Hogan Lovells

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Medicare Hospital Outpatient Prospective Payment System

PROPOSED RULE FOR CALENDAR YEAR 2019

August 8, 2018

OPPS Proposed Rule for CY 2019

QUICK FACTS

WHO?

Centers for Medicare & Medicaid (CMS)

WHAT?

Hospital Outpatient Prospective Payment System (OPPS), Ambulatory Surgical Center (ASC) Payment System, and Quality Reporting Programs Proposed Rule for calendar year (CY) 2019

CMS-1695-P
83 Fed. Reg. 37,046 (July 31, 2018)

WHERE?

- Nationwide

WHEN?

- Released on July 25, 2018
- Published in Federal Register on July 31, 2018
- Comments due September 24, 2018

37046 Federal Register / Vol. 83, No. 147 / Tuesday, July 31, 2018 / Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 416 and 419

[CMS–1695–P]

RIN 0938–AT30

Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for CY 2019 to implement changes arising from our continuing experience with these systems. In this proposed rule, we describe the proposed changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. In addition, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program. The proposed rule also includes requests for information on promoting interoperability and electronic health care information exchange, improving beneficiary access to provider and supplier charge information, and leveraging the authority for the Competitive Acquisition Program (CAP) for Part B drugs and biologicals for a potential CMS Innovation Center model. In addition, we are proposing to modify the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey measure under the Hospital Inpatient Quality Reporting (IQR) Program by removing the Communication about Pain questions.

DATES: To be assured consideration, comments on this proposed rule must be received at one of the addresses provided in the **ADDRESSES** section no later than 5 p.m. EST on September 24, 2018.

ADDRESSES: In commenting, please refer to file code CMS–1695–P when commenting on the issues in this proposed rule. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may (and we encourage you to) submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the ''submit a comment'' tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1695–P, P.O. Box 8013, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments via express or overnight mail to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1695–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call the telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: (We note that public comments must be submitted through one of the four channels outlined in the **ADDRESSES** section above. Comments may not be submitted via email.)

340B Drug Payment Policy to Nonexcepted Off-Campus Departments of a Hospital, contact Juan Cortes via email *Juan.Cortes@cms.hhs.gov* or at 410–786–4325.

Advisory Panel on Hospital Outpatient Payment (HOP Panel), contact the HOP Panel mailbox at *APCPanel@cms.hhs.gov.*

Ambulatory Surgical Center (ASC) Payment System, contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov* or at 410–786–4142.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Administration, Validation, and Reconsideration Issues, contact Anita Bhatia via email *Anita.Bhatia@cms.hhs.gov* or at 410–786–7236.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Measures, contact Vinitha Meyyur via email *Vinitha.Meyyur@cms.hhs.gov* or at 410–786–8819.

Blood and Blood Products, contact Joshua McFeeters via email *Joshua.McFeeters@cms.hhs.gov* or at 410–786–9732.

Cancer Hospital Payments, contact Scott Talaga via email *Scott.Talaga@cms.hhs.gov* or at 410–786–4142.

CMS Web Posting of the OPPS and ASC Payment Files, contact Chuck Braver via email *Chuck.Braver@cms.hhs.gov* or at 410–786–6719.

CPT Codes, contact Marjorie Baldo via email *Marjorie.Baldo@cms.hhs.gov* or at 410–786–4617.

Collecting Data on Services Furnished in Off-Campus Provider-Based Emergency Departments, contact Twi Jackson via email *Twi.Jackson@cms.hhs.gov* or at 410–786–1159.

Comment Solicitation to Control for Unnecessary Increases in Volume of Outpatient Services, contact Elise Barringer via email *Elise.Barringer@cms.hhs.gov* or at 410–786–9222.

Composite APCs (Low Dose Brachytherapy and Multiple Imaging), contact Elise Barringer via email *Elise.Barringer@cms.hhs.gov* or at 410–786–9222.

Comprehensive APCs (C–APCs), contact Lela Strong-Holloway via email *Lela.Strong@cms.hhs.gov* or at 410–786–3213.

Expansion of Clinical Families of Services at Excepted Off-Campus Departments of a Provider, contact Juan Cortes via email *Juan.Cortes@cms.hhs.gov* or at 410–786–4325.

Hospital Outpatient Quality Reporting (OQR) Program Administration, Validation, and Reconsideration Issues, contact Anita Bhatia via email *Anita.Bhatia@cms.hhs.gov* or at 410–786–7236.

Hospital Outpatient Quality Reporting (OQR) Program Measures, contact Vinitha Meyyur via email *Vinitha.Meyyur@cms.hhs.gov* or at 410–786–8819.

Hospital Outpatient Visits (Emergency Department Visits and Critical Care Visits), contact Twi Jackson via email

OPPS Proposed Rule for CY 2019

Includes Three Requests for Information (RFI)

- Leveraging the authority for the Competitive Acquisition Program (CAP) for Part B drugs for a potential Center for Medicare & Medicaid Innovation (CMMI) model
  - Test whether allowing private-sector model vendors to enter into and administer value-based arrangements with manufacturers of separately payable Medicare Part B drugs improves beneficiary access and quality of care while reducing expenditures
  - Explore former CAP-like or Medicare Payment Advisory Commission (MedPAC) Drug Value Program (DVP) approach where providers and suppliers purchase and receive drugs through vendor pricing arrangements
- Price transparency: improving beneficiary access to provider and supplier charge information
- 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

OPPS Proposed Rule for CY 2019

Highlights

- 1.25% projected update for 2019
  - market basket increase of 2.8%
  - minus 0.8% productivity adjustment
  - minus 0.75% adjustment required by the Affordable Care Act (ACA)
- 2% payment reduction for hospitals that fail to report quality data
- Total Medicare payments to OPPS providers proposed to increase by approximately $4.9 billion to approximately $74.6 billion
- Addenda available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1695-P.html.

OPPS Proposed Rule for CY 2019

What is proposed to stay the same…

Policies that are Proposed to Remain the Same

What is proposed to stay the same. . .

- Payment at Average Sales Price (ASP)+6% for drugs, biologicals, and radiopharmaceuticals with pass-through status
- Payment at ASP+6% for separately payable drugs, biologicals, and therapeutic radiopharmaceuticals without pass-through status *if not purchased under the 340B drug discount program*
- Payment for blood and blood products using the blood-specific cost-to-charge ratio (CCR) methodology
- An additional payment of $10 for radioisotopes derived from non-highly enriched uranium (non-HEU) sources
- Estimation of outlier payments to be 1% of aggregate total OPPS payments

Proposed Payment for Drugs, Biologicals, and Radiopharmaceuticals

What is proposed to stay the same. . .

- Drugs with pass-through status paid at ASP+6%, as required by statute
  - Pass-through status continues for 49 drugs
  - Pass-through status expires for 23 drugs
- Separately payable drugs, biologicals, therapeutic radiopharmaceuticals, and clotting factors not purchased under the 340B drug discount program also paid at ASP+6%
  - CMS proposes to continue to pay the "statutory default" amount as drug acquisition cost data are not available
  - Statutory default sets reimbursement at rate for drugs administered in the physician office setting
- CMS is proposing to continue to pay for biosimilar biological products based on the payment allowance of the product as determined under Social Security Act § 1847A
  - (100% of the biosimilar's ASP) + (6% of the reference product's ASP) when the product has pass-through status
- Blood clotting factors continue to be paid at ASP+6% plus an updated furnishing fee
- CMS does not propose any changes to the Comprehensive APC (C-APC) payment methodology, other than to exclude procedures assigned to New Technology APCs from being packaged

Proposed Payment for Drugs, Biologicals, and Radiopharmaceuticals

Drugs with continuing pass-through status

- Pass-through status would continue for 49 drugs

CY 2019 HCPCS CODE	CY 2019 LONG DESCRIPTOR
A9586	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries
A9587	Gallium ga-68, dotatate, diagnostic, 0.1 millicurie
A9588	Fluciclovine f-18, diagnostic, 1 millicurie
C9014	Injection, cerliponase alfa, 1 mg
C9015	Injection, c-1 esterase inhibitor (human), Haegarda, 10 units
C9016	Injection, triptorelin extended release, 3.75 mg
C9024	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine
C9028	Injection, inotuzumab ozogamicin, 0.1 mg
C9029	Injection, guselkumab, 1 mg
C9030	Injection, copanlisib, 1 mg
C9031	Lutetium Lu 177, dotatate, therapeutic, 1 mCi
C9032	Injection, voretigene neparvovec-rzyl, 1 billion vector genome
C9447	Injection, phenylephrine and ketorolac, 4 ml vial
C9462	Injection, delafloxacin, 1 mg
C9463	Injection, aprepitant, 1 mg
C9465	Hyaluronan or derivative, Durolane, for intra-articular injection, per dose

CY 2019 HCPCS CODE	CY 2019 LONG DESCRIPTOR
C9466	Injection, benralizumab, 1 mg
C9467	Injection, rituximab and hyaluronidase, 10 mg
C9468	Injection, factor ix (antihemophilic factor, recombinant), glycopegylated, Rebinyn, 1 i.u.
C9469	Injection, triamcinolone acetonide, preservative-free, ext. release, microsphere formulation, 1 mg
C9488	Injection, conivaptan hydrochloride, 1 mg
C9492	Injection, durvalumab, 10 mg
C9493	Injection, edaravone, 1 mg
J0565	Injection, bezlotoxumab, 10 mg
J0570	Buprenorphine implant, 74.2 mg
J0606	Injection, etelcalcetide, 0.1 mg
J1428	Injection, eteplirsen, 10 mg
J1627	Injection, granisetron extended release, 0.1 mg
J2326	Injection, nusinersen, 0.1 mg
J2350	Injection, ocrelizumab, 1 mg
J3358	Ustekinumab, for Intravenous Injection, 1 mg
J7179	Injection, von willebrand factor (recombinant), (vonvendi)
J7210	Injection, factor viii, (antihemophilic factor, recombinant), (afstyla), 1 i.u.

CY 2019 HCPCS CODE	CY 2019 LONG DESCRIPTOR
J7328	Hyaluronan or derivative, gelsyn-3, for intra-articular injection, 0.1 mg
J7345	Aminolevulinic acid hcl for topical administration, 10% gel, 10 mg
J9023	Injection, avelumab, 10 mg
J9034	Injection, bendamustine hcl (Bendeka), 1 mg
J9203	Injection, gemtuzumab ozogamicin, 0.1 mg
J9285	Injection, olaratumab, 10 mg
Q2040	Tisagenlecleucel, up to 250 million car-positive viable t cells
Q2041	Axicabtagene Ciloleucel, up to 200 Million Autologous AntiCD19 CAR T
Q4172	PuraPly, and PuraPly Antimicrobial, any type, per square centimeter
Q5103	Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg
Q5104	Injection, infliximab-abda, biosimilar, (renflexis), 10 mg
Q9950	Injection, sulfur hexafluoride lipid microsphere, per ml
Q9991	Injection, buprenorphine ext. release), less than or equal to 100 mg
Q9992	Injection, buprenorphine ext. release, greater than 100 mg
Q9993	Injection, rolapitant, 0.5 mg
Q9994	Injection, emicizumab-kxwh, 0.5 mg

HCPCS = Healthcare Common Procedure Coding System

Proposed Payment for Drugs, Biologicals, and Radiopharmaceuticals

Drugs with expiring pass-through status

- Pass-through status would expire for 23 drugs

CY 2019 HCPCS CODE	CY 2019 LONG DESCRIPTOR
A9515	Choline C 11, diagnostic, per study dose
C9460	Injection, cangrelor, 1 mg
C9482	Injection, sotalol hydrochloride, 1 mg
J1942	Injection, aripiprazole lauroxil, 1 mg
J2182	Injection, mepolizumab, 1 mg
J2786	Injection, reslizumab, 1 mg
J2840	Injection, sebelipase alfa, 1 mg
J7202	Injection, Factor IX, albumin fusion protein (recombinant), Idelvion, 1 i.u.
J7207	Injection, Factor VIII (antihemophilic factor, recombinant) PEGylated, 1 I.U.
J7209	Injection, Factor VIII (antihemophilic factor, recombinant) (Nuwiq), per i.u
J7322	Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg
J7342	Instillation, ciprofloxacin otic suspension, 6 mg

CY 2019 HCPCS CODE	CY 2019 LONG DESCRIPTOR
J7503	Tacrolimus, extended release, (envarsus xr), oral, 0.25 mg
J9022	Injection, atezolizumab, 10 mg
J9145	Injection, daratumumab, 10 mg
J9176	Injection, elotuzumab, 1 mg
J9205	Injection, irinotecan liposome, 1 mg
J9295	Injection, necitumumab, 1 mg
J9325	Injection, talimogene laherparepvec, 1 million plaque forming units (PFU)
J9352	Injection, trabectedin, 0.1 mg
Q5101	Injection, filgrastim-sndz, biosimilar, (zarxio), 1 microgram
Q9982	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries
Q9983	Florbetaben F18, diagnostic, per study dose, up to 8.1 millicuries

OPPS Proposed Rule for CY 2019
What is proposed to change…

Proposed Policy Changes for 2019

"What is proposed to change…"

- Reduce payment to non-excepted off-campus provider-based departments (PBDs) for separately payable, non-pass through drugs purchased under the 340B Drug Discount Program
- Reduce payment rates for certain drugs and biologicals without pass-through that are not packaged and are paid based on wholesale acquisition cost (WAC) to WAC+3% (from WAC+6%)
- Increase drug packaging threshold from $120 to $125
- Revisions to drug administration payment rates
- Payment for CAR T therapies and related services
- Modify/Expand packaging policies
- Device intensive policy changes
- Revisions to radiation oncology payment rates
- Reduce payments for clinic visits and service line expansions at excepted off-campus PBDs to equal the payment rate for non-excepted off-campus PBDs
- Update Hospital Outpatient Quality Reporting (OQR) Program measures

Payment for 340B Drugs

"What is proposed to change…"

- Last year, CMS reduced reimbursement for separately-payable drugs without pass-through status that are purchased under the 340B drug discount program to ASP-22.5% instead of ASP+6%
- For CY 2019, CMS proposes also to apply the ASP–22.5% payment rate for separately-payable drugs without pass-through status that are purchased under the 340B drug discount program to non-excepted off-campus departments of hospitals
  - CMS did not apply the 340B cut to these sites in 2018 because they are paid under the Physician Fee Schedule (PFS), not the OPPS
  - For 2019, CMS asserts that it can apply the reduction because the special version of the PFS used for these sites is based on the OPPS
- CMS also proposes to pay nonpass-through biosimilars acquired under the 340B Program at ASP-22.5% of the biosimilar's ASP instead of the (biosimilar's ASP)-(22.5% of the reference product's ASP)

Payment for Certain Drugs Paid Based on WAC

"What is proposed to change…"

- Starting in CY 2019, CMS proposes to pay separately payable drugs and biological products that do not have pass-through payment status and are not acquired under the 340B Program at WAC+3% (instead of WAC+6%)
- This payment reduction would affect drugs or biologicals during the initial sales period, where payment is based on WAC (because there is not sufficient claims data to calculate ASP)
- For drugs and biologicals acquired under the 340B Program, the 340B Program rate would apply instead

Proposed Payment for Non Pass-Through Drugs, Biologicals, and Radiopharmaceuticals

"What is proposed to change…"

- CMS proposes to increase packaging threshold from $120 to $125 per day
- "Policy packaged" regardless of cost:

Diagnostic radiopharmaceuticals	**Contrast agents**	**Stress agents**
Anesthesia drugs	**Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure**	**Drugs and biologicals that function as supplies when used in a surgical procedure**

Proposed OPPS Drug Administration Rates for CY 2019

Facts

51% — For CY 2019, approximately 51% of the drug administration rates are **proposed to increase**

1.14% to 3.01% — The range of payment **increases** among codes with increasing rates

-1.68% to -2.17% — The payment **decrease** among codes with decreasing rates

CPT* Code	Short Descriptor	2019 Proposed Payment Rate	2018 Payment Rate	Change 2019-2018
90471	Immunization admin	$59.95	$58.20	3.01%
90473	Immune admin oral/nasal	$59.95	$58.20	3.01%
96360	Hydration iv infusion init	$187.87	$191.08	-1.68%
96361	Hydrate iv infusion add-on	$37.89	$37.03	2.32%
96365	Ther/proph/diag iv inf init	$187.87	$191.08	-1.68%
96366	Ther/proph/diag iv inf addon	$37.89	$37.03	2.32%
96367	Tx/proph/dg addl seq iv inf	$59.95	$58.20	3.01%
96369	Sc ther infusion up to 1 hr	$187.87	$191.08	-1.68%
96370	Sc ther infusion addl hr	$37.89	$37.03	2.32%
96371	Sc ther infusion reset pump	$59.95	$58.20	3.01%
96372	Ther/proph/diag inj sc/im	$59.95	$58.20	3.01%
96373	Ther/proph/diag inj ia	$187.87	$191.08	-1.68%
96374	Ther/proph/diag inj iv push	$187.87	$191.08	-1.68%
96375	Tx/pro/dx inj new drug addon	$37.89	$37.03	2.32%
96379	Ther/prop/diag inj/inf proc	$37.89	$37.03	2.32%
96401	Chemo anti-neopl sq/im	$59.95	$58.20	3.01%
96402	Chemo hormon antineopl sq/im	$59.95	$58.20	3.01%
96405	Chemo intralesional up to 7	$59.95	$58.20	3.01%
96406	Chemo intralesional over 7	$187.87	$191.08	-1.68%
96409	Chemo iv push sngl drug	$187.87	$191.08	-1.68%
96411	Chemo iv push addl drug	$59.95	$58.20	3.01%
96413	Chemo iv infusion 1 hr	$291.09	$297.54	-2.17%
96415	Chemo iv infusion addl hr	$59.95	$58.20	3.01%
96416	Chemo prolong infuse w/pump	$291.09	$297.54	-2.17%
96417	Chemo iv infus each addl seq	$59.95	$58.20	3.01%
96420	Chemo ia push tecnique	$291.09	$297.54	-2.17%
96422	Chemo ia infusion up to 1 hr	$187.87	$191.08	-1.68%
96423	Chemo ia infuse each addl hr	$37.89	$37.03	2.32%
96425	Chemotherapy infusion method	$291.09	$297.54	-2.17%
96440	Chemotherapy intracavitary	$291.09	$297.54	-2.17%
96446	Chemotx admn prtl cavity	$291.09	$297.54	-2.17%
96450	Chemotherapy into cns	$291.09	$297.54	-2.17%
96521	Refill/maint portable pump	$187.87	$191.08	-1.68%
96522	Refill/maint pump/resvr syst	$187.87	$191.08	-1.68%
96523	Irrig drug delivery device	$56.6	$55.96	1.14%
96542	Chemotherapy injection	$187.87	$191.08	-1.68%
96549	Chemotherapy unspecified	$37.89	$37.03	2.32%

Proposed Payment for CAR T Therapies and Related Services

- The AMA created four new Category III codes services related to CAR T therapies, effective January 1, 2019
  - CMS proposes not to make these codes payable under the OPPS, however; CMS proposes to assign these codes status indicator (SI) "B", which means that an alternate code may be available that is recognized by OPPS
  - CMS does not discuss the codes in the proposed rule, and more guidance will be needed on how to bill for these services
- The two CAR T therapies on the market, Kymriah and Yescarta, are proposed to continue to have pass-through status (SI G)

Code	Short Descriptor	SI	APC	Payment Rate
Q2040	Tisagenlecleucel car-pos t	G	9081	$500,838.643
Q2041	Axicabtagene ciloleucel car+	G	9035	$395,380.000
05X1T	Blood-derived T lymphocyte harvesting, for development of genetically modified autologous chimeric antigen receptor CAR-T cells, per day	B	N/A	N/A
05X2T	Blood-derived T lymphocyte preparation for transportation (eg, cryopreservation, storage)	B	N/A	N/A
05X3T	Receipt and preparation of CAR-T cells for administration	B	N/A	N/A
05X4T	CAR-T cell administration, autologous	B	N/A	N/A

Revised Thresholds for High/Low Cost Status for Skin Substitutes

"What is proposed to change…"

- In 2014, CMS began unconditionally packaging skin substitutes into their associated surgical procedures under the policy that they function as supplies when used in a surgical procedure
- For 2019, CMS proposes to determine high/low cost status for each skin substitute product based on a weighted average mean unit cost (MUC) threshold of $49 per cm^2 (currently $47) and a per day cost (PDC) threshold of $895 (currently $755)
- Based on stakeholder concern, CMS proposes to continue to assign products that are in the high cost group in CY 2018 to the high cost group in CY 2019, regardless of whether they exceed or fall below the CY 2019 MUC or PDC threshold

Revised Thresholds for High/Low Cost Status for Skin Substitutes

"What is proposed to change…"

- CMS also seeks public comment on four possible methodologies related to the payment of skin substitutes that are intended to address concerns about significant fluctuations in the MUC and PDC thresholds from year to year.
- CMS will consider comments as it develops a proposal for CY 2020.
- CMS requests comments on the following methodologies:
  - Lump-Sum "episode-based" payment for a wound care episode
  - Eliminate the high/low cost categories for skin substitutes and only have one payment category and set of procedure codes for all skin substitute products
  - Allow for payment of current add-on codes or create additional procedure codes to pay for skin graft services between 26 cm^2 and 99 cm^2 and substantially over 100 cm^2
  - Maintain the high/low cost categories but change the assignment thresholds

Modify/Expand Packaging Policies

"What is proposed to change…"

Low Volume Procedures Assigned to New Technology APCs

- CMS proposes to establish a new payment methodology for services assigned to New Technology APCs with fewer than 100 claims. CMS would use up to 4 years of claims data to establish a payment rate for each applicable service - both to assign a service to a New Technology APC and ultimately to assign it to a regular APC
- CMS would continue its current policy of establishing payment for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims based on the median cost instead of the geometric mean cost
- No procedures for CY 2019 that would be subject to this policy

Modify/Expand Packaging Policies

"What is proposed to change…"

- CMS proposes to recalibrate relative payment weights for each APC based on claims and cost report data for hospital outpatient department (HOPD) services, using the most recent available data
- CMS proposes to calculate APC relative weight scales by dividing the CY 2018 estimated aggregate weight by the unscaled CY 2019 estimated aggregate weight and to adjust the estimated CY 2019 unscaled relative payment weights by a proposed weight scalar (i.e., multiplier) of 1.4553 to ensure budget neutrality
- CMS proposes to exclude payment for any procedure that is assigned to a New Technology APC from being packaged when included on a claim with a "J1" service assigned to a Comprehensive APC (C-APC)
- CMS proposes to unpackage and pay separately for the cost of non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting

Device Intensive Policy

"What is proposed to change…"

- CMS proposes to modify its device intensive determination policy to allow procedures that involve surgically inserted or implanted, single-use devices to meet the device offset percentage threshold to qualify as device intensive procedures—*regardless* of whether the device remains in the patient's body after the conclusion of the procedure
- CMS also proposes to modify its criteria to lower the device offset percentage threshold to 30% (from 40%) to allow a greater number of procedures to qualify as device-intensive
- CMS further proposes to apply a 31% default (from 41%) device offset to new HCPCs codes describing procedures that require implantation of a medical device and do not yet have associated claims data to establish a HCPCS code-level device offset for the procedures

Proposed OPPS Radiation Oncology Rates for CY 2019

Facts

96.7%

For CY 2019, approximately 96.7% of radiation oncology rates are **proposed to increase**

0.12% to 3.25%

The range of payment increases among **codes with increasing rates**

-4.16%

The payment decrease among **codes with decreasing rates**

HCPCS Code	Short Descriptor	2019 Proposed Payment Rate	2018 Payment Rate	Change 2019-2018
76873	Echograp trans r pros study	$113.80	$118.74	-4.16%
77280	Set radiation therapy field	$125.68	$125.35	0.26%
77285	Set radiation therapy field	$327.18	$323.07	1.27%
77290	Set radiation therapy field	$327.18	$323.07	1.27%
77295	3-d radiotherapy plan	$1,208.10	$1,186.60	1.81%
77300	Radiation therapy dose plan	$125.68	$125.35	0.26%
77301	Radiotherapy dose plan imrt	$1,208.10	$1,186.60	1.81%
77321	Special teletx port plan	$327.18	$323.07	1.27%
77331	Special radiation dosimetry	$125.68	$125.35	0.26%
77332	Radiation treatment aid(s)	$125.68	$125.35	0.26%
77333	Radiation treatment aid(s)	$125.68	$125.35	0.26%
77334	Radiation treatment aid(s)	$327.18	$323.07	1.27%
77336	Radiation physics consult	$125.68	$125.35	0.26%
77338	Design mlc device for imrt	$327.18	$323.07	1.27%
77370	Radiation physics consult	$125.68	$125.35	0.26%
77371	Srs multisource	$7,784.59	$7,565.16	2.90%
77372	Srs linear based	$7,784.59	$7,565.16	2.90%
77373	Sbrt delivery	$1,702.73	$1,677.10	1.53%
77401	Radiation treatment delivery	$127.79	$124.72	2.46%
77470	Special radiation treatment	$530.43	$522.28	1.56%
77520	Proton trmt simple w/o comp	$530.43	$522.28	1.56%
77522	Proton trmt simple w/comp	$1,081.08	$1,053.44	2.62%
77523	Proton trmt intermediate	$1,081.08	$1,053.44	2.62%
77525	Proton treatment complex	$1,081.08	$1,053.44	2.62%
77750	Infuse radioactive materials	$226.97	$219.82	3.25%
77761	Apply intrcav radiat simple	$530.43	$522.28	1.56%
77762	Apply intrcav radiat interm	$530.43	$522.28	1.56%
77763	Apply intrcav radiat compl	$714.95	$714.06	0.12%
77778	Apply interstit radiat compl	$714.95	$714.06	0.12%
77789	Apply surf ldr radionuclide	$127.79	$124.72	2.46%
77799	Radium/radioisotope therapy	$127.79	$124.72	2.46%

Payment for Certain Off-Campus Provider-Based Departments

Background

- Section 603 of the Bipartisan Budget Act (BBA) of 2015 requires payment for items and services furnished by certain off-campus hospital outpatient departments to be made under a payment system other than the OPPS, effective 1/1/17
- The affected ("non-excepted") departments are those that began billing for services payable under the OPPS after 11/2/15, unless they qualify for an exception for mid-build or cancer hospitals under the 21st Century Cures Act
- In the CY 2017 OPPS final rule, CMS finalized that it will pay for certain items and services furnished in non-excepted off-campus PBDs through the PFS rather than the OPPS, and it established new PFS rates equal to 50% of OPPS rates
- For CY 2018, CMS finalized a new payment rate of 40% of the OPPS rates (a reduction of 20%) for non-excepted off-campus PBDs

Payment for Certain Off-Campus Provider-Based Departments

"What is proposed to change…"

- Starting in CY 2019, CMS proposes to pay excepted off-campus PBDs at the same rate as non-excepted off-campus PBDs for clinic visit services (HCPCS code G0463)
- CMS's proposal would **not** be implemented in a budget neutral fashion, meaning the reduction would lower total Medicare payments made to OPPS providers by 1.2% or $760 million
- CMS also solicits comments on ways that CMS could make similar non-budget neutral reductions in future rulemakings, under its authority to develop methods to control unnecessary increases in the volume of outpatient services

Payment for Certain Off-Campus Provider-Based Departments

"What is proposed to change…"

- Starting in CY 2019, CMS proposes to pay excepted off-campus PBDs at 40% of the OPPS rates for expansions of service lines in certain "clinical families"
- Each hospital would have to assess the service lines at each off-campus department:
  - Did the department bill for services in these families in the baseline period (generally before November 2, 2015)?
  - If not, then the hospital would be required to report the "PN" modifier for those services and will be paid at 40% of the OPPS rates
- CMS proposed a similar policy in the 2017 OPPS but did not implement it
  - Stakeholders said it could harm access to care, impose burdens on hospitals to implement payment under different systems for services provided in the same visit, and might not comply with the statute

Proposed Clinical Families of Services

Clinical Family	APCs
Airway Endoscopy	5151–5155
Blood Product Exchange	5241–5244
Cardiac/Pulmonary Rehabilitation	5771; 5791
Diagnostic/Screening Test and Related Procedures	5721–5724; 5731–5735; 5741–5743
Drug Administration and Clinical Oncology	5691–5694
Ear, Nose, Throat (ENT)	5161–5166
General Surgery and Related Procedures	5051–5055; 5061; 5071–5073; 5091–5094; 5361–5362
Gastrointestinal (GI)	5301–5303; 5311–5313; 5331; 5341
Gynecology	5411–5416
Major Imaging	5523–5525; 5571–5573; 5593–5594
Minor Imaging	5521–5522; 5591–5592
Musculoskeletal Surgery	5111–5116; 5101–5102
Nervous System Procedures	5431–5432; 5441–5443; 5461–5464; 5471
Ophthalmology	5481, 5491–5495; 5501–5504
Pathology	5671–5674
Radiation Oncology	5611–5613; 5621–5627; 5661
Urology	5371–5377
Vascular/Endovascular/Cardiovascular	5181–5184; 5191–5194; 5200; 5211–5213; 5221–5224; 5231–5232
Visits and Related Services	5012; 5021–5025; 5031–5035; 5041; 5045; 5821–582

Collecting Data on Off-Campus Provider-Based Departments

"What is proposed to change…"

- CMS says it agrees with a MedPAC report's finding that there is a need to develop data to assess the extent to which current policies and payment incentives may be causing a shift of OPPS services to off-campus provider-based emergency departments.
- Starting in CY 2019, CMS proposes to implement a new HCPCS modifier, "ER—Items and services furnished by a provider-based off-campus emergency department" that is to be reported with every claim line for outpatient hospital services furnished in an off-campus provider-based emergency department

Examples of Proposed 2019 Payment Rates

Code	Description	Physician Office (non-facility setting)	Excepted Hospital Outpatient Department	Nonexcepted Hospital Outpatient Department
96413	Chemo iv infusion 1 hr	$129.05	$291.09	$116.44
96372	Ther/proph/diag inj sc/im	$16.94	$59.95	$23.98
G0463/ 99201-99215	Hospital outpatient clinic visit for assessment and management of a patient/ E/M visits for new or established patients	$43.26-$134.45	$115.76	$46.30
74177	Ct abd & pelv w/contrast	$329.10	$388.70	$155.48

Hospital OQR Program Measures Updated

"What is proposed to change…"

- CMS proposes no new measures for the Hospital OQR Program
- CMS proposes clarifications to its Removal Factors and a new Removal Factor 8 (burden associated with the measure outweighs the benefit of its continued use)
- CMS proposes to remove a total of 10 measures across CY 2020 and CY 2021:

Measure	Proposed Action
OP-27: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431)	Remove as of CY 2020
OP-5: Median Time to ECG (NQF #0289)	Remove as of CY 2021
OP 31: Cataracts - Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536)	
OP-29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658)	
OP-30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use (NQF #0659)	
OP-9: Mammography Follow-up Rates (no NQF number)	
OP-11: Thorax Computed Tomography (CT) – Use of Contrast Material (NQF #0513)	
OP-12: The Ability for Providers with HIT (Health Information Technology) to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data (NQF endorsement removed)	
OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT (no NQF number)	
OP-17: Tracking Clinical Results between Visits (NQF endorsement removed)	

Hogan Lovells

ACCC

Medicare Physician Fee Schedule

PROPOSED RULE FOR CALENDAR YEAR 2019

August 8, 2018

Medicare Physician Fee Schedule Proposed Rule for CY 2019

QUICK FACTS

WHO?

Centers for Medicare and Medicaid (CMS)

WHAT?

Medicare Physician Fee Schedule (PFS) Proposed Rule for CY 2018

CMS-1693-P
83 Fed. Reg. 35,704 (July 27, 2018)

WHERE?

- Nationwide

WHEN?

- Released on July 12, 2018
- Published in Federal Register on July 27, 2018
- Comments due September 10, 2018

35704 Federal Register / Vol. 83, No. 145 / Friday, July 27, 2018 / Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, 415, and 495

[CMS–1693–P]

RIN 0938–AT31

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This major proposed rule addresses changes to the Medicare physician fee schedule (PFS) and other Medicare Part B payment policies to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute.

DATES: *Comment date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 10, 2018.

ADDRESSES: In commenting, please refer to file code CMS–1693–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the "Submit a comment" instructions.
2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1693–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1693–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FOR FURTHER INFORMATION CONTACT:

Jamie Hermansen, (410) 786–2064, for any physician payment issues not identified below.

Lindsey Baldwin, (410) 786–1694, and Emily Yoder, (410) 786–1804, for issues related to evaluation and management (E/M) payment, communication technology-based services and telehealth services.

Isadora Gil, (410) 786–4532, for issues related to payment rates for nonexcepted items and services furnished by nonexcepted off-campus provider-based departments of a hospital, and work relative value units (RVUs).

Ann Marshall, (410) 786–3059, for issues related to E/M documentation guidelines.

Geri Mondowney, (410) 786–1172, or Donta Henson, (410) 786–1947, for issues related to geographic price cost indices (GPCIs).

Geri Mondowney, (410) 786–1172, or Tourette Jackson, (410) 786–4735, for issues related to malpractice RVUs.

Patrick Sartini, (410) 786–9252, for issues related to radiologist assistants.

Michael Soracoe, (410) 786–6312, for issues related to practice expense, work RVUs, impacts, and conversion factor.

Pamela West, (410) 786–2302, for issues related to therapy services.

Edmund Kasaitis, (410) 786–0477, for issues related to reduction of wholesale acquisition cost (WAC)-based payment.

Sarah Harding, (410) 786–4001, or Craig Dobyski, (410) 786–4584, for issues related to aggregate reporting of applicable information for clinical laboratory fee schedule.

Amy Gruber, (410) 786–1542, or Glenn McGuirk, (410) 786–5723, for issues related to the ambulance fee schedule.

Corinne Axelrod, (410) 786–5620, for issues related to care management services and communication technology-based services in Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs).

JoAnna Baldwin, (410) 786–7205, or Sarah Fulton, (410) 786–2749, for issues related to appropriate use criteria for advanced diagnostic imaging services.

David Koppel, (214) 767–4403, for issues related to Medicaid Promoting Interoperability Program.

Fiona Larbi, (410) 786–7224, for issues related to the Medicare Shared Savings Program Quality Measures.

Matthew Edgar, (410) 786–0698, for issues related to the physician self-referral law.

Molly MacHarris, (410) 786–4461, for inquiries related to Merit-based Incentive Payment System (MIPS).

Benjamin Chin, (410) 786–0679, for inquiries related to Alternative Payment Models (APMs).

SUPPLEMENTARY INFORMATION:

Table of Contents

Addenda Available Only Through the Internet on the CMS Website

The PFS Addenda along with other supporting documents and tables referenced in this proposed rule are available on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-*

PFS Proposed Rule for CY 2019

Highlights

- Projects a conversion factor of $36.0463
- Reflects the +0.25% update mandated by the Protecting Access to Medicare Act of 2014 (PAMA) for 2018 and the -0.12% reduction required by law because CMS failed to meet the annual target for reducing relative value units (RVUs) for misvalued codes
- Addenda available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1693-P.html

Cumulative Effect on Cancer Care Physicians

- Estimated combined impact on physicians involved in cancer care if all of the proposals in the Proposed Rule are finalized:

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

Policies that are Proposed to Remain the Same

What is proposed to stay the same. . .

- CMS continues its existing ASP+6% reimbursement methodology that applies for most Medicare Part B covered drugs and biologicals paid under the PFS
- No new proposals related to the Multiple Procedure Payment Reduction (MPPR)
- No changes to payment for mammography services
- CMS declines a request to modify 6 CPT codes for breast biopsy procedures to update the price and add the breast biopsy software (EQ370) to the codes
- For non-excepted PBDs, CMS proposes to continue to apply the PFS relativity adjuster of 40% of the OPPS rate for CY 2019

Proposals Related to Cancer Care

What is proposed to change . . .

- CMS proposes new payment rates for drug administration based on AMA Specialty Society RVU Update Committee (RUC)-recommended work RVUs, equipment times, and practice expense (PE) inputs
  - ➢ Proposal generally would decrease payment rates

Largest Proposed Reductions

Code	Description	% Change Non-Facility
96360	Hydration iv infusion init	-18.83%
96372	Ther/proph/diag inj sc/im	-18.86%
96374	Ther/proph/diag inj iv push	-18.98%
96375	Tx/pro/dx inj new drug addon	-15.58%
96401	Chemo anti-neopl sq/im	-10.90%
96409	Chemo iv push sngl drug	-11.18%
96411	Chemo iv push addl drug	-9.52%
96413	Chemo iv infusion 1 hr	-10.83%
96415	Chemo iv infusion addl hr	-10.11%
96416	Chemo prolong infuse w/pump	-11.13%
96422	Chemo ia infusion up to 1 hr	-15.73%
96423	Chemo ia infuse each addl hr	-15.02%
96425	Chemotherapy infusion method	-15.04%

Proposed PFS Drug Administration Rates for 2019

Facts

94%

For CY 2019, approximately 94% of non-facility drug administration rates are **proposed to decrease**

83%

For CY 2019, approximately 83% of facility drug administration rates are **proposed to decrease**

HCPCS	Description	2018 Non-Facility	2018 Facility	Proposed 2019 Non-Facility	Proposed 2019 Facility	Non-Facility Change	Facility Change
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
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%
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
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%

Proposals Related to Cancer Care

"What is proposed to change…"

- CMS proposes to revise its regulations to state that radiologist tests performed by registered radiologist assistants (or radiology practitioner physicians) require only direct physician supervision, when permitted by state law or regulation.
- CMS proposes updates to RVUs, PE inputs, and other inputs for:
  - Skin Biopsy CPT codes 11X02, 11X03, 11X04, 11X05, 11X06, and 11X07
  - Biopsy or Excision of Inguinofemoral Node(s) (CPT code 3853X)
  - Radioactive Tracer (CPT code 38792)
  - Biopsy of Uterus Lining (CPT codes 58100 and 58110)
  - CT Scan for Needle Biopsy (CPT code 77012)
  - Breast MRI with Computer-Aided Detection (CAD) (CPT codes 77X49, 77X50, 77X51, and 77X52)
  - Bone Marrow Interpretation (CPT code 85097)
- CMS also solicits comments on the possibility of creating multiple G-codes specific to services associated with superficial radiation treatment (SRT) delivery—and whether CMS should create separate codes associated with SRT and whether the SRT codes should be contractor priced for CY 2019

Proposals Related to Payment for Drugs

"What is proposed to change…"

- **Reduction in Add-On Percentage for Certain Wholesale Acquisition Cost (WAC)-Based Payments**
  - Consistent with its CY 2019 OPPS proposal, for the initial sales period of new drugs or biologicals that do not yet have sufficient cost data to calculate average sales price, CMS proposes to reduce payment to WAC plus 3% (from WAC plus 6%)
  - CMS also proposes various updates to its regulations and manual guidance to be more consistent with the statute and to implement the proposed change

Potential Changes to Evaluation & Management Payment and Rules

- CMS proposes to establish a single payment rate for the level 2 through 5 Evaluation & Management (E/M) visits for new and established patients
- CMS proposes various other refinements to its E/M rules and documentation requirements, which CMS says are intended to simplify and streamline the requirements (e.g., removing the requirement that the medical record must document the medical necessity of furnishing the visit in the home rather than in the office)

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

* Codes 99201-05 apply to new patients, and codes 99211-15 apply to established patients

Potential Changes to Evaluation & Management Payment and Rules

- CMS proposes to establish new add-on codes to describe the additional resources associated with level 2-5 E/M visits in certain specialties and primary care
  - GCG0X – Visit complexity inherent to evaluation and management associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, or interventional pain management-centered care (Add-on code, list separately in addition to an evaluation and management visit)
  - GPC1X – Visit complexity inherent to evaluation and management associated with primary medical care services that serve as the continuing focal point for all needed health care services (Add-on code, list separately in addition to an evaluation and management visit)

Code	Description	Non-Facility	Facility
GCG0X	Visit, complex, E/M add on	$ 13.70	$ 13.70
GPC1X	Visit, comp w prim med care	$ 5.41	$ 3.97

Modernizing Communication Technology-Based Services

"What is proposed to change…"

- CMS proposes to pay separately for two new physicians' services furnished using communication technology:
  - Brief Communication Technology-based Service, e.g. Virtual Check-in (HCPCS code GVCI1)
  - Remote Evaluation of Recorded Video and/or Images Submitted by the Patient (HCPCS code GRAS1)
- CMS proposes to pays separately for new codes for Chronic Care Remote Physiologic Monitoring (CPT codes 990X0, 990X1, and 994X9) and Interprofessional Internet Consultation (CPT codes 994X6, 994X0, 99446, 99447, 99448, and 99449)
- CMS also proposes updates to the list of Medicare telehealth services and revisions to its telehealth service regulations to address statutory amendments made by the Bipartisan Budget Act of 2018

Potentially Misvalued Codes

"What is proposed to change…"

- CMS proposes to review certain publicly nominated potentially misvalued CPT codes
- In addition to codes unrelated to oncology services, CMS proposes to review the following oncology-related codes:
  - 43239 (Egd biopsy single/multiple);
  - 45385 (Colonoscopy w/ lesion removal); and
  - 70450 (CT head w/o contrast)
- CMS is reviewing the codes based on a public submitter's nomination of the codes as potentially misvalued
- CMS seeks public comment on the submitter's nomination and the potential value of the codes

Appropriate Use Criteria for Advanced Diagnostic Imaging

Background

- Section 218(b) of the Protecting Access to Medicare Act (PAMA) of 2014 CMS to establish an appropriate use criteria (AUC) program for advanced diagnostic imaging services (including MRI, CT, PET) provided in physician offices, hospital outpatient departments, and ASCs to be effective January 1, 2017
- Implementation of the program has been delayed until January 1, 2020
- CY 2020 will serve as a one-year educational and operations testing period
- 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
- Physicians can get Merit-Based Incentive Payment System (MIPS) credit beginning this year if they participate as early adopters
- In the CY 2016 and CY 2017 rulemaking cycles, CMS established a timeline and process for provider-led entities (PLEs) to become qualified to develop, modify, or endorse AUCs and established requirements and named qualified clinical decision support mechanisms (CDSMs):
  - CMS has named 20 Qualified PLEs as of June 2018, available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/PLE.html
  - CMS has named 11 Qualified CDSMs and 7 CDSMs with Preliminary Qualification as of June 2018 at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/CDSM.html

AUC Proposals

- CMS proposes limited refinements to the AUC program, including:
  - Adding Independent Diagnostic Testing Facilities as an "applicable setting" where the AUC requirements apply;
  - Allowing clinicians to satisfy the AUC consultation requirements through auxiliary personnel under the direction of the ordering professional and incident to the ordering professional's service;
  - 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);
  - Using G-codes, modifiers, and other "established coding methods" to report the required AUC information on Medicare claims, rather than a unique consultation identifier; and
  - Requiring clinicians who request a significant hardship exception to report a modifier with their claim and to include documentation and an attestation

AUC for Advanced Diagnostic Imaging

Solicitation of Comments

- The CY 2019 Proposed Rule does not change to the schedule for implementation of AUC requirements finalized in prior rulemakings
- The fourth and final component of the AUC program will impose a prior authorization requirement on advanced diagnostic imaging services furnished by certain outlier ordering professionals
- CMS solicits comments on the data elements and thresholds that CMS should use when identifying outliers that would be subject to this final component of the AUC program

Requests for Information

Solicitation of Comments

- Similar to the OPPS Proposed Rule, the PFS Proposed Rule includes broad RFIs on changes that CMS could make to the Medicare program to:
  - Promote interoperability and electronic healthcare information exchange
  - Increase price transparency and improve beneficiary access to provider and supplier charge information
- Suggestions can be at the regulatory, sub-regulatory, policy, practice, or procedural level
- Examples include new or additional Conditions of Participation on exchange of electronic health information, how best to define standard charges in provider and supplier settings, etc.

Presenters

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