Issue Brief

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CMS Proposes Extensive CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B; Medicare Shared Savings Program Requirements; and the Quality Payment Program

The Centers for Medicare & Medicaid Services has issued a massive proposed rule that includes updated payment policies, payment rates and quality provisions for services to be furnished under the Medicare Physician Fee Schedule on or after Jan. 1, 2020 (CY 2020).

The proposed rule also addresses: (1) other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, relative value of services, and changes in the statute; (2) Medicare Shared Savings Program quality reporting requirements; (3) Medicaid Promoting Interoperability Program requirements for eligible professionals; (4) the establishment of an ambulance data collection system; (7) updates to the Quality Payment Program; (8) Medicare enrollment of Opioid Treatment Programs and (9) enhancements to provider enrollment regulations

A copy of the 1,704-Page document is currently available on the *Federal Register* website at https://s3.amazonaws.com/public-inspection.federalregister.gov/2019-16041.pdf. The rule is scheduled for publication Aug. 14. A 60-day comment period ending Sept. 27 is provided.

The PFS Addenda along with other supporting documents and tables referenced in this proposed rule are available on the CMS website at http://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.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 2020 PFS proposed rule, refer to item CMS-1715-P.

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COMMENT

This is another long and complex rule. The length of this rule at 1,704 pages appears to fly against an Administration that says it is committed to reducing regulatory burdens and requirements. Unfortunately, this rule does not seem to reinforce that conclusion.

A table of contents is totally missing. Considering the extent of the material, this makes finding items extremely difficult. In the past, we have suggested that CMS not only have a complete table of contents, but also provide page numbering, which once again is lacking in this document

CMS is making many changes to the HCPCS and the CPT-4 codes which impact payment amounts. This is evident by the numerous comments being addressed. These changes are certainly not insignificant.

Specifically, the rule includes discussions regarding:

- Practice Expense RVUs (Section II.B.)
- Malpractice RVUs (Section II.C.)
- Geographic Practice Cost Indices (GPCIs) (Section II.D.)
- Potentially Misvalued Services under the PFS (Section II.E.)
- Telehealth Services (Section II.F.)
- Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (Section II.G.)
- Bundled Payments Under the PFS for Substance Use Disorders (Section II.H.)
- Physician Supervision for Physician Assistant (PA) Services (Section II.I.)
- Review and Verification of Medical Record Documentation (Section II.J.)
- Care Management Services (Section II.K.)
- Coinsurance for Colorectal Cancer Screening Tests (Section II.L.)
- Therapy Services (Section II.M.)
- Valuation of Specific Codes (Section II.N.)
- Comment Solicitation on Opportunities for Bundled Payments under the PFS (Section II.O.)
- Payment for Evaluation and Management (E/M) Services (Section II.P.)
- Ambulance Coverage Services–Physician Certification Statement (Section III.A.)
- Ambulance Fee Schedule–Medicare Ground Ambulance Services Data Collection System (Section III.B.)
- Intensive Cardiac Rehabilitation (Section III.C.)
- Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs) (Section III.D.)
- Medicare Shared Savings Program Quality Measures (Section III.E.)
- Open Payments (Section III.F.)
- Home Infusion Therapy Benefit (Section III.G.)
- Medicare Enrollment of Opioid Treatment Programs and Enhancements to Existing General Enrollment Policies Related to Improper Prescribing and Patient Harm (Section III.H.)
- Deferring to State Scope of Practice Requirements (Section III.I.)
- Advisory Opinions on the Application of the Physician Self-Referral Law (Section III.J.)
- Updates to the Quality Payment Program (Section III.K.)

The analysis that follows does not reflect many of these changes.

A portion of information in this analysis is based on a CMS fact sheet that identifies major issues in the proposal.

Referenced page numbers in red are based on the Adobe file count in the display copy of the regulation.

continued

I. SELECT PROVISIONS OF THE PFS RULE

Proposed Payment Updates and Conversion Factors (Page 1,181)

The update adjustment factor for CY 2020, as required by Section 53106 of the Bipartisan Budget Act of 2018, is 0.00 percent before applying other adjustments.

To calculate the proposed CY 2020 CF, CMS says it multiplied the product of the current year CF and the update adjustment factor by a budget neutrality adjustment.

CMS estimates the CY 2020 PFS CF to be 36.0896, which reflects the budget neutrality adjustment under Section 1848(c)(2)(B)(ii)(II) of the Act and the 0.00 percent update adjustment factor specified under Section 1848(d)(18) of the Act. CMS estimates the CY 2020 anesthesia CF to be 22.2774, which reflects the same overall PFS adjustments with the addition of anesthesia-specific PE and MP adjustments.

Calculation of the CY 2019 PFS Conversion Factor		
CY 2019 Conversion Factor		**36.0391**
Statutory Update Factor	0.00 percent (1.0000)	
CY 2020 RVU Budget Neutrality Adjustment	0.14 percent (1.0014)	
CY 2020 Conversion Factor		**36.0896**

Calculation of the Proposed CY 2020 Anesthesia Conversion Factor		
CY 2019 National Average Anesthesia Conversion Factor		**22.2730**
Statutory Update Factor	0.00 percent (1.0000)	
CY 2019 RVU Budget Neutrality Adjustment	0.14 percent (1.0014)	
CY 2019 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment	+0.12 percent (0.9988)	
CY 2019 Conversion Factor		**22.2724**

Evaluation and Management (E/M) Visits (Page 491)

Physicians and other practitioners who are paid under the PFS bill for common office visits for evaluation and management (E/M) services under a relatively generic set of CPT codes (Level I HCPCS codes) that distinguish visits based on the level of complexity, site of service, and whether the patient is new or established.

There are 3 to 5 E/M visit code levels, depending upon site of service and the extent of the three components of history, exam, and medical decision making (MDM). For example, there are 3 to 4 levels of E/M visit codes in the inpatient hospital and nursing facility settings based on a relatively narrow range of complexity in those settings. In contrast, there are 5 levels of E/M visit codes in the office or other outpatient setting based on a broader range of complexity in those settings.

In total, E/M visits comprise approximately 40 percent of allowed charges for PFS services, and office/outpatient E/M visits comprise approximately 20 percent of allowed charges for PFS services.

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CMS is proposing to align E/M coding with changes laid out by the CPT Editorial Panel for office/outpatient E/M visits. The CPT coding changes retain 5 levels of coding for established patients, reduce the number of levels to 4 for office/outpatient E/M visits for new patients, and revise the code definitions. The CPT changes also revise the times and medical decision-making process for all of the codes, and requires performance of history and exam only as medically appropriate. The CPT code changes also allow clinicians to choose the E/M visit level based on either medical decision-making or time.

CMS is proposing to adopt the AMA RUC-recommended values for the office/outpatient E/M visit codes for CY 2021 and a new add-on CPT code for prolonged service time. The AMA RUC-recommended values would increase payment for office/outpatient E/M visits. CMS says the RUC recommendations reflect a robust survey approach by the AMA, including surveying more than 50 specialty types demonstrating that office/outpatient E/M visits are generally more complex and require additional resources for most clinicians.

CMS also is proposing to consolidate the Medicare-specific add-on code for office/outpatient E/M visits for primary care and non-procedural specialty care that the agency finalized in the CY 2019 PFS final rule for implementation in CY 2021 into a single code describing the work associated with visits that are part of ongoing, comprehensive primary care and/or visits that are part of ongoing care related to a patient's single, serious or complex chronic condition. CMS also is seeking more information and feedback from the public about the definition, application and valuation of this code.

CMS is not proposing to make AMA RUC-recommended changes to global surgery codes as CMS is in the process of gathering information on global surgery. CMS has had three reports prepared by RAND, which is released with the proposed rule. CMS is encouraging stakeholders to comment on the reports.

CMS notes that in total, E/M visits comprise approximately 40 percent of allowed charges for PFS services, and office/outpatient E/M visits comprise approximately 20 percent of allowed charges for PFS services.

- When time is used to document, practitioners will document the medical necessity of the office/outpatient E/M visit and that the billing practitioner personally spent the required amount of time face-to-face with the beneficiary. The required face-to-face time will be the typical time for the reported code, except for extended or prolonged visits where extended or prolonged times will apply.
- Implementation of HCPCS add-on G codes that describe the additional resources inherent in visits for primary care and particular kinds of non-procedural specialized medical care (HCPCS codes GPC1X and GCG0X, respectively). These codes were finalized in order to reflect the differential resource costs associated with performing certain types of office/outpatient E/M visits. These codes will only be reportable with office/outpatient E/M level 2 through 4 visits.
- Adoption of a new "extended visit" add-on G code (HCPCS code GPRO1) for use only with office/outpatient E/M level 2 through 4 visits, to account for the additional resources required when practitioners need to

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spend extended time with the patient for these visits. The existing prolonged E/M codes can continue to be used with levels 1 and 5 office/outpatient E/M visits.

CMS proposes to assign separate payment rather than a blended rate, to each of the office/outpatient E/M visit codes (except CPT code 99201, which is being deleted) and the new prolonged visit add-on CPT code (CPT code 99XXX). CMS proposes to delete the HCPCS add-on code it finalized last year for CY 2021 for extended visits (GPRO1).

CMS proposes to simplify, consolidate and revalue the HCPCS add-on codes finalized last year for CY 2021 for primary care (GPC1X) and non-procedural specialized medical care (GCG0X), and to allow the new code to be reported with all office/outpatient E/M visit levels (not just levels 2 through 4). All of these changes would be effective January 1, 2021.

Determination of Practice Expense (PE) RVUs (Page 16)

For CY 2020, CMS is proposing to clarify the expected specialty assignment for a series of cardiothoracic services.

CMS is proposing to establish 23 new scope equipment codes (refer to the rule's Table 5, page 45).

CMS is proposing to replace certain existing scopes with new scope equipment. CMS says it received recommendations from the RUC's scope workgroup regarding which HCPCS codes make use of the new scope equipment items, and CMS is proposing to make this scope replacement for approximately 100 HCPCS codes in total (refer to the rule's Table 6, page 47). CMS is proposing that CPT code 31231 (Nasal endoscopy, diagnostic, unilateral or bilateral (separate procedure)) would be the base procedure for the remainder of nasal sinus endoscopies. The codes affected by this proposal are reflected (in Table 7).

Determination of Malpractice (MP) Relative Value Units (RVUs) (Page 67)

For CY 2020, CMS is conducting the statutorily required 3-year review of the GPCIs, which coincides with the statutorily required 5-year review of the MP RVUs.

Geographic Practice Cost Indices (GPCIs) (Page 83)

See Addenda D and E to this proposed rule for the CY 2020 proposed GPCIs and summarized proposed GAFs available on the CMS website under the supporting documents section of the CY 2020 PFS proposed rule at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.

The current 112 fee schedule areas are defined alternatively by state boundaries (for example, Wisconsin), metropolitan areas (for example, Metropolitan St. Louis, MO), portions of a metropolitan area (for example, Manhattan), or rest-of-state areas that exclude metropolitan areas (for example, Rest of Missouri). This locality configuration is used to calculate the GPCIs that are in turn used to calculate locality adjusted payments for physicians' services under the PFS.

Potentially Misvalued Services under the PFS (Page 95)

The following table lists the HCPCS and CPT codes that CMS is proposing as potentially misvalued.

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CPT/HCPCS Code	Short Description
10005	Fna bx w/us gdn 1st les
10021	Fna bx w/o img gdn 1st les
76377	3d render w/intrp postproces
G0166	Extrnl counterpulse, per tx

Payment for Medicare Telehealth Services under Section 1834(m) of the Act (Page 108)

CMS is proposing to add the face-to-face portions of the following services to the telehealth list on a Category 1 basis for CY 2020:

- HCPCS code GYYY1: Office-based treatment for opioid use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month.
- HCPCS code GYYY2: Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month.
- HCPCS code GYYY3: Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; each additional 30 minutes beyond the first 120 minutes (List separately in addition to code for primary procedure).

Medicare Coverage for Opioid Use Disorder Treatment Services Furnished by Opioid Treatment Programs (OTPs)

Section 2005 of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act established a new Medicare Part B benefit for opioid use disorder (OUD) treatment services, including medications for medication-assisted treatment (MAT), furnished by opioid treatment programs (OTPs). To meet this statutory requirement, CMS is specifically proposing:

- Definitions of OTP and OUD treatment services;
- Enrollment policies for OTPs;
- Methodology and estimated bundled payment rates for OTPs that vary by the medication used to treat OUD and service intensity, and by full and partial weeks;
- Adjustments to the bundled payment rates for geography and annual updates;
- Flexibility to deliver the counseling and therapy services described in the bundled payments via two-way interactive audio-video communication technology as clinically appropriate; and
- Zero beneficiary copayment for a time limited duration.

CMS intends to implement this benefit beginning January 1, 2020, as required by the SUPPORT Act.

Bundled Payments Under the PFS for Substance Use Disorders (Page 193)

CMS is proposing to create new coding and payment for a bundled episode of care for management and counseling for OUD. The new proposed codes describe a monthly bundle of services for the treatment of OUD that includes overall management, care coordination, individual and group psychotherapy, and substance use counseling. One code describes the initial month of treatment, which would include administering assessments and developing a treatment plan; another code describes subsequent months of treatment; and an add-on

continued

code describes additional counseling. CMS is proposing that the individual psychotherapy, group psychotherapy, and substance use counseling included in these codes could be furnished as Medicare telehealth services using communication technology as clinically appropriate. CMS also is seeking comment on bundles describing services for other substance use disorder (SUDs) and on the use of medication-assisted treatment (MAT) in the emergency department setting, including initiation of MAT and the potential for either referral or follow-up care, as well as the potential for administration of long-acting MAT agents in this setting, to help inform whether CMS should consider proposing to make separate payment for such services in future rulemaking.

Physician Supervision for Physician Assistant (PA) Services (Page 207)

CMS is proposing to revise the regulation at § 410.74 that establishes physician supervision requirements for PAs. Specifically, CMS is proposing to revise § 410.74(a)(2) to provide that the statutory physician supervision requirement for PA services at Section 1861(s)(2)(K)(i) of the Act would be met when a PA furnishes their services in accordance with state law and state scope of practice rules for PAs in the state in which the services are furnished, with medical direction and appropriate supervision as provided by state law in which the services are performed. In the absence of state law governing physician supervision of PA services, the physician supervision required by Medicare for PA services would be evidenced by documentation in the medical record of the PA's approach to working with physicians in furnishing their services. Consistent with current rules, such documentation would need to be available to CMS, upon request.

Review and Verification of Medical Record Documentation (Page 211)

CMS proposes to establish a general principle to allow the physician, the PA, or the advanced practice registered nurses who furnishes and bills for their professional services to review and verify, rather than re-document, information included in the medical record by physicians, residents, nurses, students or other members of the medical team. This principle would apply across the spectrum of all Medicare-covered services paid under the PFS. Because this proposal is intended to apply broadly, CMS proposes to amend regulations for teaching physicians, physicians, PAs, and APRNs to add this new flexibility for medical record documentation requirements for professional services furnished by physicians, PAs and APRNs in all settings.

Care Management Services (Page 216)

CMS is proposing to increase payment for Transitional Care Management (TCM). CMS is proposing the RUC-recommended work RVU of 2.36 for CPT code 99495 and the RUC-recommended work RVU of 3.10 for CPT code 99496.

CMS is proposing a set of Medicare-developed HCPCS G codes for certain Chronic Care Management (CCM) services. CMS is proposing to replace a number of the CCM codes with Medicare-specific codes to allow clinicians to bill incrementally to reflect additional time and resources required in certain cases and better distinguish complexity of illness as measured by time. CMS also is proposing to adjust certain billing requirements and elements of the care planning services.

continued

Recognizing that clinicians across all specialties manage the care of beneficiaries with chronic conditions, CMS also is proposing to create new coding for Principal Care Management (PCM) services, which would pay clinicians for providing care management for patients with a single serious and high risk condition.

Note: There are many proposed coding changes discussed in this section.

Coinsurance for Colorectal Cancer Screening Tests (Page 244)

CMS is seeking comments because beneficiaries have continued to contact the agency noting their "surprise" that a coinsurance (20 or 25 percent depending on the setting) applies when they expected to receive a colorectal screening procedure to which coinsurance does not apply, but instead received what Medicare considers to be a diagnostic procedure because polyps were discovered and removed.

Therapy Services (Page 244)

In the CY 2019 PFS final rule, CMS established modifiers to identify therapy services that are furnished in whole or in part by physical therapy (PT) and occupational therapy (OT) assistants, and set a de minimis 10 percent standard for when these modifiers will apply to specific services. CMS notes that the statute reduces the payment rate for therapy assistant services, effective beginning for services furnished in CY 2022. This change will not apply to services furnished by critical access hospitals because they are not paid for therapy services at PFS rates.

Beginning Jan. 1, 2020, these modifiers are required by statute to be reported on claims. CMS is proposing a policy to implement the modifiers as required by statute, and apply the 10 percent de minimis standard.

Valuation of Specific Codes (Page 274)

CMS explains changes it is making and in many cases not making to the specific codes identified below. The material in this section covers nearly 200 pages. The table below identifies specific codes that CMS has reviewed.

In red, is the rule's display copy page on which the code(s) discussion begins.

1	Tissue Grafting Procedures (CPT Codes 15X00, 15X01, 15X02, 15X03, and 15X04) Page 289
2	Drug Delivery Implant Procedures (CPT Codes 11981, 11982, 11983, 206X0, 206X1, 206X2, 206X3, 206X4, and 206X5) Page 289
3	Bone Biopsy Trocar-Needle (CPT Codes 20220 and 20225) Page 297
4	Trigger Point Dry Needling (CPT Codes 205X1 and 205X2) Page 300
5	Closed Treatment Vertebral Fracture (CPT Code 22310) Page 302
6	Tendon Sheath Procedures (CPT Codes 26020, 26055, and 26160) Page 302
7	Closed Treatment Fracture – Hip (CPT Code 27220) Page 304
8	Arthrodesis – Sacroliliac Joint (CPT Code 27279) Page 305
9	Pericardiocentesis and Pericardial Drainage (CPT Code 3X000, 3X001, 3X002, and 3X003) Page 306
10	Pericardiotomy (CPT Codes 33020 and 33025) Page 311
11	Transcatheter Aortic Valve Replacement (TAVR) (CPT Codes 33361, 33362, 33363, 33364, 33365, and 33366) Page 313
12	Aortic Graft Procedures (CPT Codes 338XX, 338X1, 33863, 33864, 338X2, and 33866) Page 315

continued

13	Iliac Branched Endograft Placement (CPT Codes 34X00 and 34X01) Page 318
14	Exploration of Artery (CPT Codes 35701, 35X01, and 35X01) Page 319
15	Intravascular Ultrasound (CPT Codes 37252 and 37253) Page 320
16	Stab Phlebectomy of Varicose Veins (CPT Codes 37765 and 37766) Page 321
17	Biopsy of Mouth Lesion (CPT Code 40808) Page 322
18	Transanal Hemorrhoidal Dearterialization (CPT Codes 46945, 46946, and 46X48) Page 323
19	Preperitoneal Pelvic Packing (CPT Codes 490X1 and 490X2) Page 324
20	Cystourethroscopy Insertion Transprostatic Implant (CPT Codes 52441 and 52442) Page 326
21	Orchiopexy (CPT Code 54640) Page 327
22	Radiofrequency Neurootomy Sacroiliac Joint (CPT Codes 6XX00, 6XX01) Page 327
23	Lumbar Puncture (CPT Codes 62270, 622X0, 62272, and 622X1) Page 329
24	Electronic Analysis of Implanted Pump (CPT Codes 62367, 62368, 62369, and 62370) Page 331
25	Somatic Nerve Injection (CPT Codes 64400, 64408, 64415, 64416, 64417, 64420, 64421, 64425, 64430, 64435, 64445, 64446, 64447, 64448, 64449, and 64450) Page 331
26	Genicular Injection and RFA (CPT Codes 64640, 64XX0, and 64XX1) Page 344
27	Cyclophotocoagulation (CPT Codes 66711, 66982, 66983, 66984, 66X01, and 66X02) Page 347
28	X-Ray Exam – Sinuses (CPT Codes 70210 and 70220) Page 350
29	X-Ray Exam – Skull (CPT Codes 70250 and 70260) Page 352
30	X-Ray Exam – Neck (CPT Code 70360) Page 354
31	X-Ray Exam – Spine (CPT Codes 72020, 72040, 72050, 72052, 72070, 72072, 72074, 72080, 72100, 72110, 72114, and 72120) Page 355
32	CT-Orbit-Ear-Fossa (CPT Codes 70480, 70481, and 70482) Page 356
33	CT Spine (CPT Codes 72125, 72126, 72127, 72128, 72129, 72130, 72131, 72132, and 72133) Page 358
34	X-Ray Exam – Pelvis (CPT Codes 72170 and 72190) Page 360
35	X-Ray Exam – Sacrum (CPT Codes 72200, 72202, and 72220) Page 361
36	X-Ray Exam – Clavicle-Shoulder (CPT Codes 73000, 73010, 73020, 73030, and 73050) Page 364
37	CT Lower Extremity (CPT Codes 73700, 73701, and 73702) Page 365
38	X-Ray Elbow-Forearm (CPT Codes 73070, 73080, and 73090) Page 365
39	X-Ray Heel (CPT Code 73650) Page 366
40	X-Ray Toe (CPT Code 73660) Page 366
41	Upper Gastrointestinal Tract Imaging (CPT Codes 74210, 74220, 74230, 74X00, 74240, 74246, and 74X01) Page 367
42	Lower Gastrointestinal Tract Imaging (CPT Codes 74250, 74251, 74270, and 74280) Page 368
43	Urography (CPT Code 74425) Page 369
44	Abdominal Aortography (CPT Codes 75625 and 75630) Page 370
45	Angiography (CPT Codes 75726 and 75774) Page 371
46	X-Ray Exam Specimen (CPT Code 76098) Page 372
47	3D Rendering (CPT Code 76376) Page 373
48	Ultrasound Exam – Chest (CPT Code 76604) Page 373
49	X-Ray Exam – Bone (CPT Codes 77073, 77074, 77075, 77076, and 77077) Page 374
50	SPECT-CT Procedures (CPT Codes 78800, 78801, 78802, 78803, 78804, 788X0, 788X1, 788X2, and 788X3) Page 374
51	Myocardial PET (CPT Codes 78459, 78X29, 78491, 78X31, 78492, 78X32, 78X33, 78X34, and 78X35) Page 381
52	Cytopathology, Cervical-Vaginal (CPT Code 88141, HCPCS Codes G0124, G0141, and P3001) Page 388
53	Biofeedback Training (CPT Codes 908XX and 909XX)ripheral Artery Disease (PAD) Rehabilitation (CPT code 93668) Page 390
54	Corneal Hysteresis Determination (CPT Code 92145) Page 391

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55	Computerized Dynamic Posturography (CPT Codes 92548 and 92XX0) Page 391
56	Auditory Function Evaluation (CPT Codes 92626 and 92627) Page 393
57	Septostomy (CPT Codes 92992 and 92993) Page 393
58	Opthalmoscopy (CPT Codes 92X18 and 92X19) Page 394
59	Remote Interrogation Device Evaluation (CPT Codes 93297, 93298, 93299, and HCPCS code GTTT1) Page 394
60	Duplex Scan Arterial Inflow-Venous Outflow (CPT Codes 93X00 and 93X01) Page 397
61	Myocardial Strain Imaging (CPT Code 933X0) Page 398
62	Lung Function Test (CPT Code 94200) Page 399
63	Long-Term EEG Monitoring (CPT Codes 95X01, 95X02, 95X03, 95X04, 95X05, 95X06, 95X07, 95X08, 95X09, 95X10, 95X11, 95X12, 95X13, 95X14, 95X15, 95X16, 95X17, 95X18, 95X19, 95X20, 95X21, 95X22, and 95X23) Page 400
64	Health and Behavioral Assessment and Intervention (CPT Codes 961X0, 961X1, 961X2, 961X3, 961X4, 961X5, 961X6, 961X7, and 961X8) Page 411
65	N/A
66	Cognitive Function Intervention (CPT Codes 971XX and 9XXX0) Page 413
67	Open Wound Debridement (CPT Codes 97597 and 97598) Page 414
68	Negative Pressure Wound Therapy (CPT Codes 97607 and 97608) Page 416
69	Ultrasonic Wound Assessment (CPT Code 97610) Page 418
70	Online Digital Evaluation Service (e-Visit) (CPT Codes 98X00, 98X01, and 98X02) Page 418
71	Emergency Department Visits (CPT Codes 99281, 99282, 99283, 99284, and 99285) Page 420
72	Self-Measured Blood Pressure Monitoring (CPT Codes 99X01, 99X02, 93784, 93786, 93788, and 93790) Page 421
73	Online Digital Evaluation Service (e-Visit) (CPT Codes 9X0X1, 9X0X2, and 9X0X3) Page 422
74	Radiation Therapy Codes (HCPCS Codes G6001, G6002, G6003, G6004, G6005, G6006, G6007, G6008, G6009, G6010, G6011, G6012, G6013, G6014, G6015, G6016 and G6017) Page 422

- The rule's table 20 (Page 424) lists the Proposed CY 2020 Work RVUs for New, Revised and Potentially Misvalued Codes.
- The rule's table 21 (Page 442) includes the Proposed CY 2020 Direct PE Refinements.
- The rule's table 22 (Page 486) includes the Proposed CY 2020 Invoices Received for Existing Direct PE Inputs.
- The rule's table 23 (Page 486) includes the Proposed CY 2020 New Invoices
- The rule's table 24 (Page 487) includes the Proposed CY 2020 PE Refinements

Comment Solicitation on Opportunities for Bundled Payments Under the PFS (Page 489)

CMS is seeking comments on opportunities to expand the concept of bundling to improve payment for services under the PFS and more broadly align PFS payment with the broader CMS goal of improving accountability and increasing efficiency in paying for the health care of Medicare beneficiaries.

continued

II. OTHER PROVISIONS OF THE RULE

Changes to the Ambulance Physician Certification Statement Requirement (Page 525)

CMS is proposing to clarify that there is no CMS-prescribed form for physician certification statements (PCSs) for ambulance transports. So long as the elements required by regulation are clearly conveyed, ambulance suppliers and providers would be free to choose the format by which the information is displayed, and they may find that other forms that may be required by other legal requirements to perform the transport may also satisfy the function of the PCS. CMS also is proposing to grant ambulance suppliers and providers greater flexibility around who may sign a non-physician certification statement in certain circumstances. The proposal would also add licensed practical nurses (LPNs), social workers and case managers as staff members who may sign the non-physician certification statement if the provider/supplier is unable to obtain the attending physician's signature within 48 hours of the transport.

Proposal to Establish a Medicare Ground Ambulance Services Data Collection System (Page 532)

The Bipartisan Budget Act (BBA) of 2018 requires the Secretary to develop a data collection system to collect cost, revenue, utilization and other information determined appropriate with respect to ground ambulance providers' suppliers. CMS proposes the data collection format and elements, a sampling methodology that CMS would use to identify ground ambulance organizations for reporting each year through 2024 and not less than every 3 years after 2024, and reporting timeframes. CMS also is proposing to reduce by 10 percent the payments that would otherwise be made to a ground ambulance organization that is identified for reporting but fails to sufficiently submit data, as well as a process under which a ground ambulance organization can request a hardship exemption that, if granted by CMS, would allow it to avoid the payment reduction.

Note: The ambulance ground data collection section is long and complex. It spans some 70 pages.

Expanded Access to Medicare Intensive Cardiac Rehabilitation (ICR) (Page 602)

Section 51004 of the Bipartisan Budget Act of 2018 (BBA of 2018), amended section 1861(eee)(4)(B) of the Act directing CMS to add covered conditions for intensive cardiac rehabilitation (ICR). This proposed rule includes proposals for implementing this expansion of coverage through revisions to § 410.49(b)(1).

Medicare Shared Savings Program (Page 617)

CMS is soliciting comments on how to potentially align the Medicare Shared Savings Program quality performance scoring methodology more closely with the Merit-based Incentive Payment System (MIPS) quality performance scoring methodology. CMS says it recognizes that accountable care organizations (ACOs) and their participating providers and suppliers dedicate resources to performing well on quality metrics. CMS believes that aligning quality metrics across programs will reduce burden and will allow ACOs to more effectively target their resources toward improving care.

continued

In addition, CMS proposes refining the Shared Savings Program measure set by:

- (1) removing one measure – ACO – 14 Preventive Care and Screening Influenza Immunization, starting with reporting for performance year 2020:
- (2) adding another to the CMS Web Interface, to maintain alignment with proposals under the Quality Payment Program, – ACO-47 Adult Immunization Status:
- (3) reverting one measure to pay-for-reporting due to a substantive change made by the measure owner – ACO-43 as pay-for-reporting for 2020 and 2021.

The rule's table 32 (Page 626) shows the Shared Savings Program quality measure set for performance year 2020 and subsequent performance years

Open Payments (Page 643)

CMS's Open Payments program promotes a transparent and accountable health care system by annually publishing the financial relationships that physicians and teaching hospitals (known as "covered recipients") have with applicable manufacturers and group purchasing organizations (GPOs). CMS is proposing several changes to Open Payments: (1) expanding the definition of "covered recipient;" (as required by the SUPPORT Act) and (2); modifying payment categories; and (3) standardizing data on reported medical devices.

Advisory Opinions on the Application of the Physician Self-Referral Law (Page 694)

CMS issues written advisory opinions on a case-by-case basis about whether a physician referral for certain health services is prohibited under Section 1877 of the Social Security Act (the "Stark Law"). Last year, CMS issued a Request for Information (RFI) to gather public input on how to address unnecessary burden created by the physician self-referral law, focusing in part on how it may impede care coordination, a key aspect of value-based health care. In response to the RFI, many health systems and provider groups urged CMS to update the regulations governing its advisory opinion process on physician referrals to reduce provider burden and uncertainty around compliance with the Stark Law. Therefore, CMS is soliciting comment on potential changes to its advisory opinion process to address these stakeholder comments. Other comments in response to the RFI are expected to be addressed in separate rulemaking.

III. CY 2020 UPDATES TO THE QUALITY PAYMENT PROGRAM (PAGE 711)

CMS estimates that Merit-based Incentive Payment System (MIPS) payment adjustments will be approximately equally distributed between negative MIPS payment adjustments ($584 million) and positive MIPS payment adjustments ($584 million) to MIPS eligible clinicians, as required by the statute to ensure budget neutrality. Up to an additional $500 million is also available for the 2022 MIPS payment year for additional positive MIPS payment adjustments for exceptional performance for MIPS eligible clinicians whose final score meets or exceeds the additional performance threshold of 80 points that CMS is proposing in Section III.K.3.e.(3) of this proposed rule. However, the distribution will change based on the final population of MIPS-eligible clinicians for the 2022 MIPS payment year and the distribution of final scores under the program.

continued

COMMENT

CMS says that approximately 818,000 clinicians would be MIPS-eligible clinicians for the 2020 MIPS performance period. Dividing $584 million by 818,000 equals $714.00. If physicians are at the top end of the bonus spectrum, they would receive $1,428 while those at the bottom would lose a corresponding $1,428.00.

CMS estimates that between 175,000 and 225,000 clinicians will become Qualifying APM Participants (QPs). CMS estimates that the total lump sum APM Incentive Payments will be approximately $500-600 million for the 2022 Quality Payment Program. Dividing $500 million by 200,000 equals $2,500.

The question is, are these amounts enough to incentivize physicians and what are the costs of complying?

This is a difficult section to comprehend. The section and subsection heads do not always follow. In some places there are repeated headings and/or missing sections. For example, on page 756 there is a heading "Enhanced Information for Patients." It is followed by a subsection (a) patient reported measures. It is followed by subsection (b) on page 758. The next subsection is another (b) on page 761.

The Quality preamble section of this rule extends 359 pages (pages 711 to 1,070). A major issue contributing to overall understanding and the length of section is the amount of repeated and redundant history. Proposed changes would stand out if CMS just addressed those items without going back years and years.

IV. REGULATORY ANALYSIS (PAGE 1,176–1,261)

CMS is spending considerable effort in justifying its proposals and changes in terms of monetary impacts. Below is the estimate regarding E/M changes.

Estimated Impacts Related to Proposed Changes for Office/Outpatient E/M Services for CY 2021 (Page 1,186)

CMS says that "although we are not proposing changes to E/M coding and payment for CY 2020, we are proposing certain changes for CY 2021. We provide the following impact estimate only for illustrative purposes. We believe these estimates provide insight into the magnitude of potential changes for certain physician specialties.

TABLE 111: Estimated Specialty Level Impacts of Proposed E/M Payment and Coding Policies if Implemented for CY 2021

(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	$236	4%	3%	0%	7%
Anesthesiology	$1,993	-5%	-1%	0%	-7%
Audiologist	$70	-4%	-2%	0%	-6%
Cardiac Surgery	$279	-5%	-2%	-1%	-8%
Cardiology	$6,595	2%	1%	0%	3%
Chiropractor	$750	-5%	-3%	-1%	-9%
Clinical Psychologist	$787	-7%	0%	0%	-7%

continued

TABLE 111: Estimated Specialty Level Impacts of Proposed E/M Payment and Coding Policies if Implemented for CY 2021					
(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
Clinical Social Worker	$781	-7%	0%	0%	-6%
Colon And Rectal Surgery	$162	-3%	-1%	-1%	-4%
Critical Care	$346	-5%	-1%	0%	-6%
Dermatology	$3,541	0%	1%	-1%	-1%
Diagnostic Testing Facility	$697	-1%	-4%	0%	-4%
Emergency Medicine	$3,021	-6%	-2%	1%	-7%
Endocrinology	$488	11%	5%	1%	16%
Family Practice	$6,019	8%	4%	1%	12%
Gastroenterology	$1,713	-2%	-1%	-1%	-4%
General Practice	$405	5%	2%	0%	8%
General Surgery	$2,031	-3%	-1%	0%	-4%
Geriatrics	$187	2%	1%	0%	3%
Hand Surgery	$226	-1%	0%	0%	-1%
Hematology/Oncology	$1,673	8%	4%	1%	12%
Independent Laboratory	$592	-3%	-1%	0%	-4%
Infectious Disease	$640	-3%	-1%	0%	-3%
Internal Medicine	$10,507	2%	2%	0%	4%
Interventional Pain Mgmt	$885	4%	3%	1%	8%
Interventional Radiology	$432	-3%	-3%	0%	-6%
Multispecialty Clinic/Other Phys	$148	-2%	0%	0%	-2%
Nephrology	$2,164	-2%	0%	0%	-2%
Neurology	$1,503	2%	5%	0%	8%
Neurosurgery	$802	-3%	-1%	-2%	-6%
Nuclear Medicine	$50	-4%	0%	0%	-5%
Nurse Anes/Anes Asst	$1,291	-7%	-2%	0%	-9%
Nurse Practitioner	$4,503	5%	3%	0%	8%
Obstetrics/Gynecology	$620	4%	3%	0%	7%
Ophthalmology	$5,398	-4%	-5%	0%	-10%
Optometry	$1,325	-2%	-3%	0%	-5%
Oral/Maxillofacial Surgery	$71	-1%	-1%	-1%	-4%
Orthopedic Surgery	$3,734	-1%	0%	0%	-2%
Other	$34	-3%	-2%	0%	-5%
Otolaryngology	$1,225	3%	2%	0%	5%
Pathology	$1,203	-5%	-3%	-1%	-8%
Pediatrics	$62	3%	2%	0%	6%
Physical Medicine	$1,110	-2%	0%	0%	-2%
Physical/Occupational Therapy	$4,248	-4%	-3%	0%	-8%
Physician Assistant	$2,637	4%	2%	0%	7%
Plastic Surgery	$369	-3%	-1%	-1%	-5%
Podiatry	$1,998	0%	1%	0%	1%
Portable X-Ray Supplier	$94	-1%	-3%	0%	-4%
Psychiatry	$1,120	4%	3%	0%	7%
Pulmonary Disease	$1,658	0%	1%	0%	1%

continued

TABLE 111: Estimated Specialty Level Impacts of Proposed E/M Payment and Coding Policies if Implemented for CY 2021					
(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
Radiation Oncology And Radiation Therapy Centers	$1,756	-2%	-2%	0%	-4%
Radiology	$4,971	-5%	-3%	0%	-8%
Rheumatology	$534	9%	5%	1%	15%
Thoracic Surgery	$352	-5%	-2%	-1%	-7%
Urology	$1,739	4%	4%	0%	8%
Vascular Surgery	$1,203	-2%	-3%	0%	-5%
TOTAL	$92,979	0%	0%	0%	0%

APPENDICES (PAGE 1,345)

Appendix 1 contains the following tables:

- Table A: New Quality Measures Proposed for Addition for the 2022 MIPS Payment Year and Future Years. (Page 1,345)
- Table B; Group B: New Specialty Measures Sets Proposed for Addition and Previously Finalized Specialty Measure Sets Proposed for Modification for the 2022 MIPS Payment Year and Future Years. (Page 1,353)
- Table C; Previously Finalized Quality Measures Proposed for Removal in the 2022 MIPS Payment Year and Future Years. (Page 1,569)
- Table Group D; Previously Finalized Quality Measures with Substantive Changes Proposed for the 2022 MIPS Payment Year and Future Years. (Page 1,598)
- Table Group DD: Previously Finalized Quality Measures with Substantive Changes Proposed for the 2021 MIPS Payment Year and Future Years (Page 1,689)

APPENDIX 2: IMPROVEMENT ACTIVITIES (PAGE 1,690)

- Table A: Proposed New Improvement Activities for the MIPS CY 2020 Performance Period and Future Years (Page 1,690)
- Table B: Proposed Changes to Previously Adopted Improvement Activities for the MIPS CY 2020 Performance Period and Future Years (Page 1,692)
- Table C: Improvement Activities Proposed for Removal for the MIPS CY 2020 MIPS Performance Period and Future Years (Page 1,699)

FINAL THOUGHTS

CMS' rulemaking is growing and growing in length. True the program is becoming much more complex and complicated. But, CMS' major rules are not consistent. For example, some provide clear decision sections while others do not

CMS needs to rethink rulemaking. It needs to reduce history citations. Simply explain changes, add a full table of contents, and include page numbering in both the table of contents and the full document.

Analysis provided for MHA by Larry Goldberg, Goldberg Consulting

One needs to reflect on the entire quality agenda. Is the unbelievable data collection effort truly identifying quality? Is the data effort with all its attendant burdens cost effective?

The quality material in this rule is simply overwhelming, complex and exhaustive. Those engaged in this activity need to carefully review the material to insure compliance. This is not a simple task.

The quality material presented above is only a brief capsule of the actual material in the rule.