

The logo for Hogan Lovells, consisting of the name "Hogan Lovells" in a black serif font, positioned inside a solid lime green square.

Hogan
Lovells

Medicare Hospital Outpatient Prospective Payment System

PROPOSED RULE FOR CALENDAR YEAR 2018

August 9, 2017

OPPS Proposed Rule for CY 2018

QUICK FACTS

WHO?

Centers for Medicare and Medicaid (CMS)

WHAT?

Hospital outpatient prospective payment system (OPPS), ambulatory surgical center (ASC) payment system, and quality reporting programs proposed rule for the calendar year (CY) 2018

CMS-1678-P

82 Fed. Reg. 33,558 (Jul. 20, 2017)

WHERE?

- Nationwide

WHEN?

- Published in Federal Register on July 20, 2017
- Comments due September 11, 2017



33558

Federal Register / Vol. 82, No. 138 / Thursday, July 20, 2017 / Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 416 and 419

[CMS-1678-P]

RIN 0938-AT03

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

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 2018 to implement changes arising from our continuing experience with these systems and certain provisions under the 21st Century Cures Act (Pub. L. 114-255). 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 (ASQQR) Program.

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. ET on September 11, 2017.

ADDRESSES: In commenting, please refer to file code CMS-1678-P when commenting on the issues in this proposed rule. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

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-1678-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-1678-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal Government identification,

commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

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.)

Advisory Panel on Hospital Outpatient Payment (HOP Panel), contact the HOP Panel mailbox at APPanel@cms.hhs.gov. Ambulatory Surgical Center (ASC) Payment System, contact Elisabeth

Daniel at 410-786-0237 or via email Elisabeth.Daniel@cms.hhs.gov.

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

Blood and Blood Products, contact Josh McFeeters at 410-786-0732 or via email Joshua.McFeeters@cms.hhs.gov.

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

Care Management Services, contact Scott Talaga at 410-786-4142 or via email Scott.Talaga@cms.hhs.gov.

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

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

Composite APCs (Low Dose Brachytherapy and Multiple Imaging), contact Twi Jackson at 410-786-1159 or via email Twi.Jackson@cms.hhs.gov.

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

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

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

Hospital Outpatient Visits (Emergency Department Visits and Critical Care Visits), contact Twi Jackson at 410-786-1159 or via email Twi.Jackson@cms.hhs.gov.

Inpatient Only (IPO) Procedures List, contact Lela Strong at 410-786-3213 or via email Lela.Strong@cms.hhs.gov.

New Technology Intracranial Lenses (NTILs), contact Scott Talaga at 410-786-4142 or via email Scott.Talaga@cms.hhs.gov.

No Cost/Full Credit and Partial Credit Devices, contact Twi Jackson at 410-786-1159 or via email Twi.Jackson@cms.hhs.gov.

OPPS Brachytherapy, contact Scott Talaga at 410-786-4142 or via email Scott.Talaga@cms.hhs.gov.

OPPS Data (APC Weights, Conversion Factor, Copayments, Cost-to-Charge Ratio (CCR), Data Claims, Geometric Mean Calculation, Outlier Payments, and Wage Index), contact Erick Chuang

OPPS Proposed Rule for CY 2018

Highlights

- 1.75% projected update for 2018
 - market basket increase of 2.9%
 - minus 0.4% 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 OPSS providers proposed to **increase** by approximately \$5.7 billion to approximately **\$70 billion**
- Addenda available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1678-P.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending>.

OPPS Proposed Rule for CY 2018

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 38 drugs
 - Pass-through status expires for 19 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

Proposed Payment for Drugs, Biologicals, and Radiopharmaceuticals

Drugs with continuing pass-through status

- Pass-through status would continue for 38 drugs

CY 2018 HCPCS CODE	CY 2018 LONG DESCRIPTOR
A9515	Choline C 11, diagnostic, per study dose
A9587	Gallium ga-68, dotatate, diagnostic, 0.1 millicurie
A9588	Fluciclovine f-18, diagnostic, 1 millicurie
C9140	Injection, Factor VIII (antihemophilic factor, recombinant) (Afstyla), 1 I.U.
C9460	Injection, cangrelor, 1 mg
C9482	Injection, sotalol hydrochloride, 1 mg
C9483	Injection, atezolizumab, 10 mg
C9484	Injection, eteplirsen, 10 mg
C9485	Injection, olaratumab, 10 mg
C9486	Injection, granisetron extended release, 0.1 mg
Q9989	Ustekinumab, for Intravenous Injection, 1 mg
C9488	Injection, conivaptan hydrochloride, 1 mg
C9489	Injection, nusinersen, 0.1 mg
C9490	Injection, bezlotoxumab, 10 mg
J0570	Buprenorphine implant, 74.2 mg
J1942	Injection, aripiprazole lauroxil, 1 mg
J2182	Injection, mepolizumab, 1 mg
J2786	Injection, reslizumab, 1 mg
J2840	Injection, sebelipase alfa, 1 mg
J7179	Injection, von willebrand factor (recombinant), (vonvendi), 1 i.u. vwf:rc0

CY 2018 HCPCS CODE	CY 2018 LONG DESCRIPTOR
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
J7328	Hyaluronan or derivative, gel-syn, for intra-articular injection, 0.1 mg
J7342	Instillation, ciprofloxacin otic suspension, 6 mg
J7503	Tacrolimus, extended release, (envarsus xr), oral, 0.25 mg
J9034	Injection, bendamustine hcl (Bendeka), 1 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 (G-CSF), Biosimilar, 1 microgram
Q5102	Injection, Infliximab, Biosimilar, 10 mg
Q9982	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries
Q9983	Florbetaben F18, diagnostic, per study does, up to 8.1 millicuries

HCPCS = Healthcare Common Procedure Coding System

Proposed Payment for Drugs, Biologicals, and Radiopharmaceuticals

Drugs with expiring pass-through status

- Pass-through status will expire for 19 drugs

CY 2018 HCPCS CODE	CY 2018 LONG DESCRIPTOR	CY 2018 STATUS INDICATOR	CY 2018 APC
A9586	Florbetapir fl 8, diagnostic, per study dos, up to 10 millicuries	N	
C9447	Injection, phenylephrine and ketorolac, 4 ml vial	N	
J0596	Injection, c-1 esterase inhibitor (human), Ruconest, 10 units	K	9445
J0695	Injection, ceftolozane 50 mg and tazobactam 25 mg	K	9452
J0875	Injection, dalbavancin, 5 mg	K	1823
J1833	Injection, isavuconazonium sulfate, 1 mg	K	9456
J2407	Injection, oritavancin, 10 mg	K	1660
J2502	Injection, pasireotide long acting, 1 mg	K	9454
J2547	Injection, peramivir, 1 mg	K	9451
J2860	Injection, siltuximab, 10 mg	K	9455
J3090	Injection, tedizolid phosphate, 1 mg	K	1662
J7313	Injection, fluocinolone acetonide intravitreal implant, 0.01 mg	K	9450
J8655	Netupitant (300 mg) and palonosetron (0.5 mg)0	K	9448
J9032	Injection, belinostat, 10 mg	K	1658
J9039	Injection, blinatumomab, 1 mcg	K	9449
J9271	Injection, pembrolizumab, 1 mg	K	1490
J9299	Injection, nivolumab, 1 mg	K	9453
Q4172	PuraPly, and PuraPly Antimicrobial, any type, per square centimeter	N	
Q9950	Injection, sulfur hexafluoride lipid microsphere, per ml	N	

OPPS Proposed Rule for CY 2018

What is proposed to change...

Proposed Policy Changes for 2018

“What is proposed to change...”

- Reduce payment for separately payable, non-pass through drugs purchased under the 340B drug discount program
- Increase drug packaging threshold from \$110 to \$120
- Revise thresholds for high/low cost status for skin substitute products
- Modify/expand packaging policies
 - Drug Administration Services
 - Laboratory Date of Service Proposal
 - New Technology Ambulatory Payment Classifications (APCs) & Comprehensive APCs (C-APCs)
- Payment rates for radiation oncology services
- Payment for off-campus provider-based departments (PBDs)
- Update Hospital Outpatient Quality Reporting (OQR) Program measures

Payment for 340B Drugs

“What is proposed to change...”

- CMS proposes to reduce 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%
- CMS proposes to exclude from this proposal drugs with pass-through status and vaccines (that already are excluded from the definition of 340B covered outpatient drugs)
- To operationalize this proposal, CMS proposes to adopt a modifier, effective January 1, 2018, for hospitals to report when submitting claims for separately payable drugs “*not acquired* under the 340B program”
 - CMS would assume that the remaining OPSS drugs were purchased through the 340B program
- CMS seeks comment on how to apply the savings achieved as well as whether the proposal should be phased-in and whether certain exceptions should be granted

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

“What is proposed to change...”

- Packaging threshold proposed to increase from \$110 to **\$120** per day
- “Policy packaged” regardless of cost:



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 2018, CMS proposes to determine high/low cost status for each skin substitute product based on a weighted average mean unit cost (MUC) threshold of **\$47 per cm²** (currently \$33) and a per day cost (PDC) threshold of **\$755** (currently \$719)
- Based on stakeholder concern, CMS proposes to continue to assign products that are in the high cost group in 2017 to the high cost group in 2018, regardless of whether they exceed the CY 2018 MUC or PDC threshold
- Where ASP is not available, CMS proposes that Wholesale Acquisition Cost (WAC)+6% would be used instead
- New skin substitutes without pricing data automatically will be assigned to the low cost category

Revised Thresholds for High/Low Cost Status for Skin Substitutes

“What is proposed to change...”

- Based on CMS’s 2018 proposal, the following products are proposed to be assigned to the high cost group because they were assigned to the high cost group in CY 2017

CY 2018 HCPCS Code	CY 2018 Short Descriptor
Q4103	Oasis Burn Matrix
Q4110	Primatrix
Q4122	Dermacell
Q4127	Talymed
Q4147	Architect ecm, 1 cm
Q4158	MariGen 1 Square cm
Q4161	Bio-Connekt per square cm

Modify/Expand Packaging Policies

“What is proposed to change...”

Packaging of Level 1 and Level 2 Drug Administration Services

- CMS currently excludes packaging of low-cost drug administration services with a geometric mean cost of less than or equal to \$100 from the ancillary services packaging policy
- CMS proposes to package Level 1 drug administration (APC 5691) and Level 2 drug administration (APC 5692) services when they are performed with another separately payable service
- The agency proposes to pay for them separately when they are performed alone
- CMS believes that conditional packaging of drug administration services would promote equitable payment between physician offices and hospital outpatient departments
- The agency proposes to continue to pay vaccine administration services separately, because preventive services are excluded from the packaging policy
- CMS seeks comment on whether it should package all drug administration add-on codes and whether it should consider an encounter-based payment approach for drug administration services

Proposed OPPS Drug Administration Rates for CY 2018

Facts

97%

For CY 2018, approximately 97% of drug administration rates are proposed to increase

2.44% to 5.77%

The range of payment increases among codes with increasing rates

-2.44%

The payment decrease among codes with decreasing rates

HCPCS Code	Short Descriptor	2018		Change 2018-2017
		Payment Rate	2017 Payment Rate	
90471	Immunization admin	56.24	53.17	5.77%
90473	Immune admin oral/nasal	56.24	53.17	5.77%
96360	Hydration iv infusion init	184.16	179.77	2.44%
96361	Hydrate iv infusion add-on	35.73	34.78	2.73%
96365	Ther/proph/diag iv inf init	184.16	179.77	2.44%
96366	Ther/proph/diag iv inf addon	35.73	34.78	2.73%
96367	Tx/proph/dg addl seq iv inf	56.24	53.17	5.77%
96369	Sc ther infusion up to 1 hr	184.16	179.77	2.44%
96370	Sc ther infusion addl hr	35.73	34.78	2.73%
96371	Sc ther infusion reset pump	56.24	53.17	5.77%
96372	Ther/proph/diag inj sc/im	56.24	53.17	5.77%
96373	Ther/proph/diag inj ia	184.16	179.77	2.44%
96374	Ther/proph/diag inj iv push	184.16	179.77	2.44%
96375	Tx/pro/dx inj new drug addon	35.73	34.78	2.73%
96379	Ther/prop/diag inj/inf proc	35.73	34.78	2.73%
96401	Chemo anti-neopl sq/im	56.24	53.17	5.77%
96402	Chemo hormon antineopl sq/im	56.24	53.17	5.77%
96405	Chemo intralesional up to 7	56.24	53.17	5.77%
96406	Chemo intralesional over 7	184.16	179.77	2.44%
96409	Chemo iv push snl drug	184.16	179.77	2.44%
96411	Chemo iv push addl drug	56.24	53.17	5.77%
96413	Chemo iv infusion 1 hr	286.62	279.45	2.57%
96415	Chemo iv infusion addl hr	56.24	53.17	5.77%
96416	Chemo prolong infuse w/pump	286.62	279.45	2.57%
96417	Chemo iv infus each addl seq	56.24	53.17	5.77%
96420	Chemo ia push technique	286.62	279.45	2.57%
96422	Chemo ia infusion up to 1 hr	184.16	179.77	2.44%
96423	Chemo ia infuse each addl hr	35.73	34.78	2.73%
96425	Chemotherapy infusion method	286.62	279.45	2.57%
96440	Chemotherapy intracavitary	286.62	279.45	2.57%
96446	Chemotx admn prt cavity	286.62	279.45	2.57%
96450	Chemotherapy into cns	286.62	279.45	2.57%
96521	Refill/maint portable pump	184.16	179.77	2.44%
96522	Refill/maint pump/resvr syst	184.16	179.77	2.44%
96523	Irrig drug delivery device	53.22	54.55	-2.44%
96542	Chemotherapy injection	184.16	179.77	2.44%
96549	Chemotherapy unspecified	35.73	34.78	2.73%

Modify/Expand Packaging Policies

“What is proposed to change...”

Current policy

- The current Medicare laboratory date of service (DOS) policy is used to determine when a hospital may bill Medicare for a clinical diagnostic laboratory test (CDLT) and when the laboratory performing the test may bill Medicare directly
- When the DOS falls during an inpatient or outpatient stay, payment for the laboratory test usually is bundled with the hospital service and is not separately payable if it is ordered within 14 days of discharge.

Laboratory Date of Service Proposal

- CMS is considering potential modifications to the DOS policy that would allow laboratories to bill Medicare directly for molecular pathology tests and advanced diagnostic laboratory tests (ADLTs)
- CMS is soliciting public comment on whether these tests may be separated from the hospital stay that preceded the test and therefore should have a DOS that is the date of performance rather than the date of collection
- CMS also is considering an alternative option under which the contemplated DOS rule exception would apply only to ADLTs and not to molecular pathology tests

Modify/Expand Packaging Policies

“What is proposed to change...”

Revision of new technology APCs

- CMS proposes to narrow the cost bands of New Technology APCs 1901 (\$100,001-\$115,000) through 1906 (\$130,001-\$145,000) from \$19,999 cost bands to \$14,999 cost bands
- CMS also proposes to add one additional pair of New Technology APCs
- The new pair will have a payment level, ranging from \$145,001-\$160,000, with one set subject to the multiple procedure payment reduction (status indicator T) and the other set not subject to the multiple procedure payment reduction (status indicator S)

Modify/Expand Packaging Policies

“What is proposed to change...”

C-APCs

- CMS does not propose any new C-APCs for 2018
- CMS proposes minor changes to the C-APC payment methodology, including:
 - Establishing a code edit that requires a brachytherapy treatment code when a brachytherapy insertion code is billed
 - Deleting the “CP” modifier (currently used to identify adjunctive services reported on separate claims) and discontinuing its required use for stereotactic radiosurgery (SRS), C-APC 5627 (Level 7 Radiation Therapy), codes 77371 and 77372
 - Proposing to create a new HCPCS C-code to describe blue light cystoscopy (HCPCS code C97XX (Adjunctive blue light cystoscopy with fluorescent imaging agent (List separately in addition to code for primary procedure)) and to allow for a complexity adjustment to APC 5374 (Level 4 Urology and Related Services) when a white light followed by blue light cystoscopy procedure is performed

Proposed OPPS Radiation Oncology Rates for CY 2018

Facts

74%

For CY 2018, approximately 74% of radiation oncology rates are proposed to increase

1.30% to 32.8%

The range of payment increases among codes with increasing rates

-1.0% to -6.0%

The range of payment decrease among codes with decreasing rates

HCPCS Code	Short Descriptor	2018		Change
		Payment Rate	2017 Payment Rate	2018-2017y
76873	Echograp trans r pros study	149.67	112.73	32.8%
77280	Set radiation therapy field	122.37	117.59	4.1%
77285	Set radiation therapy field	315.51	311.57	1.3%
77290	Set radiation therapy field	315.51	311.57	1.3%
77295	3-d radiotherapy plan	1158.79	1066.24	8.7%
77300	Radiation therapy dose plan	122.37	117.59	4.1%
77301	Radiotherapy dose plan imrt	1158.79	1066.24	8.7%
77321	Special telext port plan	315.51	311.57	1.3%
77331	Special radiation dosimetry	122.37	117.59	4.1%
77332	Radiation treatment aid(s)	122.37	117.59	4.1%
77333	Radiation treatment aid(s)	122.37	117.59	4.1%
77334	Radiation treatment aid(s)	315.51	311.57	1.3%
77336	Radiation physics consult	122.37	117.59	4.1%
77338	Design mlc device for imrt	315.51	311.57	1.3%
77370	Radiation physics consult	122.37	117.59	4.1%
77371	Srs multisource	7335.22	7455.99	-1.6%
77372	Srs linear based	7335.22	7455.99	-1.6%
77373	Sbrt delivery	1635.59	1651.29	-1.0%
77401	Radiation treatment delivery	124.45	114.35	8.8%
77470	Special radiation treatment	511.67	494.63	3.4%
77520	Proton trmt simple w/o comp	511.67	494.63	3.4%
77522	Proton trmt simple w/comp	941.77	994.12	-5.3%
77523	Proton trmt intermediate	941.77	994.12	-5.3%
77525	Proton treatment complex	941.77	994.12	-5.3%
77750	Infuse radioactive materials	213.83	204.51	4.6%
77761	Apply intrcav radiat simple	511.67	494.63	3.4%
77762	Apply intrcav radiat interm	511.67	494.63	3.4%
77763	Apply intrcav radiat compl	694.43	738.63	-6.0%
77778	Apply interstit radiat compl	694.43	738.63	-6.0%
77789	Apply surf ldr radionuclide	124.45	114.35	8.8%
77799	Radium/radioisotope therapy	124.45	114.35	8.8%
76873	Echograp trans r pros study	149.67	112.73	32.8%
77280	Set radiation therapy field	122.37	117.59	4.1%
77285	Set radiation therapy field	315.51	311.57	1.3%
77290	Set radiation therapy field	315.51	311.57	1.3%
77295	3-d radiotherapy plan	1158.79	1066.24	8.7%
77300	Radiation therapy dose plan	122.37	117.59	4.1%

Payment for Certain Off-Campus Provider-Based Departments

“What is proposed to change...”

- 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 (“nonexcepted”) 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 nonexcepted 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 does not propose to make any changes “to limit clinical service line expansion or volume increases” at excepted off-campus PBDs

Payment for Certain Off-Campus Provider-Based Departments

CY 2018 Proposals in the Physician Fee Schedule Proposed Rule

- For CY 2018, CMS proposes to reduce the payment rates by half, from 50% to 25% of the OPPS rates, but requests comment and suggests 40% as a middle-ground alternative
 - This proposed rate is based on a comparison of payment rates for clinic and office visits under both payment systems, although CMS previously recognized that these rates are not entirely comparable due to OPPS packaging policies that do not apply in the physician office setting
- CMS is concerned that paying 50% of the OPPS rate might result in payments for items and services in PBDs that are greater than would otherwise be paid under the PFS in the non-facility setting
- CMS does not address whether the payment reduction for drugs acquired under the 340B Program or the modifier for drugs not acquired under that program would apply to these departments

Examples of Proposed 2018 Payment Rates

Code	Description	Physician Office (non-facility setting)	Excepted Hospital Outpatient Department	Nonexcepted Hospital Outpatient Department
96413	Chemo iv infusion 1 hr	\$143.60	\$286.62	\$71.65
96372	Ther/proph/diag inj sc/im	\$20.87	\$56.24	\$14.06
G0463/ 99201-99215	Hospital outpatient clinic visit for assessment and management of a patient/ E/M visits for new or established patients	\$21.95 - \$210.18	\$109.58	\$27.40
74177	Ct abd & pelv w/contrast	\$221.34 (TC)	\$339.14	\$84.79

Hospital OQR Program Measures Updated

“What is proposed to change...”

- CMS proposes no new measures for the Hospital OQR Program
- CMS proposes to remove a total of six measures and, beginning with the CY 2020 payment determination, and to delay implementation of five measures for CY2020:

Measure	Proposed Action
OP-21: Median Time to Pain Management for Long Bone Fracture	Remove as of CY2020
OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures	
OP-1: Median Time to Fibrinolysis	Remove as of CY2021
OP-4: Aspirin at Arrival	
OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional	
OP-25: Safe Surgery Checklist	
OP-37a-e: The Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey Based Measures	Delay implementation in CY2020

The logo for Hogan Lovells, consisting of the name "Hogan Lovells" in a black serif font, positioned inside a solid lime green square.

Hogan
Lovells

Medicare Physician Fee Schedule

PROPOSED RULE FOR CY 2018

August 9, 2017

Medicare Physician Fee Schedule Proposed Rule for CY 2018

QUICK FACTS

WHO?

Centers for Medicare and Medicaid (CMS)

WHAT?

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

CMS-1676-P

82 Fed. Reg. 33,950 (Jul. 21, 2017)

WHERE?

- Nationwide

WHEN?

- Published in Federal Register on July 21, 2017
- Comments due September 11, 2017

33950 Federal Register / Vol. 82, No. 139 / Friday, July 21, 2017 / Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
42 CFR Parts 405, 410, 414, 424, and 425
(CMS-1676-P)
RIN 0938-A702

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program
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.

DATES: To be assessed consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 11, 2017. (See the **SUPPLEMENTARY INFORMATION** section of this final rule with comment period for a list of provisions open for comment.)

FOR FURTHER INFORMATION CONTACT:
Jamie Hermansen, (410) 786-2064, for issues related to the valuation of ambulatory services and any physician payment issues not identified below.
Lindsay Baldwin, (410) 786-1694, and Emily Yodanis, (410) 786-1604, for issues related to telehealth services and primary care.
Roberta Epps, (410) 786-4503, for issues related to PAMA section 216(a) policy and transition from traditional X-ray imaging to digital radiography.
Isadora Gill, (410) 786-8532, for issues related to the valuation of cardiovascular services, bone marrow services, surgical respiratory services, dermatological procedures, and payment rates for nonexempted items and services furnished by nonexempted off-campus provider-based departments of a hospital.
Dusti Henson, (410) 786-1947, for issues related to ophthalmology services.
Tourette Jackson, (410) 786-4735, for issues related to the valuation of musculoskeletal services, allergy and clinical immunology services, endocrinology services, genital surgical services, nervous system services, INR monitoring services, injections and infusions, and chemotherapy services.
Ann Marshall, (410) 786-3009, for issues related to primary care, chronic case management (CCM), and evaluation and management (E/M) services.
Geri Mandowicz, (410) 786-4554, for issues related to malpractice RVUs.
Patrick Sartini, (410) 786-9232, for issues related to the valuation of imaging services and malpractice RVUs.
Michael Sorocan, (410) 786-6132, for issues related to the practice expense methodology, impacts, conversion factor, and valuation of pathology and surgical procedures.
Pamela West, (410) 786-2302, for issues related to therapy services.
Corinne Axelrod, (410) 786-5620, for issues related to rural health clinics or federally qualified health centers.
Felicia Eggleston, (410) 786-0287, for issues related to DME infusion drugs.
Rasheda Johnson, (410) 786-3434, for issues related to initial data collection and reporting periods for the clinical laboratory fee schedule.
Edmund Kasitis, (410) 786-0477, for issues related to biosimilars.
JoAnna Baldwin, (410) 786-7205, or Sarah Fulton, (410) 786-7249, for issues related to appropriate use criteria for advanced diagnostic imaging services.
Alesia Hovatter, (410) 786-0861, for issues related to PQRS.
Alexandra Mlogge, (410) 786-4457, or Elizabeth Holland, (410) 786-1309, for issues related to the EHR incentive program.
Kahin Khan or Terri Postma, (410) 786-8084 or (410) 786-8084, for issues related to the Medicare Shared Savings Program.
Kimberly Spalding Bush, (410) 786-3232, or Fiona Larbi, (410) 786-7224, for issues related to Value-based Payment Modifier and Physician Feedback Program.
Willert Agnewsky, (410) 786-4399, for issues related to MACRA patient relationship categories and codes.
Carlye Bird, (410) 786-1972, or Albert Wrenn, (410) 786-4264, for issues related to diabetes prevention program.

SUPPLEMENTARY INFORMATION:
Table of Contents
I. Executive Summary
II. Provisions of the Proposed Rule for PFS
A. Background
B. Determination of Practice Expense Relative Value Units (PE RVUs)
C. Determination of Medicare Relative Value Units (MRVUs)
D. Medicare Telehealth Services
E. Potentially Misvalued Services Under the PFS
F. Implementation of Reduced Payment for File-Based Imaging Services
G. Proposed Payment Rates Under the Medicare PFS for Nonexempted Items and Services Furnished by Nonexempted Off-Campus Provider-Based Departments of a Hospital

PFS Proposed Rule for CY 2018

Overview

- Projects a conversion factor of **\$35.9903**
- Reflects the **+0.5%** update mandated by the Protecting Access to Medicare Act of 2014 (PAMA) for 2018 and the **-0.19%** 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-1676-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	\$1,802	0%
Radiation Oncology and Radiation Therapy Centers	\$1,784	1%
Radiology	\$4,863	-1%

Policies that are Proposed to Remain the Same

What is proposed to stay the same. . .

- No changes to payment at ASP+6% for drugs, biologicals, and radiopharmaceuticals
- No new proposals related to the Multiple Procedure Payment Reduction (MPPR)
- No changes to payment for mammography services that have seen major revisions in recent years
- No major additions or changes to care management and collaborative care codes that have seen major revisions in recent years

Proposals Related to Cancer Care

What is proposed to change . . .

- CMS proposes new payment rates for chemotherapy administration (Current Procedural Terminology (CPT®)* 96401, 96402, 96409, 96411) 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 with the exception of 96401 (Chemo anti-neopl sq/im)
 - These codes were identified as potentially misvalued in the CY 2016 PFS proposed rule through CMS's high-expenditure screen

Proposed PFS Drug Administration Rates for 2018

Facts

44%

For CY 2018, approximately 44% of non-facility drug administration rates are proposed to decrease

50%

For CY 2018, approximately 50% of facility drug administration rates are proposed to decrease

HCPCS	Description	2017 Non-Facility	2017 Facility	Proposed 2018 Non-Facility	Proposed 2018 Facility	Non-Facility Change	Facility Change
96360	Hydration iv infusion init	\$58.50	NA	\$47.51	NA	-18.79%	NA
96365	Ther/proph/diag iv inf init	\$69.98	NA	\$73.06	NA	4.40%	NA
96369	Sc ther infusion up to 1 hr	\$180.52	NA	\$174.91	NA	-3.11%	NA
96375	Tx/pro/dx inj new drug addon	\$22.61	NA	\$18.36	NA	-18.82%	NA
96401	Chemo anti-neopl sq/im	\$75.37	NA	\$80.62	NA	6.97%	NA
96402	Chemo hormon antineopl sq/im	\$33.02	NA	\$29.15	NA	-11.71%	NA
96405	Chemo intralesional up to 7	\$82.90	\$30.86	\$82.78	\$31.31	-0.15%	1.45%
96406	Chemo intralesional over 7	\$121.30	\$47.37	\$121.65	\$48.59	0.28%	2.56%
96409	Chemo iv push sngl drug	\$112.33	NA	\$110.49	NA	-1.64%	NA
96411	Chemo iv push addl drug	\$63.16	NA	\$59.74	NA	-5.41%	NA
96413	Chemo iv infusion 1 hr	\$139.61	NA	\$143.60	NA	2.86%	NA
96415	Chemo iv infusion addl hr	\$28.71	NA	\$30.95	NA	7.80%	NA
96416	Chemo prolong infuse w/pump	\$141.04	NA	\$146.12	NA	3.60%	NA
96417	Chemo iv infus each addl seq	\$66.04	NA	\$69.10	NA	4.64%	NA
96420	Chemo ia push technique	\$107.67	NA	\$106.53	NA	-1.05%	NA
96422	Chemo ia infusion up to 1 hr	\$187.34	NA	\$175.27	NA	-6.44%	NA
96423	Chemo ia infuse each addl hr	\$76.08	NA	\$84.58	NA	11.16%	NA
96425	Chemotherapy infusion method	\$185.54	NA	\$185.35	NA	-0.10%	NA
96440	Chemotherapy intracavitary	\$789.91	\$128.84	\$793.95	\$126.33	0.51%	-1.95%
96446	Chemotx admn prtl cavity	\$205.64	\$29.43	\$209.10	\$28.79	1.68%	-2.16%
96450	Chemotherapy into cns	\$184.11	\$82.54	\$186.43	\$82.42	1.26%	-0.15%
96523	Irrig drug delivery device	\$25.12	NA	\$28.07	NA	11.74%	NA
96542	Chemotherapy injection	\$125.97	\$43.07	\$134.96	\$43.19	7.14%	0.28%

Proposals Related to Cancer Care

- CMS proposes to update the payment rates for radiation therapy planning (CPT codes 77261-77263) to reflect RUC-recommended RVUs
 - CMS is concerned that the RUC proposals don't appear to reflect decreased service times associated with these codes
 - CMS seeks comment on whether it should adopt the RUC recommendation or alternative payment rates
- CMS proposes separate payment for superficial radiation treatment planning and management through a new HCPCS code and to adopt the RUC-recommended RVUs with some revisions, including certain inputs related to radiation physics consultation

Proposals Related to Payment for Drugs

Payment for Biosimilars

- In the CY 2016 PFS final rule, CMS determined that it would pay for biosimilars based on the ASP of all biosimilar products included in a single HCPCS code, resulting in the same payment rate for all biosimilars that rely on a common reference product
- CMS acknowledges continuing concerns about this policy and requests comment on the effects of this policy on fostering a robust, competitive marketplace for biosimilars, and whether the policy should be revised to account for innate differences in biological products

DME Infusion Drugs

- The 21st Century Cures Act changed the payment methodology for DME infusion drugs from 95% of 2003 Average Wholesale Price (AWP) to ASP+6% effective 1/1/17
- CMS proposes to update its regulations accordingly

Payment Changes Related to Transition from X-Ray to Digital Imaging

- The Consolidated Appropriations Act of 2016 reduced payment under the PFS for certain imaging services using older technologies
- CMS began implementation in CY 2017
 - Reduced by 20% payment under the PFS for technical component of imaging services using film X-rays
- CMS now proposes further implementation for CY 2018
 - Would reduce payment for computed radiography X-rays under the PFS by 7% (for CY 2018 to CY 2022) and then by 10% (CY 2023 and thereafter)
- CMS also proposes to add the new equipment PE input for the professional Picture Archiving and Communication System (PACS) used by physicians to interpret digital images, priced at \$14,616.93, to 26 additional CPT codes requested by stakeholders

Potentially Misvalued Codes

- CMS proposes to review as potentially misvalued a limited number of CPT codes
- The proposed codes were not identified through a screen and do not involve oncology services
- Proposed Rule continues PAMA requirement that CMS meet target for net reduction in PFS services through adjustments to misvalued codes
- Target set at 0.5% of PFS expenditures for 2018
- CMS's proposed changes do not meet this target, resulting in a required reduction of -0.19% across all PFS expenditures

Appropriate Use Criteria for Advanced Diagnostic Imaging

- PAMA directs 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 1/1/17
- When the program is fully implemented, professionals who furnish such services (FPs) must report, as a condition of payment for the service, that the professional who ordered the service (OP) consulted AUCs through a qualified clinical decision support mechanism (CDSM)
- In the Proposed Rule, CMS acknowledges that implementation will be **delayed until 1/1/19**

AUC for Advanced Diagnostic Imaging

- 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 for the CDSMs
 - CMS has named 17 Qualified PLEs as of June 2017, available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/PLE.html>
 - CMS has named 7 Qualified CDSMs and 9 CDSMs with Preliminary Qualification as of June 2017 at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/CDSM.html>
- CMS also codified statutory exceptions to the AUC consultation requirement for:
 - Emergency services when provided to individuals with emergency medical conditions
 - Hospital inpatients
 - OPs who are granted a significant hardship exemption

AUC for Advanced Diagnostic Imaging

- The Proposed Rule would implement the requirement to consult AUCs and report that consultation as a condition of payment, effective 1/1/19
- FPs would be required to report the following with each claim for an applicable advanced diagnostic imaging service furnished in a physician's office (under the PFS), hospital outpatient department or emergency department (under the OPPOS), or ASC (under the ASC Prospective Payment System):
 - which qualified CDSM the OP consulted;
 - whether the service ordered would adhere to the AUCs, would not adhere, or had no applicable AUCs;
 - the National Provider Identifier (NPI) for the OP, if different from the FP

AUC for Advanced Diagnostic Imaging

- CMS proposes three new HCPCS level 3 G-codes to report AUC consultation and will eventually provide a separate G-code for each qualified CDSM
- CMS proposes a voluntary reporting period to be available before 1/1/19 to allow clinicians to educate themselves and test operations before the consultation requirement takes effect
- In the Quality Payment Program (QPP) Proposed Rule, CMS also proposes to give Merit-Based Incentive Payment System (MIPS) credit to OPs for consulting AUC using a qualified CDSM as a high-weight improvement activity for the performance period beginning 1/1/18 to incentivize early adoption by motivated eligible physicians
- CMS also proposes a new automatic exemption for OPs who are exempt from the advancing care information category under the MIPS, e.g., if the clinician lacks control over availability of certified EHR technology

Potential Changes to Evaluation & Management Codes

- CMS seeks comment on changes that it should make to update the existing guidelines for billing evaluation and management (E/M) codes
- CMS suggests it may begin by focusing on the guidelines for the history and physical exam components that CMS believes are the most outdated
- CMS seeks comment on:
 - Removing documentation requirements for the history and physical exam for E/M services at all levels
 - Eliminate the current focus on details of history and physical exam in favor of allowing the medical decision-making guidelines to serve as the key determinant of the E/M visit level

Request for Information on CMS Flexibilities and Efficiencies

- Both the OPPS and the PFS Proposed Rules include a broad Request for Information (RFI) on changes that CMS could make to the Medicare program to:
 - Reduce unnecessary burdens for providers, physicians, and patients
 - Improve outcomes
 - Improve the quality of care
 - Reduce costs
- Suggestions can be at the regulatory, sub-regulatory, policy, practice, or procedural level
- Examples include payment system redesign, elimination or streamlining of reporting, monitoring, and documentation requirements, operational flexibility, and data sharing or feedback that would enhance patient care

Presenters



Beth Roberts

Partner, Washington, D.C.

T +1 202.637.8626

beth.roberts@hoganlovells.com

Areas of Focus

Health Law
Government Relations and
Policy Advocacy
Medical Device Law
Life Sciences & Healthcare



Beth Halpern

Partner, Washington, D.C.

T +1 202.637.8609

elizabeth.halpern@hoganlovells.com

Areas of Focus

Health Law
Government Relations and
Policy Advocacy
Medical Device Law
Life Sciences & Healthcare