

NCHA Financial Feature



November 9, 2018

CMS Finalizes CY 2019 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 and Medicaid Services (CMS) has issued a final rule that includes update payment policies, payment rates, and quality provisions for services furnished under the Medicare Physician Fee Schedule (PFS) on or after Jan. 1, 2019 (CY 2019).

A copy of the 2,378 document is currently available on the **Federal Register** web site at: <https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-14985.pdf>. The rule is scheduled for publication on Nov. 23.

The PFS Addenda along with other supporting documents and tables referenced in the final rule are online at <https://go.cms.gov/2vG4lah>.

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 2019 PFS final rule, refer to item CMS-1693-F.

Comment

This is another long and complex rule.

CMS is making many changes to the HCPCS and the CPT- 4 codes which impact payment amounts. This is clearly evident by the numerous comments being addressed. These changes are certainly not insignificant. However, the analysis that follows does not reflect many, if not most, of those changes. To do so would make this summary almost as long as the rule itself.

A suggestion to those looking for a specific code is to use the Adobe "find" tool located in the edit tool head.

Perhaps the most controversial aspect of the proposed MPFS rule was the concept to revamp and change how payments are made for Evaluation and Management (E/M) services; i.e., coding and documentation. CMS is moving forward, but with a revised schedule. CMS is delaying till 2021 the merging of the E/M coding structure.

The rule includes discussions regarding:

- Potentially Misvalued Codes.
- Communication Technology-Based Services.
- Provisions Expanding Telehealth Services for the Treatment of Opioid Use Disorder and Other Substance Use Disorders under the SUPPORT Act.
- Valuation of New, Revised, and Misvalued Codes.

- Payment Rates under the PFS for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Provider-Based Departments of a Hospital.
- Evaluation & Management (E/M) Visits.
- Therapy Services.
- Part B Drugs: Application of an Add-on Percentage for Certain Wholesale Acquisition Cost (WAC)-based Payments.
- Potential Model for Radiation Therapy.
- Clinical Laboratory Fee Schedule.
- Ambulance Fee Schedule – Provisions in the Bipartisan Budget Act of 2018.
- Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs).
- Appropriate Use Criteria for Advanced Diagnostic Imaging Services.
- Medicaid Promoting Interoperability Program Requirements for Eligible Professionals.
- Medicare Shared Savings Program Quality Measures.
- Physician Self-Referral Law.
- Physician Self-Referral Law: Annual Update to the List of CPT/HCPCS Codes.
- CY 2019 Updates to the Quality Payment Program (including the extreme and uncontrollable circumstances MIPS eligible clinicians faced as a result of widespread catastrophic events affecting a region or locale in CY 2017).
- Comments in response to the Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers.
- Comments in response to the Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information.

Note: The material that follows does not reflect all of the items above. Page numbers in red identify the start of the items under discussion in the display copy of the regulation.

Payment Updates and Conversion Factors (Page 1,916)

Section 101(a) of the **Medicare Access and CHIP Reauthorization Act of 2015** (MACRA) repealed the previous statutory update formula and amended section 1848(d) of the Act to specify the update adjustment factors for calendar years 2015 and beyond. The update adjustment factor for CY 2019, as required by section 53106 of the **Bipartisan Budget Act of 2018**, is 0.25 percent before applying other adjustments.

Calculation of the CY 2019 PFS Conversion Factor

CY 2018 Conversion Factor		35.9996
Statutory Update Factor	0.25 percent (1.0025)	
CY 2019 RVU Budget Neutrality Adjustment	-0.14 percent (0.9986)	
CY 2019 Conversion Factor		36.0391

Calculation of the CY 2019 Anesthesia Conversion Factor

CY 2018 National Average Anesthesia Conversion Factor		22.1887
Statutory Update Factor	0.25 percent (1.0025)	
CY 2019 RVU Budget Neutrality Adjustment	-0.14 percent (0.9986)	
CY 2019 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment	+0.27 percent (1.0027)	
CY 2019 Conversion Factor		22.2730

The PFS CF increases less than 4 cents, while the Anesthesia CF increases slightly more than 8 cents.

I. Major Provisions of the Rule for PFS

A. Evaluation and Management (E/M) Visits (Page 537)

CMS proposed several changes to E/M visit documentation and payment. The changes would only apply to office/outpatient visit codes (CPT codes 99201 through 99215), except where CMS specified otherwise. The changes were to be effective January 1, 2019. CMS notes that 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.

For CY 2019 and 2020, CMS will continue the current payment structure (5 levels), and, therefore, practitioners should continue to use either the 1995 or 1997 versions of the E/M guidelines to document E/M office/outpatient visits billed to Medicare for 2019 and 2020.

CMS is finalizing the following policies:

- Elimination of the requirement to document the medical necessity of a home visit in lieu of an office visit;
- For established patient office/outpatient visits, when relevant information is already contained in the medical record, practitioners may choose to focus their documentation on what has changed since the last visit, or on pertinent items that have not changed, and need not re-record the defined list of required elements if there is evidence that the practitioner reviewed the previous information and updated it as needed. CMS says practitioners should still review prior data, update as necessary, and indicate in the medical record that they have done so;
- Also, CMS is clarifying that for E/M office/outpatient visits, for new and established patients for visits, practitioners need not re-enter in the medical record information on the patient's chief complaint and history that has already been entered by ancillary staff or the beneficiary. The practitioner may simply indicate in the medical record that he or she reviewed and verified this information; and
- Removal of potentially duplicative requirements for notations in medical records that may have previously been included in the medical records by residents or other members of the medical team for E/M visits furnished by teaching physicians.

Beginning in CY 2021 CMS is finalizing the following policies:

- Reduction in the payment variation for E/M office/outpatient visit levels by paying a single rate for E/M office/outpatient visit levels 2 through 4 for established and new patients while maintaining the payment rate for E/M office/outpatient visit level 5.
- CMS will allow for flexibility in how visit levels are documented— specifically a choice to use the current framework, medical decision-making (MDM), or time. For E/M office/outpatient level 2 through 4 visits, when using MDM or current framework to document the visit, CMS will also apply a minimum supporting documentation standard associated with level 2 visits. For these cases, Medicare would require information to support a level 2 E/M office/outpatient visit code for history, exam and/or medical decision-making;
- When time is used to document, practitioners will document the medical necessity of the visit and that the billing practitioner personally spent the required amount of time face-to-face with the beneficiary;

- Implementation of add-on codes that describe the additional resources inherent in visits for primary care and particular kinds of non-procedural specialized medical care, though they would not be restricted by physician specialty. These codes would only be reportable with E/M office/outpatient level 2 through 4 visits, and their use generally would not impose new per-visit documentation requirements;
- Finalizing the proposal to introduce add-on codes that would adjust payment for new and established E/M office/outpatient visits to account for inherent complexity in primary care and non-procedural specialty care;

Finalized Code Descriptors for Visit Complexity Add-ons

HCPCS Code	Descriptor
GPC1X	Visit complexity inherent to evaluation and management associated with primary medical care services that serve as the continuing focal point for all needed health care services (Add-on code, list separately in addition to level 2 through 4 office/outpatient evaluation and management visit, new or established)
GCG0X	Visit complexity inherent to evaluation and management associated with non-procedural specialty care including endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, interventional pain management, cardiology, nephrology, infectious disease, psychiatry, and pulmonology. (Add-on code, list separately in addition to level 2 through 4 office/outpatient evaluation and management visit, new or established)

Comparison of 2018 and 2021 Estimated National Payment Amounts for Visits

	Complexity Level under CPT	Visit Code	Visit Code	Visit Code with Either Primary or specialized care add-on code*	Visit Code with New Extended Services Code
New Patient	Level 2	\$76	\$130	\$143	\$197
	Level 3	\$110			
	Level 4	\$167			
	Level 5	\$211	\$212		
Established Patient	Level 2	\$45	\$90	\$103	\$157
	Level 3	\$74			
	Level 4	\$109			
	Level 5	\$148	\$149		

*In cases where one could bill both the primary and specialized care add-on, there would be an additional \$13.

Comment

While CMS has “delayed” its proposed changes to reduce the number of E/M code payment levels till CY 2021, it has not abandoned the concept.

This material begins on page 537 and extends some 100 pages. Most of the material addresses documentation and coding.

CMS has provided a table (pages 628-629) that estimates by specialty level impacts of final E/M payment and coding policies if implemented for 2019. Most appear to reduce overall payments.

B. Payment Rates under the Medicare PFS for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Provider-Based Departments of a Hospital (Page 191)

Section 603 of the **Bipartisan Budget Act of 2015** requires that certain items and services furnished by certain off-campus hospital outpatient provider-based departments are no longer to be paid under the Hospital Outpatient Prospective Payment System (OPPS) and are instead to be paid under an applicable payment system. In CY 2017, CMS finalized the PFS as the applicable payment system for most of these items and services.

Since CY 2017, payment for these items and services furnished in non-excepted off-campus provider-based departments has been made under the PFS using a PFS Relativity Adjuster based on a percentage of the OPPS payment rate. The PFS Relativity Adjuster in CY 2018 is 40 percent, meaning that non-excepted items and services are paid 40 percent of the amount that would have been paid for those services under the OPPS.

CMS is finalizing that the PFS Relativity Adjuster remain at 40 percent for CY 2019.

Also, CMS is finalizing its proposal to continue to allow nonexcepted off-campus PBDs to bill for nonexcepted items and services on an institutional claim using a “PN” modifier until the agency can identify a workable alternative mechanism to improve payment accuracy

C. Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services (Page 104)

1. Brief Communication Technology-based Service, e.g. Virtual Check-in (HCPCS code GVC11)

CMS proposed to pay separately, beginning January 1, 2019, for a newly defined type of physicians’ service furnished using communication technology. This service would be billable when a physician or other qualified health care professional has a brief non-face-to-face check-in with a patient via communication technology.

CMS is adopting this proposal. The HCPCS code GVC11 was a placeholder code. The code is now described as HCPCS code G2012 (Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion).

CMS says that this service can only be furnished for established patients because the practitioner needs to have an existing relationship with the patient, and therefore, basic knowledge of the patient’s medical condition and needs, in order to perform this service.

2. Remote Evaluation of Pre-Recorded Patient Information (HCPCS code G2010)

CMS proposed to create specific coding that describes the remote professional evaluation of patient-transmitted information conducted via pre-recorded “store and forward” video or image technology. These services would not be subject to the Medicare telehealth restrictions in section 1834(m) of the Act, and the valuation would reflect the resource costs associated with furnishing services utilizing communication technology.

CMS is adopting this proposal.

3. Inter-professional Internet Consultation (CPT codes 99451, 99452, 99446, 99447, 99448, and 99449)

CMS is also finalizing policies to pay separately for new coding describing chronic care remote physiologic monitoring (CPT codes 99453, 99454, and 99457) and inter-professional internet consultation (CPT codes 99451, 99452, 99446, 99447, 99448, and 99449).

D. Medicare Telehealth Services (Page 137)

CMS proposed, and is adopting, the following services to the telehealth list on a Category 1 basis for CY 2019:

- HCPCS codes G0513 and G0514 (Prolonged preventive service(s) (beyond the typical service time of the primary procedure), in the office or other outpatient setting requiring direct patient contact beyond the usual service; first 30 minutes (list separately in addition to code for preventive service) and (Prolonged preventive service(s) (beyond the typical service time of the primary procedure), in the office or other outpatient setting requiring direct patient contact beyond the usual service; each additional 30 minutes (list separately in addition to code G0513 for additional 30 minutes of preventive service). The work RVUs for G0513 and G0514 would both be 1.17.

CMS is also finalizing policies to implement the requirements of the ***Bipartisan Budget Act of 2018*** for telehealth services related to beneficiaries with end-stage renal disease (ESRD) receiving home dialysis and beneficiaries with acute stroke effective Jan. 1, 2019. CMS will add renal dialysis facilities and the homes of ESRD beneficiaries receiving home dialysis as originating sites, and to not apply originating site geographic requirements for hospital-based or critical access hospital-based renal dialysis centers, renal dialysis facilities, and beneficiary homes, for purposes of furnishing the home dialysis monthly ESRD-related clinical assessments. CMS will also add mobile stroke units as originating sites and not to apply originating site type or geographic requirements for telehealth services furnished for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke.

E. Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder and Other Substance Use Disorders (Page 157)

Through an interim final rule, CMS is implementing a provision from the ***Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act*** that removes the originating site geographic requirements and adds the home of an individual as a permissible originating site for telehealth services furnished for purposes of treatment of a substance use disorder or a co-occurring mental health disorder for services furnished on or after July 1, 2019.

Additionally, the ***SUPPORT for Patients and Communities Act*** establishes a new Medicare benefit category for opioid use disorder treatment services furnished by opioid treatment programs (OTP) under Medicare Part B, beginning on or after Jan. 1, 2020. CMS notes that there is a 60-day period to comment on these provisions during which CMS is requesting information regarding services furnished by OTPs, payments for these services, and additional conditions for Medicare participation for OTPs that stakeholders believe may be useful for CMS to consider for future rulemaking to implement this new Medicare benefit category.

F. Determination of Practice Expense (PE) Relative Value Units (RVUs) (Page 11)

Practice expense (PE) is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding malpractice expenses.

CMS directs readers to a file called “Calculation of PE RVUs under Methodology for Selected Codes” which is available at <https://go.cms.gov/2NWDm9P>.

This file contains a table that illustrates the calculation of PE RVUs as described in this final rule for individual codes.

Comment

This material, extending some 90+ pages, provides technical and detailed information about the methodology, inputs and resources involved in transforming each service into service-specific PE RVU.

CMS reports on numerous CPT code refinements and its decisions on adopting or rejecting modification requests.

G. Determination of Malpractice Relative Value Units (RVUs) (Page 102)

For CY 2019, CMS does not appear to be changing its methodology to determine the Malpractice RVUs. However, CMS is seeking additional comments regarding the next MP RVU update which must occur by CY 2020.

H. Radiologist Assistants (Page 186)

CMS is revising the physician supervision requirements so that diagnostic tests performed by a Radiologist Assistant (RA) that meets certain requirements, that would otherwise require a personal level of physician supervision as specified in CMS’s regulations, may be furnished under a direct level of physician supervision to the extent permitted by state law and state scope of practice regulations.

This is in response to stakeholder comments that the current requirement of personal supervision that applies to some diagnostic tests is overly restrictive when the test is performed by an RA, and does not allow for radiologists to make full use of RAs, and that reducing the required level of supervision will improve efficiency of care.

I. Valuation of Specific Codes (Page 219)

CMS reviews the resource inputs for several hundred codes under the annual process referred to as the potentially misvalued code initiative. CMS says recommendations from the American Medical Association-Relative Value Scale Update Committee (RUC) are critically important to this work.

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.

The red page number below reflects the rule’s display copy page on which the code(s) discussion begins:

1	Fine Needle Aspiration (CPT codes 10021, 10004, 10005, 10006, 10007, 10008, 10009, 10010, 10011, 10012, 76492, 77002 and 77021) Page 236
2	Biopsy of Nail (CPT code 11755) Page 250
3	Skin Biopsy (CPT codes 11102, 11103, 11104, 11105, 11106, and 11107) Page 254
4	Injection Tendon Origin-Insertion (CPT code 20551) Page 261
5	Structural Allograft (CPT codes 20932, 20933, and 20934) Page 263
6	Knee Arthrography Injection (CPT code 27369) Page 264
7	Application of Long Arm Splint (CPT code 29105) Page 267
8	Strapping Lower Extremity (CPT codes 29540 and 29550) Page 268
9	Bronchoscopy (CPT codes 31623 and 31624) Page 270

10	Pulmonary Wireless Pressure Sensor Services (CPT codes 33289 and 93264) Page 272
11	Cardiac Event Recorder Procedures (CPT codes 33285 and 33286) Page 273
12	Aortoventriculoplasty with Pulmonary Autograft (CPT code 33440) Page 273
13	Hemi-Aortic Arch Replacement (CPT code 33866) Page 275
14	Leadless Pacemaker Procedures (CPT codes 33274 and 33275) Page 277
15	PICC Line Procedures (CPT codes 36568, 36569, 36572, 36573, and 36584) Page 282
16	Biopsy or Excision of Inguinofemoral Node(s) (CPT code 38531) Page 297
17	Radioactive Tracer (CPT code 38792) Page 299
18	Percutaneous Change of G-Tube (CPT code 43760) Page 300
19	Gastrostomy Tube Replacement (CPT codes 43762 and 43763) Page 301
20	Diagnostic Proctosigmoidoscopy – Rigid (CPT code 45300) Page 302
21	Hemorrhoid Injection (CPT code 46500) Page 303
22	Removal of Intraperitoneal Catheter (CPT code 49422) Page 310
23	Dilation of Urinary Tract (CPT codes 50436, 50437, 52334, and 74485) Page 311
24	Transurethral Destruction of Prostate Tissue (CPT codes 53850, 53852, and 53854) Page 320
25	Vaginal Treatments (CPT codes 57150 and 57160) Page 326
26	Biopsy of Uterus Lining (CPT codes 58100 and 58110) Page 327
27	Injection Greater Occipital Nerve (CPT code 64405) Page 328
28	Injection Digital Nerves (CPT code 64455) Page 329
29	Removal of Foreign Body – Eye (CPT codes 65205 and 65210) Page 330
30	Injection – Eye (CPT codes 67500, 67505, and 67515) Page 338
31	X-Ray Spine (CPT codes 72020, 72040, 72050, 72052, 72070, 72072, 72074, 72080, 72100, 72110, 72114, and 72120) Page 343
32	X-Ray Sacrum (CPT codes 72200, 72202, and 72220) Page 349
33	X-Ray Elbow-Forearm (CPT codes 73070, 73080, and 73090) Page 351
34	X-Ray Heel (CPT code 73650) Page 352
35	X-Ray Toe (CPT code 73660) Page 353
36	X-Ray Esophagus (CPT codes 74210, 74220, and 74230) Page 354
37	X-Ray Urinary Tract (CPT code 74420) Page 356
38	Fluoroscopy (CPT code 76000) Page 358
39	Echo Exam of Eye Thickness (CPT code 76514) Page 358
40	Ultrasound Elastography (CPT codes 76981, 76982, and 76983) Page 362
41	Ultrasound Exam – Scrotum (CPT code 76870) Page 364
42	Contrast-Enhanced Ultrasound (CPT codes 76978 and 76979) Page 366
43	Magnetic Resonance Elastography (CPT code 76391) Page 371
44	Computed Tomography (CT) Scan for Needle Biopsy (CPT code 77012) Page 374
45	Dual-Energy X-Ray Absorptiometry (CPT code 77081) Page 377
46	Breast MRI with Computer-Aided Detection (CPT codes 77046, 77047, 77048, and 77049) Page 377
47	Blood Smear Interpretation (CPT code 85060) Page 388
48	Bone Marrow Interpretation (CPT code 85097) Page 392
49	Fibrinolysins Screen (CPT code 85390) Page 398
50	Electroretinography (CPT codes 92273, 92274, and 0509T) Page 398
51	Cardiac Output Measurement (CPT codes 93561 and 93562) Page 415
52	Coronary Flow Reserve Measurement (CPT codes 93571 and 93572) Page 419
53	Peripheral Artery Disease (PAD) Rehabilitation (CPT code 93668) Page 422
54	Home Sleep Apnea Testing (CPT codes 95800, 95801, and 95806) Page 423
55	Neurostimulator Services (CPT codes 95970, 95976, 95977, 95983, and 95984) Page 430
56	Psychological and Neuropsychological Testing (CPT codes 96105, 96110, 96116, 96125, 96127, 96112, 96113, 96121, 96130, 96131, 96132, 96133, 96136, 96137, 9613896138, 96139, 96X11, and 96146) Page 444
57	Electrocorticography (CPT code 95836) Page 451
58	Chronic Care Remote Physiologic Monitoring (CPT codes 99453, 99454, and 99457) Page 453
59	Inter-professional Internet Consultation (CPT codes 99451, 99452, 99446, 99447, 99448, and 99449) Page 460
60	Chronic Care Management Services (CPT code 99491) Page 463
61	Diabetes Management Training (HCPCS codes G0108 and G0109) Page 466
62	External Counterpulsation (HCPCS code G0166) Page 468
63	Wound Closure by Adhesive (HCPCS code G0168) Page 469
64	Removal of Impacted Cerumen (HCPCS code G0268) Page 472
65	Structured Assessment, Brief Intervention, and Referral to Treatment for Substance Use Disorders (HCPCS codes G0396, G0397, and G2011) Page 473
66	Prolonged Services (HCPCS code GPRO1) Page 476
67	Remote pre-recorded services (HCPCS code G2010) Page 478
68	Brief Communication Technology-based Service, e.g. Virtual Check-in (HCPCS code G2012) Page 479
69	Visit Complexity Inherent to Certain Specialist Visits (HCPCS code GCG0X) Page 481
70	Visit Complexity Inherent to Primary Care Services (HCPCS code GPC1X) Page 482

71	Podiatric Evaluation and Management Services (HCPCS codes GPD0X and GPD1X) Page 484
72	Comment Solicitation on Superficial Radiation Treatment Planning and Management Page 484
73	Adaptive Behavior Analysis Services Page 491

The rule's table 13 (**Page 492**) contains the CPT code descriptors for all new, revised, and potentially misvalued codes discussed in this section. Table 14 (**Page 507**) contains CY 2019 Direct PE Refinements.

J. Therapy Services (Page 639)

1. Repeal of the Therapy Caps and Limitation to Ensure Appropriate Therapy

Section 50202 of the **Bipartisan Budget Act of 2018** (BBA 2018) amended section 1833(g) of the Act, effective January 1, 2018, to repeal the application of the Medicare outpatient therapy caps and the therapy cap exceptions process while retaining and adding limitations to ensure therapy services are furnished when appropriate.

Section 50202 also adds section 1833(g)(7)(A) of the Act to require that after expenses incurred for the beneficiary's outpatient therapy services for the year have exceeded one or both of the previous therapy cap amounts, all therapy suppliers and providers must continue to use an appropriate modifier such as the KX modifier on claims for subsequent services in order for Medicare to pay for the services.

2. Payment for Outpatient PT and OT Services Furnished by Therapy Assistants

The **Bipartisan Budget Act of 2018** requires payment for services furnished in whole or in part by a therapy assistant at 85 percent of the applicable Part B payment amount for the service effective Jan. 1, 2022. In order to implement this payment reduction, the law requires CMS to establish a new modifier by Jan. 1, 2019.

CMS is finalizing its proposal to establish two new modifiers – one for Physical Therapy Assistants (PTA) and another for Occupational Therapy Assistants (OTA) – when services are furnished in whole, or in part by a PTA or OTA. However, CMS is finalizing the new modifiers as “payment” rather than as “therapy” modifiers. These will be used alongside of the current PT and OT modifiers, instead of replacing them, which retains the use of the three existing therapy modifiers to report all PT, OT, and Speech Language Pathology services, that have been used since 1998 to track outpatient therapy services that were subject to the therapy caps. CMS is also finalizing a de minimis standard under which a service is furnished in whole or in part by a PTA or OTA when more than 10 percent of the service is furnished by the PTA or OTA, instead of the proposed definition that applied when a PTA or OTA furnished any minute of a therapeutic service. The new therapy modifiers for services furnished by PTAs and OTAs are not required on claims until Jan. 1, 2020.

3. KX Amounts

The KX modifier thresholds were established through section 50202 of the **Bipartisan Budget Act**. These KX modifier thresholds were formerly referred to as therapy caps and are a permanent provision of the law, meaning that the statute does not specify an end date. These per-beneficiary amounts under section 1833(g) of the Act (as amended by section 4541 of the **Balanced Budget Act of 1997**) are updated each year based on the MEI. Specifically, these amounts are calculated by updating the previous year's amount by the MEI for the upcoming calendar year and rounding to the nearest \$10.00. Increasing the CY 2018 KX modifier threshold amount of \$2,010 by the CY 2019 MEI of 1.5 percent and rounding to the nearest \$10.00 results in a CY 2019 KX threshold amount of \$2,040 for PT and SLP services combined and \$2,040 for OT services.

K. Part B Drugs: Application of an Add-on Percentage for Certain Wholesale Acquisition Cost (WAC)-based Payments (Page 667)

CMS proposed that effective Jan. 1, 2019, WAC based payments for Part B drugs made under section 1847A(c)(4) of the Act, utilize a 3.0 percent add-on in place of the 6.0 percent add-on that is currently being used.

CMS has finalized that policy. Effective Jan. 1, 2019, WAC-based payments for Part B drugs determined under section 1847A of the Social Security Act, during the first quarter of sales when ASP is unavailable, will be subject to a 3.0 percent add-on in place of the 6.0 percent add-on that is currently being used. In addition, CMS will also update manual provisions to permit Medicare Administrative Contractors to use an add-on percentage of up to 3.0 percent, rather than 6.0 percent, when utilizing WAC for pricing new drugs. CMS is reiterating that these changes only apply to WAC-based payment for new Part B drugs.

II. Other Provisions of the Rule

A. Clinical Laboratory Fee Schedule (CLFS) (Page 687)

Beginning Jan. 1, 2018, the payment amount for a test on the CLFS is generally equal to the weighted median of private payer rates determined for the test, based on the data of “applicable laboratories” that is collected during a specified data collection period and reported to CMS during a specified data reporting period. The first data collection period was from Jan. 1 through June 30, 2016, and the first data reporting period was from Jan. 1, 2017, through March 31, 2017.

CMS has a threshold regarding whether or not a laboratory needs to report data as an applicable laboratory. CMS defined total Medicare revenues for purposes of the majority of Medicare revenues threshold calculation to include fee-for-service payments under Medicare Parts A and B, as well as Medicare Advantage (MA) payments under Medicare Part C, prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance amounts for Medicare services furnished during the data collection period.

CMS proposed a change to the way Medicare Advantage payments are treated in its definition of “applicable laboratory.” CMS is finalizing this proposal, which may result in additional laboratories of all types that serve a significant population of beneficiaries enrolled in Medicare Part C in meeting the majority of Medicare revenues threshold and potentially qualifying as an applicable laboratory and having to report data to CMS. CMS will exclude MA plan revenues from total Medicare revenues (the denominator of the majority of Medicare revenues threshold).

CMS is amending the applicable laboratory definition to include hospital laboratories that bill for their non-patient laboratory services on the CMS 1450 14X TOB bill.

B. Changes to the Regulations Associated with the Ambulance Fee Schedule (Page 739)

The ***Bipartisan Budget Act of 2018*** extended the temporary add-on payments for ground ambulance services for 5 years. The 3 temporary add-on payments include: (1) a 3.0 percent increase to the base and mileage rate for ground ambulance transports that originate in rural areas; (2) a 2.0 percent increase to the base and mileage rate for ground ambulance transports that originate in urban areas; and (3) a 22.6 percent increase in the base rate for ground ambulance transports that originate in super rural areas. These provisions were set to expire on Dec. 31, 2017, but have been extended through Dec. 31, 2022. The ***Bipartisan Budget Act*** also increased the reduction from 10 percent to 23 percent in payments for non-emergency basic life support transports of beneficiaries with end-stage renal disease for renal dialysis services. This provision is effective with services on or after Oct. 1, 2018.

CMS has revised the regulations to conform with these requirements

C. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (Page 746)

For CY 2019, CMS has finalized a payment for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) for communication technology-based services and remote evaluation services that are furnished by an RHC or FQHC practitioner when there is no associated billable visit. These services will be payable for medical discussions or remote evaluations of conditions not related to an RHC or FQHC service provided within the previous 7 days or within the next 24 hours or at the soonest available appointment. RHCs and FQHCs will be able to bill for these services using a newly created RHC/FQHC Virtual Communication Service HCPCS code, G0071, with payment set at the average of the PFS national non-facility payment rates for communication technology-based services and remote evaluation services.

D. Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Services (Page 765)

Section 1834(q) of the Act includes rapid timelines for establishing a Medicare AUC program for advanced diagnostic imaging services. The impact of this program is extensive as it will apply to every physician or other practitioner who orders or furnishes advanced diagnostic imaging services (for example, MRI, computed tomography (CT) or positron emission tomography (PET)).

CMS is finalizing the revision of the significant hardship criteria in the AUC program to include: 1) insufficient internet access; 2) electronic health record (EHR) or clinical decision support mechanism (CDSM) vendor issues; or 3) extreme and uncontrollable circumstances. CMS is also finalizing allowing ordering professionals experiencing a significant hardship to self-attest their hardship status.

In addition, CMS is adding independent diagnostic testing facilities (IDTFs) to the definition of applicable setting under this program. CMS is also allowing AUC consultations, when not personally performed by the ordering professional, to be performed by clinical staff under the direction of ordering professional. This will allow the ordering professional to exercise their discretion to delegate the performance of this consultation.

E. Medicare Shared Savings Program (Page 837)

This final rule also addresses a subset of changes to the Medicare Shared Savings Program for ACOs proposed in an August 2018 proposed rule “Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations Pathways to Success” and other revisions designed to update program policies under the Shared Savings Program. In order to ensure continuity of participation, finalize time-sensitive program policy changes for currently participating ACOs, and streamline the ACO core quality measure set to reduce burden and encourage better outcomes, CMS is finalizing the following policies.

- A voluntary 6-month extension for existing ACOs whose participation agreements expire on December 31, 2018, and the methodology for determining financial and quality performance for this 6-month performance year from Jan. 1, 2019, through June 30, 2019.
- Allowing beneficiaries who voluntarily align to a Nurse Practitioner, Physician Assistant, Certified Nurse Specialist, or a physician with a specialty not used in assignment to be prospectively assigned to an ACO if the clinician they align with is participating in an ACO, as provided for in the ***Bipartisan Budget Act of 2018***.
- Revising the definition of primary care services used in beneficiary assignment.
- Providing relief for ACOs and their clinicians impacted by extreme and uncontrollable circumstances in 2018 and subsequent years.

CMS is reducing the Shared Savings Program core quality measure set by eight measures; and promoting interoperability among ACO providers and suppliers by adding a new CEHRT threshold criterion to determine ACOs’ eligibility for program participation and retiring the current Shared Savings Program quality measure on the percentage of eligible clinicians using CEHRT.

G. Physician Self-Referral Law: Annual Update to the List of CPT/HCPCS Codes (Page 869)

Revisions to the comprehensive Code List effective Jan. 1, 2019, is available on the CMS website at http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.html.

The rule's Tables 28 and 29 identify the additions and deletions, respectively, to the comprehensive Code List that becomes effective January 1, 2019. (Page 873).

F. CY 2019 Updates to the Quality Payment Program (Page 875)

CMS notes that the **Medicare Access and CHIP Reauthorization Act of 2015** (MACRA) amended title XVIII of the Act to repeal the Medicare sustainable growth rate (SGR) formula. The MACRA advances the Quality Payment Program in one of two ways:

- The Merit-based Incentive Payment System (MIPS).
- Advanced Alternative Payment Models (Advanced APMs)."

For the 2019 MIPS performance period, CMS is finalizing the following updates: (1) *adding 8* new MIPS quality measures that include 4 patient reported outcome measures, 6 high priority measures, and 2 measures on important clinical topics in the Meaningful Measures framework; and (2) *removing 26* quality measures

Comment

The Quality preamble section of this rule extends more almost 750 pages (pages 875 to 1,620). In addition, Appendix 1 (Page 2168) spanning some 192 pages, contains the following tables:

- Table A: Finalized New Quality Measures for Inclusion in MIPS for the 2021 MIPS Payment Year and Future Years (Page 2168)
- Table B; Group B: Finalized New and Modified MIPS Specialty Measure Sets for the 2021 MIPS Payment Year and Future Years (Page 2182)
- Table C; Quality Measures Finalized for Removal in the 2021 MIPS Payment Year and Future Years (Page 2302)
- Table D; Measures with Substantive Changes Finalized for the 2021 MIPS Payment Year and Future Years (Page 2315)

The Quality section is nearly 1000 pages, approximately 50 percent of the rule.

New and removed measures

New:

1. Continuity of Pharmacotherapy for Opioid Use Disorder
2. Average Change in Functional Status Following Lumbar Spine Fusion Surgery
3. Average Change in Functional Status Following Total Knee Replacement Surgery
4. Average Change in Functional Status Following Lumbar Discectomy Laminotomy Surgery
5. Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture
6. Average Change in Leg Pain Following Lumbar Spine Fusion Surgery
7. Zoster (Shingles) Vaccination
8. HIV Screening

Removed:

1. Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy:
2. Coronary Artery Bypass Graft (CABG): Use of Internal Mammary Artery (IMA) in Patients with Isolated CABG Surgery:
3. Breast Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade:
4. Colorectal Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade:
5. Adult Kidney Disease: Blood Pressure Management:
6. Age-Related Macular Degeneration (AMD): Counseling on Antioxidant Supplement:
7. Oncology: Radiation Dose Limits to Normal Tissues:
8. Comprehensive Diabetes Care: Foot Exam:
9. Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet:
10. Melanoma: Avoidance of Overutilization of Imaging Studies:
11. Quantitative Immunohistochemical (IHC) Evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) for Breast Cancer Patients:
12. Statin Therapy at Discharge after Lower Extremity Bypass (LEB):
13. Sleep Apnea: Assessment of Sleep Symptoms:
14. Sleep Apnea: Positive Airway Pressure Therapy Prescribed:
15. Preoperative Diagnosis of Breast Cancer:
16. Pediatric Kidney Disease: Adequacy of Volume Management:
17. Adult Sinusitis: More than One Computerized Tomography (CT) Scan Within 90 Days for Chronic Sinusitis (Overuse): Optimizing Patient
18. Exposure to Ionizing Radiation: Utilization of a Standardized Nomenclature for Computed Tomography (CT) Imaging:
19. Optimizing Patient Exposure to Ionizing Radiation: Search for Prior Computed Tomography (CT) Studies Through a Secure, Authorized, Media-Free, Shared Archive:
20. Bipolar Disorder and Major Depression: Appraisal for alcohol or chemical substance use:
21. Pregnant women that had HBsAg testing:
22. Hypertension: Improvement in Blood Pressure:
23. Perioperative Anti-platelet Therapy for Patients Undergoing Carotid Endarterectomy:
24. Post-Anesthetic Transfer of Care Measure: Procedure Room to a Post Anesthesia Care Unit (PACU):
25. Post-Anesthetic Transfer of Care: Use of Checklist or Protocol for Direct Transfer of Care from Procedure Room to Intensive Care Unit (ICU):
26. Chlamydia Screening and Follow-up:

Some prominent Year 3 quality policies adopted in the final rule include:

- Expanding the definition of MIPS eligible clinicians to include new clinician types (physical therapists, occupational therapists, speech-language pathologists, audiologists, clinical psychologists, and registered dietitians or nutrition professionals);
- Adding a third element to the low-volume threshold determination, and giving eligible clinicians who meet one or two elements of the low-volume threshold the choice to participate in MIPS (referred to as the opt-in policy).;
- Adding new episode-based measures to the Cost performance category, restructuring the Promoting Interoperability (formerly Advancing Care Information) performance category, and creating an option to use facility-based Quality and Cost performance measures for certain facility-based clinicians;
- Overhauling the MIPS Promoting Interoperability performance category to support greater electronic health record interoperability and patient access while aligning with the Medicare Promoting Interoperability Program requirements for hospitals;
- Moving clinicians to a single, smaller set of objectives and measures with scoring based on measure performance for the Promoting Interoperability performance category;

- Allowing the use of a combination of collection types for the Quality performance category;
- Retaining and increasing some bonus points;
- For the Cost or Quality performance categories, providing the option to use facility-based scoring for facility-based clinicians, who are planning to participate in MIPS as a group. This option does not require data submission. CMS says it expects to release a facility-based scoring preview in Q1 of 2019;
- Increasing the small practice bonus to 6 points, but including it in the Quality performance category score of clinicians in small practices instead of as a standalone bonus;
- Continuing to award small practices 3 points for submitted quality measures that don't meet the data completeness requirements;
- Allowing small practices to continue submitting quality data for covered professional services through the Medicare Part B claims submission type for the Quality performance category;
- Continuing to provide small practices with the option to participate in MIPS as a virtual group;
- Offering no-cost, customized support to small and rural practices through the Small, Underserved, and Rural Support (SURS) technical assistance initiative;

Final Thoughts

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.

CMS has issued a fact sheet that provides additional information regarding the movement of Year 2 MIPS policy changes to CY 2019 – Year 3. This 29-page document is at: <https://go.cms.gov/2zpsuU3>.

Our Washington liaison, Larry Goldberg of Larry Goldberg Consulting, has provided us with this summary. Please contact Jeff Weegar, NCHA, at 919-677-4231, jweegar@ncha.org or Ronnie Cook, NCHA, at 919-4225, rcook@ncha.org if you have questions.