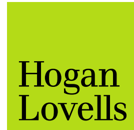
ACCC 2019 Policy and Provider Insights Summit



Overview of the Medicare Hospital Outpatient Prospective Payment System and Physician Fee Schedule Proposed Rules for CY 2020

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OPPS Proposed Rule for CY 2020

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) 2020

CMS-1717-P
84 Fed. Reg. 39,398
(August 9, 2019)

WHERE?

- Nationwide

WHEN?

- Released on July 29, 2019
- Published in Federal Register on August 9, 2019
- Comments due September 27, 2019

39398 Federal Register / Vol. 84, No. 154 / Friday, August 9, 2019 / Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 412, 416, 419, and 486

Office of the Secretary

45 CFR Part 180

[CMS–1717–P]

RIN 0938–AT74

Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals-Within-Hospitals

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

ACTION: Proposed rule.

SUMMARY: This proposed rule proposes revisions to the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for CY 2020 based on 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. In addition, in this proposed rule, we are proposing to establish requirements for all hospitals in the United States for making hospital standard charges available to the public; establish a process and requirements for prior authorization for certain covered outpatient department services; revise the conditions for coverage of organ procurement organizations; and revise the regulations to allow grandfathered children's hospitals-within-hospitals to increase the number of beds without resulting in the loss of grandfathered status. We also solicit comments on potential revisions to the laboratory date of service policy under the Clinical Laboratory Fee Schedule. Finally, we solicit comments on an appropriate remedy in litigation involving our OPPS payment policy for 340B-acquired drugs, which would inform future rulemaking in the event of an adverse decision on appeal in that litigation.

DATES: *Comment period:* 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 27, 2019.

ADDRESSES: In commenting, please refer to file code CMS–1717–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–1717–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–1717–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.

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

FOR FURTHER INFORMATION CONTACT:

2-Midnight Rule (Short Inpatient Hospital Stays), contact Lela Strong-Holloway via email *Lela.Strong@cms.hhs.gov* or at 410–786–3213.

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 Josh 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.

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, or Mitali Dayal via email at *Mitali.Dayal2@cms.hhs.gov* or at 410–786–4329.

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

Grandfathered Children's Hospitals-within-Hospitals, contact Michele Hudson via email *Michele.Hudson@cms.hhs.gov* or 410–786–4487.

Hospital Cost Reporting and Chargemaster Comment Solicitation, contact Dr. Terri Postma via email at *PriceTransparencyHospitalCharges@cms.hhs.gov*.

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 Elise Barringer via email

OPPS Proposed Rule for CY 2020

Highlights

- 2.7% projected update for 2020
  - ➢ market basket increase of 3.2%
  - ➢ minus 0.5% productivity adjustment 2% payment reduction for hospitals that fail to report quality data
- Total Medicare payments to OPPS providers will increase by approximately $6 billion to approximately $79 billion
- Total Medicare payments to ASCs would increase by approximately $200 million to approximately $4.89 billion
- Addenda available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1717-P.html.

OPPS Proposed Rule for CY 2020

What is proposed to stay the same. . .

Policies 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 non-pass through drugs acquired under the 340B Program at ASP-22.5%
- Payment for blood and blood products using the blood-specific cost-to-charge ratio (CCR) methodology
- Estimation of outlier payments to be 1% of aggregate total OPPS payments

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 would continue for 61 drugs
  - Pass-through status would be extended for 4 drugs per by section 1301(a)(1)(C) of the Consolidated Appropriations Act of 2018.
  - Pass-through status would expire for 6 drugs
- Separately payable drugs, biologicals, therapeutic radiopharmaceuticals, and clotting factors not purchased under the 340B drug discount program also paid at ASP+6%
  - CMS would 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 would 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 would continue to be paid at ASP+6% plus an updated furnishing fee

Payment for Drugs, Biologicals, and Radiopharmaceuticals

65 drugs with continuing pass-through status

CY 2020 HCPCS CODE	CY 2020 LONG DESCRIPTOR	PROPOSED CY 2020 STATUS INDICATOR	PROPOSED CY 2020 APC	PASS-THROUGH PAYMENT EFFECTIVE DATE	PASS-THROUGH PAYMENT EXPIRATION DATE
A9513	Lutetium lu 177, dotatate, therapeutic, 1 millicurie	G	9067	07/01/2018	6/30/2021
A9586*	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries	G	9084	10/01/2018	9/30/2020
C9035	Injection, aripiprazole lauroxil (aristada initio), 1 mg	G	9179	01/01/2019	12/31/2021
C9036	Injection, patisiran, 0.1 mg	G	9180	01/01/0219	12/31/2021
C9037	Injection, risperidone (perseris), 0.5 mg	G	9181	01/01/2019	12/31/2021
C9038	Injection, mogamulizumab-kpkc, 1 mg	G	9182	01/01/2019	12/31/2021
C9039	Injection, plazomicin, 5 mg	G	9183	01/01/2019	12/31/2021
C9040	Injection, fremanezumab-vfrm, 1 mg	G	9197	04/01/2019	3/31/2022
C9041	Injection, coagulation factor Xa(recombinant), inactivated (andexxa), 10mg	G	9198	04/01/2019	3/31/2022
C9043	Injection, levoleucovorin	G	9303	04/01/2019	3/31/2022
C9044	Injection, cemiplimab-rwlc, 1 mg	G	9304	04/01/2019	3/31/2022
C9045	Injection, moxetumomab pasudotox-tdfk, 0.01 mg	G	9305	04/01/2019	3/31/2022
C9046	Cocaine hydrochloride nasal solution for topical administration, 1 mg	G	9307	04/01/2019	3/31/2022

CY 2020 HCPCS CODE	CY 2020 LONG DESCRIPTOR	PROPOSED CY 2020 STATUS INDICATOR	PROPOSED CY 2020 APC	PASS-THROUGH PAYMENT EFFECTIVE DATE	PASS-THROUGH PAYMENT EXPIRATION DATE
C9141	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl (jivi) 1 i.u.	G	9299	04/01/2019	3/31/2022
C9407	Iodine i-131 iobenguane, diagnostic, 1 millicurie	G	9184	01/01/2019	12/31/2021
C9408	Iodine i-131 iobenguane, therapeutic, 1 millicure	G	9185	01/01/2019	12/31/2021
C9447*	Injection, phenylephrine and ketorolac, 4 ml vial	G	9083	10/01/2018	9/30/2020
C9462	Injection, delafloxacin, 1 mg	G	9462	04/01/2018	3/31/2021
C9488	Injection, conivaptan hydrochloride, 1 mg	G	9488	04/01/2017	3/31/2020
J0185	Injection, aprepitant, 1 mg	G	9463	04/01/2018	3/31/2021
J0517	Injection, benralizumab, 1 mg	G	9466	04/01/2018	3/31/2021
J0565	Injection, bezlotoxumab, 10 mg	G	9490	07/01/2017	6/30/2020
J0567	Injection, cerliponase alfa, 1 mg	G	9014	01/01/2018	12/31/2021
J0599	Injection, c-1 esterase inhibitor (human), (haegarda), 10 units	G	9015	01/01/2018	12/31/2021
J1095	Injection, dexamethasone 9%, intraocular, 1 microgram	G	9172	10/01/2018	9/30/2021
J1301	Injection, edaravone, 1 mg	G	9493	10/01/2017	9/30/2020

* Pass-through status extended through September 30, 2020 due to the Consolidated Appropriations Act of 2018

Payment for Drugs, Biologicals, and Radiopharmaceuticals

65 drugs with continuing pass-through status

CY 2020 HCPCS CODE	CY 2020 LONG DESCRIPTOR	PROPOSED CY 2020 STATUS INDICATOR	PROPOSED CY 2020 APC	PASS-THROUGH PAYMENT EFFECTIVE DATE	PASS-THROUGH PAYMENT EXPIRATION DATE
J1428	Injection, eteplirsen, 10 mg	G	9484	04/01/2017	3/31/2020
J1454	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg	G	9099	10/01/2018	9/30/20201
J1627	Injection, granisetron extended release, 0.1 mg	G	9486	04/01/2017	3/31/2020
J1628	Injection, guselkumab, 1 mg	G	9029	01/01/2018	12/31/2020
J2326	Injection, nusinersen, 0.1 mg	G	9489	07/01/2017	6/30/2020
J2350	Injection, ocrelizumab, 1 mg	G	9494	10/01/2017	9/30/2020
J2797	Injection, rolapitant, 0.5 mg	G	9464	04/01/2018	3/31/2021
J3245	Injection, tildrakizumab, 1 mg	G	9306	04/01/2019	3/31/2022
J3304	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	G	9469	04/01/2018	3/31/2021
J3316	Injection, triptorelin, extended-release, 3.75 mg	G	9016	01/01/2018	12/31/2020
J3358	Ustekinumab, for intravenous injection, 1 mg	G	9487	04/01/2017	3/31/2020
J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes	G	9070	07/01/2018	6/30/2021
J7170	Injection, emicizumab-kxwh, 0.5 mg	G	9257	07/01/2018	6/30/2021

CY 2020 HCPCS CODE	CY 2020 LONG DESCRIPTOR	PROPOSED CY 2020 STATUS INDICATOR	PROPOSED CY 2020 APC	PASS-THROUGH PAYMENT EFFECTIVE DATE	PASS-THROUGH PAYMENT EXPIRATION DATE
J7203	Injection factor ix, (antihemophilic factor, recombinant), glycopegylated, (rebinyn), 1 iu	G	9468	04/01/2018	3/31/2021
J7318	Hyaluronan or derivative, durolane, for intra-articular injection, 1 mg	G	9174	04/01/2018	3/31/2021
J7328	Hylauronan or derivative, gelsyn-3, for intra-articular injection, 0.1 mg	G	1862	04/01/2017	3/31/2020
J7345	Aminolevulinic acid hcl for topical administration, 10% gel, 10 mg	G	9301	01/01/2018	12/31/2020
J9023	Injection, avelumab, 10 mg	G	9491	10/01/2017	9/30/2020
J9057	Injection, copanlisib, 1 mg	G	9030	07/01/2018	6/30/2121
J9153	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine	G	9302	01/01/2018	12/31/2020
J9173	Injection, durvalumab, 10 mg	G	9492	10/01/2017	9/30/2020
J9203	Injection, gemtuzumab ozogamicin, 0.1 mg	G	9495	01/01/2018	12/31/2020
J9229	Injection, inotuzumab ozogamicin, 0.1 mg	G	9028	01/01/2018	12/31/2020
J9285	Injection, olaratumab, 10 mg	G	9485	04/01/2017	3/31/2020
J9311	Injection, rituximab 10 mg and hyaluronidase	G	9467	04/01/2018	3/31/2021

Payment for Drugs, Biologicals, and Radiopharmaceuticals

65 drugs with continuing pass-through status

CY 2020 HCPCS CODE	CY 2020 LONG DESCRIPTOR	PROPOSED CY 2020 STATUS INDICATOR	PROPOSED CY 2020 APC	PASS-THROUGH PAYMENT EFFECTIVE DATE	PASS-THROUGH PAYMENT EXPIRATION DATE
Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9035	04/01/2018	3/31/2021
Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9194	04/01/2018	3/31/2021
Q4195*	Puraply, per square centimeter	G	9175	10/01/2018	9/30/2020
Q4196*	Puraply am, per square centimeter	G	9176	10/01/2018	9/30/2020
Q5103	Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg	G	1847	04/01/2017	3/31/2020
Q5104	Injection, infliximab-abda, biosimilar, (renflexis), 10 mg	G	9036	04/01/2018	3/31/2021
Q5105	Injection, epoetin alfa, biosimilar, (retacrit) (for esrd on dialysis), 100 units	G	9096	10/01/2018	9/30/2021
Q5106	Injection, epoetin alfa, biosimilar, (retacrit) (for non-esrd use), 1000 units	G	9097	10/01/2018	9/30/2021
Q5108	Injection, pegfilgrastim-jmdb, biosimilar, (fulphila), 0.5 mg	G	9173	04/01/2019	3/31/2022
Q5110	Injection, filgrastim-aafi, biosimilar, (nivestym), 1 microgram	G	9193	04/01/2019	3/31/2022
Q5111	Injection, pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg	G	9195	04/01/2019	3/31/2022
Q9950*	Injection, sulfur hexafluoride lipid microsphere, per ml	G	9085	10/01/2018	9/30/2020
Q9991	Injection, buprenorphine extended-release (sublocade), less than or equal to 100 mg	G	9073	07/01/2018	6/30/2021
Q9992	Injection, buprenorphine extended-release (sublocade), greater than 100 mg	G	9239	07/01/2018	6/30/2021

* Pass-through status extended through September 30, 2020 due to the Consolidated Appropriations Act of 2018

Payment for Drugs, Biologicals, and Radiopharmaceuticals

Drugs with expiring pass-through status

- Pass-through status would expire for 6 drugs on 12/31/19

CY 2020 HCPCS CODE	CY 2020 LONG DESCRIPTOR	CY 2020 STATUS INDICATOR	CY 2020 APC
A9587	Gallium ga-68, dotatate, diagnostic, 0.1 millicurie	G	9056
A9588	Fluciclovine f-18, diagnostic, 1 millicurie	G	9052
J0570	Buprenorphine implant, 74.2 mg	G	9058
J7179	Injection, von willebrand factor (recombinant), (Vonvendi), 1 i.u. vwf:rco	G	9059
J7210	Injection, factor viii, (antihemophilic factor, recombinant), (afstyla), 1 i.u.	G	9043
J9034	Injection, bendamustine hcl (Bendeka), 1 mg	G	1861

OPPS Proposed Rule for CY 2020

What is proposed to change. . .

Proposed Policy Changes for 2020

What is proposed to change. . .

- Increase drug packaging threshold from $125 to $130
- Revisions to drug administration payment rates
- Payment rates for Chimeric Antigen Receptor (CAR) T cell therapies and related services
- Revise thresholds for skin substitutes
- Revisions to radiation oncology payment rates
- Solicitation of comments on payment methodology for 340B purchased drugs
- Proposed changes in the level of supervision of outpatient therapeutic services in hospitals and critical access hospitals
- Completion of phased-in payment cuts for clinic visit services furnished in excepted off-campus provider-based departments (PBDs)
- Laboratory date of service proposals
- Hospital price transparency proposals
- Prior authorizations for specific outpatient department (OPD) services
- Update Hospital Outpatient Quality Reporting (OQR) Program measures

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

What is proposed to change. . .

- CMS proposes to increase the packaging threshold from $125 to $130 per day
- "Policy packaged" regardless of cost:

Proposed OPPS Drug Administration Rates for CY 2020

Facts

68% — For CY 2020, approximately 68% of the drug administration rates would **increase**

1.58% to 9.07% — The range of payment **increases** among codes with increasing rates

-0.05% to -0.80% — The payment **decrease** among codes with decreasing rates

HCPCS/ CPT* Code	Short Descriptor	Proposed 2020 Rates			Q3 2019 Rates			% Change 2019-2020
		SI	APC	Payment Rate	SI	APC	Payment Rate	
90461	Im admin each addl component	B			B			
90471	Immunization admin	Q1	5692	$60.85	Q1	5692	$59.75	1.84%
90472	Immunization admin each add	N			N			
90473	Immune admin oral/nasal	Q1	5692	$60.85	Q1	5692	$59.75	1.84%
90474	Immune admin oral/nasal addl	N			N			
96360	Hydration iv infusion init	S	5693	$185.68	S	5693	$187.18	-0.80%
96361	Hydrate iv infusion add-on	S	5691	$38.48	S	5691	$37.88	1.58%
96365	Ther/proph/diag iv inf init	S	5693	$185.68	S	5693	$187.18	-0.80%
96366	Ther/proph/diag iv inf addon	S	5691	$38.48	S	5691	$37.88	1.58%
96367	Tx/proph/dg addl seq iv inf	S	5692	$60.85	S	5692	$59.75	1.84%
96368	Ther/diag concurrent inf	N			N			
96369	Sc ther infusion up to 1 hr	S	5693	$185.68	S	5693	$187.18	-0.80%
96370	Sc ther infusion addl hr	S	5691	$38.48	S	5691	$37.88	1.58%
96371	Sc ther infusion reset pump	Q1	5692	$60.85	Q1	5692	$59.75	1.84%
96372	Ther/proph/diag inj sc/im	Q1	5692	$60.85	Q1	5692	$59.75	1.84%
96373	Ther/proph/diag inj ia	S	5693	$185.68	S	5693	$187.18	-0.80%
96374	Ther/proph/diag inj iv push	S	5693	$185.68	S	5693	$187.18	-0.80%
96375	Tx/pro/dx inj new drug addon	S	5691	$38.48	S	5691	$37.88	1.58%
96376	Tx/pro/dx inj same drug adon	N			N			
96379	Ther/prop/diag inj/inf proc	Q1	5691	$38.48	Q1	5691	$37.88	1.58%
96401	Chemo anti-neopl sq/im	Q1	5692	$60.85	Q1	5692	$59.75	1.84%

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Proposed OPPS Drug Administration Rates for CY 2020

Facts

68%

For CY 2020, approximately 68% of the drug administration rates would **increase**

1.58% to 9.07%

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

-0.05% to -0.80%

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

HCPCS/ CPT Code	Short Descriptor	Proposed 2020 Rates			Q3 2019 Rates			% Change 2019-2020
		SI	APC	Payment Rate	SI	APC	Payment Rate	
96402	Chemo hormon antineopl sq/im	Q1	5692	$60.85	Q1	5692	$59.75	1.84%
96405	Chemo intralesional up to 7	Q1	5692	$60.85	Q1	5692	$59.75	1.84%
96406	Chemo intralesional over 7	S	5693	$185.68	S	5693	$187.18	-0.80%
96409	Chemo iv push sngl drug	S	5693	$185.68	S	5693	$187.18	-0.80%
96411	Chemo iv push addl drug	S	5692	$60.85	S	5692	$59.75	1.84%
96413	Chemo iv infusion 1 hr	S	5694	$314.54	S	5694	$288.38	9.07%
96415	Chemo iv infusion addl hr	S	5692	$60.85	S	5692	$59.75	1.84%
96416	Chemo prolong infuse w/pump	S	5694	$314.54	S	5694	$288.38	9.07%
96417	Chemo iv infus each addl seq	S	5692	$60.85	S	5692	$59.75	1.84%
96420	Chemo ia push technique	S	5694	$314.54	S	5694	$288.38	9.07%
96422	Chemo ia infusion up to 1 hr	S	5693	$185.68	S	5693	$187.18	-0.80%
96423	Chemo ia infuse each addl hr	S	5691	$38.48	S	5691	$37.88	1.58%
96425	Chemotherapy infusion method	S	5694	$314.54	S	5694	$288.38	9.07%
96440	Chemotherapy intracavitary	S	5694	$314.54	S	5694	$288.38	9.07%
96446	Chemotx admn prtl cavity	S	5694	$314.54	S	5694	$288.38	9.07%
96450	Chemotherapy into cns	S	5694	$314.54	S	5694	$288.38	9.07%
96521	Refill/maint portable pump	S	5693	$185.68	S	5693	$187.18	-0.80%
96522	Refill/maint pump/resvr syst	S	5693	$185.68	S	5693	$187.18	-0.80%
96523	Irrig drug delivery device	Q1	5733	$55.87	Q1	5733	$55.90	-0.05%
96542	Chemotherapy injection	S	5693	$185.68	S	5693	$187.18	-0.80%
96549	Chemotherapy unspecified	Q1	5691	$38.48	Q1	5691	$37.88	1.58%

Payment for CAR T Cell Therapies and Related Services

- CMS proposes to increase the payment rate for the procedure to administer CAR T cell therapies

HCPCS Code	Short Descriptor	Proposed 2020 Rates			Q3 2019 Rates			% Change 2019-2020
		SI	APC	Payment Rate	SI	APC	Payment Rate	
Q2042	Tisagenlecleucel car-pos t	G	9194	$449,128.31	G	9194	$440,577.09	1.94%
Q2041	Axicabtagene ciloleucel car+	G	9035	$395,380.00	G	9035	$395,380.00	0.00%
0537T	Bld drv t lymphcyt car-t cell	B			B			
0538T	Bld drv t lymphcyt prep trns	B			B			
0539T	Receipt & prep car-t cell admn	B			B			
0540T	Car-t cell admn autologous	S	5694	$314.54	S	5694	$288.38	9.07%

- Pass-through status would continue for Kymriah™ and Yescarta®

Code	Long Descriptor	SI	APC	Payment Rate
Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9035	$395,380.00
Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9194	$449,128.31

Revised Thresholds for High/Low Cost Status for Skin Substitutes

What is proposed to change. . .

- In 2014, CMS began packaging skin substitutes without pass-through status into their associated surgical procedures because CMS believes that they function as supplies when used in a surgical procedure
- CMS divided skin substitutes into a high cost group and a low cost group
- For 2020, 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 $49) and a per day cost (PDC) threshold of $789 (currently $895)
- CMS proposes to continue to assign products that are in the high cost group in CY 2019 to the high cost group in CY 2020, regardless of whether they exceed or fall below the CY 2020 MUC or PDC threshold

Revised Thresholds for High/Low Cost Status for Skin Substitutes

What is proposed to change. . .

- CMS indicated that it is considering eliminating the high cost and low cost categories for skin substitutes and having only one payment category and set of procedure codes for the application of all graft skin substitute products with a CY 2020 payment rate of approximately $1,465.18.
  - CMS believes that a single payment category potentially could provide a more equitable payment for many products used with graft skin substitute procedures
  - CMS solicits comment on this proposal and notes that it may consider modifying the skin substitute payment policy in the CY 2020 OPPS final rule
  - CMS also solicits comment on ways that CMS should transition from the current low cost/high cost payment methodology to a single payment category

OPPS Radiation Oncology Proposed Rates for CY 2020

Facts

97%

For CY 2020, approximately 97% of radiation oncology rates would **increase**

3.78% to 11.46%

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

-1.31%

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

HCPCS/ CPT Code	Short Descriptor	Proposed 2020 Rates			Q3 2019 Rates			% Change 2019-2020
		SI	APC	Payment Rate	SI	APC	Payment Rate	
76873	Echograp trans r pros study	S	5522	$111.04	S	5522	$112.51	-1.31%
77280	Set radiation therapy field	S	5611	$128.45	S	5611	$123.77	3.78%
77285	Set radiation therapy field	S	5612	$339.20	S	5612	$321.82	5.40%
77290	Set radiation therapy field	S	5612	$339.20	S	5612	$321.82	5.40%
77295	3-d radiotherapy plan	S	5613	$1,260.81	S	5613	$1,191.92	5.78%
77300	Radiation therapy dose plan	S	5611	$128.45	S	5611	$123.77	3.78%
77301	Radiotherapy dose plan imrt	S	5613	$1,260.81	S	5613	$1,191.92	5.78%
77321	Special teletx port plan	S	5612	$339.20	S	5612	$321.82	5.40%
77331	Special radiation dosimetry	S	5611	$128.45	S	5611	$123.77	3.78%
77332	Radiation treatment aid(s)	S	5611	$128.45	S	5611	$123.77	3.78%
77333	Radiation treatment aid(s)	S	5611	$128.45	S	5611	$123.77	3.78%
77334	Radiation treatment aid(s)	S	5612	$339.20	S	5612	$321.82	5.40%
77336	Radiation physics consult	S	5611	$128.45	S	5611	$123.77	3.78%
77338	Design mlc device for imrt	S	5612	$339.20	S	5612	$321.82	5.40%
77370	Radiation physics consult	S	5611	$128.45	S	5611	$123.77	3.78%
77371	Srs multisource	J1	5627	$8,037.04	J1	5627	$7,644.24	5.14%
77372	Srs linear based	J1	5627	$8,037.04	J1	5627	$7,644.24	5.14%
77373	Sbrt delivery	S	5626	$1,790.84	S	5626	$1,690.57	5.93%
77401	Radiation treatment delivery	S	5621	$123.88	S	5621	$116.99	5.89%
77470	Special radiation treatment	S	5623	$547.14	S	5623	$519.85	5.25%
77520	Proton trmt simple w/o comp	S	5623	$547.14	S	5623	$519.85	5.25%
77522	Proton trmt simple w/comp	S	5625	$1,202.61	S	5625	$1,078.97	11.46%
77523	Proton trmt intermediate	S	5625	$1,202.61	S	5625	$1,078.97	11.46%
77525	Proton treatment complex	S	5625	$1,202.61	S	5625	$1,078.97	11.46%
77750	Infuse radioactive materials	S	5622	$239.51	S	5622	$224.46	6.70%
77761	Apply intrcav radiat simple	S	5623	$547.14	S	5623	$519.85	5.25%
77762	Apply intrcav radiat interm	S	5623	$547.14	S	5623	$519.85	5.25%
77763	Apply intrcav radiat compl	S	5624	$754.19	S	5624	$704.72	7.02%
77778	Apply interstit radiat compl	S	5624	$754.19	S	5624	$704.72	7.02%
77789	Apply surf ldr radionuclide	S	5621	$123.88	S	5621	$116.99	5.89%
77799	Radium/radioisotope therapy	S	5621	$123.88	S	5621	$116.99	5.89%

Proposed Payment Methodology for 340B Purchased Drugs

Developments Based on Ongoing Litigation

- For CY 2020, CMS is proposing to continue to pay ASP-22.5 percent for 340B-acquired drugs including when furnished in nonexcepted off-campus PBDs paid under the Medicare Physician Fee Schedule (PFS)
- In May 2019, the United States District Court for the District of Columbia issued an opinion that reiterated that the 2018 rate reduction exceeded the Secretary's authority and declared that the rate reduction for 2019 also exceeded his authority
- The court remanded to HHS to devise an appropriate remedy
- CMS notes in the Proposed Rule that it intends to appeal the district court's decision, but is also taking the steps necessary to craft an appropriate remedy in the event of an unfavorable decision on appeal
- Accordingly, in the Proposed Rule, CMS solicits comment on several proposed solutions to remedy underpayments for CY 2018 and CY 2019 (assuming the policy for those years is found to be unlawful) as well as future payment policy for CY 2020 and beyond
- CMS also seeks comment on whether a rate of ASP+3 percent could be an appropriate remedial payment amount for these drugs, both for CY 2020 and for purposes of determining the remedy for CYs 2018 and 2019
- With regard to remediation for CY 2018 and CY 2019, CMS seeks comment on whether such a remedy should be retrospective in nature (e.g., made on a claim-by-claim basis) or whether such remedy could be prospective in nature (for example, an upward adjustment to 340B claims in the future to account for any underpayments in the past)

What is proposed to change. . .

- CMS proposes to change the generally applicable minimum required level of supervision for hospital outpatient therapeutic services from direct supervision to general supervision for services furnished by all hospitals and Critical Access Hospitals (CAHs)
  - Direct supervision: the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed.
  - General supervision: the procedure is furnished under the physician's overall direction and control, but that the physician's presence is not required during the performance of the procedure

Background

- Since 2010, there have been two different levels of supervision required for hospital outpatient therapeutic services:
  1. direct supervision for hospital outpatient therapeutic services covered and paid by Medicare that are furnished in hospitals and PBDs of hospitals (other than CAHs) and small rural hospitals); and
  2. general supervision for CAHs and small rural hospitals with 100 or fewer beds
- The exception to the direct supervision requirement for CAHs and small rural hospitals was implemented in 2010
- CMS states in the Proposed Rule that it believes it is time to end this two-tiered system, particularly given the additional burden on providers that reduces their flexibility to provide medical care, that there have been no reported issues with general supervision in CAHs and small rural hospitals, and that hospitals still need to comply with Conditions of Participation which may require a higher level of supervision for specific situations

Method to Control Unnecessary Increases in the Volume of Clinic Visit Services Furnished in Excepted Off-Campus PBDs

What is proposed to change. . .

- CMS proposes to complete its two-year phase-in of payment reductions for clinic visit services furnished at excepted off-campus provider-based departments (PBDs)
- In the CY 2019 OPPS/ASC final rule, CMS indicated that it would phase-in over two years a policy whereby payment for excepted off-campus PBDs would gradually be reduced to the same level as that applied to nonexcepted off-campus PBDs for clinic visit services (HCPCS code G0463)
- For CY 2020 (i.e., the second year of the phase-in), CMS proposes that the PFS-equivalent rate for CY 2020 would be 40% of the proposed OPPS payment
- Under the CY 2019 policy, the CY 2019 payment level was 70% of the OPPS payment (implementing 50% of the ultimate reduction)

Potential Revisions to the Laboratory Date of Service Policy

What is proposed to change. . .

- CMS is considering three options for potential changes to the molecular pathology and advanced diagnostic laboratory test (ADLT) date of service (DOS) exception
- Currently, the molecular pathology and ADLT exception provides that the date of service of the test is the date the test is performed (and therefore billable by the laboratory and separately payable under Medicare Part B) if:

  i. the test was performed following a hospital outpatient's discharge from the hospital outpatient department;

  ii. the specimen was collected from a hospital outpatient during an encounter;

  iii. it was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter;

  iv. the results of the test do not guide treatment provided during the hospital outpatient encounter; and

  v. the test was reasonable and medically necessary for the treatment of an illness.

Potential Revisions to the Laboratory Date of Service Policy

What is proposed to change. . .

- CMS proposes the following potential changes to the exception for CY 2020:

  1. Revising criterion (iv) to determine whether a molecular pathology test or ADLT is separable from a hospital service by specifying that the ordering physician would determine whether the results of the ADLT or molecular pathology test are intended to guide treatment provided during a hospital outpatient encounter
  2. Removing molecular pathology tests from the exception such that only tests designated by CMS as an ADLT would be included in the exception
  3. To exclude blood banks and centers from the exception meaning that the DOS for laboratory testing performed by blood banks and centers on specimens collected from a hospital outpatient during a hospital outpatient encounter would, depending on the underlying service, be the date of specimen collection (and therefore the hospital would bill for the laboratory test under arrangements and the blood bank or center would seek payment from the hospital)

Hospital Price Transparency Proposal

What is proposed to change. . .

- CMS proposes expansive new public disclosure requirements under section 2718(e) of the Public Health Service Act (PHSA)
- This would, among other things, require all non-federally owned or operated hospitals to publicly display *gross and payer-specific negotiated charges* for all items and services.
- CMS would also be required to provide, in a more *"consumer friendly" fashion, pricing information related to 300 "shoppable" services* as defined by CMS.
- CMS proposes that all entities that meet CMS's new proposed definition of "hospital" (except for federally-owned or operated hospitals) make public a list of the hospital's "standard charges" for "items and services" provided by the hospital, including for Diagnosis Related Groups (DRGs).
- CMS proposes to interpret this new requirement in a broad manner that would require hospitals to develop substantial (and likely costly) new processes for public disclosure and display of both gross charges and payer-negotiated rates and pricing information.

Proposed Prior Authorization for Certain Services

What is proposed to change. . .

- CMS proposes to use its authority under section 1833(t)(2)(F) of the Social Security Act (SSA) to establish a process through which providers would submit a prior authorization request for a provisional affirmation of coverage for designated services before an OPD service is furnished to the beneficiary and before the claim is submitted for processing
- CMS defines the relevant terms as follows:
  - "Prior authorization" means a process through which a request for provisional affirmation of coverage is submitted to CMS or its contractors for review before the service is provided to the beneficiary and before the claim is submitted
  - "Provisional affirmation" means a preliminary finding that a future claim for the service will meet Medicare's coverage, coding, and payment rules
  - "List of hospital outpatient department services requiring prior authorization" as the list of OPD services that CMS publishes
- CMS proposes that the list of covered OPD services that would require prior authorization include 40 CPT codes for procedures that could be cosmetic: blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation.

Hospital OQR Program Measures Updated

What is proposed to change. . .

- There are no new measures for the Hospital OQR Program for CY 2020
- CMS proposes the removal of one measure from the Hospital OQR Program beginning with October 2020 encounters used for the CY 2022 payment determination, on the grounds that the costs of continuing collection outweigh the benefit of continued use:
  - *OP-33: External Beam Radiotherapy (EBRT) (NQF# 1822)* (percentage patients with painful bone metastases and no prior history of radiation who receive acceptable EBRT).
- CMS also requests comment on four potential new Hospital OQR Program patient safety measures that may be proposed in a future rulemaking:
  1. patient burn;
  2. patient fall;
  3. wrong site, wrong side, wrong procedure, wrong implant; and
  4. all-cause hospital.

Medicare Physician Fee Schedule Proposed Rule for CY 2020

QUICK FACTS

WHO?

Centers for Medicare and Medicaid (CMS)

WHAT?

Medicare Physician Fee Schedule (PFS) Proposed Rule for CY 2020

CMS-1717-P
84 Fed. Reg. 39,398
(August 14, 2019)

WHERE?

- Nationwide

WHEN?

- Released on July 29, 2019
- Published in Federal Register on August 14, 2019
- Comments due September 27, 2019

40482 Federal Register / Vol. 84, No. 157 / Wednesday, August 14, 2019 / Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 410, 414, 415, 416, 418, 424, 425, 489, and 498

[CMS–1715–P]

RIN 0938–AT72

Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations

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

ACTION: Proposed rule.

SUMMARY: This major proposed rule addresses: Changes to the physician fee schedule (PFS); other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, relative value of services, and changes in the statute; Medicare Shared Savings Program quality reporting requirements; Medicaid Promoting Interoperability Program requirements for eligible professionals; the establishment of an ambulance data collection system; updates to the Quality Payment Program; Medicare enrollment of Opioid Treatment Programs and enhancements to provider enrollment regulations concerning improper prescribing and patient harm; and amendments to Physician Self-Referral Law advisory opinion regulations.

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 27, 2019.

ADDRESSES: In commenting, please refer to file code CMS–1715–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–1715–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–1715–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FURTHER INFORMATION CONTACT:

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

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

Geri Mondowney, (410) 786–1172, or Tourette Jackson, (410) 786–4735, for issues related to malpractice RVUs and geographic practice cost indicies (GPCIs).

Larry Chan, (410) 786–6864, for issues related to potentially misvalued services under the PFS.

Lindsey Baldwin, (410) 786–1694, or Emily Yoder, (410) 786–1804, for issues related to telehealth services.

Pierre Yong, (410) 786–8896, or Lindsey Baldwin, (410) 786–1694, for issues related to Medicare coverage of opioid use disorder treatment services furnished by opioid treatment programs (OTPs).

Lindsey Baldwin, (410) 786–1694, for issues related to bundled payments under the PFS for substance use disorders.

Emily Yoder, (410) 786–1804, or Christiane LaBonte, (410) 786–7237, for issues related to the comment solicitation on opportunities for bundled payments under the PFS.

Regina Walker-Wren, (410) 786–9160, for issues related to physician supervision for physician assistant (PA) services and review and verification of medical record documentation.

Ann Marshall, (410) 786–3059, Emily Yoder, (410) 786–1804, Liane Grayson, (410) 786–6583, or Christiane LaBonte, (410) 786–7237, for issues related to care management services.

Kathy Bryant, (410) 786–3448, for issues related to coinsurance for colorectal cancer screening tests.

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

Ann Marshall, (410) 786–3059, Emily Yoder, (410) 786–1804, or Christiane LaBonte, (410) 786–7237, for issues related to payment for evaluation and management services.

Kathy Bryant, (410) 786–3448, for issues related to global surgery data collection.

Thomas Kessler, (410) 786–1991, for issues related to ambulance physician certification statement.

Felicia Eggleston, (410) 786–9287, or Amy Gruber, (410) 786–1542, for issues related to the ambulance fee schedule-BBA of 2018 requirements for Medicare ground ambulance services data collection system.

Linda Gousis, (410) 786–8616, for issues related to intensive cardiac rehabilitation.

David Koppel, (303) 844–2883, or Elizabeth LeBreton, (202) 615–3816, for issues related to the Medicaid Promoting Interoperability Program.

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

Katie Mucklow, (410) 786–0537, or Diana Behrendt, (410) 786–6192, for issues related to open payments.

Cheryl Gilbreath, (410) 786–5919, for issues related to home infusion therapy benefit.

Joseph Schultz, (410) 786–2656, for issues related to Medicare enrollment of opioid treatment programs, and enhancements to provider enrollment regulations concerning improper prescribing and patient harm.

Jacqueline Leach, (410) 786–4282, for issues related to Deferring to State Scope of Practice Requirements: Ambulatory Surgical Centers (ASC).

Mary Rossi-Coajou, (410) 786–6051, for issues related to Deferring to State Scope of Practice Requirements: Hospice.

1877AdvisoryOpinion@cms.hhs.gov, for issues related to Advisory Opinions on Application of the Physician Self-referral law.

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

Megan Hyde, (410) 786–3247, for inquiries related to Alternative Payment Models (APMs).

SUPPLEMENTARY INFORMATION:

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 2020

Highlights

- Proposed conversion factor of **$36.0896**
- Reflects the **0%** update mandated by the Protecting Access to Medicare Act of 2014 (PAMA)
- Addenda available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1715-P.html

Cumulative Effect on Cancer Care Physicians

- Estimated combined impact on physicians involved in cancer care:

Specialty	Allowed Charges (Millions)	Combined Impact
Hematology/Oncology	$1,673	0%
Radiation Oncology and Radiation Therapy Centers	$1,756	0%
Radiology	$4,971	-1%

Policies Proposed to Remain the Same

What is proposed to stay the same. . .

- CMS would continue its existing ASP+6% reimbursement methodology that applies for most Medicare Part B covered drugs and biologicals paid under the PFS
- For non-excepted PBDs, CMS will continue to apply the PFS relativity adjuster of 40% of the OPPS rate for CY 2020

Proposed PFS Drug Administration Rates for 2020

Facts

71%

For CY 2020, approximately 71% of non-facility drug administration rates are proposed to **decrease** by-**0.14%** to **14.77%.** 29% of rates will **increase** by **0.14%** to **6.39%**

83%

For CY 2020, approximately 83% of facility drug administration rates are proposed to **increase** by **0.14%** to **1.33%.** 17% of rates will **decrease** by **6.2%**

CPT Code	Description	CY 2020 Proposed Payment		Q3 CY 2019 Payment		% Change	
		Non Facility	Facility	Non Facility	Facility	Non Facility	Facility
96360	Hydration iv infusion init	$34.65	N/A	$38.56	N/A	-10.15%	N/A
96361	Hydrate iv infusion add-on	$13.71	N/A	$13.69	N/A	0.14%	N/A
96365	Ther/proph/diag iv inf init	$71.46	N/A	$72.80	N/A	-1.84%	N/A
96366	Ther/proph/diag iv inf addon	$22.01	N/A	$21.98	N/A	0.14%	N/A
96367	Tx/proph/dg addl seq iv inf	$31.40	N/A	$31.71	N/A	-1.00%	N/A
96368	Ther/diag concurrent inf	$21.29	N/A	$21.26	N/A	0.14%	N/A
96369	Sc ther infusion up to 1 hr	$161.32	N/A	$169.02	N/A	-4.56%	N/A
96370	Sc ther infusion addl hr	$15.52	N/A	$15.86	N/A	-2.14%	N/A
96371	Sc ther infusion reset pump	$64.60	N/A	$66.31	N/A	-2.58%	N/A
96372	Ther/proph/diag inj sc/im	$14.44	N/A	$16.94	N/A	-14.77%	N/A
96373	Ther/proph/diag inj ia	$18.77	N/A	$19.10	N/A	-1.75%	N/A
96374	Ther/proph/diag inj iv push	$40.06	N/A	$39.64	N/A	1.05%	N/A
96375	Tx/pro/dx inj new drug addon	$16.60	N/A	$16.94	N/A	-1.99%	N/A
96376	Tx/pro/dx inj same drug adon	$0.00	$0.00	$0.00	$0.00	N/A	N/A
96379	Ther/prop/diag inj/inf proc	$0.00	$0.00	$0.00	$0.00	N/A	N/A
96401	Chemo anti-neopl sq/im	$79.76	N/A	$80.73	N/A	-1.20%	N/A
96402	Chemo hormon antineopl sq/im	$31.76	N/A	$31.35	N/A	1.29%	N/A
96405	Chemo intralesional up to 7	$84.81	$30.68	$83.25	$30.27	1.87%	1.33%
96406	Chemo intralesional over 7	$129.56	$47.28	$124.70	$47.21	3.90%	0.14%
96409	Chemo iv push sngl drug	$109.35	N/A	$109.92	N/A	-0.52%	N/A
96411	Chemo iv push addl drug	$59.19	N/A	$59.46	N/A	-0.47%	N/A
96413	Chemo iv infusion 1 hr	$141.47	N/A	$143.08	N/A	-1.12%	N/A
96415	Chemo iv infusion addl hr	$30.68	N/A	$30.99	N/A	-1.02%	N/A
96416	Chemo prolong infuse w/pump	$141.47	N/A	$143.44	N/A	-1.37%	N/A
96417	Chemo iv infus each addl seq	$68.57	N/A	$69.20	N/A	-0.90%	N/A
96420	Chemo ia push tecnique	$104.66	N/A	$106.32	N/A	-1.56%	N/A
96422	Chemo ia infusion up to 1 hr	$172.87	N/A	$174.79	N/A	-1.10%	N/A
96423	Chemo ia infuse each addl hr	$80.12	N/A	$80.73	N/A	-0.75%	N/A
96425	Chemotherapy infusion method	$184.42	N/A	$185.24	N/A	-0.44%	N/A
96440	Chemotherapy intracavitary	$908.74	$129.92	$854.13	$129.02	6.39%	0.70%
96446	Chemotx admn prtl cavity	$204.63	$26.71	$208.31	$28.47	-1.77%	-6.20%
96450	Chemotherapy into cns	$183.34	$81.92	$184.88	$81.81	-0.84%	0.14%
96521	Refill/maint portable pump	$147.97	N/A	$148.84	N/A	-0.59%	N/A
96522	Refill/maint pump/resvr syst	$123.07	N/A	$122.17	N/A	0.73%	N/A
96523	Irrig drug delivery device	$27.79	N/A	$27.75	N/A	0.14%	N/A
96542	Chemotherapy injection	$132.45	$42.95	$135.87	$42.89	-2.52%	0.14%

Proposed Changes to Evaluation & Management Payment and Rules

What is proposed to change. . .

- In the CY 2019 PFS final rule, CMS finalized a policy to develop a set of single payment rates for level 2 through 4 evaluation and management (E/M) visits (one each for new and established patients), **effective January 1, 2021**
- Since then, the CPT Editorial Panel has adopted a number of changes to the E/M code descriptors, also effective January 1, 2021.
- CMS proposes to adopt the new coding, prefatory language, and interpretive guidance framework because they believe it would accomplish greater burden reduction than the policies finalized for CY 2021 and would be more intuitive and consistent with the current practice of medicine
- For 2021, CMS will establish separate values for level 2 through 4 E/M visits for new and established patients, similar to the current values, instead of the blended rate it finalized in 2019
- CMS also proposes to establish values for add-on codes for prolonged services and ongoing care

Changes to E/M Payment and Rules

What is proposed to change. . .

These changes would include:

- Deletion of CPT code 99201 (Level 1 office/outpatient visit, new patient), which the CPT Editorial Panel decided to eliminate as CPT codes 99201 and 99202 are both straightforward medical decision making (MDM) and only differentiated by history and exam elements
  - Level 1 visits would only describe or include visits performed by clinical staff for established patients (CPT code 99211)
- For levels 2 through 5 office/outpatient E/M visits, the code level reported would be decided based on either the level of MDM or the total time personally spent by the reporting practitioner on the day of the visit (including face-to-face and non-face-to-face time)
- A single add-on CPT code for prolonged office/outpatient E/M visits (CPT code 99XXX) would only be reported when time is used for code level selection and the time for a level 5 office/outpatient visit is exceeded by 15 minutes or more on the date of service
  - CPT codes 99358–9 (Prolonged E/M without Direct Patient Contact) would no longer be reportable in association or "conjunction" with office/outpatient E/M visits
  - HCPCS code GPRO1 (extended office/ outpatient E/M time) would no longer be needed because the time described by this code would instead be described by a level 3, 4 or 5 office/outpatient E/ M visit base code and, if applicable, the single new add-on CPT code 99XXX
- New add-on code GPC1X for visits that are part of ongoing, comprehensive primary care and/or visits that are part of ongoing care related to a patient's single, serious, or complex chronic condition

Potentially Misvalued Codes

What is proposed to change. . .

- CMS received three public nominations for potentially misvalued codes
- CMS nominated one additional code for review
- CMS also received a comment suggesting that the E/M code set (CPT codes 99201–99215) warrants re-evaluation because it has not been reviewed in over 12 years
- CMS agrees in principle that the existing office/outpatient E/M CPT codes may not be correctly valued and indicates that it will continue to consider opportunities to revalue these codes

Care Management Services

What is proposed to change. . .

- CMS proposes to revise its billing requirements for Transitional Care Management (TCM) by allowing TCM codes to be billed concurrently with any of the codes in this table
- CMS believes that these codes complement TCM services as opposed to duplicating them

Code Family	HCPCS Code	Descriptor
Prolonged Services without Direct Patient Contact	99358	Prolonged E/M service before and/or after direct patient care; first hour; non-face-to-face time spent by a physician or other qualified health care professional on a given date providing prolonged service
	99359	Prolonged E/M service before and/or after direct patient care; first hour; non-face-to-face time spent by a physician or other qualified health care professional on a given date providing prolonged service
Home and Outpatient International Normalized Ratio (INR) Monitoring Services	93792	Patient/caregiver training for initiation of home INR monitoring
	92793	Anticoagulant management for a patient taking warfarin; includes review and interpretation of a new home, office, or lab INR test result, patient instructions, dosage adjustment and scheduling of additional test(s)
End Stage Renal Disease (ESRD) Services (patients who are 20+ years)	90960	ESRD related services monthly with 4 or more face-to-face visits per month; for patients 20 years and older
	90961	ESRD related services monthly with 2-3 face-to-face visits per month; for patients 20 years and older
	90962	ESRD related services with 1 face-to-face visit per month; for patients 20 years and older
	90966	ESRD related services for home dialysis per full month; for patients 20 years and older
	90970	ESRD related services for dialysis less than a full month of service; per day; for patient 20 years and older
Interpretation of Physiological Data	99091	Collection & interpretation of physiologic data, requiring a minimum of 30 minutes each 30 days
Complex Chronic Care Management Services	99487	Complex Chronic Care with 60 minutes of clinical staff time per calendar month
	99489	Complex Chronic Care; additional 30 minutes of clinical staff time per month
Care Plan Oversight Services	G0181	Physician supervision of a patient receiving Medicare-covered services provided by a participating home health agency (patient not present) requiring complex and multidisciplinary care modalities within a calendar month; 30+ minutes
	G0182	Physician supervision of a patient receiving Medicare-covered hospice services (Pt not present) requiring complex and multidisciplinary care modalities; within a calendar month; 30+ minutes

Care Management Services

What is proposed to change. . .

- CMS is seeking comment on whether the newest CPT code in the chronic care management (CCM) services family (CPT code 99491 for CCM by a physician or other qualified health professional, established in 2019) overlaps with TCM or should be reportable and separately payable in the same service period.
- CMS also proposes to make separate payment for principal care management (PCM) services via two proposed new HCPCS codes
- CMS proposes to make some updates to Chronic Care remote physiologic monitoring (RPM) service code RVUs to reflect changes to the revised code structure approved by the CPT Editorial Panel
- CMS also makes a number of proposals or comment solicitations with respect to CCM services including:
  - Adopting two new G-codes to identify additional time increments for complex CCM services
  - Simplifying the list of services that would be included in the typical comprehensive care plan for CCM services

Colorectal Cancer Screening Coinsurance

What is proposed to change. . .

- CMS explains that beneficiaries continue to be surprised by their copayment obligations when they receive a colorectal screening procedure and polyps are discovered and removed
- Coinsurance generally does not apply to the colorectal screening procedure
- Coinsurance does apply if polyps are discovered and removed because Medicare considers that to be a diagnostic procedure
- CMS does not propose to revisit its interpretation of colorectal cancer screening services or to extend the cost sharing exclusion to diagnostic procedures that were initiated as cost sharing exempt screening services
- CMS is inviting public comment on whether it should adopt notification requirements, oral or written, that physicians or their staff would be required to provide to patients prior to a colorectal cancer screening

Comment Solicitation on Opportunities for Bundled Payments

What is proposed to change. . .

- CMS is requesting comments on how it can expand bundled payments to more physician services that are paid under the PFS
- Specifically, CMS seeks "public comments on opportunities to expand the concept of bundling to recognize efficiencies among physician services paid under the PFS and better align Medicare payment policies with CMS's broader goal of achieving better care for patients, better health for our communities, and lower costs through improvement in our health care system."
- CMS defines a "bundled payment" to mean circumstances where a set of services is grouped together for purposes of rate-setting and payment, and offers the Comprehensive Primary Care Plus (CPC+) model and the Oncology Care Model (OCM) as examples of bundled payment models

What is proposed to change. . .

- The 21st Century Cures Act created a new Medicare Part B benefit for professional services related to home infusion therapy
- The law requires that the physician who establishes the home infusion plan must notify the beneficiary of the options available for infusion, including the beneficiary's home, the physician's office, a hospital outpatient department, etc.
- In the Proposed Rule, CMS solicits comments regarding the appropriate form, manner and frequency of the notice that physicians must provide under this statutory requirement

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