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Overview of Selected Provisions of the Medicare Physician Fee Schedule Proposed Rule for Calendar Year 2018

On July 13, 2017, the Centers for Medicare and Medicaid Services (CMS) released 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) 2018 (the "Proposed Rule"). It was published in the Federal Register on July 21, 2017,[1] and CMS will accept comments on it until September 11, 2017.

CMS estimates the conversion factor for CY 2018 at $35.9903, reflecting the 0.50 percent annual increase specified by the Protecting Access to Medicare Act (PAMA) and the -0.19 percent reduction required by law because CMS failed to meet the annual target for reductions in PFS expenditures by reducing relative value units (RVUs) for misvalued codes.[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	$1,802	0%
Radiation Oncology and Radiation Therapy Centers	$1,784	1%
Radiology	$4,863	-1%

At the end of this summary, we have provided a table comparing payment rates for certain drug administration codes from the third quarter 2017 payment rate to the proposed CY 2018 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-1676-P.html.

This Summary Addresses the Following Topics in the CY 2018 Proposed Rule:

(1) Practice Expense (PE) Relative Value Unit (RVU) methodology:
   a. Changes to the calculation of low-value PE RVUs
   b. PE inputs for digital imaging services: adding the Picture Archiving and Communication System (PACS) to more Current Procedural Terminology (CPT®)[4] codes

[1] Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program Model, 82 Fed. Reg. 33950 (July 21, 2017), *available at* https://www.gpo.gov/fdsys/pkg/FR-2017-07-21/pdf/2017-14639.pdf.
[2] *Id*. at 34,176.
[3] *Id.* at 34,177-78.
[4] CPT is a trademark of the American Medical Association (AMA).

c. Review of standard pre-service clinical labor for 0-day and 10-day global services
d. Adding more clinical labor time for obtaining vital signs
e. Streamlining scope equipment codes
f. Setting a minimum indirect PE for some office-based services

(2) Review of malpractice RVUs
(3) Potentially misvalued codes
(4) RVU updates for specific procedures:
a. Radiation therapy planning (CPT codes 77261, 77262, 77263)
b. Superficial radiation treatment planning and management (Healthcare Common Procedure Coding System (HCPCS) code GRRR1)
c. Chemotherapy administration (CPT codes 96401, 96402, 96409, 96411)
d. Photochemotherapy (CPT code 96910)
e. Photodynamic therapy (CPT codes 96567, 96X73, 96X74)
f. Tumor immunohistochemistry (CPT codes 88360, 88361)
g. Cryoblation of pulmonary tumor (CPT codes 32998, 32X99)
(5) Solicitation of comment on guidelines for Evaluation & Management (E/M) codes and payment for services for individuals with disabilities
(6) Payment incentive for transition from traditional X-ray imaging to digital radiography and other imaging services
(7) Payment for Durable Medical Equipment (DME) infusion drugs
(8) Solicitation of public comments on biosimilar product payment policy
(9) Reduced payment for off-campus provider-based departments (PBDs)
(10) Medicare telehealth services
a. Adding services to the list of CPT codes eligible for telehealth payment
b. Adding services as add-ons to CPT codes currently included on the telehealth list
c. Solicitation of comment on separate payment for remote patient monitoring
d. Solicitation of comments on facilitating access to telehealth
(11) Continued implementation of appropriate use criteria (AUC) for advanced diagnostic imaging services
a. Proposals to implement requirement to report consultation of AUCs with each advanced diagnostic imaging service claim
b. Proposed effective date of January 1, 2019 for making AUC consultation a condition of payment
(12) Accountable Care Organizations (ACOs) under the Medicare Shared Savings Program (MSSP)
(13) Medicare Access and CHIP Reauthorization Act (MACRA) Patient Relationship Categories and Codes
(14) Physician Quality Reporting System (PQRS), Medicare Electronic Health Record (EHR) Incentive, and Value-Based Payment Modifier (VBPM)
(15) Medicare Diabetes Prevention Program (MDPP) expanded model
(16) Request for Information on CMS Flexibilities and Efficiencies
(17) Collection of information requirements

Details about the proposed changes are provided below.

(1) PE RVU Methodology

a. Changes to the calculation of low-volume PE RVUs

- CMS identified possible distortions and wide variability in the specialty mix for PE and malpractice (MP) RVUs for low volume services.[5]
- To address this, CMS proposes to use the most recent year of claims data to determine which codes are low volume for the coming year. For these codes, instead of assigning specialty mix based on the specialties reporting the code for the past three years, CMS instead will use the expected specialty based on a list created from the previous year's claims data.[6] The specialty list will be displayed as a part of the annual set of data files for review.

b. PE Inputs for Digital Imaging Services: Adding the PACS for More CPT Codes

- In the CY 2017 PFS final rule, CMS added a professional PACS workstation used to interpret digital images as a PE input for a series of CPT codes to address costs related to the use of film that had previously been incorporated as direct PE expenses for those services.
- In this year's Proposed Rule, CMS requests comment on whether use of the professional PACS workstation would be typical for 26 additional CPT codes submitted by stakeholders.[7]

c. Review of Standard Preservice Clinical Labor for 0-Day and 10-Day Global Services

- CPT codes for 0-day and 10-day global periods currently are assumed to have no preservice clinical staff time unless the specialty can provide evidence that preservice time is appropriate. However, CMS identified that 77 percent of reviewed codes deviate from this "standard" and include preservice clinical labor of some kind, suggesting that it is typical for clinical staff to prepare for procedures prior to the patient's arrival.
- CMS seeks comment on whether the standard preservice clinical labor time of zero minutes should be consistently applied for 0-day and 10-day global codes.[8]

d. More Clinical Labor Time for Obtaining Vital Signs

CMS proposes to assign five minutes of clinical labor time for all CPT codes that include the "obtain vital signs" task, an increase from three minutes under several

[5] 82 Fed. Reg. at 33,956.
[6] *Id.*
[7] *Id.* at 33,959.
[8] *Id.* at 33,960.

codes.[9] CMS also proposes to update the equipment times of these codes to match the changes in clinical labor time.

e. Streamlining Scope Equipment Codes

- CMS proposes to create a single scope equipment code for each of five categories of scopes, including ridged scopes, semi-rigid scopes, non-video flexible scopes, non-channeled flexible video scopes, and channeled flexible video scopes.[10] CMS also seeks comment on any pricing information regarding these five new scope categories.
- CMS also proposes two minor changes to PE inputs related to scopes, including adding an LED light source into the cost of the scope video system and increasing the price of the scope video system to $1,000 to cover the expense of miscellaneous small equipment costs.[11]

f. Setting a Minimum Indirect PE for Some Office-Based Services

- For certain face-to-face services provided in both the facility and non-facility setting, CMS proposes to set a minimum non-facility indirect PE RVU to better reflect the resources involved in furnishing those services.[12]
- CMS proposes to set this minimum value based on the indirect PE RVU to work RVU ratio for the most commonly furnished office-based, face-to-face service (CPT 99213) as a marker.

(2) Review of Malpractice RVUs

- Before CY 2016, MP RVUs were updated only once every five years, except in the case of new and revised codes. In CY 2016, CMS began conducting annual MP RVU updates to reflect changes in the mix of practitioners providing services and to adjust MP RVUs for risk, intensity and complexity, while retaining the five-year update to specialty-specific risk factors.
- In the Proposed Rule, CMS proposes to align the update of MP RVUs with the update of the MP Geographic Practice Cost Index (GPCI) every three years.[13] CMS proposes to use the most recent data for the proposed MP RVUs for CY 2018 and seeks comment on the methodologies and sources to improve the next update of MP premium data.

(3) Potentially Misvalued Codes

- CMS identified several codes as potentially misvalued and seeks comments on the potential value of those codes.

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[9] *Id.*
[10] *Id.* at 33,961.
[11] *Id.* at 33,962.
[12] *Id.* at 33,965.
[13] *Id.* at 33,965-66.

- Potentially misvalued codes would include:
    - 27279 (Athrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device);
    - 36901 – 36909, or codes newly created last year for dialysis vascular access;
    - 88184 and 88185 for flow cytometry; and
    - 99281 – 99385, which includes codes for emergency department visits for the evaluation and management of a patient.[14]
- CMS also seeks comments on the best approach for developing screens to identify potentially misvalued codes.[15]

(4) RVU Updates for Specific Procedures

As in previous years, CMS proposes updates to the RVUs for certain procedures, including the following proposals.

a. Radiation Therapy Planning (CPT codes 77261, 77262, 77263)[16]

CMS is proposing the RUC-recommended RVUs for these codes but expresses its concern about these RVUs given the decreased service times associated with them, which does not appear to be accounted for in the RUC proposals.[17] CMS is asking for comments on these valuations or whether an alternative would be preferable.

b. Superficial Radiation Treatment Planning and Management (HCPCS code GRRR1)[18]

- CMS notes that it had previously solicited comment on a change in language for this code that meant that more services were being bundled with the code that had been billed separately. The RUC had not evaluated whether these changes should change the valuation for these services. Due to an edit that is no longer active, E/M services billed with this code also are commonly denied payment by the Medicare Administrative Contractors (MACs).[19]
- Because of these issues, CMS is proposing separate payment for professional treatment planning and management tied to this code and to add physician work and work time tied to radiation management services. CMS proposes to adopt the RUC-recommended inputs for this code with some adjustments and to make some modifications to the supply items associated with this code. Finally, CMS is

[14] *Id.* at 33,977-78.
[15] *Id.* at 33,978.
[16] *Id*. at 34,002-03.
[17] *Id*. at 34,003.
[18] *Id*. at 34,012-13.
[19] *Id*. at 34,012.

proposing to include certain inputs related to radiation physics consultation in the code.[20]

c. *Chemotherapy Administration (CPT codes 96401, 96402, 96409, and 96411)*[21]

CMS notes that it identified these codes in the CY 2016 PFS proposed rule as high expenditure (Medicare allowed charges above $10 million). CMS is proposing the RUC-recommended work RVUs, equipment times, and direct PE inputs for these codes.[22]

d. *Photochemotherapy (CPT code 96910)*[23]

CMS notes that this code also appeared on high-expenditure screens and is proposing to refine the clinical labor time for some aspects of this code, proposing a new supply code and price for the sauna suit used with it, and proposing to adjust equipment times and clinical labor times included in the code.[24] CMS is seeking comment on its proposed updated values. CMS also proposes to replace the "Single patient discard bag, 400ml" supply code with "biohazard specimen transport bag" and asks for comment on whether this would be more appropriate for storing the sauna suit.[25]

e. *Photodynamic Therapy (CPT codes 96567, 96X73, and 96X74)*[26]

CMS stated that CPT code 96567 has been identified as potentially misvalued as it includes clinician time but no physician work. The CPT editorial panel also created two new codes, 96X73 and 96X74. CMS is proposing RUC-recommended work RVUs and PE inputs for these new codes and some refinements to equipment formulas. CMS also is proposing various prices for supply items for these codes.[27] CMS seeks comment in particular on the PE inputs and supply items for these codes.

f. *Tumor Immunohistochemistry (CPT codes 88360 and 88361)*[28]

CMS proposes to adopt the RUC-recommended work RVUs for these codes but also proposes to refine or remove the clinical labor time for them, as well as making proposals to refine equipment time. CMS seeks comment specifically on invoices for the DNA image analyzer equipment used as part of these procedures.[29]

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[20] *Id*. at 34,013.
[21] *Id*. at 34,007.
[22] *Id*.
[23] *Id*.
[24] *Id*.
[25] *Id*.
[26] *Id*. at 34,007-08.
[27] *Id*.
[28] *Id*. at 34,003.
[29] *Id*.

g. Cryoblation of Pulmonary Tumor (CPT codes 32998 and 32X99)[30]

CMS expresses its concern "about the descriptions of these codes and recommended valuations assuming th[at] imaging guidance is inherent in the procedures."[31] CMS proposes the RUC-recommended work RVUs and direct PE inputs for these codes and seeks comment on its proposal and suggested alternatives.[32]

(5) Solicitation of Comment on Guidelines for E/M Codes and Payment for Services for Individuals with Disabilities

a. E/M Code Guidelines

- CMS seeks comment on changes that it should make to update the existing guidelines for billing E/M codes. CMS suggests that it may begin by focusing on the history and physical exam components, as CMS believes that these guidelines are the most outdated.
- Specifically, CMS seeks comment on removing the documentation requirements for the history and physical exam for E/M at all levels as CMS believes that "medical decision-making and time are more significant factors in distinguishing visit levels, and that the need for extended histories and exams is being replaced by population-based screening and intervention, at least for some specialties."[33]
- CMS also notes that while it may in the long term update the "MDM" or Medical decision-making guidelines, it believes that in the near term "it may be possible to eliminate the current focus on details of history and physical exam, and allow MDM to serve as the key determinant in the E/M visit level." CMS seeks comment on this proposal, and how to update the MDM guidelines, and also "on whether CMS should leave it largely to the discretion of individual practitioners to what degree they should perform and document the history and physical exam."[34]

b. Valuation of Services for Individuals with Disabilities

CMS also notes its efforts to ensure that the coding and value of services accurately reflects the cost of services provided to individuals with disabilities and requests comment on how to further reduce the administrative burden for these and related services.[35]

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[30] *Id*. at 33,994-95.
[31] *Id*.
[32] *Id*. at 33,995.
[33] *Id*. at 34,079.
[34] *Id*.
[35] *Id*. at 34,078.

(6) *Payment Incentive for Transition from Traditional X-Ray Imaging to Digital Radiography and Other Imaging Services*

- The Proposed Rule would continue implementation of a provision of the Consolidated Appropriations Act of 2016 that reduced payment under the PFS for certain imaging services using older technologies.
- Effective January 1, 2018, CMS proposes to require use of a newly-established modifier on all claims for imaging services that are X-rays (including the X-ray component of a packaged service) taken using computed radiography technology. The modifier would be used to report specific services that are subject to payment reduction, and accurate use of the modifier would be subject to audit. The use of the modifier would result in a seven percent reduction for CYs 2018 through 2022 and a 10 percent reduction for CY 2023 and calendar years thereafter.[36]

(7) *Payment for DME Infusion Drugs*

- Section 5004(a) of the 21st Century Cures Act changed the payment methodology for DME infusion drugs from 95 percent of the 2003 Average Wholesaler Price (AWP) to payment based on Average Sales Price (ASP) under section 1847A of the Social Security Act (SSA).
- Accordingly, CMS proposes to limit its previous exception to ASP-based payments for DME infusion drugs to drugs that were furnished before January 1, 2017.[37]

(8) *Solicitation of Public Comments on Biosimilar Biological Product Payment Policy*

- In the CY 2016 PFS final rule, CMS finalized a proposal to provide payment for biosimilar biological products based on the ASP of all National Drug Codes assigned to the biosimilar biological products included within the same billing and payment code. This generally means that a single HCPCS code is used for biosimilar biological products that rely on a common reference product's biologics license application (BLA), and these products are grouped into the same payment calculation for the purposes of determining a single ASP payment limit.[38]
- Acknowledging continuing concerns regarding this already-implemented policy, CMS expresses interest in "assessing the effects of Medicare payment policy on this important portion of the Part B drug marketplace . . . , particularly for fostering a robust, and competitive marketplace and encouraging the innovation that is necessary to bring these products to the marketplace."[39] The agency also is interested in better understanding whether and how Medicare's biosimilar payment policy should account for innate

[36] *Id*. at 33,978.
[37] *Id.* at 34,089.
[38] 80 Fed. Reg. 70,886, 71,096-71,101 (Nov. 16, 2015), *available at* https://www.gpo.gov/fdsys/pkg/FR-2015-11-16/pdf/2015-28005.pdf; 82 Fed. Reg. at 34,090.
[39] 82 Fed. Reg. at 34,091.

differences in biological products, particularly when biosimilars are licensed for fewer than all indications for which the reference product is licensed, or when different biosimilars may be licensed for different subsets of indications for which the reference product is licensed.[40]

- The agency specifically seeks new or updated information on the effects of the current biosimilar policy based on experience within the U.S. marketplace, particularly market analyses or research articles that provide data and other information (from the U.S. and, as applicable, from more established markets in Europe) regarding the current economics of the biosimilar marketplace.
- The agency also seeks data that demonstrates how individual HCPCS codes could impact the biosimilar marketplace, including innovation, patient access, drug expenditures, and the overall number of products coming to market.
- Finally, CMS seeks public comment on other novel payment policies for biological products that would promote competition, increase access, and facilitate overall cost savings.[41]

(9) Reduced Payment for Off-Campus 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.[42]
- For CY 2018, CMS proposes to reduce the payment rates PBDs receive for non-excepted items and services by half, from 50 to 25 percent of the OPPS rates.[43]
- CMS states that it is concerned that paying 50 percent of the OPPS rate might result in payments for PBDs for non-excepted items and services that are greater than would otherwise be paid under the PFS in the non-facility setting.[44] This proposed rate is based on a comparison of payment rates for clinic and office visits under both payment systems. CMS requests comment on the proposed 25 percent rate and suggests that a 40 percent rate could be a potential middle ground.[45]
- CMS did not respond to comments on the interim final rule that established payment rates for these departments for 2017.

(10) Medicare Telehealth Services

Under the PFS, physicians may bill for certain telehealth services if the services are furnished by a physician or other authorized practitioner to an eligible individual in a telehealth originating site via

[40] *Id*. at 34,090-91.
[41] *Id*. at 34,091.
[42] 81 Fed. Reg. 79,562, 79,713 (Nov. 14, 2016).
[43] 82 Fed. Reg. at 33,982-83.
[44] *Id*. at 33,983.
[45] *Id.*

an interactive telecommunications system and if the services are on the list of approved Medicare telehealth services. When these conditions 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.

a. Proposed additions to telehealth codes

CMS proposes to add the following three services to the list of eligible CPT codes, having determined that these services are sufficiently similar to services currently on the approved telehealth list:

- HCPCS code G0296 (Counseling visit to discuss need for lung cancer screening using low dose CT scan (service is for eligibility determination and shared decision making));
- CPT 90839 (psychotherapy for crisis; first 60 minutes); and
- CPT 90840 (psychotherapy for crisis; each additional 30 minutes (list separately in addition to code for primary service)).

CPT codes 90839 and 90840 each would have the explicit condition of payment that the distant site practitioner be able to mobilize resources at the originating site to defuse the crisis and restore safety, when applicable.[46]

b. Proposed add-on services to currently included telehealth codes

CMS proposes to add the following four services as add-ons to services currently included on the telehealth list:

- CPT 90785 (interactive complexity (list separately in addition to the code for primary procedure));
- CPT 96160 (administration of patient-focused health risk assessment instrument with scoring and documentation, per standardized instrument);
- CPT 96161 (administration of caregiver-focused health risk assessment instrument for the benefit of the patient, with scoring and documentation, per standardized instrument)); and
- HCPCS G0506 (comprehensive assessment of and care planning for patients requiring chronic care management services (list separately in addition to primary monthly care management service)).

c. Other proposals

- CMS proposes to eliminate the required use of the GT modifier on professional claims for telehealth services because such claims already provide certification that the telehealth requirements have been satisfied via the submission of a valid place of service (POS) code.[47]
- CMS solicits comments regarding whether the agency should make separate payment for:

[46] *Id.* at 33,971-72.
[47] *Id*. at 33,975.

    - CPT codes that describe remote patient monitoring (e.g., CPT 99091 (collection and interpretation of physiologic data digitally stored and/or transmitted by patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time) or
    - CPT codes that describe extensive use of communications technology (e.g., CPT 99090 (analysis of clinical data stored in computers (e.g., ECGs, blood pressures, hematologic data)).
- More broadly, the agency solicits comments regarding ways that it might further expand access to telehealth services within its current statutory authority as well as to remote patient monitoring services.[48]

(11) AUCs for Advanced Diagnostic Imaging Services

- Section 218(b) of PAMA directed CMS to establish an AUC program that would make consultation of such 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. In the CY 2017 PFS rulemaking, CMS acknowledged that implementation would be delayed.
- In the 2016 and 2017 PFS rulemaking cycles, CMS implemented the first two stages of the AUC program by establishing a timeline and process for provider-led entities (PLEs) to become qualified to develop, modify, or endorse AUCs, and by defining the clinical decision support mechanisms (CDSMs) that clinicians may use to satisfy the requirement to report consultation of AUCs. CMS released a list of qualified CDSMs on its website at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/CDSM.html.
- In the Proposed Rule, CMS proposes to implement the third stage of the AUC program, which will require an ordering professional (OP) to consult AUCs through a qualifying CDSM when ordering an applicable imaging service and communicate information about the AUCs to the furnishing professional (FP), and will require the FP to report that information on claims for the imaging service furnished in an applicable setting.
- These requirements would take effect on January 1, 2019, meaning that applicable imaging services billed on or after that date would need to meet the AUC requirements as a condition of Medicare payment (under both the OPPS and the PFS). CMS proposes this delay to allow OPs and FPs to align with qualified CDSMs and to allow CDSMs to make changes to become more user-friendly and less burdensome.[49]
- Consistent with PAMA, FPs would be required to report the following with each claim for an applicable imaging service as a condition of Medicare payment:
    - Which qualified CDSM the OP consulted;
    - Whether the service ordered would adhere to specified applicable AUCs, would not adhere to applicable AUCs, or had no applicable AUCs; and

[48] *Id*. at 33,975-76.
[49] *Id.* at 34,093.

    - The National Provider Identifier (NPI) of the OP (if different from the FP).[50]
- Although CMS proposes to offer the option of satisfying the AUC consultation requirements by reporting that there were no applicable AUC for the advanced imaging service, CMS states that it expects this situation to be "limited in scope and number, and to decrease over time."[51]
- CMS proposes three new HCPCS level 3 G-codes to report AUC consultation. Ultimately CMS intends to provide a separate G-code for each qualified CDSM, but also proposes to provide a G-code for FPs to use if their chosen CDSM is newly qualified and does not yet have its own G-code for reporting AUC. CMS also proposes modifiers for these G-codes to reflect whether the service adhered to specified AUCs, did not adhere, or did not have applicable AUCs.[52]
- CMS proposes a voluntary reporting period to be available ahead of January 1, 2019, to allow clinicians to educate themselves and test operations before the AUC consultation requirement takes effect.[53] In the Quality Payment Program (QPP) Proposed Rule, CMS also proposes to give Merit-Based Incentive Payment System (MIPS) credit to OPs for consulting AUC using a qualified CDSM as a high-weight improvement activity for the performance period beginning January 1, 2018, to incentivize early adoption by motivated eligible physicians.[54]
- CMS also proposes changes to the hardship exceptions that would exempt certain OPs from the AUC consultation requirements.
    - OPs would be automatically exempt if they are exempt from the advancing care information performance category of the MIPS under the QPP, an exemption granted to certain clinicians based on, for example, lack of control over the availability of certified EHR technology or the lack of face-to-face patient interactions.[55]
    - There also would be a process for exemption of OPs who are not automatically exempted based on the MIPS exemption but who meet one of a number of specified hardship factors, e.g., lack of Internet connectivity or lack of control over the availability of EHR technology.[56]
- CMS does not make any proposals related to the fourth and final component that will impose a prior authorization requirement on advanced diagnostic imaging services furnished by certain outlier FPs, effective January 1, 2020, unless it is delayed by CMS.

(12) *Proposals related to the MSSP*

CMS proposes to refine the rules applicable to ACOs participating in the MSSP. Specifically, CMS proposes to:

[50] *Id.* at 34,093-94.
[51] *Id.* at 34,094.
[52] *Id.*
[53] *Id.*
[54] *Id.* at 34,095.
[55] *Id.*
[56] *Id.* at 34,095-96.

- Revise the methodology for assigning beneficiaries to an ACO for performance years beginning in CY 2019 to take into account utilization of services furnished by rural health clinics or federally qualified health centers;[57]
- Add three new chronic care management codes and behavioral health integration codes to the definition of primary care services used in assigning beneficiaries to an ACO;[58] and
- Streamline the process for submitting an initial MSSP application and for using the Skilled Nursing Facility (SNF) 3-Day Rule Waiver.[59]

(13) MACRA Patient Relationship Categories and Codes

MACRA requires CMS to create classification codes for care episode and patient condition groups for various purposes including attribution of patients and care episodes to clinicians to assess the cost of care under the QPP. CMS posted a draft list of patient relationship categories in April 2016 and, after considering public comment, posted an operational list of patient relationship categories on May 17, 2017, at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-AssessmentInstruments/Value-Based-Programs/MACRA-MIPS-and-APMs/CMS-Patient-RelationshipCategories-and-Codes.pdf.[60] These categories are:

- Continuous/broad services
- Continuous/focused services
- Episodic/broad services
- Episodic/focused services
- Only as ordered by another clinician

MACRA requires CMS to make annual revisions to the list, as appropriate, and CMS requests comment on potential revisions to be made by November 1, 2018.[61]

MACRA also requires clinicians to report a patient relationship category for all claims for items and services on or after January 1, 2018. CMS proposes to create HCPCS code modifiers to enable this reporting. CMS proposes that Medicare claims on or after January 1, 2018, should include the applicable modifier, but that reporting of the modifiers would not be a condition of payment for an initial period while clinicians gain familiarity with the system.[62]

(14) Proposals Related to the PQRS, EHR Incentive, and VBPM

CMS proposes only minor changes to the PQRS, EHR incentive, and VBPM for CY 2018, which will be based on eligible professionals' quality and cost performance in CY 2016. All three programs will be replaced by the QPP in CY 2019.[63]

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[57] *Id*. at 34,108-09.
[58] *Id*. at 34,110.
[59] *Id*. at 34,115-18.
[60] *Id.* at 34,128.
[61] *Id.* at 34,128-29.
[62] *Id.* at 34,129.
[63] *Id*. at 34,124.

- With respect to the PQRS, CMS proposes to reduce the minimum quality reporting requirement from nine measures to six measures and eliminate the requirement that the reported measures cover three National Quality Strategy domains.[64]
- With respect to the EHR incentive, CMS proposes an identical change in the minimum quality reporting requirement.[65]
- With respect to the VBPM, CMS proposes to:
    - Reduce the automatic negative adjustment for professionals who fail to meet minimum quality reporting requirements from -4.0% to -2.0% for groups of 10 or more clinicians, and from -2.0% to -1.0% for groups of two to nine clinicians and solo practitioners;[66]
    - Hold harmless from any negative adjustment all physician groups and solo practitioners who met minimum quality reporting requirements;[67] and
    - Limit the maximum positive adjustment to two times the adjustment factor for all physician groups and solo practitioners.[68]

(15) *Proposals related to the MDPP Expanded Model*

- CMS makes a number of proposals to expand the MDPP model, a clinical intervention designed to prevent individuals diagnosed with pre-diabetes from progressing to type 2 diabetes, through a combination of core educational sessions and follow-up meetings between providers and pre-diabetic patients.
    - CMS proposes to delay the start date for the expanded MDPP from January 1, 2018, to April 1, 2018, to give organizations time to enroll in Medicare before they begin furnishing and billing for MDPP services.[69]
    - CMS proposes revisions to existing policies and the addition of new policies necessary for suppliers to begin furnishing MDPP services beginning on April 1, 2018, including the MDPP payment structure, enrollment requirements, and supplier compliance standards designed to ensure program integrity. Specifically, CMS proposes to:
        - Remove, revise, and add a number of definitions that would more precisely define the parameters of the MDPP expanded model.[70]
        - Establish a total MDPP services period of up to three years, including one year of core sessions and core maintenance sessions, followed by two years of ongoing maintenance sessions.[71]
        - Clarify a number of eligibility criteria for MDPP beneficiaries, including clarifying that an individual who has started receiving MDPP services will lose

[64] *Id.* at 34,099.
[65] *Id.* at 34,104.
[66] *Id.* at 34,125.
[67] *Id.*
[68] *Id.*
[69] *Id.* at 34,131.
[70] *Id.* at 34,131-32; 34,139-40; 34,153-54; 34,167.
[71] *Id.* at 34,132.

eligibility if he or she is diagnosed with end-stage renal disease (ESRD), but an individual who develops diabetes during the MDPP services will remain eligible for MDPP services.[72]

- Establish an MDPP payment structure that seeks to incentivize MDPP suppliers to prioritize the achievement and maintenance of weight loss, while providing a balance between performance-based payments related to weight loss and MDPP session attendance.[73] CMS proposes a maximum total performance amount per beneficiary for the full set of MDPP services of $810.[74]
- Establish 19 unique HCPCS G-codes for MDPP suppliers to submit claims showing that all the requirements for billing the codes have been met. CMS notes that certain G-codes may be paid only once each in a beneficiary's lifetime. If two MDPP suppliers meet all requirements for billing one of these HCPCS G-codes, CMS would pay the first valid claim received and deny the second.[75]
- Establish an MDPP interim preliminary recognition standard to permit organizations with demonstrated capacity to furnish MDPP services to enroll in Medicare as of April 1, 2018, and prior to achieving the full Centers for Disease Control and Prevention (CDC) recognition that is required to provide MDPP services.[76]
- Establish and require the use of a new enrollment application specific to MDPP suppliers that will require: (1) the NPI, first name, last name, date of birth, and Social Security Number of all coaches who will furnish services on the supplier's behalf; and (2) a list of all supplier administrative locations.[77] The proposed enrollment application fee is $560 for CY 2017, and the application fee will be adjusted annually.[78]
- Establish policies related to MDPP supplier engagement incentives that are offered to MDPP beneficiaries, imposing stricter guidelines on high-value and technology-related incentives.[79]

(16) Request for Information (RFI) on CMS Flexibilities and Efficiencies

The Proposed Rule includes a broad RFI on changes that CMS might make to the Medicare program to reduce unnecessary burdens for providers, physicians, and patients; improve outcomes; improve the quality of care; and decrease costs.[80] CMS solicits suggestions on regulatory, sub-

[72] *Id.* at 34,133.
[73] *Id.* at 34,137-55.
[74] *Id.* at 34,137.
[75] *Id.* at 34,149-50.
[76] *Id.*at 34,156.
[77] *Id.* at 34,158.
[78] *Id.* at 34,133.
[79] *Id.* at 34,166-72.
[80] *Id.* at 34,172.

regulatory, policy, practice, and procedural changes to accomplish these goals, and offers examples including payment system redesign, elimination or streamlining of reporting, monitoring, and documentation requirements, operational flexibility, feedback mechanisms and data sharing that would enhance patient care, and support of the physician-patient relationship in care delivery. CMS notes that it is particularly interested in ideas for incentivizing organizations and professionals to provide screening, assessment and evidence-based treatment for individuals with opioid use disorders and other substance abuse disorders. Proposals should be clear and concise and include data and specific examples that could be implemented within the law.

(17) 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 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 four ICRs[81]:

- The MDPP Expanded Model. CMS states that the MDPP Expanded Model is an Innovation Center model test and expansion and, as such, is exempt from the provisions of the PRA under Section 1115A(d)(3) of the SSA;
- The Physician Quality Reporting System. CMS notes that although the Proposed Rule would revise the PQRS reporting criteria for the 2016 reporting period to avoid the 2018 payment adjustment, the agency is not proposing to accept additional data for the 2016 reporting period and, hence, the Proposed Rule does not set forth any new or revised burden or requirements that trigger the PRA's requirements.
- Appropriate Use Criteria for Advanced Diagnostic Imaging Services. The agency estimates the following burdens associated with this ICR:
    - In connection with the requirement that OPs consult AUCs through a qualified CDSM for applicable imaging services ordered on or after January 1, 2019, the agency offers burden estimates for a one-time burden associated with a potential six-month voluntary consulting period and a mandatory burden beginning January 1, 2019.
    - In connection with the requirement that FPs report certain information on Medicare claims for advanced diagnostic imaging services ordered on or after January 1, 2019, the agency offers burden estimates for a one-time burden associated with a potential six-month voluntary reporting period and a mandatory burden in connection with the annual reporting requirement beginning January 1, 2019.
- The Medicare Shared Savings Program. The agency states that the MSSP is not subject to the PRA under Section 1899(e) of the SSA.

[81] *Id*. at 34,173-74.

Comparison of Proposed 2018 and Q3 2017 Physician Fee Schedule Payment Rates for Drug Administration Services

CPT Code	Description	CY 2018 Proposed Payment		Q3 CY 2017 Payment		% Change	
		Non Facility	Facility	Non Facility	Facility	Non Facility	Facility
96360	Hydration iv infusion init	$ 47.51	N/A	$ 58.50	N/A	-18.79%	N/A
96361	Hydrate iv infusion add-on	$ 14.04	N/A	$ 15.43	N/A	-9.05%	N/A
96365	Ther/proph/diag iv inf init	$ 73.06	N/A	$ 69.98	N/A	4.40%	N/A
96366	Ther/proph/diag iv inf addon	$ 22.31	N/A	$ 19.02	N/A	17.31%	N/A
96367	Tx/proph/dg addl seq iv inf	$ 31.31	N/A	$ 31.22	N/A	0.28%	N/A
96368	Ther/diag concurrent inf	$ 21.23	N/A	$ 20.82	N/A	2.01%	N/A
96369	Sc ther infusion up to 1 hr	$174.91	N/A	$180.52	N/A	-3.11%	N/A
96370	Sc ther infusion addl hr	$ 15.84	N/A	$ 15.43	N/A	2.62%	N/A
96371	Sc ther infusion reset pump	$ 63.70	N/A	$ 69.27	N/A	-8.03%	N/A
96372	Ther/proph/diag inj sc/im	$ 20.87	N/A	$ 25.84	N/A	-19.22%	N/A
96373	Ther/proph/diag inj ia	$ 19.07	N/A	$ 19.38	N/A	-1.57%	N/A
96374	Ther/proph/diag inj iv push	$ 47.15	N/A	$ 58.14	N/A	-18.91%	N/A
96375	Tx/pro/dx inj new drug addon	$ 18.36	N/A	$ 22.61	N/A	-18.82%	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	$ 80.62	N/A	$ 75.37	N/A	6.97%	N/A
96402	Chemo hormon antineopl sq/im	$ 29.15	N/A	$ 33.02	N/A	-11.71%	N/A
96405	Chemo intralesional up to 7	$ 82.78	$ 31.31	$ 82.90	$ 30.86	-0.15%	1.45%
96406	Chemo intralesional over 7	$121.65	$ 48.59	$121.30	$ 47.37	0.28%	2.56%
96409	Chemo iv push sngl drug	$110.49	N/A	$112.33	N/A	-1.64%	N/A
96411	Chemo iv push addl drug	$ 59.74	N/A	$ 63.16	N/A	-5.41%	N/A
96413	Chemo iv infusion 1 hr	$143.60	N/A	$139.61	N/A	2.86%	N/A
96415	Chemo iv infusion addl hr	$ 30.95	N/A	$ 28.71	N/A	7.80%	N/A
96416	Chemo prolong infuse w/pump	$146.12	N/A	$141.04	N/A	3.60%	N/A
96417	Chemo iv infus each addl seq	$ 69.10	N/A	$ 66.04	N/A	4.64%	N/A
96420	Chemo ia push tecnique	$106.53	N/A	$107.67	N/A	-1.05%	N/A
96422	Chemo ia infusion up to 1 hr	$175.27	N/A	$187.34	N/A	-6.44%	N/A
96423	Chemo ia infuse each addl hr	$ 84.58	N/A	$ 76.08	N/A	11.16%	N/A
96425	Chemotherapy infusion method	$185.35	N/A	$185.54	N/A	-0.10%	N/A
96440	Chemotherapy intracavitary	$793.95	$126.33	$789.91	$128.84	0.51%	-1.95%
96446	Chemotx admn prtl cavity	$209.10	$ 28.79	$205.64	$ 29.43	1.68%	-2.16%
96450	Chemotherapy into cns	$186.43	$ 82.42	$184.11	$ 82.54	1.26%	-0.15%

96521	Refill/maint portable pump	$148.64	N/A	$141.76	N/A	4.85%	N/A
96522	Refill/maint pump/resvr syst	$120.21	N/A	$115.56	N/A	4.02%	N/A
96523	Irrig drug delivery device	$ 28.07	N/A	$ 25.12	N/A	11.74%	N/A
96542	Chemotherapy injection	$134.96	$ 43.19	$125.97	$ 43.07	7.14%	0.28%