (AUC) is accessed and would provide a determination of whether the order adheres to AUC requirements. CMS previously finalized within the CY 2022 Physician Fee Schedule rule that the program would be implemented on January 1, 2023 or the January 1 that follows the declared end of the public health emergency for COVID-19, which would be January 1, 2024. CMS has now

proposed to pause efforts to implement the AUC program for reevaluation and rescind current AUC program regulations. CMS is not proposing a time frame within which implementation efforts may recommence.

MEDICARE AND MEDICAID PROVIDER AND SUPPLIER ENROLLMENT (SECTION III.K.) (Page 817)

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

- Creation of a new Medicare provider enrollment status labeled a "stay of enrollment," which CMS believes will ease the burden on providers and suppliers while strengthening Medicare program integrity.
- 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.

Comment

This is a fairly large section comprising more than 40 pages. It contains extensive technical changes.

EXPAND DIABETES SCREENING AND DIABETES DEFINITIONS (SECTION III.L.) (Page 859)

For CY 2024, CMS proposes 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 of not more often than twice within the 12-month period following the date of the most recent diabetes screening test of that individual; 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).

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 873)

CMS is proposing to remove the same entity exception at § 423.160(a)(5)(i) from the CMS EPCS Program requirements and to redesignate paragraphs (a)(5)(ii) through (iv) as paragraphs (a)(5)(i) through (iii), respectively.

Under this proposed change, prescriptions that are prescribed and dispensed within the same legal entity would be included in CMS EPCS Program compliance calculations as part of the 70 percent compliance threshold at § 423.160(a)(5), and prescribers will not be exempt from the requirement to prescribe electronically at least 70 percent of their Schedule II-V controlled substances that are Part D drugs – but such prescriptions would only have to meet the applicable standards in § 423.160(b) subject to the exemption in § 423.160(a)(3)(iii).

PROPOSED CHANGES TO THE REGULATIONS ASSOCIATED WITH THE AMBULANCE FEE SCHEDULE AND THE MEDICARE GROUND AMBULANCE DATA COLLECTION SYSTEM (GADCS) (SECTION III.N.) (Page 889)

Section 4103 of the CAA, 2023 extended three existing add-on payments to the ambulance base and mileage rates under the Ambulance Fee Schedule through December 31, 2024. CMS is revising its regulations at 42 CFR §414.610(c)(1)(ii) and 414.610(c)(5)(ii) to align with existing law.

Section 50203(b) of the ***Bipartisan Budget Act*** (BBA) of 2018 required CMS to finalize regulations for a ground ambulance data collection system by December 31, 2019. This legislation also required CMS to identify the providers and suppliers required to submit information each year through 2024 and no less than once every three years after 2024. The GADCS is required to collect cost, revenue, utilization, and other information with respect to providers and suppliers of ground ambulance services in order to evaluate the extent to which reported costs relate to payment rates. The GADCS portal went live on January 1, 2023 and, for the first time, CMS will collect this information and provide the data to MedPAC for its report to Congress. CMS identified opportunities to improve the GADCS instrument through stakeholder engagement.

CMS is proposing the following changes to the instrument: Adding the ability to address partial year responses from ground ambulance organizations, and introducing a minor edit to improve the reporting consistency of hospital-based ambulance organizations.

HOSPICE: CHANGES TO THE HOSPICE CONDITIONS OF PARTICIPATION (SECTION III.O.) (Page 900)

CMS is proposing to modify the requirements for the hospice CoPs at § 418.56 "Interdisciplinary group, care planning and coordination of service" and §418.114 "Personnel qualifications."

RFI: HISTOPATHOLOGY, CYTOLOGY, AND CLINICAL CYTOGENETICS REGULATIONS UNDER THE CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) OF 1988 (SECTION III.P.) (Page 904)

CMS is soliciting comments in the following areas of CLIA: Histopathology, Cytology, and Clinical cytogenetics. The requirements have not been updated since 1992.

CHANGES TO THE BASIC HEALTH PROGRAM REGULATIONS (SECTION III.Q.) (Page 911)

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.

CMS proposes at § 600.140(b)(1) that States wishing to suspend their BHP must submit an application to HHS. As of the date of this proposed rule, only New York and Minnesota have implemented a BHP.

UPDATES TO THE DEFINITIONS OF CERTIFIED ELECTRONIC HEALTH RECORD TECHNOLOGY (SECTION III.R.) (Page 925)

CMS is proposing to revise the definitions of CEHRT in 42 CFR 495.4 and 42 CFR 414.1305 for the Medicare Promoting Interoperability Program and for the Quality Payment Program so these definitions would be consistent with the "edition-less" approach to health IT certification as proposed in the "Office of the National Coordinator for Health Information Technology (ONC) ONC HT-1 proposed rule, should the ONC proposal be finalized.

A SOCIAL DETERMINANTS OF HEALTH RISK ASSESSMENT IN THE ANNUAL WELLNESS VISIT (SECTION III.S.) (Page 933)

CMS is proposing to add a new Social Determinants of Health (SDOH) Risk Assessment as an optional element within the Annual Wellness Visit (AWV). CMS is also proposing the SDOH Risk Assessment be paid at 100 percent of the fee schedule amount of the risk assessment. CMS is proposing that the new SDOH Risk Assessment be separately payable with no beneficiary cost sharing when furnished as part of the same visit with the same date of service as the AWV.

UPDATES TO THE QUALITY PAYMENT PROGRAM (SECTION IV.) (Page 946)

CMS is proposing policies that continue the development and maintenance of Merit-based Incentive Payment System (MIPS) Value Pathways (MVPs), support the use of digital measurement and health information technology, support the integrity of program data, and increase the potential return on investment for MIPS participation.

CMS is proposing 5 new MVPs to be available with the 2024 performance year, along with revisions to all previously finalized MVPs.

The 5 newly proposed MVPs 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 quality discussion extends more than 250 pages, making this the longest section of the proposed rule. 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 1,266)

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

APPENDICES (Page 1,536)

Appendix 1: MIPS Quality Measures

- Table Group A: New Quality Measures Proposed for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years (Page 1,536)

- Table Group B: Modifications to Previously Finalized Specialty Measures Sets Proposed for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years (Page 1,559)

- Table Group C: Previously Finalized Quality Measures Proposed for Removal in the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years (Page 1,880)

- Table Group CC: Proposed Partial Removal of Three Previously Finalized Quality Measures as Component Measures in Traditional MIPS and Proposed Retention of These Three Measures for Use in Relevant MVPs for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years (Page 1,891)

- Table Group D: Previously Finalized Quality Measures with Substantive Changes Proposed for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years (Page 1,895)

- Table Group DD: Previously Finalized Quality Measures with Substantive Changes Proposed for Partial Removal as Component Measures in Traditional MIPS and Proposed for Retention for Use in Relevant MVPs for the CY 2024 Performance (Page 1,958)

- Table Group E: Previously Finalized CMS Web Interface Quality Measures with Substantive Changes Proposed for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years (Page 1,961)

Appendix 2: Improvement Activities (Page 1,968)

- Table A: New Improvement Activities for the CY 2024 Performance Period/2026 MIPS (Page 1,968)

- Table B: Changes to Previously Adopted Improvement Activities for the CY 2024 Performance Period/2026 MIPS Payment Year and for Future Years (Page 1,977)

- Table C: Improvement Activities Proposed for Removal for the CY 2024 Performance
- Period/2026 MIPS Payment Year and for Future Years (Page 1,978)

Appendix 3: MVP Inventory

This appendix contains two groups of proposed MVP tables: Group A: proposed new MVPs and Group B: proposed modifications to previously finalized MVPs. Group A includes five new proposed MVPs. Group B includes 12 previously finalized MVPs with proposed modifications. (Page 1,979)

- Group A: New MVPs for the CY 2024 Performance Period/2026 MIPS Payment Year and Future Years (Page 1,982)
    - 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 2,003)
    - 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

The actual changes to the reg text extends some 100+ pages. (Page 1,397)

This has been one of the more difficult rule's to navigate. It contains much history about origins of the issues being addressed, but much of that material is no longer relevant since early items have been updated, replaced or superseded with newer criteria. It is amazing that CMS needs more than 2,000 pages to detail its proposals when the agency can muster fact sheets that touch upon the issues in under 100 pages.

CMS has and is requiring that certain provider files be made available on-line with "links." Yet, all of the prior history cites by CMS to it prior rulemaking do not contain "links."

It is understandable why commenters/ stakeholders and others say the quality material is both burdensome and confusing.

CMS has listed more than 450 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.

As we have noted in the past, with constant changes and revisions, to us, the basic question remains. Is CMS achieving any quality changes or just collecting statistics for payment purposes?

On a final point, the issues of future estimates and budget neutrality deserve more attention. CMS needs to be more transparent in addressing such and more importantly accounting for errors. CMS has argued that reconciling estimates and actual outcomes "on retrospective basis" violates the concept of a prospective payment system. Reconciliation adjustments need not be retrospectively. They can be incorporated prospectively into future rulemaking.