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Overview of Selected Provisions of the Medicare Physician Fee Schedule Proposed Rule for Calendar Year 2019

On July 27, 2018, the Centers for Medicare and Medicaid Services (CMS) published a proposed rule addressing revisions to payment policies under the Medicare Physician Fee Schedule (PFS) and other policy revisions under Part B for calendar year (CY) 2019 (the "Proposed Rule"). It is available at: https://www.gpo.gov/fdsys/pkg/FR-2018-07-27/pdf/2018-14985.pdf. CMS will accept comments on the Proposed Rule until September 10, 2018.[1]

CMS estimates the conversion factor for CY 2019 at $36.0463, reflecting the annual increase specified by the Protecting Access to Medicare Act (PAMA) and the budget neutrality adjustment based on the limitation of annual adjustments specified in section 1848(c)(2)(B)(ii)(II) of the Social Security Act.[2]

The cumulative effect on total Medicare payments to physicians involved in the provision of cancer care, if all of the proposals in the Proposed Rule are finalized, would be:[3]

Specialty	Allowed Charges (Millions)	Combined Impact
Hematology/Oncology	$1,737	-4%
Radiation Oncology and Radiation Therapy Centers	$1,760	-2%
Radiology	$4,891	0%

At the end of this summary, we have provided a table comparing payment rates for certain drug administration codes from the third quarter 2018 payment rate to the proposed CY 2019 payment rate. The addenda containing payment rates and other information referred to in this summary are available only on the CMS web site at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1693-P.html.

This Summary Addresses the Following Topics in the CY 2019 Proposed Rule:

(1) Determination of Practice Expense (PE) Relative Value Units (RVUs):
   a. Proposal to Crosswalk Indirect PE RVUs for Two New Specialities
   b. Identification of 28 Codes as Low Volume Services to Receive Assigned Expected Specialty
   c. Solicitation of Comment on the Source for Certain Equipment Cost Factors
   d. Delay for Consideration of Changes to Scope Equipment Costs
   e. Valuation of the Balloon Sinus Surgery Kit
   f. Technical Corrections to Direct PE Input Database and Supporting Files
   g. Updates to Prices for Existing Direct PE Inputs

[1] 83 FR 35,704 (July 27, 2018) ("Proposed Rule").
[2] *Id*. at 36,044.
[3] *Id.* at 36,044-45.

(2) Review of Malpractice (MP) RVUs
(3) Potentially Misvalued Codes
    a. Review of Publicly Nominated Potentially Misvalued Codes
    b. Update on the Global Surgery Data Collection
(4) Modernizing Medicare Physician Payment by Recognizing Communication Technology Based Services
    a. Proposed Brief Communication Technology-Based Service Codes
    b. Remote Evaluation of Pre-Recorded Patient Information (Healthcare Common Procedure Coding System (HCPCS) code GRAS1)
    c. Chronic Care Remote Physiologic Monitoring (Current Procedure Terminology (CPT®[4]) codes 990X0, 990X1, and 994X9)
    d. Interprofessional Internet Consultation (CPT codes 994X6, 994X0, 99446, 99447, 99448, and 99449)
    e. Medicare Telehealth Services
    f. Expanding the Use of Telehealth under the Bipartisan Budget Act of 2018
    g. Technical Modification to Regulatory Provisions Regarding List of Telehealth Services
    h. Comment Solicitation on Creating a Bundled Episode of Care for Management and Counseling Treatment for Substance Use Disorders
(5) Radiologist Assistants
(6) Reduced Payment for Off-Campus Provider-Based Departments (PBDs)
(7) Valuation of Specific Codes
    a. Skin Biopsy (CPT codes 11X02, 11X03, 11X04, 11X05, 11X06, and 11X07)
    b. Biopsy or Excision of Inguinofemoral Node(s) (CPT code 3853X)
    c. Radioactive Tracer (CPT code 38792)
    d. Biopsy of Uterus Lining (CPT codes 58100 and 58110)
    e. Computed Tomography (CT) Scan for Needle Biopsy (CPT code 77012)
    f. Breast Magnetic Resonance Imaging (MRI) with Computer-Aided Detection (CAD) (CPT codes 77X49, 77X50, 77X51, and 77X52)
    g. Bone Marrow Interpretation (CPT code 85097)
    h. Comment Solicitation on Superficial Radiation Treatment Planning and Management
(8) Proposed changes to the Evaluation & Management (E/M) visit documentation requirements
(9) Teaching Physician Documentation Requirements for E/M Services
(10) Solicitation of Public Comments on the Low Expenditure Threshold Component of the Applicable Laboratory Definition under the Medicare Clinical Laboratory Fee Schedule (CLFS)
(11) Geographic Price Cost Indices (GPCI) Comment Solicitation
(12) Therapy Services
    a. Repeal of Public Comments on the Low Expenditure Threshold Component of the Applicable Laboratory Definition under the Medicare Clinical Laboratory Fee Schedule (CLFS)

[4] CPT is a registered trademark of the American Medical Association.

b. Proposed Payment for Outpatient physical therapy (PT) and occupational therapy (OT) Services Furnished by Therapy Assistants
c. Proposed Functional Reporting Modifications

(13) Application of an Add-on Percentage for Certain Wholesale Acquisition Cost (WAC)-Based Payments for Part B Drugs
(14) Payment for Care Management Services and Communication Technology-based Services in Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)
(15) Continued Implementation of Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Services, Including Refinements to the Settings in which AUC Consultation is Required, How Consultation is Reported, and Significant Hardship Exceptions
(16) Updates to the Medicaid Promoting Interoperability Incentive Program
(17) Updates to quality measures for Accountable Care Organizations (ACOs) under the Medicare Shared Savings Program (MSSP)
(18) Technical Updates to the Stark Law (Physician Self-Referral) Regulations
(19) Updates to the Quality Payment Program (QPP), including the Merit-Based Incentive Payment System (MIPS) and the Advanced Alternative Payment Model (Advanced APM) Incentive, for CY 2019
(20) Request for Information (RFI) 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
(21) RFI on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information
(22) Collection of Information Requirements

Details about the proposed changes are provided below.

(1) <u>Determination of Practice Expense (PE) Relative Value Units (RVUs)</u>

a. Proposal to Crosswalk Indirect PE RVUs for Two New Specialties

Indirect PEs generally are developed using physician survey data to calculate the PEs incurred per hour worked. However, survey data is not available for two new specialties, Hospitalists and Advanced Heart Failure and Transplant Cardiology, which became recognized Medicare specialties in 2017. CMS is proposing to use proxy data by crosswalking the new specialties to specialties that furnish similar services. Specifically, CMS proposes to base the indirect PE RVU for Hospitalists on Emergency Medicine data and for Advanced Heart Failure and Transplant Cardiology on Cardiology data.[5]

b. Identification of 28 Codes as Low Volume Services to Receive Assigned Expected Specialty

[5] 83 FR 35,708.

As finalized in the 2018 final rule, CMS uses the most recent year of claims data to determine which codes are low volume for the coming year. For codes that fall in this category, instead of assigning specialty mix based upon the individual claims data, CMS uses the expected specialty that identifies and assigns to low volume codes based on medical review and input from expert stakeholders. For CY 2019, CMS proposes to add 28 additional codes as low volume services to the list for which it assigns an expected specialty.[6]

c. *Solicitation of Comment on the Source for Certain Equipment Cost Factors*

While CMS is not proposing changes in these areas, the agency welcomes comments on the following topics related to PE RVUs:

- Whether the current equipment utilization assumption rate of 50% for most equipment is accurate, and if not, the identification of robust, objective, auditable data regarding the use of equipment to illustrate an alternative rate;[7] and
- Whether the current annual maintenance factor for all equipment should remain at 5%, and if not, the identification of robust, objective, auditable data regarding equipment maintenance cost or another systematic data collection methodology for determining maintenance factor.[8]

d. *Delay for Consideration of Changes to Scope Equipment Costs*

In the CY 2018 final rule, CMS announced it would propose changes to scope equipment costs in this year's Proposed Rule to incorporate feedback from expert stakeholders. Because the American Medical Association (AMA)/Specialty Society Relative Value Scale Update Committee's (RUC) Scope Equipment Reorganization Workgroup was not convened in time to submit recommendations for the CY 2019 rulemaking cycle, CMS proposes to delay proposals for further changes until CY 2020. Despite this delay, CMS proposes to update the scope video system (ES031) from its current price of $33,391 to $36,306 to reflect the addition of the LED light and miscellaneous small equipment, and to update the name of the ES031 equipment item to reflect that the scope video system is not limited to endoscopy procedures.[9]

e. *Valuation of the Balloon Sinus Surgery Kit*

CMS received comments from stakeholders that the price of the balloon sinus surgery (SA106) supply has decreased significantly since it was initially priced in 2011. The RUC recommended for the CY 2012 rulemaking cycle that CMS remove the balloon sinus surgery kit from the relevant CPT codes and instead establish a separate billable

[6] *Id.* at 35,709-10.
[7] *Id.* at 35,712.
[8] *Id.*
[9] *Id.* at 35,714-15.

HCPCS code to allow practitioners to be paid for the cost of the disposable kits per patient encounter instead of through the CPT coded. However, CMS rejected this proposal and noted its concern about how it prices high cost disposable supply items. To that end, while CMS does not propose any changes in this rulemaking, it is seeking comment on whether the 0.5 supply quantity of the balloon sinus surgery kit in CPT codes 31295-31297 would be typical for these procedures and is seeking comment on the pricing of the balloon sinus surgery kit.[10]

f. Technical Corrections to Direct PE Input Database and Supporting Files

CMS proposes to correct certain clerical inconsistencies in the direct PE input data base:

- Refinements to the required minimum quantity of multi-specialty visit pack supply items (SA048) associated with the 165 CPT codes listed in Table 6 of the Proposed Rule;[11]
- Revisions to the direct PE inputs for CPT code 11311 to resolve a rank order anomaly with CPT code 11310;[12]
- Refinements to the "Obtain vital signs" clinical labor task for three codes to return the time allocated for that task back to the previous times of one minute for CPT codes 97124 and 99750 and to three minutes for CPT code 97755;[13] and
- Adding an essential piece of equipment, the endoscope disinfector (ES005), to the direct PE inputs for CPT code 52000, and adding 22 minutes of equipment time for that item to match the equipment time of the other non-scope items included in this code.[14]

g. Updates to Prices for Existing Direct PE Inputs

CMS accepts public submission of invoices as part of its process for developing payment rates for new, revised, and potentially misvalued codes.[15] For CY 2019, CMS proposes the following revisions to direct PE input prices.

- Based on the findings of contractor StrategyGen's market research study, CMS proposes to update the pricing of direct PE inputs for supplies and equipment. The full StrategyGen report, including the updated supply and equipment pricing as proposed, is available on the CMS website.[16] StrategyGen found that, while the average commercial price for medical equipment and supplies has remained relatively consistent with the current CMS price, certain medical specialties will

[10] *Id.* at 35,715.
[11] *Id.* at 35,716-18.
[12] *Id.* at 35,718.
[13] *Id.*
[14] *Id.* at 35,718-19.
[15] *Id.* at 35,719.
[16] *Id.* at 35,719-20.

experience increases and decreases in their Medicare payments if the payment adjustments are adopted.[17] Specifically, CMS stated that the proposed price changes will disproportionately affect the Allergy/Immunology specialty.[18] Consistent with past practice, CMS proposes to phase in the use of the new direct PE input pricing over a four-year period using a 25/75 percent (CY 2019), 50/50 percent (CY 2020), 7/25 percent (CY 2021) and 100/0 percent (CY 2022) split between old and new pricing.[19] CMS also seeks comment on whether to update the clinical labor wages used in developing PE RVUs in future calendar years during the four-year pricing transition for supplies and equipment, or whether it would be more appropriate to update the clinical labor wages at a later date following the conclusion of the transition.[20]

- CMS received a request to update the price for the Breast Biopsy software (EQ370) equipment used for six CPT codes. CMS declines to update the price or add the software to these procedures on the grounds that the equipment item EQ370 serves clinical functions similar to other items already included in the Magnetic Resonance (MR) room equipment package (EL007) and that it would be duplicative to include this Breast Biopsy software as a separate direct PE input. CMS noted that the RUC recommendations for the applicable CPT codes do not include EQ370 and CMS does not believe the inclusion of the additional Breast Biopsy software would be typical. CMS proposes to update the name of the EQ370 equipment item, however, to help better describe the equipment in question.[21]

(2) *Review of Malpractice (MP) RVUs*

CMS does not propose to review or adjust the MP RVUs in this rulemaking, but solicits comments regarding the next MP RVU update which must occur by CY 2020. Specifically, CMS solicits comments on how it could improve the way that specialties in the state-level raw rate filings data are crosswalked for categorization into CMS specialty codes that are used to develop the specialty-level risk factors and the MP RVUs.[22]

(3) *Potentially Misvalued Codes*

a. Review of Publicly Nominated Potentially Misvalued Codes

CMS identifies the following codes as potentially misvalued and seeks comments on the potential value of them:

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[17] *Id.* See report at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.
[18] *Id.* at 35,720.
[19] *Id.*
[20] *Id.* at 35,721.
[21] *Id.*
[22] *Id.* at 35,722.

- 27130 (Total hip arthroplasty);
- 27447 (Total knee arthroplasty);
- 43239 (Egd biopsy single/multiple);
- 45385 (Colonoscopy w/ lesion removal);
- 70450 (CT head w/o contrast);
- 93000 (Electrocardiogram complete); and
- 93306 (Tte w/ Doppler complete).

CMS also received a request to review CPT codes 92992 ((Atrial septectomy or septostomy; transvenous method, balloon (eg, Rashkind type) (includes cardiac catheterization)) and 92993 (Atrial septectomy or septostomy; blade method (Park septostomy) (includes cardiac catheterization)), but noted that these codes currently are priced by the Medicare Administrative Contractors (MACs).[23]

b. Update on the Global Surgery Data Collection

CMS collects data on how many postoperative visits are performed during the global period for certain 10-day and 90-day surgical procedures by requiring practitioners in groups with 10 or more practitioners in nine states to use the no-pay CPT code 99024 to report postoperative visits.[24] CMS reviewed the use of this code during the second half of 2017 and found that only 45% of likely eligible practitioners reported one or more visit using the required code during the six-month period. CMS also found that the share of practitioners who reported any CPT code 99024 claims varied by specialty and by state, and that practitioners were more likely to report the code for 90-day global procedures than for 10-day global procedures.[25]

CMS is soliciting comment on the following:

- How to encourage reporting to ensure the validity of the data without imposing undue burden, and specifically whether CMS should do more to make practitioners aware of their obligation and whether CMS should implement an enforcement mechanism;
- Whether it would be reasonable for CMS to assume that many visits included in the valuation of 10-day global packages are not being furnished, or whether there are alternative explanations for what could be a significant level of underreporting of postoperative visits;
- Whether CMS should consider requiring the use of modifiers in cases where the surgeon does not expect to perform the postoperative visits, regardless of whether or not the transfer of care is formalized; and

[23] *Id.* at 35,733.
[24] *Id.*
[25] *Id.* at 35,733-37.

- The best approach to 10-day global codes for which the preliminary data suggest that postoperative visits are rarely performed by the practitioner reporting the global code.[26]

CMS also noted that it anticipates beginning, in the near future, a separate survey-based data collection effort on the level of post-operative visits including the time, staff, and activities involved in furnishing post-operative visits and non-face-to-face-services.[27]

(4) *Modernizing Medicare Physician Payment by Recognizing Communication Technology Based Services*

Under the current PFS payment rules, physicians and other authorized practitioners may bill for certain medical services that would otherwise be furnished in-person but are instead furnished via real-time, interactive communication technology (often referred to as "telehealth" services). Section 1834(m)(4)(F) of the Social Security Act (SSA) enumerates certain Medicare-covered telehealth services and permits the Secretary to specify additional Medicare telehealth services using an annual process to add or delete services from the list of approved Medicare-covered telehealth services. The SSA includes certain limits on and conditions of coverage for telehealth services. When an authorized telehealth service is performed, and other conditions of coverage are satisfied, the SSA requires that a practitioner who furnishes a telehealth service to an eligible individual be paid an amount equal to the amount that the practitioner would have been paid if the service had been furnished without the use of a telecommunications system.

For CY 2019, the agency aims to increase access to physicians' services that are routinely furnished via communication technology by recognizing a discrete set of services that are defined by and involve the use of communication technology, but would not be regarded as telehealth services and, hence, would not be subject to the limitations and conditions of coverage specified in Section 1824(m) of SSA.[28] The agency also proposes adding certain services to the list of Medicare-covered telehealth services.

a. Proposed brief communication technology-based service codes

CMS recognizes that advances in communication technology have changed patients' and practitioners' expectations regarding the quantity and quality of information that can be conveyed via communication technology.[29] Accordingly, the agency proposes to pay separately, beginning January 1, 2019, for a newly-defined type of service; specifically, the agency proposes payment when a physician or other qualified health care professional has a brief non-face-to-face check-in with a patient via communication

[26] *Id.* at 35,733.
[27] *Id.*
[28] *Id*. at 36,069.
[29] *Id*.

technology, to assess whether the patient's condition necessitates an office visit.[30] The proposed code would be described as GVCI1 (Brief communication technology-based services, 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 seven days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; five to 10 minutes of medical discussion).

CMS proposes that, where such a brief communication technology-based service originates from a related E/M service provided within the previous seven days by the same physician or other qualified health care professional, this service would be considered bundled into the previous E/M service and would not be separately billable. CMS proposes that, where the brief communication technology-based service leads to an E/M in-person service with the same physician or other qualified health care professional, this service would be considered bundled into the pre- or post- visit time of the associated E/M service, and therefore, would not be separately billable. The agency notes that the service could be used as part of a treatment regimen for opioid and other substance use disorders.[31]

CMS seeks comment on the types of communication technology that are used by physicians or other qualified health care professionals in furnishing these services.[32] CMS proposes pricing this service at a rate lower than that for existing E/M in-person visits to reflect the low work time and intensity and to account for the resource costs and efficiencies associated with the use of communication technology. The agency seeks comment on the manner in which it should obtain and require consent from patients. It also proposes that this service only be furnished for patients with whom a practitioner has an existing relationship.

CMS does not propose to apply a frequency limit on the use of this code by the same practitioner with the same patient, but seeks comment on this proposal. It also seeks comment on the timeframes under which this service would be separately billable compared to when it would be bundled, as well as comment on when which this service should be bundled into the subsequent related visit. The agency seeks comment on how clinicians can document and demonstrate the medical necessity of the service. More broadly, the agency seeks comment on the proposed definition and valuation of the code.[33]

b. Remote Evaluation of Pre-Recorded Patient Information (HCPCS code GRAS1)

[30] *Id*. at 35,724.
[31] *Id*.
[32] *Id*.
[33] *Id*. at 35,725-27.

Effective January 1, 2019, CMS proposes to create a specific code that describes the remote professional evaluation of patient-transmitted information conducted via pre-recorded "store and forward" video or image technology. Such services would not be subject to the Medicare telehealth restrictions, and the valuation of such services would reflect the costs associated with furnishing services utilizing communication technology. The services could be used to determine whether or not an office visit is needed. The agency also proposes that, in instances when the remote service originates from a related E/M service provided within the previous seven days by the same physician or qualified health care professional, the service would be considered bundled into that previous E/M service and would not be separately billable.[34]

The proposed code for this service would be described as GRAS1 (Remote evaluation of recorded video and/or images submitted by the patient (e.g., store and forward), including interpretation with verbal follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous seven days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment).

The agency seeks general comment on the proposed definition and valuation of the code, as well as comment as to whether such services should be limited to established patients; or whether there are certain cases where it might be appropriate for a new patient to receive these services.[35]

c. Chronic Care Remote Physiologic Monitoring (CPT codes 990X0, 990X1, and 994X9)

In September 2017, the CPT Editorial Panel created three new codes to describe remote physiologic monitoring and management. For CY 2019, CMS proposes to adopt CPT codes 990X0, 990X1, and 994X9 to describe chronic care remote physiologic monitoring services.[36] The proposed descriptors and payment rates under the PFS for these new codes are as follows:

CPT Code	CPT Description	CY 2019 Proposed Payment Rate	
		Facility	Non-Facility
990X0	Remote monitoring of physiologic parameter(s) (*e.g.*, weight, blood pressure,	N/A	$20.91

[34] *Id*. at 35,724-25.
[35] *Id*. at 35,724.
[36] *Id.* at 35,725.

	pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment		
990X1	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days	N/A	$69.21
994X9	Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified healthcare professional time in a calendar month requiring interactive communication with the patient/caregiver during the month	$33.16	$53.71

d. Interprofessional Internet Consultation (CPT codes 994X6, 994X0, 99446, 99447, 99448, and 99449)

CMS proposes to make separate payment for the following interprofessional consultations, performed via communications technology such as telephone or Internet, and undertaken for the benefit of treatment a patient:

- CPT 994X0 (Interprofessional telephone/Internet/electronic health record referral service(s) provided by a treating/requesting physician or qualified health care professional, 30 minutes),
- CPT 994X6 (Interprofessional telephone/Internet/electronic health record assessment and management service provided by a consultative physician including a written report to the patient's treating/requesting physician or other qualified health care professional, five or more minutes of medical consultative time),
- CPT 99446 (Interprofessional telephone/Internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; five to ten minutes of medical consultative discussion and review),
- CPT 99447 (Interprofessional telephone/Internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 11-20 minutes of medical consultative discussion and review),
- CPT 99448 (Interprofessional telephone/Internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 21-30 minutes of medical consultative discussion and review), and

- CPT 99449 (Interprofessional telephone/Internet assessment and management service provided by a consultative physician including a verbal and written report to the patient's treating/requesting physician or other qualified health care professional; 31 minutes or more of medical consultative discussion and review).[37]

CMS seeks comment on its assumption that these are separately identifiable services and how such services may be distinguished from activities undertaken for the benefit of the practitioner. The agency also seeks comment on how best to minimize potential program integrity issues. It notes particular interest in learning whether such services are paid separately by private payers and if so, what limitations private payers have instituted to ensure appropriate billing.

The agency also proposes, and seeks comment on, the requirement that beneficiaries provide advance verbal beneficiary consent to receipt of such services.[38]

e. Medicare Telehealth Services

CMS has changed the process through which it intends to accept requests to add services to the list of Medicare telehealth services. While, historically, requests had to be submitted and received by December 31 of each calendar year in order to be considered for the next rulemaking cycle, beginning in CY 2019, the agency intends to accept requests through February 10th for the following CY (e.g., to be considered for CY 2020, requests to add services must be submitted and received by February 10, 2019).[39]

CMS proposes to add the following services as Medicare telehealth services for CY 2019, given that the agency found these services to be sufficiently similar to office visits currently on the telehealth list:[40] 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).[41]

f. Expanding the Use of Telehealth Under the Bipartisan Budget Act of 2018

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[37] *Id*. at 35,725-26.
[38] *Id*. at 35,726.
[39] *Id*. at 35,727.
[40] *Id*.
[41] *Id*.

To address amendments to Section 1881(b)(3) and 1834(m) of the SSA, under the Bipartisan Budget Act of 2018, CMS proposes to revise its regulations pertaining to telehealth services to:

- Add a renal dialysis facility and the home of an individual as Medicare telehealth originating sites, but only for purposes of the home dialysis monthly end stage renal disease-related clinical assessment in Section 1881(b)(3)(B) of the SSA.
- Reflect the requirement in Section 1834(m)(2)(B)(ii) of the SSA that there is no originating site facility fee a when the originating site for these services is the patient's home.
- Specify that the statutory geographic requirements described in Section 1834(m)(4)(C)(i) of the SSA do not apply with respect to telehealth services furnished on or after January 1, 2019, in originating sites that are hospital-based or critical access hospital-based renal dialysis centers, renal dialysis facilities, or the patient's home.[42]

CMS proposes other telehealth-related changes due to amendments to Section 1834(m) of the SSA made under the Bipartisan Budget Act of 2018. Specifically, the agency proposes to:

- Create a new modifier that would be used to identify acute stroke telehealth services. The practitioner and, as appropriate, the originating site, would append this modifier when clinically appropriate to the HCPCS code when billing for an acute stroke telehealth service or an originating site facility fee, respectively. By billing with this modifier, practitioners would indicate that the codes billed were used to furnish telehealth services for diagnosis, evaluation, or treatment of symptoms of an acute stroke.
- Revise the telehealth regulations to add mobile stroke unit as a permissible originating site for acute stroke telehealth services. CMS proposes to define a mobile stroke unit as a mobile unit that furnishes services to diagnose, evaluate, and/or treat symptoms of an acute stroke and seeks comment on this definition, as well as information on how these units are used in current medical practice. CMS seeks comment on other possible appropriate originating sites for telehealth services furnished for the diagnosis, evaluation, or treatment of symptoms of an acute stroke.
- Amend the telehealth regulations to specify that the requirements under Section 1834(m)(4)(C) of the SSA (e.g., the original site type and geographic requirements) do not apply with respect to telehealth services furnished on or after January 1, 2019, for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke.[43]

[42] *Id*. at 35,729-30.
[43] *Id*.

g. Technical Modification to Regulatory Provisions Regarding the List of Telehealth Services

CMS proposes a technical revision to regulatory provisions regarding individual services and exceptions for Medicare payment for telehealth services (specifically, a technical amendment to 42 CFR §414.65(a) to note that Medicare payment for telehealth services is addressed in §410.78 and a deletion of §414.65(a)(1)).[44]

h. Comment Solicitation on Creating a Bundled Episode of Care for Management and Counseling Treatment for Substance Use Disorders

CMS believes that creating separate payment for a bundled episode of care for components of mediation assisted treatment (MAT) such as management and certain treatment related to substance use disorders (SUDs) could help leverage services furnished with communication technology and increase access to SUD treatment. It also believes that making separate payment for a bundled episode of care for management and counseling for SUDs could be effective in preventing the need for more acute services. Accordingly, the agency is considering whether it would be appropriate to develop a separate bundled payment for an episode of care for treatment of SUDs. It seeks public comment on the following:

- Whether such a bundled episode-based payment would be beneficial to improve access, quality and efficiency for SUD treatment.
- How to develop coding and payment for a bundled episode of care for treatment for SUDs that could include overall treatment management, any necessary counseling, and components of a MAT program such as treatment planning, medication management, and observation of drug dosing.
- Whether the concept of a global period might be applicable to treatment for SUDs.
- Whether the counseling portion and other MAT components could also be provided by qualified practitioners "incident to" the services of the billing physician who would administer or prescribe any necessary medications and manage the overall care, as well as supervise any other counselors participating in the treatment.
- Whether and how it should create a bundled episode of care for management and counseling treatment for SUDs.
- What general regulatory and subregulatory changes could help prevent opioid use disorder and improve access to treatment under the Medicare program.
- How to help identify non-opioid alternatives for pain treatment and management, as well as barriers that may inhibit access to these non-opioid alternatives including barriers related to payment or coverage.

[44] *Id*.

- Generally, how to improve existing requirements in order to more effectively address the opioid epidemic.[45]

(5) *Radiologist Assistants*

In response to comments from stakeholders representing the radiology community, CMS proposes to revise its regulations to specify that all diagnostic imaging tests may be furnished under the direct supervision of a physician when performed by a radiologist assistant in accordance with state law and state scope of practice rules. Specifically, the agency proposes to revise its regulation at 42 C.F.R. §410.32 to state that diagnostic tests performed by a registered radiologist assistants or radiology practitioner assistants require only a direct level of physician supervision, when permitted by state law and state scope of practice regulations.[46]

(6) *Reduced Payment for Off-Campus Provider-Based Departments (PBDs)*

In the CY 2017 Outpatient Prospective Payment System (OPPS) final rule, CMS finalized that it would pay for certain items and services furnished in non-excepted off-campus PBDs (generally, entities that began billing Medicare as off-campus PBDs after November 2015) through the PFS rather than the OPPS, and that the payment rates for such items and services would be based on a percentage of the OPPS rates.[47]

For CY 2019, CMS proposes no changes to the site-neutral payment policies finalized for CY 2018. CMS proposes to continue to allow nonexcepted PBDs to bill for nonexcepted services on the institutional claim and to maintain payment for nonexcepted services at 40% of the OPPS rates.[48]

(7) *Valuation of Specific Codes*

CMS proposes updates to RVUs, PE inputs, and other inputs for the following select codes:

a. Skin Biopsy CPT codes 11X02, 11X03, 11X04, 11X05, 11X06, and 11X07)[49]

CMS proposes updated work RVUs for five of the six codes listed for skin biopsies. These include work RVUs of:

- "0.66 for CPT code 11X02 (Tangential biopsy of skin (eg, shave, scoop, saucerize, curette), single lesion;"

[45] *Id*. at 35,730-31.
[46] *Id*. at 35,738.
[47] 81 FR 79,562, 79,713 (Nov. 14, 2016).
[48] 83 FR 35,738-39.
[49] *Id*. at 35,748.

- "0.83 for CPT code 11X04 (Punch biopsy of skin, (including simple closure when performed), single lesion);"
- "0.45 for CPT code 11X05 (Punch biopsy of skin, (including simple closure when performed), each separate/additional lesion);"
- 1.01 for CPT code 11X06 (Incisional biopsy of skin (e.g., wedge), (including simple closure when performed), single lesion); and
- 0.54 for CPT code 11X07 (Incisional biopsy of skin (e.g., wedge), (including simple closure when performed), each separate additional lesion.[50]

CMS states that it disagrees "with the [RUC]-recommended work RVU of 0.38" for CPT code 11X03 (Tangential biopsy of skin, (e.g., shave, scoop, saucerize, curette), each separate/additional lesion) and proposes instead a work RVU of 0.29.[51] CMS provides additional explanation of the basis for this work RVU in the preamble to the Proposed Rule.[52] CMS also proposes "to remove the two minutes of clinical labor time for the 'Review home care instructions, coordinate visits/prescriptions' (CA035) activity for CPT codes 11X02, 11X04, and 11X06."[53] Finally, CMS proposes "to refine the quantity of the 'grown, staff, impervious' (SB024) and the 'mask, surgical, with face shield' (SB034) supplies from two to one for CPT codes 11X02, 1104, and 11X06."[54]

b. Biopsy or Excision of Inguinofemoral Node(s) (CPT code 3853X)[55]

The CPT Editorial Panel created CPT code 3853X in September of 2017 "to describe biopsy or excision of inguinofemoral node(s)."[56] This code describes "a lymph node biopsy without complete lymphadenectomy."[57] CMS is proposing a "work RVU of 6.74 for CPT code 3853X" and a 90-day global indicator to match the global indicators for CPT code 56630 (Vulvectomy, radical, partial) and CPT code 56633 (Vulvectomy, radical, complete), which are most commonly reported with the new code.[58] The 90-day global indicator is different from the 10-day global indicator proposed by the RUC.[59] CMS did not propose PE inputs for this code.[60]

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[50] *Id*.
[51] *Id*.
[52] *Id*.
[53] *Id*.
[54] *Id*.
[55] *Id*. at 35,753.
[56] *Id*.
[57] *Id*.
[58] *Id*.
[59] *Id*.
[60] *Id*.

c. *Radioactive Tracer (CPT code 38792)*[61]

CMS proposes a work RVU of 0.65 for CPT code 38792 (Injection procedure; radioactive tracer for identification of sentinel node).[62] CMS is "proposing to refine the clinical labor time for the 'Prepare room, equipment and supplies' (CA013) activity to three minutes and to refine the clinical labor time for 'Confirm order, protocol exam' (CA014) activity to 0 minutes."[63] Finally, CMS proposes "to refine the equipment times in accordance with our standard equipment time formulas."[64]

d. *Biopsy of Uterus Lining (CPT codes 58100 and 58110)*[65]

CMS proposes a work RVU of 1.21 for CPT code 58100 (Endometrial sampling (biopsy) with or without endocervical sampling (biopsy), without cervical dilation, any method).[66] CMS proposes "to remove the clinical labor time for the 'Review/read post-procedure x-ray, lab and pathology reports' (CA028) activity for CPT code 58100."[67] CMS states that because this code is typically billed with an E/M service, it is duplicative to assign it clinical labor time to review these reports.[68] CMS also proposes "to refine the equipment times in accordance with our standard equipment time formulas."[69]

e. *CT Scan for Needle Biopsy (CPT code 77012)*[70]

CMS proposes "a work RVU of 1.50 for CPT code 77012 (Computed tomography guidance for needle placement (*e.g.*, biopsy, aspiration, injection, localization device), radiological supervision and interpretation)."[71] CMS also proposes "to refine the clinical labor time for the 'Prepare room, equipment and supplies' (CA013) activity to three minutes and to refine the clinical labor time for the 'Confirm order, protocol exam' (CA014) activity to 0 minutes."[72] CMS also proposes "to refine the equipment time for the CT room (EL007) to maintain the current time of 9 minutes" consistent with other radiological supervision and interpretation procedures.[73] Finally, CMS proposes "to refine the equipment time for the Technologist [picture

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[61] *Id*.
[62] *Id*.
[63] *Id*.
[64] *Id*.
[65] *Id*. at 35,756.
[66] *Id*.
[67] *Id*.
[68] *Id*.
[69] *Id*.
[70] *Id*. at 35,762.
[71] *Id*.
[72] *Id*.
[73] *Id*.

archiving and communications system] workstation (ED050)" consistent with standard equipment time formulas.[74]

f. Breast MRI with Computer-Aided Detection (CAD) (CPT codes 77X49, 77X50, 77X51, and 77X52)[75]

CMS proposes a work RVU of 1.15 for CPT code 77X49 (Magnetic resonance imaging, breast, without contrast material; unilateral), a proposal that is different from the RUC recommendation.[76] CMS states that it does not believe the RUC adequately accounted for the reduction in time of 15 minutes between CPT code 77X49 and 74177.[77] CMS proposes a corresponding reduction to the work RVUs for 77X50 (Magnetic resonance imaging, breast, without contrast material; bilateral), which is the bilateral equivalent of 77X49.[78] CMS also proposes a corresponding reduction in the work RVU for CPT code 77X51 (Magnetic resonance imaging, breast, without and with contrast(s) materials with CAD, including computer-aided detection (CAD-real time lesion detection, characterization and pharmacokinetic analysis) to 1.80.[79] Finally, CMS proposes a corresponding reduction in the work RVU for 77X52 (Magnetic resonance imaging, breast, without and with contrast material(s), including computer-aided detection (CAD-real time lesion detection, characterization and pharmoaocokinetic analysis) to 2.00.[80]

Regarding direct PE inputs for these codes, CMS proposes "to refine the clinical labor time for the 'Prepare, set-up and start IV, initial positioning and monitoring of patient' (CA016) activity from 7 minutes to 3 minutes for CPT codes 77X49 and 77X50, and from 9 minutes to 5 minutes for CPT codes 77X51 and 77X52."[81] CMS also proposes new pricing for five new equipment items for these codes, computer-aided detection (CAD) Software (ED058), Breast Coil (EQ388), and CAD Workstation (ED056) by crosswalking them to existing equipment items, namely flow cytometry analytics software (EQ380), Breast biopsy device (EQ371), and Professional PACS workstation (ED056) respectively.[82]

g. Bone Marrow Interpretation (CPT code 85097)[83]

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[74] *Id*.
[75] *Id*. at 35,762-63.
[76] *Id*.
[77] *Id*.
[78] *Id*.
[79] *Id*.
[80] *Id*.
[81] *Id*.
[82] *Id*.
[83] *Id*. at 35,764.

CMS proposes a work RVU for CPT code 85097 (Bone marrow, smear interpretation) of 0.94.[84] This proposal is distinct from the RUC recommendation and is intended to reflect a decrease in "work time to perform" this service from 30 minutes to 25.[85] CMS also proposes "to remove the clinical labor time for the 'Accession and enter information' (PA001) and 'File specimen, supplies, and other materials' (PA008) activities" on the grounds that this is more appropriately reflected as indirect PE.[86]

h. Comment Solicitation on Superficial Radiation Treatment Planning and Management[87]

CMS had previously noted "that changes to the CPT prefatory language limited the codes that could be reported when describing services associate with superficial radiation treatment (SRT) delivery, described by CPT code 77401 (radiation treatment delivery, superficial and/or ortho voltage, per day). The changes effectively meant that many other related services were bundled with CPT code 88401."[88] Accordingly, CMS has previously asked for comment on how to value this code.[89] Noting the ongoing feedback about these services following the CY 2018 PFS final rule, CMS believes there may still be "coding gaps for SRT-related professional services."[90] CMS is therefore "seeking comment on the possibility of creating multiple G-codes specific to services associated with SRT" in a way that is similar to "other types of radiation treatment delivery."[91] CMS also is interested in comment on whether it should "create separate codes for professional services associated with SRT" and whether the SRT codes "should be contractor priced for CY 2019."[92]

(8) *E/M Visits*[93]

As a follow-up to the request for comment on changes to the E/M documentation rules in last year's PFS proposed rule, CMS is proposing several substantial changes to E/M documentation and payment:

- CMS proposes "to remove the requirement that the medical record must document the medical necessity of furnishing the visit in the home rather than in the office."[94]

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[84] *Id*.
[85] *Id*.
[86] *Id*.
[87] *Id*. at 35,775.
[88] *Id*.
[89] *Id*.
[90] *Id*.
[91] *Id*.
[92] *Id*.
[93] *Id*. at 35,833-49. These changes apply to CPT codes 99201 through 99215 unless otherwise specified.

- CMS asks for feedback on whether it "should eliminate the manual provision [stating that 'except where specifically noted, the MACs may not pay two E/M office visits billed by a physician (or physician of the same specialty from the same group practice) for the same beneficiary on the same day unless the physician documents that the visits were for unrelated problems . . .' given the changes in the practice of medicine or whether there is concern that eliminating it might have unintended consequences for practitioners and beneficiaries."[95]]
- CMS proposes "to allow practitioners to choose, as an alternative to the current framework specified under the 1995 or 1997 guidelines, either [Medical Decision-Making (MDM)] or time as a basis to determine the appropriate level of E/M visit."[96] CMS also asks for comment "on whether and how guidelines for MDM might be changed in subsequent years."[97] Where a practitioner does use time as an alternative to the current framework, CMS proposes "to require the practitioner to document the medical necessity of the visit and show the total amount of time spent by the billing practitioner face-to-face with the patient" and asks for comment "on what the total time should be for payment for E/M visits levels 2 through 5."[98] Finally, CMS asks for comment on the use of time more generally "as a framework for documentation of office/outpatient E/M visits"[99] and how these proposals impact provider choice in how they provide care.[100]
- CMS proposes to expand its policy of not requiring "documentation of information in the billing practitioner's note that is already present in the medical record, particularly with regard to history and exam" to "further simplify the documentation of history and exam for established patients" and also asks for comment on whether it could "implement a similar provision for any aspects of medical decision-making, or for new patients, such as when prior data is available to the billing practitioner through an interoperable EHR or other data exchange."[101] CMS also proposes that "for both new and established patients, practitioners would no longer be required to re-enter information in the medical record regarding the chief complaint and history that are already entered by ancillary staff or the beneficiary."[102]
- CMS proposes that "rather than reporting visits under the general E/M office/outpatient visit code set, podiatrists instead would report visits under new G-codes that more specifically identify and value their services" under "substantially the same documentation standards for these proposed new podiatry-specific codes as

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[94] *Id*. at 35,835.
[95] *Id*. at 35,836.
[96] *Id*.
[97] *Id*. at 35,837.
[98] *Id*.
[99] *Id*.
[100] *Id*. at 35,837-38.
[101] *Id*. at 35,838.
[102] *Id*. at 35,838-39.

[proposed] for other office/outpatient E/M visits."[103] CMS also is requesting comment on the use of time for documenting these visits.[104]

- CMS proposes "to simplify the office-based and outpatient E/M payment rates and documentation requirements, and create new add-on codes to better capture the differential resources involved in furnishing certain types of E/M visits."[105] CMS also proposes "to simplify the payment for these services by paying a single rate for the level 2 through 5 E/M visits"[106] and "to develop a single set of RVUs under the PFS for E/M office-based and outpatient visit levels 2 through 5 for new patients (CPT codes 99202 through 99205) and a single set of RVUs for visit levels 2 through 5 for established patients (CPT codes 99212 through 99215)."[107] CMS would retain the existing code set.[108] CMS proposes that it would "develop resource inputs based on the current inputs for the individual E/M codes, generally weighted by the frequency at which they are currently billed, based on the 5 most recent years of Medicare claims data . . ."[109] CMS provides specifics on these inputs in the Proposed Rule.[110]
- CMS has also "identified three types of E/M visits that differ from the typical E/M visit and are not appropriately reflected in the current office/outpatient E/M code set and valuation."[111] These include:

  (1) Separately identifiable E/M visits furnished in conjunction with a 0-day global procedure,

  (2) Primary care E/M visits for continuous patient care, and

  (3) Certain types of specialist E/M visits, including those with inherent visit complexity.[112]

CMS makes detailed proposals regarding the resource costs for different types of visits in the Proposed Rule.[113] These proposals cover the E/M resource overlap between stand-alone visits and global periods,[114] proposed HCPCS G-code add-ons to recognize additional relative resources for certain visits,[115] a proposed HCPCS G-code for podiatric E/M visits,[116] a proposed adjustment to the PE/HR calculation,[117]

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[103] *Id*. at 35,839.
[104] *Id*.
[105] *Id*..
[106] *Id*.
[107] *Id*.
[108] *Id*.
[109] *Id*. at 35,840.
[110] *Id*.
[111] *Id*.
[112] *Id*.
[113] *Id*. at 35,840-48.
[114] *Id*. at 35,840-41.
[115] *Id*. at 35,841-43.
[116] *Id*. at 35,843.
[117] *Id*. at 35,843-44.

and a proposed HCPCS G-code for prolonged services.[118] CMS also considered certain alternatives to these proposals.[119]

- CMS did not propose any changes to the E/M code set for the emergency department or settings other than office-based and outpatient settings.[120] But the agency did ask for comment on whether it should make such changes in future years.[121]

CMS proposes that these changes, if adopted, would be effective January 1, 2019.[122] Below is a comparison of the CY 2018 payment rates for E/M office visits with those under the Proposed Rule, which were calculated using the proposed RVUs for 2019 from addendum B of the Proposed Rule.[123] Codes 99201-05 apply to new patients, and codes 99211-15 apply to established patients. This chart does not reflect any geographical adjustments that might be made.

Comparison of CY 2018 and Proposed CY 2019 Payment Rates for E/M Office Visits

CPT Code	Facility		Non-Facility	
	2018	Proposed 2019	2018	Proposed 2019
99201	$27.36	$25.59	$45.36	$43.26
99202	$51.48	$102.37	$76.32	$134.45
99203	$78.12	$102.37	$109.80	$134.45
99204	$131.76	$102.37	$167.40	$134.45
99205	$172.08	$102.37	$210.60	$134.45
99211	$9.36	$9.73	$21.96	$24.15
99212	$25.92	$65.60	$44.64	$91.92
99213	$52.20	$65.60	$74.16	$91.92
99214	$79.92	$65.60	$109.44	$91.92
99215	$113.04	$65.60	$147	$91.92

(9) *Teaching Physician Documentation Requirements for E/M Services*

CMS makes various proposals "to eliminate potentially duplicative requirements for notations that may have previously been included in the medical records by residents or other members of the medical team."[124] These changes include that, except for services provided in certain hospital outpatient and ambulatory settings, certain renal dialysis services, and

[118] *Id*. at 35,844-47
[119] *Id*.
[120] *Id*. at 35,847-48.
[121] *Id*.
[122] *Id*. at 35,848.
[123] *Id.* at 35,840.
[124] *Id*. at 35,848-49.

certain psychiatric services, "the medical records must document that the teaching physician was present at the time the service is furnished."[125] These notations could be made by a physician, resident, or nurse.[126] CMS also proposes to delete a requirement that the teaching physician "document the extent of their participation in the review and direction of the services furnished to each beneficiary" and to add that the medical record must include this information as input by the physician, resident, or nurse.[127]

(10) *Solicitation of Public Comments on the Low Expenditure Threshold Component of the Applicable Laboratory Definition under the Medicare Clinical Laboratory Fee Schedule (CLFS)*

As of January 1, 2018, the payment amount for Clinical Diagnostic Laboratory Tests (CDLTs), according to the Clinical Laboratory Fee Schedule (CLFS), is generally equal to a weighted median of private payer rates determined for a test based on the data of "applicable laboratories" collected during a specified data collection period and reported to CMS during a specific data reporting period.[128] An "applicable laboratory" is an entity that bills Medicare Part B under its own National Provider Identifier (NPI) and receives more than 50% of its Medicare revenues for a given data collection period from the CLFS. Included in the definition of applicable laboratory is a "low expenditure threshold" component, requiring an entity to receive at least $12,500 of its Medicare revenues from the CLSF for a given data collection period for its CDLTs that are not advanced diagnostic laboratory tests (ADLTs).[129] In order to better determine payment rates under the CLFS, CMS proposes to change the "low expenditure threshold" to obtain as much applicable information as possible from a broader range of laboratories, especially small laboratories and physician office laboratories, without imposing an additional burden on these entities.[130]

CMS is seeking public comment, especially from small independent laboratories and the physician community, on the potential effects of reducing the low expenditure threshold from $12,500 to $6,250 (alternatively, increasing the low expenditure threshold from $12,500 to $6,250, which CMS expects would decrease the number of applicable laboratories).[131]

More specifically, CMS is also soliciting comments on what effects reducing the low expenditure threshold may have on the administrative burden on physician office laboratories and small independent laboratories.[132]

(11) *Geographic Price Cost Indices (GPCI) Comment Solicitation*[133]

[125] *Id*. at 35,849.
[126] *Id*.
[127] *Id*.
[128] *Id.*
[129] *Id.*
[130] *Id.*
[131] *Id.*
[132] *Id.*

The SSA requires CMS to review and make any necessary revisions to the GPCI at least every three years. As the last update occurred in CY 2017, CMS is "required to review and make any necessary revisions to the GPCIs for CY 2020."

In response to stakeholders who have expressed concerns regarding the data sources used to develop the PFS geographic adjustment, specifically with respect to the "use [of] residential rent data as a proxy for commercial rent in the rent index component of the PE GPCI," CMS seeks comment "regarding potential sources of commercial rent data for potential use in the next GPCI update for CY 2020."

(12) *Therapy Services*

a. Repeal of the Therapy Caps and Limitation to Ensure Appropriate Therapy[134]

To implement the repeal of the therapy caps introduced in the Bipartisan Budget Act of 2018, CMS will continue to use the KX modifier, which indicates that "the therapist or therapy provider is confirming that the services are medically necessary as justified by appropriate documentation in the medical record."

b. Proposed Payment for Outpatient Physical Therapy (PT) and Occupational Therapy (OT) Services Furnished by Therapy Assistants[135]

CMS proposes to define "therapy assistant" as "an individual who meets the personnel qualifications set forth [In CMS's regulations] for a physical therapist assistant and an occupational therapy assistant (PTA and OTA, respectively)."

CMS further proposes to establish two new therapy modifiers "to identify services furnished in whole or in part by a PTA or an OTA; and, that these new therapy modifiers would be used instead of the GP and GO modifiers that are currently used to report [PT] and [OT] services delivered under the respective plan of care whenever the service is furnished in whole or in part by a PTA or OTA."

In order to implement the two new therapy modifiers, CMS proposes to revise the definitions of the three existing therapy modifiers (i.e., GP, GO, and GN).

c. Proposed Functional Reporting Modifications[136]

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[133] *Id.* at 35,850.

[134] *Id.*

[135] *Id.* at 35,850-52.

[136] *Id.* at 35,852-54.

CMS notes that it has not published or shared the results of its analysis of the collected functional reporting data, because the agency does not find the results informative. Consequently, CMS proposes "to discontinue the functional reporting requirements for services furnished on or after January 1, 2019," because the agency believes that "allowing the current functional reporting requirements to remain in place could result in unnecessary burden for providers of therapy services without providing further benefit to the Medicare program in the form of additional data." CMS seeks comment on this proposal.

(13) *Part B Drugs: Application of an Add-on Percentage for Certain Wholesale Acquisition Cost (WAC)-Based Payments*[137]

Under the Medicare statute, CMS can make payments for drugs or biologicals based on WAC "during an initial sales period in which data on the prices for sales for the drug or biological is not sufficiently available from the manufacturer."[138] These payments have historically included a "6 percent add-on" similar to the additional 6% paid on the average sales prices (ASP) reimbursement system for other separately payable drugs and biologicals.[139] CMS proposes to reduce this add-on payment to 3%, consistent with a Medicare Payment Advisory Commission (MedPAC) recommendation.[140] CMS also proposes various edits and changes to the applicable regulations and manual provisions to bring them more in line with the statute and to implement this change.[141]

(14) *Payment for Care Management Services and Communication Technology-Based Services in Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)*[142]

CMS is proposing a new CPT code for CY 2019, 994X7 for "30 minutes or more of [Chronic Care Management (CCM)] furnished by a physician or other qualified health care professional," which is similar to CPT codes 99490 and 99487, for practitioners billing under the PFS.[143] CMS also is proposing to add this code for RHCs and FQHCs to be included in the calculation of HCPCS code G0511.[144] CMS proposes to make corresponding regulatory changes to reflect these new codes and to reflect the payment methodology that was finalized in the CY 2018 PFS.[145]

CMS also proposes separate payment for certain communication-technology based services for CY 2019 for practitioners billing under the PFS, including "Brief Communication

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137 *Id*. at 35,854.
138 *Id*.
139 *Id*. at 35,855.
140 *Id*.
141 *Id*.
142 *Id*. at 35,863-65.
143 *Id*. at 35,863.
144 *Id*.
145 *Id*.

Technology-based Service" for virtual check-ins and remote evaluation services.[146] CMS further proposes that RHCs and FQHCs "receive an additional payment for the costs of communication technology-based services or remote evaluation services that are not" otherwise captured in the payment systems for these facilities.[147] CMS proposes to adopt a Virtual Communications G code for use by these facilities only.[148] CMS also outlines additional options that it considered but did not propose.[149]

(15) Appropriate Use Criteria (AUC) for Advanced Diagnostic Imaging Services[150]

Section 218(b) of PAMA required CMS to establish an AUC program that would make consultation of AUCs a condition of payment for advanced diagnostic imaging services provided in physician offices, hospital outpatient departments and ambulatory surgical centers, effective January 1, 2017. Implementation of the program has been delayed until January 1, 2020, through previous years' PFS rulemaking. A voluntary reporting period from July 2018 through December 2019 allows clinicians to educate themselves and test operations before the AUC consultation requirement takes effect. In last year's QPP Final Rule, CMS finalized that it will give MIPS credit to physicians beginning January 1, 2018 if they participate as early adopters.

CMS already has implemented the first three stages of the AUC program: (1) establishing a timeline and process for provider-led entities (PLEs) to become qualified to develop, modify, or endorse AUCs; (2) defining the clinical decision support mechanisms (CDSMs) that clinicians may use to satisfy the requirement to report consultation of AUCs; and (3) establishing consultation and reporting requirements that are scheduled to take effect beginning January 1, 2020. CY 2020 will serve as a one-year educational and operations testing period during which clinicians will not be penalized for failing to report AUC consultations.

The Proposed Rule does not change the schedule for implementation of the AUC requirements. CMS proposes the following limited refinements to the AUC program:

- Adding Independent Diagnostic Testing Facilities (IDTFs) as an "applicable setting" where the AUC requirements apply;[151]
- Allowing clinicians to satisfy the requirement to consult AUCs through auxiliary personnel under the direction of the ordering professional and incident to the ordering professional's service;[152]

[146] *Id*. at 35,864.
[147] *Id*.
[148] *Id*.
[149] *Id*. at 35,865.
[150] *Id.* at 35,865-71.
[151] *Id.* at 35,868.
[152] *Id.*

- Clarifying that information on consultation of AUCs must be included on both practitioner claims (for the professional component) and facility or supplier claims (for the facility portion or technical component);[153]
- Using G-codes, modifiers, and other "established coding methods" to report the required AUC information on Medicare claims;[154] and
- Requiring clinicians who request a significant hardship exception to report a modifier with their claim and to include documentation and an attestation to the significant hardship.[155]

CMS does not make any proposals related to the fourth and final component of the AUC program, which will impose a prior authorization requirement on advanced diagnostic imaging services furnished by certain outlier ordering professionals, effective January 1, 2020. Instead, CMS solicits comments on the data elements and thresholds that CMS should use when identifying outliers.[156]

(16) Medicaid Promoting Interoperability Incentive Program

CMS proposes minor updates to the Medicaid Promoting Interoperability Program, previously known as the Medicaid Electronic Health Record (EHR) Incentive Program.[157] The program was closed to new participants in 2016 and will end with incentive payments in 2021. CMS proposes updated measures and updated reporting requirements for clinicians who wish to participate in the Medicaid Promoting Interoperability Program. Many of the proposed changes are intended to align the program more closely with the requirements for the Promoting Interoperability component of MIPS, discussed below under the updates to the QPP.

(17) Proposals Related to the Medicare Shared Savings Program

CMS proposes minor refinements to the quality measures reported by ACOs participating in the Medicare Shared Savings Program (MSSP). The refinements are intended to align with other quality-based payment systems, including the QPP, and to emphasize outcome measures and other "meaningful" measures. The proposed changes include:

- Changes to the measures related to the Patient Experience of Care Survey; and
- Changes to CMS web interface and claims-based measures.[158]

(18) Stark Law (Physician Self-Referral) Regulations

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[153] *Id.*
[154] *Id.* at 35,869.
[155] *Id.* at 35,869-70.
[156] *Id.* at 35,870.
[157] *Id.* at 35,871.
[158] *Id*. at 35,874.

CMS proposes refinements to the regulations implementing the Stark Law, also known as the physician self-referral law.[159] CMS notes that the proposed changes are intended to implement the requirements of the Bipartisan Budget Act of 2018, which CMS believes were intended merely to codify existing CMS policy and regulations. With respect to the Stark Law exception for physician compensation arrangements, which requires that the arrangement be set out in writing and signed by the parties, CMS proposes:

- To allow the writing requirement to be satisfied by "a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties"; and
- To allow parties who satisfied every requirement except the signature requirement to comply with the law by obtaining the required signature within 90 days after the compensation arrangement became non-compliant.

(19) *Quality Payment Program Updates for CY 2019*

CMS proposes several significant updates to the Quality Payment Program, including new policies to further implement the Merit-Based Incentive Payment System (MIPS) and the Advanced Alternative Payment Model (Advanced APM) option.

a. Overview

The Proposed Rule retains the essential structure of the QPP that CMS used for CYs 2017 and 2018: clinicians must choose between two tracks – pay for performance MIPS (resulting in a Part B payment bonus or penalty of up to 7% in CY 2021) or successful participation in an Advanced APM (resulting in exemption from MIPS and a Part B payment bonus of 5% in CY 2021).

The Proposed Rule increases the weight of the MIPS cost component from 10% of the overall score to 15%. The weight of the quality score would decrease from 50% to 45%. CMS also proposes to introduce eight episode-based cost measures in addition to the two overall spending measures that it finalized last year.

The Proposed Rule would streamline the scoring for the promoting interoperability (EHR) component of the MIPS score by eliminating required measures and instead scoring clinicians on their performance for whichever measures they choose to submit.

CMS does not propose to allow group practices to report separately as different sub-groups or virtual groups, but CMS does suggest that it might make that option available next year (CY 2020) and requests input on how such an option might be

[159] *Id.* at 35,879-80.

structured. CMS proposes a new exemption for clinicians who perform 200 or fewer covered professional services to individuals enrolled in Medicare Part B.

As required by the Bipartisan Budget Act of 2018, CMS would apply MIPS adjustments only to Part B professional covered services, and not to Part B drugs or other items that are furnished by an eligible clinician.[160]

Compared to CY 2018, CMS expects slightly decreased participation in Advanced APMs (160,000 to 215,000 eligible clinicians) and expects a slightly larger number of clinicians to be subject to MIPS adjustments (650,000).

b. Eligibility, Exemptions, and Special Scoring

CMS proposes to create a third exemption from the QPP based on low volume of Medicare patients. Currently, clinicians are exempt from the QPP if they provided care to no more than 200 Part B beneficiaries or had Part B allowed charges of no more than $90,000 during the applicable determination period. Under the Proposed Rule, clinicians also would be exempt from the QPP if they provided no more than 200 covered professional services to Part B beneficiaries during the determination period.[161]

CMS proposes to establish a facility-based scoring option for CY 2019, under which clinicians who furnish 75% or more of their covered professional services in the inpatient hospital, emergency room, or on-campus outpatient hospital setting may have part of their MIPS score be based on that facility's score under the Hospital Value-Based Purchasing Program (VBP).[162] Under this option:

- CMS will automatically apply the facility-based scoring option to qualifying clinicians, unless the clinician submits quality and cost data that would result in a higher combined quality and cost performance score.
- The eligible clinician must bill at least one service in the inpatient hospital or emergency room setting.
- The eligible clinician's quality and cost scores would be based on the facility's VBP score, but not the clinician's improvement activity or promoting interoperability scores.
- The eligible clinician would receive scores derived from the VBP score for the facility at which the clinician provided services for the most Medicare beneficiaries.

[160] *Id.* at 35,890.
[161] *Id.* at 35,887.
[162] *Id.* at 35,956-63.

- The Proposed Rule includes detailed proposals about how the VBP score for the clinician's facility would be translated into a quality and cost score for each clinician who is scored using facility-based scoring.

CMS proposes no significant changes to a number of the other exemptions and special scoring rules that it finalized in previous years, including the exemption for newly enrolled clinicians and the special scoring for non-patient-facing clinicians, small and rural practices, and clinicians based in hospitals and ambulatory surgery centers.

CMS proposes to make several new categories of clinicians subject to the QPP, including certified clinical social workers, clinical psychologists, and physical and occupational therapists. In addition, CMS would make qualified speech-language pathologists and audiologists, certified nurse-midwives, and registered dietitians subject to the QPP, but only if CMS decides to retain adequate quality measures for those clinicians to report at least six quality measures.[163] CMS proposes that the newly eligible clinicians would not receive a promoting interoperability score for CY 2019.[164]

c. Groups

For CY 2019, CMS proposes to continue defining a group practice as a single Tax Identification Number (TIN), which must be scored together.[165] However, the Proposed Rule acknowledges that many groups are interested in being able to participate in MIPS as sub-groups within a single TIN, and CMS is considering making this option available for CY 2020 and beyond.[166] In anticipation of a possible sub-group reporting option, CMS requests input on the following:

- Whether and how a sub-group should be treated as a separate group from the primary group (for example, how CMS would assess the sub-group's eligibility, performance, scoring, and application of the payment adjustment);
- Whether all of the sub-group's MIPS performance data should be aggregated with that of the primary group or treated as a distinct entity for determining the sub-group's final score, payment adjustments, and eligibility;
- Possible low-burden solutions for identifying sub-groups*, e.g.*, requiring registration of sub-groups similar to the CMS web interface; and

[163] *Id.* at 35,872.
[164] *Id.*
[165] *Id.* at 35,891.
[166] *Id.*

- Potential issues or solutions needed for sub-groups using submission mechanisms, measures, or activities (including APM participation) that are different from the primary group.[167]

CMS proposes to continue offering the option to participate in MIPS as a virtual group, but with the same restrictions imposed in CY 2018 (i.e., no splitting of TINs, minimum of two TINs or solo practitioners, only one virtual group per eligible clinician, no restrictions on virtual group size, location, or specialty). CMS also proposes that it will establish a new mechanism for electing to participate as a virtual group, which it suggests will be a web-based mechanism.[168]

d. Scoring Categories and Methodology

Quality:

- For CY 2019, CMS proposes that quality will count 45% toward each clinician's overall score (down from 50% in CY 2018).
- CMS proposes to add 10 new quality measures for clinicians to choose from for CY 2019 and to remove 34 existing quality measures.[169] Otherwise, the quality measures available for reporting will remain the same as in CY 2018. CMS does not propose significant changes to the minimum number of required measures or data completeness requirements for quality measures.
- CMS proposes to continue offering specialty measure sets for many clinical specialties, but proposes to add or remove certain measures from most of the sets. The changes in the specialty measure sets are listed in Appendix 1, Table Group B.[170]
- CMS proposes to accelerate the process of removing measures that are "extremely topped out" (average mean performance in the 98th to 100th percentile) by allowing CMS to remove such measures in the next rulemaking cycle, rather than removing the measure over four years as previously finalized for other "topped out" measures.[171]
- CMS also plans to accelerate the shift from process measures to outcome measures in coming years, because CMS views outcome measures as more valuable than process measures and more useful in improving quality of care. CMS notes that 102 out of 275 available measures are process measures, and that it expects to begin removing these measures through notice and comment rulemaking based on factors like the number of measures available for a specialty, whether the measure promotes positive outcomes, whether the

[167] *Id.*
[168] *Id.* at 35,892.
[169] *Id.* at 35,881. The proposed measures to be added are listed in Appendix 1, Table A, at page 36,092, and the proposed measures to be removed are listed in Appendix 1, Table C, at page 36,335.
[170] *Id.* at 36,103.
[171] *Id.* at 35,900.

measure is extremely topped out, and whether the measure is designated as high priority.[172]

- CMS requests input on whether it should establish tiers (i.e., gold, silver, bronze) that designate the value of a quality measure and award more points for reporting higher-tier measures.[173]

Cost:

- For CY 2019, CMS proposes that cost will count 15% toward each clinician's overall score (up from 10% in CY 2018).
- CMS proposes to retain the two overall cost measures used in CY 2018 (total per capita cost for all attributed beneficiaries and Medicare spending per beneficiary).
- CMS also proposes to add eight new episode-based cost measures, which were field tested in late 2017 and 2018.[174]
- The proposed measures include five "procedural" episode-based measures:
  (1) elective outpatient percutaneous coronary intervention (PCI)
  (2) knee arthroplasty
  (3) revascularization for lower extremity chronic critical limb ischemia
  (4) routine cataract removal with intraocular lens (IOL) implantation
  (5) screening/surveillance colonoscopy
- The proposed measures include three "acute inpatient" episode-based measures:
  (1) intracranial hemorrhage or cerebral infarction
  (2) simple pneumonia with hospitalization
  (3) ST-elevation myocardial infarction (STEMI) with Percutaneous Coronary Intervention (PCI).
- A procedural episode would be attributed to a clinician if the clinician billed the triggering HCPCS or CPT code for that procedure, and an acute inpatient episode would be attributed to a clinician if the clinician billed at least 30% of the E/M codes billed during the inpatient stay.[175]
- A clinician would be scored on a cost measure only if he or she reaches the case minimum for the measure:
  - 10 cases for procedural episode-based measures
  - 20 cases for acute inpatient episode-based measures and total per capita cost
  - 35 cases for Medicare spending per beneficiary

Improvement Activities:

- The improvement activities score, which will count 15% toward the overall score, is largely unchanged for CY 2019. CMS proposes to add six new activities,

[172] *Id.*
[173] *Id.*
[174] *Id.* at 35,902-03.
[175] *Id.* at 35,905.

remove one, and modify five others.[176]

Promoting Interoperability:

- CMS proposes a new scoring system for the promoting interoperability component (previously known as advancing care information).[177] Instead of requiring clinicians to report specific measures as a prerequisite for earning a base score and only then allowing clinicians to choose additional measures to report, CMS would provide greater flexibility by allowing clinicians to report whatever measures they would like and to earn points based on their performance on those measures.
- CMS proposes to scale back the number of available measures to report, focusing on four key objectives: (1) e-prescribing, (2) health information exchange, (3) provider to patient exchange, and (4) clinical data exchange. Each of these objectives would include one or a handful of measures and would be worth a certain number of points toward the clinician's promoting interoperability score.
- CMS summarizes the proposed measures and scoring in Tables 36 and 37,[178] and provides details on the proposed measures in Table 38.[179]

Composite Score:

- CMS does not propose major changes to the calculation of the composite score or the calculation of each clinician's final adjustment, which will apply to Part B payments in CY 2021 based on the clinician's performance in CY 2019.
- CMS proposes a performance threshold of 30 points for CY 2019. This is the minimum number of points (totaled across the four categories) that a clinician must earn to avoid a negative adjustment. CMS plans to increase the performance threshold gradually in future years, to allow clinicians time to adjust, until CMS can establish a performance threshold based on the mean or median score across the program for previous years, which CMS estimates will be between 63.50 and 68.98 points for CY 2024.[180]
- The table below shows how MIPS adjustments will be calculated for CY 2019.

Composite Score	MIPS Adjustment (Based on Final Performance Threshold)
0 – 7.5	-7%
7.51 – 29.99	Negative adjustment between -7% and 0% on a linear sliding scale
30.0	0%

[176] *Id.* at 35,905-07. The proposed changes are listed in Appendix 2 at page 36,359.
[177] *Id.* at 35,914.
[178] *Id.* at 35,917.
[179] *Id.*
[180] *Id.* at 35,972.

30.01 – 79.99	Positive adjustment between 0% and 7% × a scaling factor to preserve budget neutrality, on a linear sliding scale
80.0 – 100	Positive adjustment as described above, plus additional MIPS payment adjustment for exceptional performance (starting at 0.5% and increasing on a linear sliding scale to 10% multiplied by a scaling factor)

As noted above, CMS would apply MIPS adjustments only to Part B professional covered services, and **not** to Part B drugs or other items that are furnished by an eligible clinician.[181]

e. Advanced APM Incentive

CMS proposes to continue most aspects of the Advanced APM incentive as finalized in the CY 2018 final rule, including the criteria required for an APM to qualify as an Advanced APM, the requirements for an eligible clinician to successfully participate in an Advanced APM, and application of the APM incentive.

As expected, CMS proposes to implement an All-Payer Combination Option through which an eligible clinician can qualify for the APM incentive (and exemption from MIPS) based on the clinician's participation in a combination of a Medicare Advanced APM and an Advanced APM sponsored by a non-Medicare payer. Under this proposal:

- An APM sponsored by a non-Medicare payer would qualify as an Advanced APM only if it satisfies criteria similar to the criteria for Medicare Advanced APMs (requires use of certified EHR technology, provides payment based on quality measures comparable to MIPS quality measures, requires participants to bear more than nominal financial risk of losses).
- For CY 2019, the All-Payer Combination Option would be available only for Advanced APMs authorized under Medicaid, Medicare health plan arrangements (e.g., Medicare Advantage), and payment arrangements in CMS Multi-Payer Models. Commercial and other private payers will be eligible for the All-Payer Combination Option beginning in CY 2020.
- Under the Proposed Rule, CMS first would assess whether a clinician receives sufficient patient volume or revenue through a Medicare Advanced APM to qualify for the APM incentive. If the clinician does not meet the required threshold to qualify based on participation in a Medicare APM alone, CMS then would look at the clinician's participation in other payers' Advanced APMs to determine whether the combined patient volume or revenue meets the required threshold to qualify for the APM incentive under the All-Payer Combination Option. CMS provides a detailed flow chart describing this calculation in the Proposed Rule.[182]

[181] *Id.* at 35,890.
[182] *Id.* at 35,995.

(20) *Request for Information (RFI) 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*

In the Proposed Rule, the agency notes that, given the widespread adoption of electronic health records (EHRs) and the increased availability of health information exchange infrastructure, it seeks information from stakeholders regarding how CMS health and safety standards that are required of providers and suppliers participating in the Medicare and Medicaid programs may be used to advance electronic exchange of information that supports safe, effective transitions of care between hospitals and community-based providers. The agency includes a broad RFI on changes that CMS might make to the following standards in support of this goal: Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation (RfPs) for Long-Term Care (LTC) Facilities.[183]

The agency specifically invites stakeholder feedback on various questions regarding possible new or revised CoPs/CfCs/RfPs for interoperability and electronic exchange of health information. The agency poses various questions, including but not limited to the following:

- Should CMS propose new CoPs/CfCs/RfPs for hospitals and other participating providers and suppliers to ensure a patient's or resident's (or his or her caregiver's or representative's) right and ability to electronically access his or her health information without undue burden?
- Are new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information necessary to ensure patients/residents and their treating providers routinely receive relevant electronic health information from hospitals on a timely basis or will this be achieved in the next few years through existing Medicare and Medicaid policies, the implementing regulations related to the privacy and security standards of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104-91), and implementation of relevant policies in the 21st Century Cures Act?
- Do stakeholders believe that new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information would help improve routine electronic transfer of health information as well as overall patient/resident care and safety?
- Are there any other operational or legal considerations (for example, implementing regulations related to the HIPAA privacy and security standards), obstacles, or barriers that hospitals and other providers and suppliers would face in implementing changes to meet new or revised interoperability and health information exchange

[183] *Id*. at 36,007.

requirements under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future?

- What types of exceptions, if any, to meeting new or revised interoperability and health information exchange requirements should be allowed under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future? Should exceptions under the QPP, including CEHRT hardship or small practices, be extended to new requirements? Would extending such exceptions impact the effectiveness of these requirements?[184]

CMS further invites public comment on items such as:

- How best to accomplish the goal of fully interoperable health IT and EHR systems for Medicare- and Medicaid-participating providers and suppliers,
- How best to help advance the MyHealthEData initiative for patients, and
- How to encourage adoption of certified health IT and interoperability among Medicare- and Medicaid-participating providers and suppliers.[185]

(21) *RFI on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information*[186]

CMS indicates that it is "considering potential actions that would be appropriate to further our objective of having providers and suppliers undertake efforts to engage in consumer-friendly communication of their charges to help patients understand what their potential financial liability might be for services they obtain from the provider or supplier, and to enable patients to compare charges for similar services across providers an suppliers, including services that could be offered in more than one setting."[187] CMS therefore asks for comment on diverse issues such as how to define standard charges in provider and supplier settings, what types of information is most helpful to patients, whether providers and suppliers should "be required to inform patients how much their out-of-pocket costs for a service will be" before furnishing that service, whether CMS can "require providers and suppliers to provide patients with information on what Medicare pays for a particular service," and how Medigap coverage could change a patient's "understanding of their out-of-pocket costs before they receive care."[188]

(22) *Collection of Information Requirements*

Consistent with the requirements of the Paperwork Reduction Act of 1995 (PRA), CMS requests public comments regarding the following issues for certain proposed information

[184] *Id*. at 36,006-09.
[185] *Id*.
[186] *Id*. at 36,009-10.
[187] *Id*. at 36,009.
[188] *Id*. at 36,010.

collection requirements (ICRs): (1) the need for the information collection and its usefulness in carrying out CMS's proper functions; (2) the accuracy of CMS's published burden estimates; (3) the quality, utility, and clarity of the information to be collected; and (4) CMS's effort to minimize the information collection burden on the affected public, including the use of automated collection techniques.

CMS seeks comment on these issues in connection with the following ICRs, which we have summarized at a high-level:[189]

- CLFS. CMS proposes to revise the majority of Medicare revenues threshold component of the definition of applicable laboratory at §414.502(3) to exclude Medicare Advantage payments from the definition of total Medicare revenues (that is, the denominator of the majority of Medicare threshold equation). The agency notes that its proposal may result in more data being reported, which it would use to set CLFS payment rates. With regard to the CLFS-related requirements and burden, CMS notes that section 1834A(h)(2) of the SSA exempts information collected under Section 1834A from the PRA.[190]

- AUC for Advanced Diagnostic Imaging Services. The agency provides detailed estimates of burdens associated with the AUC consultation, annual reporting, and recordkeeping in connection with the AUC ICR. The agency notes its belief that the exception for ordering professionals who experience a significant hardship affecting their consultation of AUC when ordering an advanced diagnostic imaging service imposes no burden beyond the provision of identifying information and attesting to the applicable information. Therefore, the agency views this hardship exception process as exempt from the PRA requirements.[191]

- MSSP. The agency notes that, pursuant to Section 1899(e) of the SSA, the PRA does not apply to the MSSP.[192]

- Physician Self-Referral Law. CMS notes a burden associated with the writing and signature requirements in certain compensation arrangement exceptions to the physician self-referral law's referral and billing prohibitions. The agency believes that, while the writing and signature requirements are subject to the PRA, the associated burden is exempt under 5 CFR 1320.3(b)(2). It believes that the time, effort, and financial resources necessary to comply with the writing and signature requirements would be incurred by persons without federal regulation during the

[189] *Id*. at 36,010-11.
[190] *Id*. at 36,011.
[191] *Id*. at 36,011-12.
[192] *Id*. at 36,012.

normal course of their activities (i.e., as usual and customary business practices).[193]

- QPP. The agency notes that, with respect to the PRA, the QPP is comprised of a series of ICRs associated with MIPS and Advanced APMs.

  The MIPS ICRs consist of registration for virtual groups; qualified registry and Qualified Clinical Data Registry (QCDR) self-nomination; Consumer Assessment of Healthcare Provider and Systems (CAHPS) survey vendor application; QPP Identity Management Application Process; quality performance category data submission by claims collection type, QCDR and MIPS clinical quality measures (CQM) collection type, electronic clinical quality measures (eCQM) collection type, and CMS web interface submission type; CAHPS for MIPS survey beneficiary participation; group registration for CMS web interface; group registration for CAHPS for MIPS survey; call for quality measures; Promoting Interoperability reweighting applications; Promoting Interoperability performance category data submission; call for Promoting Interoperability measures; improvement activities performance category data submission; nomination of improvement activities; and opt-out of Physician Compare for voluntary participants.

  ICRs for Advanced APMs consist of partial qualifying APM participant (QP) election; other payer Advanced APM identification: Payer Initiated and Eligible Clinician Initiated Processes; and submission of data for All-Payer QP determinations under the All-Payer combination option.

  The agency provides information relating to its burden estimates and related assumptions for MIPS and Advanced APMs.[194]

- QPP ICRs Regarding the Virtual Group Election. The agency states that it is not proposing any new or revised reporting, record-keeping, or third-party disclosure requirements with respect to the virtual group election.[195]

- QPP ICRs Regarding Third-Party Reporting. The agency estimates burdens associated with qualified registry self-nomination, QCDR self-nomination, and the CAHPS for MIPS survey vendor applications.[196]

- QPP ICRs Regarding Data Submission. CMS provides detailed burden estimates regarding the various data submission components of the QPP.[197]

[193] *Id*. at 36,012-13.
[194] *Id*. at 36,013-16.
[195] *Id*. at 36,016.
[196] *Id*. at 36,016-19.
[197] *Id*. at 36,019-28.

- QPP ICRs Regarding the Nomination of Quality Measures. CMS provides burden estimates related to the submission and selection of quality-related measures.[198]

- QPP ICRs Regarding Promoting Interoperability Data. CMS provides burden estimates, including for activities including the submission of interoperability data.[199]

- QPP ICRs Regarding the Nomination of Promoting Interoperability (PI) Measures. CMS notes that it does not propose any new or revised reporting, recordkeeping, or third-party disclosure requirements related to the nomination of PI measures. However, the agency proposes adjustments to its currently approved burden estimates based on more recent data.[200]

- QPP ICRs Regarding Improvement Activities Submission. CMS provides burden estimates, including burdens associated with the activities of organizations, and in some cases, individual clinicians, submitting improvement activity performance category data.[201]

- QPP ICRs Regarding the Nomination of Improvement Activities. CMS provides burden estimates relating to the nomination of improvement activities.[202]

- QPP ICRs Regarding CMS Study on Factors Associated with Reporting Quality Measures. CMS states that Section 1848(s)(7) of the SSA, as added by section 102 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114-10), states that the PRA shall not apply to the collection of information for the development of quality measures. Consequently, the agency does not set forth such a burden estimate in this Proposed Rule.[203]

- QPP ICRs Regarding the Cost Performance Category. CMS states that it does not anticipate any new or additional submission requirements and/or burden for MIPS eligible clinicians.[204]

- QPP ICRs Regarding Partial QP Elections. The Proposed Rule does not propose any new or revised reporting, recordkeeping, or third-party disclosure requirements related to QP elections. However, CMS proposes adjustments to its currently-

[198] *Id*. at 36,028-30.
[199] *Id*. at 36,030-32.
[200] *Id*. at 36,032-33.
[201] *Id*. at 36,033-34.
[202] *Id*. at 36,034-35.
[203] *Id*. at 36,035-36.
[204] *Id*. at 36,036.

approved burden estimates based on more recent data.[205]

- QPP ICRs Regarding Other Payer Advanced APM Determinations: Payer-Initiated Process and Eligible Clinician Initiated Process. With respect to the payer-initiated process and eligible clinician-initiated process-related rulemakings, CMS does not propose any new or revised reporting, recordkeeping, or third-party disclosure requirements. However, the agency proposes certain adjustments to its currently-approved burden estimates based on more recent data.[206]

- QPP ICRs Regarding Voluntary Participants Election to Opt-Out of Performance Data Display on Physician Compare. CMS provides burden estimates related to clinicians and groups who will voluntarily participate in MIPS and will also elect not to participate in public reporting.[207]

- Summary of Annual QPP Burden Estimates. CMS provides a detailed table (Table 89) that summarizes this proposed rule's burden estimates for the QPP.[208] In order to understand the burden implications of the policies set forth in the Proposed Rule, it has also estimated a baseline burden of continuing the policies and information collections set forth in the CY 2018 QPP final rule into the 2019 MIPS performance period. The agency's baseline burden estimates reflect the recent availability of data sources to help capture the organizations exempt from the Promoting Interoperability performance category and the exclusion of QPs from all MIPS performance categories. The agency also provides a detailed table (Table 90) that provides reasons for changes in its burden estimates related to information collections in the Proposed Rule – including adjustments due to newly-available data, and burdens that were erroneously excluded from the agency's original estimates.[209]

[205] *Id*.
[206] *Id*. at 36,036-39.
[207] *Id*. at 36,038-39.
[208] *Id*. at 36,038-41.
[209] *Id*. at 36,041.

Comparison of Proposed 2019 and Q3 2018 Physician Fee Schedule Payment Rates for Drug Administration Services

CPT Code	Description	CY 2019 Proposed Payment		Q3 CY 2018 Payment		% Change	
		Non Facility	Facility	Non Facility	Facility	Non Facility	Facility
96360	Hydration iv infusion init	$ 38.57	N/A	$ 47.52	N/A	-18.83%	N/A
96361	Hydrate iv infusion add-on	$ 12.98	N/A	$ 14.04	N/A	-7.57%	N/A
96365	Ther/proph/diag iv inf init	$ 69.21	N/A	$ 74.16	N/A	-6.68%	N/A
96366	Ther/proph/diag iv inf addon	$ 21.27	N/A	$ 22.32	N/A	-4.72%	N/A
96367	Tx/proph/dg addl seq iv inf	$ 29.20	N/A	$ 32.04	N/A	-8.87%	N/A
96368	Ther/diag concurrent inf	$ 19.83	N/A	$ 21.24	N/A	-6.66%	N/A
96369	Sc ther infusion up to 1 hr	$ 167.25	N/A	$ 176.76	N/A	-5.38%	N/A
96370	Sc ther infusion addl hr	$ 14.78	N/A	$ 15.84	N/A	-6.70%	N/A
96371	Sc ther infusion reset pump	$ 64.16	N/A	$ 64.80	N/A	-0.98%	N/A
96372	Ther/proph/diag inj sc/im	$ 16.94	N/A	$ 20.88	N/A	-18.86%	N/A
96373	Ther/proph/diag inj ia	$ 19.47	N/A	$ 19.44	N/A	0.13%	N/A
96374	Ther/proph/diag inj iv push	$ 38.21	N/A	$ 47.16	N/A	-18.98%	N/A
96375	Tx/pro/dx inj new drug addon	$ 15.50	N/A	$ 18.36	N/A	-15.58%	N/A
96376	Tx/pro/dx inj same drug adon	$ -	$ -	$ -	$ -	N/A	N/A
96379	Ther/prop/diag inj/inf proc	$ -	$ -	$ -	$ -	N/A	N/A
96401	Chemo anti-neopl sq/im	$ 72.81	N/A	$ 81.72	N/A	-10.90%	N/A
96402	Chemo hormon antineopl sq/im	$ 29.92	N/A	$ 31.32	N/A	-4.47%	N/A
96405	Chemo intralesional up to 7	$ 80.02	$ 28.84	$ 82.44	$ 30.60	-2.93%	-5.76%
96406	Chemo intralesional over 7	$ 120.03	$ 45.42	$ 120.96	$ 47.52	-0.76%	-4.42%
96409	Chemo iv push sngl drug	$ 99.13	N/A	$ 111.60	N/A	-11.18%	N/A
96411	Chemo iv push addl drug	$ 54.07	N/A	$ 59.76	N/A	-9.52%	N/A
96413	Chemo iv infusion 1 hr	$ 129.05	N/A	$ 144.72	N/A	-10.83%	N/A
96415	Chemo iv infusion addl hr	$ 28.48	N/A	$ 31.68	N/A	-10.11%	N/A
96416	Chemo prolong infuse w/pump	$ 130.85	N/A	$ 147.24	N/A	-11.13%	N/A
96417	Chemo iv infus each addl seq	$ 62.72	N/A	$ 69.48	N/A	-9.73%	N/A
96420	Chemo ia push tecnique	$ 104.53	N/A	$ 108.00	N/A	-3.21%	N/A
96422	Chemo ia infusion up to 1 hr	$ 158.96	N/A	$ 188.64	N/A	-15.73%	N/A
96423	Chemo ia infuse each addl hr	$ 72.81	N/A	$ 85.68	N/A	-15.02%	N/A
96425	Chemotherapy infusion method	$ 167.62	N/A	$ 197.28	N/A	-15.04%	N/A
96440	Chemotherapy intracavitary	$ 865.11	$ 130.13	$ 803.87	$ 129.24	7.62%	0.69%

96446	Chemotx admn prtl cavity	$ 196.45	$ 27.76	$ 212.04	$ 29.52	-7.35%	-5.98%
96450	Chemotherapy into cns	$ 182.39	$ 81.10	$ 186.84	$ 82.44	-2.38%	-1.62%
96521	Refill/maint portable pump	$ 148.15	N/A	$ 150.12	N/A	-1.31%	N/A
96522	Refill/maint pump/resvr syst	$ 116.07	N/A	$ 121.68	N/A	-4.61%	N/A
96523	Irrig drug delivery device	$ 25.95	N/A	$ 28.44	N/A	-8.74%	N/A
96542	Chemotherapy injection	$ 126.88	$ 40.37	$ 136.44	$ 43.20	-7.00%	-6.55%