Hogan Lovells

Overview of Selected Provisions of the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule for Calendar Year 2019

On July 31, 2018, the Centers for Medicare & Medicaid Services (CMS) published the Hospital Outpatient Prospective Payment (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems and Quality Reporting Programs proposed rule for the calendar year (CY) 2019 (the "Proposed Rule"). The Proposed Rule also includes requests for information (RFIs) on promoting interoperability and electronic health care information, price transparency, and leveraging authority for the Competitive Acquisition Program (CAP) for Part B drugs and biologicals for a potential Center for Medicare and Medicaid Innovation (CMMI) model. Comments on the Proposed Rule are due September 24, 2018.[1]

CMS proposes to increase payment rates under the OPPS by an outpatient department (OPD) fee schedule increase factor of 1.25 percent. This increase factor is based on the proposed hospital inpatient market basket percentage increase of 2.8 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the proposed multifactor productivity (MFP) adjustment of 0.8 percentage point, and minus a 0.75 percentage point adjustment required by the Affordable Care Act (ACA). CMS estimates that total payments to OPPS providers for CY 2019 would be approximately $74.6 billion, an increase of approximately $4.9 billion compared to estimated CY 2018 OPPS payments. CMS proposes to continue to implement the statutory 2.0 percentage point reduction in payments for hospitals failing to meet the hospital outpatient quality reporting requirements by applying a reporting factor of 0.980 to the OPPS payments and copayments for all applicable services.[2]

The addenda containing relative weights, payment rates, wage indices, and other payment information are available only on the CMS web site. Addenda relating to the OPPS are available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1695-P.html, and addenda relating to the ASC payment system are available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices-Items/CMS-1695-P.html. In conjunction with the Proposed Rule release, CMS also published a fact sheet, available at: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-items/2018-07-25.html, and a press release, available at:

[1] 83 Fed. Reg. 37,046. Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model (July 31, 2018), *available at:* https://www.gpo.gov/fdsys/pkg/FR-2018-07-31/pdf/2018-15958.pdf ("Proposed Rule").

[2] *Id.* at 37,049.

https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2018-Press-releases-items/2018-07-25.html.

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

(1) Proposed Updates Affecting OPPS Payments
   a. Proposed payment adjustment for certain cancer hospitals
   b. Proposed hospital outpatient outlier payments
(2) Proposed Ambulatory Payment Classification (APC) Group Policies
   a. Proposed treatment of new and revised CY 2019 Category I and III CPT®[3] codes
   b. Proposed treatment of new CY 2019 CPT and Level II Healthcare Common Procedure Coding System (HCPCS) codes
   c. Proposed APC exceptions to the 2 Times Rule
(3) Proposed Recalibration of APC Relative Payments
(4) Proposed Conversion Factor Update
(5) HCPCS Code-level Device-intensive Determination
(6) Proposed Estimate of Pass-through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices
(7) Proposed OPPS Transitional Pass-through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals
   a. Drugs and biologicals with expiring pass-through payment status
   b. Proposed drugs, biologicals, and radiopharmaceuticals with new or continuing pass-through payment status in CY 2019
(8) Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-through Payment Status
   a. Packaging policies
   b. Packaging of skin substitutes
   c. Payment for drugs and biologicals without pass-through status that are not packaged
(9) Proposed Payment Rates
   a. Drug Administration Services
   b. Radiation Therapy Services
   c. Payment for CAR-T Therapies
   d. Proposed Payment for Partial Hospitalization Services
(10) Collecting Data on Services Furnished in Off-Campus Provider-Based Emergency Departments
(11) Payment for Clinical Families of Services Furnished by Certain Off-Campus Provider Based Departments
(12) Proposal to Apply the 340B Drug Payment Policy to Nonexcepted Off-Campus Departments of a Hospital
(13) Proposal and Comment Solicitation on Method to Control Unnecessary Increases in the Volume of Outpatient Services
   a. Proposed payment modification for clinic visits provided by excepted off-campus provider based departments
   b. Solicitation for comments on methods to control unnecessary increases in the volume of outpatient services
(14) Proposed Updates to the Ambulatory Surgical Center (ASC) Payment System

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

a. Designation of HCPCS code as office-based or ASC covered
b. Device-intensive procedures performed in the ASC
c. Definition of surgical procedure in the ASC
d. Temporary hospital market basket update for ASCs
e. ASC conversion factor

(15) Requirements for the Hospital Outpatient Quality Reporting (OQR) Program
a. Proposed updates to hospital OQR removal factors
b. Proposed removal of hospital OQR measures
c. Possible hospital OQR program measures and topics for future consideration
d. Proposals related to QualityNet Security Administrator administrative requirements

(16) Requirements for the ASC Quality Reporting (ASCQR) Program
a. Proposed updates to ASCQR removal factors
b. Proposed removal of ASCQR measures
c. Possible ASCQR program measures and topics for future consideration
d. Proposals related to requirements for non-Quality Data Codes (QDC) based, claims-based measure data

(17) Requests for Information (RFIs)
a. RFI on Promoting Interoperability and Electronic Healthcare Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers
b. RFI on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information
c. Leveraging the Authority for the CAP for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model

(18) Proposed Additional Hospital Inpatient Quality Reporting (IQR) Program Policies

CMS Has *Not* Proposed Changes to the Following Policies:

a. *Payments for Magnetic Resonance Imaging (MRI) and Computed Tomography (CT).* CMS proposes to extend its transition policy for calculating costs associated with the APCs for MRI and CT to remove claims from providers that use a cost allocation method of "square feet" to calculate cost-to-charge ratios (CCRs) used to estimate costs associated with the APCs for CT and MRI. CMS notes that it does not believe another extension in CY 2020 will be warranted and expects to determine imaging APC relative payment weights for CY 2020 using cost data from all providers, regardless of the cost allocation method employed. Extending the transition policy for 2019 is projected to increase payment rates for most imaging APCs between 2.8 and 13.9 percent compared to the rates if cost data from all providers were included.[4]
b. *Comprehensive APC (C-APC) payment methodology*.[5]
c. *Biosimilar pass-through payment eligibility.* CMS does not propose changes to the CY 2018 policy that all biosimilar biological products are eligible for pass-through payment, not just the first biosimilar biological product for a reference product.[6]
d. *Therapeutic radiopharmaceuticals payment.* CMS does not propose changes to continue its current policy of paying all nonpass-through, separately payable therapeutic

[4] 83 Fed. Reg. 37,056.
[5] *Id.* at 37,062.
[6] *Id*. at 37,123.

radiopharmaceuticals at average sales price (ASP) plus six (ASP+6) percent.[7] The agency's proposed CY 2019 payment rates for nonpass-through, separately payable therapeutic radiopharmaceuticals are in Addenda A and B of the Proposed Rule.

e. *Payments for radioisotopes derived from non-highly enriched uranium sources.* CMS proposes to continue its current policy of providing an additional $10 payment for radioisotopes produced by non-HEU sources. CMS intends to reassess this payment policy once conversion to non-HEU sources is closer to completion or has been completed.[8]
f. *Blood clotting factors payment.* For CY 2019, CMS proposes to pay for blood clotting factors at ASP+6 percent, consistent with its proposed payment policy for other nonpass-through, separately payable drugs and biologicals, and to continue to update the furnishing fee by the Consumer Price Index (CPI) for medical care.[9]
g. *Nonpass-through drugs without OPPS hospital claims data.* CMS does not propose changes to its current payment policy for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data.[10]
h. *Separately payable nonpass-through drugs not acquired under the 340B Program.* CMS proposes to continue to pay ASP+6 percent for separately payable nonpass-through drugs that were not acquired under the 340B Program.[11]
i. *Types of hospitals excepted from CMS's 340B drug payment adjustment.* CMS proposes to continue to exempt rural sole community hospitals (SCHs), children's hospitals, and PPS-exempt cancer hospitals from its 340B payment adjustment. Such hospitals will continue to be required to report modifier "TB" for 340B-acquired drugs and will continue to be paid ASP+6 percent.[12]
j. *Payments for separately payable drugs.* CMS proposes to continue to pay for separately payable drugs and biologicals at ASP+6 percent, and to continue to pay for separately payable non pass-through drugs acquired with a 340B discount at a rate of ASP minus 22.5 (ASP-22.5) percent.[13]
k. *Proposed Adjustment for Rural Sole Community Hospitals (SCHs) and Essential Access Community Hospitals (EACHs).* For CY 2019, CMS proposes to continue its current policy of a 7.1 percent payment adjustment in a budget neutral manner for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs. In addition, rather than addressing the payment adjustment and proposing specific payment adjustment rates for the following year in the annual rulemaking, CMS proposes to maintain the 7.1 percent payment adjustment for subsequent years until it identifies data that would support a change to this payment adjustment.[14]

Details about the proposed changes are provided below.

[7] *Id*. at 37,123-24.
[8] *Id*. at 37,124.
[9] *Id*.
[10] *Id*. at 37,125.
[11] *Id*. at 37,125-26.
[12] *Id*.
[13] *Id*.
[14] *Id.* at 37,126.

(1) *Proposed Updates Affecting OPPS Payments*

a. Proposed Payment Adjustment for Certain Cancer Hospitals

CMS proposes to use a target payment-to-cost ratio (PCR) of 0.88 to determine the CY 2019 cancer hospital payment adjustment.[15] Eleven cancer hospitals currently receive this payment adjustment to reflect the greater costs incurred by these cancer hospitals as compared to other OPPS hospitals. This PCR reflects the requirement in the 21st Century Cures Act that the PCR adjustment be reduced by 1.0 percentage point than would otherwise apply.[16] Table 6 in the Proposed Rule provides the estimated percentage increase in OPPS payments for CY 2019 due to payment adjustment for these 11 cancer hospitals.[17]

b. Proposed hospital outpatient outlier payments

CMS proposes to continue the policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS. To ensure that the estimated CY 2019 aggregate outlier payments would equal 1.0 percent of the estimated aggregate total payments under the OPPS, CMS proposes that the hospital outlier threshold be set so that outlier payments would be triggered when a hospital's cost of furnishing a service exceeds 1.75 times the APC payment amount plus $4,600.[18]

(2) *Proposed APC Group Policies*

a. Proposed treatment of new and revised CY 2019 Category I and III CPT codes

CMS received the CY 2019 CPT codes from the American Medical Association (AMA) that will be effective January 1, 2019 in time for inclusion in the Proposed Rule. These codes appear in Addendum B and are assigned to new comment indicator "NP" to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code description in the next calendar year with a proposed APC assignment and that comments will be accepted on the proposed APC assignment and status indicator. The long descriptors for these codes are available in Addendum O of the Proposed Rule. The final CPT code numbers will be included in the final rule.[19]

b. Proposed treatment of new CY 2019 CPT and Level II HCPCS codes

CMS solicits comments on the proposed CY 2019 status indicators, APC assignments, and payment rates for ten Level II HCPCS codes and four Category III CPT codes that were made effective April 1, 2018 and July 1, 2018. These codes are listed in Tables 8 and 10 of the Proposed Rule.[20]

---

[15] *Id.* at 37,080.
[16] *Id.*
[17] *Id.*
[18] *Id.* at 37,081.
[19] *Id*. at 37,088.
[20] *Id*. at 37,084-86.

c. Proposed APC exceptions to the 2 Times Rule

CMS generally requires the highest cost item or service in an APC group to not be more than two times greater than the lowest cost one (i.e., the "2 times rule"). For CY 2019, CMS proposes exceptions from the 2 times rule for 16 APCs.[21]

Proposed CY 2019 APC	Proposed CY 2019 APC title
5071	Level 1 Excision/ Biopsy/ Incision and Drainage
5113	Level 3 Musculoskeletal Procedures
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5571	Level 1 Imaging with Contrast
5612	Level 2 Therapeutic Radiation Treatment Preparation
5691	Level 1 Drug Administration
5692	Level 2 Drug Administration
5721	Level1 Diagnostic Tests and Related Services
5724	Level 4 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5732	Level 2 Minor Procedures
5735	Level 5 Minor Procedures
5822	Level 2 Health and Behavior Services
5823	Level 3 Health and Behavior Services

(3) Proposed Recalibration of APC Relative Payments

CMS proposes to recalibrate relative payment weights for each APC based on claims and cost report data for hospital outpatient department (HOPD) services, using the most recent available data to construct database for calculating APC group weights.[22] CMS proposes new calculations of single procedure APC criteria-based costs for blood and blood products and brachytherapy sources.[23]

For brachytherapy sources, CMS proposes to use the costs derived from CY 2017 claims data to set the proposed CY 2019 payment rates and to base the payment rates for brachytherapy sources on the geometric mean unit costs for each source.[24] This methodology is consistent with the methodology that CMS uses for other items and services paid under the OPPS.[25] CMS also proposes to continue the other, previously finalized payment policies for brachytherapy sources.[26]

[21] *Id.* at 37,090-91.
[22] *Id.* at 37,055.
[23] *Id.* at 37,057-58.
[24] *Id.* at 37,058.
[25] *Id.*
[26] *Id.*

In order to address concerns raised with assigning new services to the most appropriate clinical APC and that there is sufficient claims data for services assigned to New Technology APCs, CMS proposes to exclude payment for any procedure that is assigned to a New Technology APC from being packaged when included on a claim with a "J1" service assigned to a Comprehensive APC (C-APC).[27]

CMS proposes to continue composite APC payment policies for mental health services and multiple imaging services. With respect to mental health services, CMS proposes that when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service exceeds the maximum per diem payment rate for partial hospitalization services, those specified mental health services would be paid through composite APC 8010 (Mental Health Services Composite) for CY 2019.[28]

CMS also seeks public comment on whether separate payment would further incentivize appropriate use of Exparel, a local anesthetic used for postsurgical analgesia, in the hospital outpatient setting and peer-reviewed evidence that such increased utilization would lead to a decrease in opioid use and addiction among Medicare beneficiaries.[29]

In relation to the packaging of policy for non-opioid pain management treatments, CMS proposes to unpackage and pay separately for the cost of non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting for CY 2019.[30]

CMS proposes to calculate APC relative weight scales by dividing the CY 2018 estimated aggregate weight by the unscaled CY 2019 estimated aggregate weight.[31] CMS further proposes to adjust the estimated CY 2019 unscaled relative payment weights by multiplying them by a proposed weight scalar of 1.4553 to ensure the proposed CY 2019 relative payment weights are budget neutral.[32]

(4) *Proposed Conversion Factor Update*

For CY 2019, CMS proposes to reduce the OPD fee schedule increase factor required to satisfy certain statutory requirements. Specifically, CMS proposes to use a reduced conversion factor of $77.955 to calculate payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of -1.591).[33] CMS proposes using a conversion factor of $79.546 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs.

A conversion factor of $79.546 results from the proposed OPD fee schedule increase factor of 1.25 percent, the required proposed wage index budget neutrality adjustment of

[27] *Id.* at 37,063.
[28] *Id.* at 37,064.
[29] *Id.* at 37,069.
[30] *Id.* at 37,069-70.
[31] *Id.* at 37,071-72.
[32] *Id.* at 37,072.
[33] *Id.* at 37,073.

approximately 1.0004, the proposed cancer hospital payment adjustment of 1.0000, and the proposed adjustment of 0.02 percent of projected OPPS spending for the difference in pass-through spending and outlier payments.[34]

(5) *HCPCS Code-Level Device-Intensive Determination*

CMS proposes the following changes to the HCPCS code-level device-intensive determination:

- CMS is "proposing to allow procedures that involve surgically inserted or implanted, single-use devices that meet the device offset percentage threshold to qualify as device-intensive procedures, regardless of whether the device remains in the patient's body after the conclusion of the procedure, because [CMS] no longer believe[s] that whether a device remains in the patient's body should affect its designation as a device-intensive procedure because such devices could, nonetheless, comprise a large cost of the applicable procedure."[35]
- CMS is "proposing to modify [its] criteria to lower the device offset percentage threshold from 40 percent to 30 percent, to allow a greater number of procedures to qualify as device-intensive."[36]

The proposed updated list of HCPCS code-level device-intensive determination criteria, including these changes, is listed in the Proposed Rule.[37] CMS also solicits comment on:

- Whether there are any devices that should be deemed part of the device-intensive procedures but that would not meet the new criteria and
- The proposed list of device-intensive procedures found at Addendum P and whether there are any devices in that list that should not receive device-intensive status.[38]

Finally, CMS is "proposing to . . . apply a 31-percent default device offset to new HCPCS codes describing procedures requiring the implantation of a medical device that do not yet have associated claims data until claims data are available to establish the HCPCS code-level device offset for the procedures."[39] This threshold was previously set at 41 percent.[40] CMS also proposes to clarify that the claims data to be used to determine device intensive status is data for a new HCPCS code or its predecessor code or, in limited circumstances where there may not be a predecessor code, a code that CMS identifies as clinically related to or similar to the new HCPCS code.[41] Where there are multiple such codes, CMS will use the code with the highest individual HCPCS level device offset percentage.[42]

---

[34] *Id.*
[35] *Id*. at 37,108.
[36] *Id*.
[37] *Id*.
[38] *Id*.
[39] *Id*. at 37,108-09.
[40] *Id* at 37,109.
[41] *Id*.
[42] *Id*. at 37,109-10.

(6) *Proposed Estimate of Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices*

CMS estimates total pass-through spending for the devices, drugs, and biologicals receiving pass-through payment in CY 2019 to be approximately $126.7 million.[43] This projected spending is less than 2.0 percent of total program payments and therefore will not trigger a uniform prospective reduction. The estimate includes $10 million for device categories that are anticipated to become newly eligible for pass-through payment in CY 2019, $61.5 million for known drugs and biologicals eligible for pass-through payment, and $55.2 million for drugs and biologicals that are anticipated to become newly eligible for pass-through payment in CY 2019.[44]

Currently, there are no device categories with pass-through payment status.[45] CMS considered seven applications for pass-through payment status during the quarterly review process, none of which were ultimately approved:[46]

- AquaBeam System[47]
- BioBag® (Larval Debridement Therapy in a Contained Dressing)[48]
- BlastX™ Antimicrobial Wound Gel[49]
- EpiCord®[50]
- remedē System Transvenous Neurostimulator[51]
- Restrata® Wound Matrix[52]
- SpaceOAR® System[53]

For all drugs and biologicals eligible for pass-through payments, the agency proposes to continue to update pass-through payment rates on a quarterly basis on the CMS website during CY 2019 if price reporting-related submissions indicated that such adjustments are necessary. CMS seeks comments on whether these devices meet the criteria for pass-through status.[54]

[43] *Id.* at 37,127.
[44] *Id.*
[45] *Id*. at 37,099.
[46] *Id*. at 37,098.
[47] *Id*. at 37,098-100.
[48] *Id*. at 37,100-01.
[49] *Id*. at 37,101.
[50] *Id*. at 37,101-03.
[51] *Id*. at 37,103-04.
[52] *Id*. at 37,104-05.
[53] *Id*. at 37,105-07.
[54] *Id*. at 37,107.

(7) *Proposed OPPS Transitional Pass-through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals*

a. Drugs and biologicals with expiring pass-through payment status

CMS proposes that the pass-through payment status of the 23 drugs and biologicals listed below would expire on December 31, 2018. All of these drugs and biologicals will have received OPPS pass-through payment for at least 2 years and no more than 3 years by December 31, 2018.[55]

CY 2019 HCPCS CODE	CY 2019 LONG DESCRIPTOR	CY 2019 STATUS INDICATOR	CY 2019 APC
A9515	Choline C 11, diagnostic, per study dose	G	9461
C9460	Injection, cangrelor, 1 mg	G	9460
C9482	Injection, sotalol hydrochloride, 1 mg	G	9482
J1942	Injection, aripiprazole lauroxil, 1 mg	G	9470
J2182	Injection, mepolizumab, 1 mg	G	9473
J2786	Injection, reslizumab, 1 mg	G	9481
J2840	Injection, sebelipase alfa, 1 mg	G	9478
J7202	Injection, Factor IX, albumin fusion protein (recombinant), Idelvion, 1 i.u.	G	9171
J7207	Injection, Factor VIII (antihemophilic factor, recombinant) PEGylated, 1 I.U.	G	1844
J7209	Injection, Factor VIII (antihemophilic factor, recombinant) (Nuwiq), per i.u	G	1846
J7322	Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg	G	9471
J7342	Instillation, ciprofloxacin otic suspension, 6 mg	G	9479
J7503	Tacrolimus, extended release, (envarsus xr), oral, 0.25 mg	G	1845
J9022	Injection, atezolizumab, 10 mg	G	9483
J9145	Injection, daratumumab, 10 mg	G	9476
J9176	Injection, elotuzumab, 1 mg	G	9477

[55] *Id*. at 37,112.

CY 2019 HCPCS CODE	CY 2019 LONG DESCRIPTOR	CY 2019 STATUS INDICATOR	CY 2019 APC
J9205	Injection, irinotecan liposome, 1 mg	G	9474
J9295	Injection, necitumumab, 1 mg	G	9475
J9325	Injection, talimogene laherparepvec, 1 million plaque forming units (PFU)	G	9472
J9352	Injection, trabectedin, 0.1 mg	G	9480
Q5101	Injection, filgrastim-sndz, biosimilar, (zarxio), 1 microgram	G	1822
Q9982	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries	G	9459
Q9983	Florbetaben F18, diagnostic, per study dose, up to 8.1 millicuries	G	9458

With the exception of policy packaged drugs (anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including contrast agents, diagnostic radiopharmaceuticals, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), CMS's standard methodology for providing payment for drugs and biologicals with expiring pass-through payment status in an upcoming calendar year is to determine the product's estimated per day cost and compare it to the OPPS drug packaging threshold for that calendar year (which is proposed to be $125 for CY 2019). CMS proposes that if the estimated per day cost for the drug or biological is less than or equal to the applicable OPPS drug packaging threshold, the agency would package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimated per day cost of the drug or biological is greater than the OPPS drug packaging threshold, CMS proposes to provide separate payment at ASP+6 percent for CY 2019.[56]

b. *Proposed drugs, biologicals, and radiopharmaceuticals with new or continuing pass-through payment status in CY 2019*

CMS proposes to continue pass-through payment status in CY 2019 for (i) 45 drugs and biologicals that were approved for pass-through payment status between January 1, 2017 and July 1, 2018, and (ii) four drugs and biologicals that already have had three years of pass-through payment status but are eligible for pass-through payment under section 1833(t)(6)(G) of the Social Security Act (SSA), as added by section 1301(a)(1)(C) of the Consolidated Appropriations Act of 2018. These drugs and biologicals are included in the table below.[57]

[56] *Id*.
[57] *Id*. at 37,112-14.

CY 2019 HCPCS CODE	CY 2019 LONG DESCRIPTOR	PROPOSED CY 2019 STATUS INDICATOR	PROPOSED CY 2019 APC	PASS-THROUGH PAYMENT EFFECTIVE DATE
A9586	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries	G	9084	10/01/2018
A9587	Gallium ga-68, dotatate, diagnostic, 0.1 millicurie	G	9056	01/01/2017
A9588	Fluciclovine f-18, diagnostic, 1 millicurie	G	9052	01/01/2017
C9014	Injection, cerliponase alfa, 1 mg	G	9014	01/01/2018
C9015	Injection, c-1 esterase inhibitor (human), Haegarda, 10 units	G	9015	01/01/2018
C9016	Injection, triptorelin extended release, 3.75 mg	G	9016	01/01/2018
C9024	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine	G	9302	01/01/2018
C9028	Injection, inotuzumab ozogamicin, 0.1 mg	G	9028	01/01/2018
C9029	Injection, guselkumab, 1 mg	G	9029	01/01/2018
C9030	Injection, copanlisib, 1 mg	G	9030	07/01/2018
C9031	Lutetium Lu 177, dotatate, therapeutic, 1 mCi	G	9067	07/01/2018
C9032	Injection, voretigene neparvovec-rzyl, 1 billion vector genome	G	9070	07/01/2018
C9447	Injection, phenylephrine and ketorolac, 4 ml vial	G	9083	10/01/2018
C9462	Injection, delafloxacin, 1 mg	G	9462	04/01/2018
C9463	Injection, aprepitant, 1 mg	G	9463	04/01/2018
C9465	Hyaluronan or derivative, Durolane, for intra-articular injection, per dose	G	9465	04/01/2018
C9466	Injection, benralizumab, 1 mg	G	9466	04/01/2018
C9467	Injection, rituximab and hyaluronidase, 10 mg	G	9467	04/01/2018
C9468	Injection, factor ix (antihemophilic factor, recombinant), glycopegylated, Rebinyn, 1 i.u.	G	9468	04/01/2018
C9469	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	G	9469	04/01/2018
C9488	Injection, conivaptan hydrochloride, 1 mg	G	9488	04/01/2017

CY 2019 HCPCS CODE	CY 2019 LONG DESCRIPTOR	PROPOSED CY 2019 STATUS INDICATOR	PROPOSED CY 2019 APC	PASS-THROUGH PAYMENT EFFECTIVE DATE
C9492	Injection, durvalumab, 10 mg	G	9492	10/01/2017
C9493	Injection, edaravone, 1 mg	G	9493	10/01/2017
J0565	Injection, bezlotoxumab, 10 mg	G	9490	07/01/2017
J0570	Buprenorphine implant, 74.2 mg	G	9058	01/01/2017
J0606	Injection, etelcalcetide, 0.1 mg	G	9031	01/01/2018
J1428	Injection, eteplirsen, 10 mg	G	9484	04/01/2017
J1627	Injection, granisetron extended release, 0.1 mg	G	9486	04/01/2017
J2326	Injection, nusinersen, 0.1 mg	G	9489	07/01/2017
J2350	Injection, ocrelizumab, 1 mg	G	9494	10/01/2017
J3358	Ustekinumab, for Intravenous Injection, 1 mg	G	9487	04/01/2017
J7179	Injection, von willebrand factor (recombinant), (vonvendi), 1 i.u. vwf:rco	G	9059	01/01/2017
J7210	Injection, factor viii, (antihemophilic factor, recombinant), (afstyla), 1 i.u.	G	9043	01/01/2017
J7328	Hyaluronan or derivative, gelsyn-3, for intra-articular injection, 0.1 mg	G	1862	01/01/2016
J7345	Aminolevulinic acid hcl for topical administration, 10% gel, 10 mg	G	9301	01/01/2018
J9023	Injection, avelumab, 10 mg	G	9491	10/01/2017
J9034	Injection, bendamustine hcl (Bendeka), 1 mg	G	1861	01/01/2017
J9203	Injection, gemtuzumab ozogamicin, 0.1 mg	G	9495	01/01/2018
J9285	Injection, olaratumab, 10 mg	G	9485	04/01/2017
Q2040	Tisagenlecleucel, up to 250 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per infusion	G	9081	01/01/2018
Q2041	Axicabtagene Ciloleucel, up to 200 Million Autologous AntiCD19 CAR T Cells, Including Leukapheresis And Dose Preparation Procedures, Per Infusion	G	9035	04/01/2018
Q4172	PuraPly, and PuraPly Antimicrobial, any type, per square centimeter	G	9082	10/01/2018
Q5103	Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg	G	1847	04/01/2018

CY 2019 HCPCS CODE	CY 2019 LONG DESCRIPTOR	PROPOSED CY 2019 STATUS INDICATOR	PROPOSED CY 2019 APC	PASS-THROUGH PAYMENT EFFECTIVE DATE
Q5104	Injection, infliximab-abda, biosimilar, (renflexis), 10 mg	G	9036	04/01/2018
Q9950	Injection, sulfur hexafluoride lipid microsphere, per ml	G	9085	10/01/2018
Q9991	Injection, buprenorphine extended-release (Sublocade), less than or equal to 100 mg	G	9073	07/01/2018
Q9992	Injection, buprenorphine extended-release (Sublocade), greater than 100 mg	G	9239	07/01/2018
Q9993	Injection, rolapitant, 0.5 mg	G	9464	04/01/2018
Q9994	Injection, emicizumab-kxwh, 0.5 mg	G	9257	07/01/2018

In the case of policy-packaged drugs, CMS proposes a pass-through payment amount of ASP+6 percent for CY 2019 minus a payment offset for any predecessor drug products contributing to the pass-through payment.[58]

Consistent with the agency's CY 2018 policy for diagnostic and therapeutic radiopharmaceuticals, CMS proposes to provide CY 2019 payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status at ASP+6 percent. If ASP data are not available for a radiopharmaceutical, CMS proposes to provide pass-through payment at Wholesale Acquisition Cost (WAC) plus three (WAC+3) percent; and if WAC information is not available, CMS proposes to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent Average Wholesale Price (AWP).[59]

In the case of the four drugs and biologicals that are eligible for continued pass-through payment despite the fact that have already had three years of pass-through payment status, CMS proposes that, for January 1, 2019 through March 31, 2019, pass-through payment would be the greater of: (1) ASP+6 percent based on current ASP data; or (2) the payment rate for the drug or biological on December 31, 2017. For the period of April 1, 2019 through December 31, 2019, CMS proposes that the pass-through payment amount for these drugs and biologicals would be the amount that applies under section 1833(t)(6)(D)(i) of the SSA.[60]

[58] *Id*. at 37,112-13.
[59] *Id*. at 37,113-14.
[60] *Id*. at 37,114-15.

(8) *Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-through Payment Status*

a. Packaging policies

CMS is proposing a packaging threshold for CY 2019 of $125, an increase from the current level of $120. The agency would package items with a per day cost less than or equal to $125, and identify items with a per day cost greater than $125 as separately payable unless they are policy-packaged.[61]

Consistent with the agency's historical practice, CMS proposes to apply the following policies to these HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals whose relationship to the drug packaging threshold changes based on the updated drug packaging threshold and on the final updated data:

- HCPCS codes for drugs and biologicals that were paid separately in CY 2018 and that were proposed for separate payment in CY 2019, and that then have per day costs equal to or less than the CY 2019 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2019 final rule, would continue to receive separate payment in CY 2019,
- HCPCS codes for drugs and biologicals that were packaged in CY 2018 and that were proposed for separate payment in CY 2019, and that then have per day costs equal to or less than the CY 2019 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2019 final rule, would remain packaged in CY 2019, *and*
- HCPCS codes for drugs and biologicals for which we proposed packaged payment in CY 2019 but then have per day costs greater than the CY 2019 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2019 final rule, would receive separate payment in CY 2019.[62]

CMS also proposes to make a payment offset applicable to the APCs for certain diagnostic radiopharmaceuticals, contrast agents, stress agents, and skin substitutes.[63]

CMS proposes to continue to make packaging determinations for HCPCS codes that describe the same drug or biological but are in different doses on a drug-specific basis (as opposed to a HCPCS code basis) to avoid creating financial incentives to pick one HCPCS code over the other. Table 24 in the Proposed Rule provides a list of the HCPCS codes to which the CY 2019 drug-specific packaging determination methodology applies.

[61] *Id*. at 37,116-17.
[62] *Id*. at 37,117.
[63] *Id.*

b. Packaging of skin substitutes

With regard to the packaging of skin substitutes, CMS's current policy is to divide skin substitutes into a "high cost group" and a "low cost group" to ensure adequate resource homogeneity among APC assignments for the skin substitute application procedures.[64] CMS is proposing to assign each skin substitute to one of these groups based on whether its mean unit cost (MUC) or per day cost (PDC) exceeds either the MUC threshold of $49/cm^2 or the PDC threshold of $895. The agency also proposes to continue to assign skin substitutes with pass-through payment status to the high cost category, and to assign to the high cost group those products that were assigned to the high cost group in CY 2018, irrespective of whether the product exceeds the CY 2019 MUC or PDC threshold. New skin substitutes without pricing information would be assigned to the low cost category until pricing information is available to compare to the CY 2019 MUC threshold.

CMS notes that some skin substitute manufacturers have raised concerns about significant fluctuation in the MUC threshold and the PDC threshold from year to year. CMS says that it continues to study and seek feedback on issues related to the payment of skin substitutes. The agency seeks public comment on the following four potential methodologies, as well as any other ideas not captured under these methodologies:

- Establishing a lump-sum "episode-based" payment for a wound care episode,
- Eliminating the high cost/low cost categories for skin substitutes and only having one payment category and set of procedure codes for all skin substitute products,
- Allowing for the payment of current add-on codes or create additional procedure codes to pay for skin graft services between 26 cm^2 and 99 cm^2 and substantially over 100 cm^2, *and*
- Maintaining the existing high cost/low cost skin substitute categories, but changing the threshold used to assign skin substitutes in the high-cost or low-cost group.[65]

The agency notes that it will consider the feedback received in response to this proposed rule as it develops proposals for CY 2020. Table 23 in the Proposed Rule provides the proposed CY 2019 2019 high cost or low cost category assignment for each skin substitute product.[66]

[64] *Id.* at 37,118.
[65] *Id*. at 37,118-19.
[66] *Id*. at 37,120.

c. Payment for drugs and biologicals without pass-through status that are not packaged

CMS proposes to apply the payment methodology set forth in section 1833(t)(14)(A)(iii)(II) of the SSA to all separately payable drugs and biologicals, including specified covered outpatient drugs (SCODs).[67]

CMS also proposes that, effective January 1, 2019, WAC-based payments for Part B drugs, as well as for non-SCOD separately payable drugs, would receive a three percent add-on in place of the six percent add-on that is currently is applied.[68] The agency proposes that it would pay for drugs or biologicals at WAC+3 percent, rather than WAC+6 percent, whenever WAC-based pricing is used for a drug or biological. For drugs and biologicals that otherwise would be subject to a payment reduction because they were acquired under the 340B Program, the 340B Program rate would continue to apply.[69] The agency also proposes to pay nonpass-through biosimilars acquired under the 340B Program at ASP-22.5 percent of the biosimilar's ASP instead of the biosimilar's ASP-22.5 percent of the reference product's ASP.[70]

With respect to 340B Program payment policies, CMS proposes, for CY 2019, to continue the policies it implemented in CY 2018 with the exception of the way the agency calculates payment for 340B-acquired biosimilars. CMS proposes to pay for separately payable Medicare Part B drugs (assigned status indicator "K"), other than vaccines and drugs on pass-through payment status, that meet the definition of "covered outpatient drug" under section 1927(k) of the SSA, that are acquired through the 340B Program at ASP-22.5 percent when billed by a hospital paid under the OPPS that is not excepted from the payment adjustment. Medicare Part B drugs or biologicals excluded from the 340B payment adjustment include vaccines (assigned status indicator "L" or "M") and drugs with OPPS transitional pass-through payment status (assigned status indicator "G"). Additionally, CMS proposes that hospitals paid under the OPPS (other than a type of hospital excluded from the OPPS or excepted from the 340B drug payment policy for CY 2018) continue to be required to report modifier "JG" on the same claim line as the drug HCPCS code to identify a 340B-acquired drug.

(9) Proposed Payment Rates

a. Drug Administration Rates

A chart comparing the current 2018 drug administration payment rates to the proposed CY 2019 drug administration payment rates is provided below.

[67] *Id*.
[68] *Id*. at 37,122.
[69] *Id*. at 37,122-23.
[70] *Id*. at 37,121.

Comparison of Hospital OPPS Drug Administration Rates, July 2018 to Proposed CY 2019

HCPCS Code	Short Descriptor	Proposed 2019 Rates			Q3 2018 Rates			% Change 2018-2019
		SI	APC	Payment Rate	SI	APC	Payment Rate	
90461	Im admin each addl component	B			B			
90471	Immunization admin	Q1	5692	$59.95	Q1	5692	$58.20	-3.0%
90472	Immunization admin each add	N			N			
90473	Immune admin oral/nasal	Q1	5692	$59.95	Q1	5692	$58.20	-3.0%
90474	Immune admin oral/nasal addl	N			N			
96360	Hydration iv infusion init	S	5693	$187.87	S	5693	$191.09	1.7%
96361	Hydrate iv infusion add-on	S	5691	$37.89	S	5691	$37.03	-2.3%
96365	Ther/proph/diag iv inf init	S	5693	$187.87	S	5693	$191.09	1.7%
96366	Ther/proph/diag iv inf addon	S	5691	$37.89	S	5691	$37.03	-2.3%
96367	Tx/proph/dg addl seq iv inf	S	5692	$59.95	S	5692	$58.20	-3.0%
96368	Ther/diag concurrent inf	N			N			
96369	Sc ther infusion up to 1 hr	S	5693	$187.87	S	5693	$191.09	1.7%
96370	Sc ther infusion addl hr	S	5691	$37.89	S	5691	$37.03	-2.3%
96371	Sc ther infusion reset pump	Q1	5692	$59.95	Q1	5692	$58.20	-3.0%
96372	Ther/proph/diag inj sc/im	Q1	5692	$59.95	Q1	5692	$58.20	-3.0%
96373	Ther/proph/diag inj ia	S	5693	$187.87	S	5693	$191.09	1.7%
96374	Ther/proph/diag inj iv push	S	5693	$187.87	S	5693	$191.09	1.7%
96375	Tx/pro/dx inj new drug addon	S	5691	$37.89	S	5691	$37.03	-2.3%
96376	Tx/pro/dx inj same drug adon	N			N			
96379	Ther/prop/diag inj/inf proc	Q1	5691	$37.89	Q1	5691	$37.03	-2.3%
96401	Chemo anti-neopl sq/im	Q1	5692	$59.95	Q1	5692	$58.20	-3.0%
96402	Chemo hormon antineopl sq/im	Q1	5692	$59.95	Q1	5692	$58.20	-3.0%
96405	Chemo intralesional up to 7	Q1	5692	$59.95	Q1	5692	$58.20	-3.0%
96406	Chemo intralesional over 7	S	5693	$187.87	S	5693	$191.09	1.7%
96409	Chemo iv push sngl drug	S	5693	$187.87	S	5693	$191.09	1.7%
96411	Chemo iv push addl drug	S	5692	$59.95	S	5692	$58.20	-3.0%
96413	Chemo iv infusion 1 hr	S	5694	$291.09	S	5694	$297.57	2.2%
96415	Chemo iv infusion addl hr	S	5692	$59.95	S	5692	$58.20	-3.0%
96416	Chemo prolong infuse w/pump	S	5694	$291.09	S	5694	$297.57	2.2%
96417	Chemo iv infus each addl seq	S	5692	$59.95	S	5692	$58.20	-3.0%
96420	Chemo ia push tecnique	S	5694	$291.09	S	5694	$297.57	2.2%
96422	Chemo ia infusion up to 1 hr	S	5693	$187.87	S	5693	$191.09	1.7%
96423	Chemo ia infuse each addl hr	S	5691	$37.89	S	5691	$37.03	-2.3%
96425	Chemotherapy infusion method	S	5694	$291.09	S	5694	$297.57	2.2%
96440	Chemotherapy intracavitary	S	5694	$291.09	S	5694	$297.57	2.2%
96446	Chemotx admn prtl cavity	S	5694	$291.09	S	5694	$297.57	2.2%
96450	Chemotherapy into cns	S	5694	$291.09	S	5694	$297.57	2.2%

96521	Refill/maint portable pump	S	5693	$187.87	S	5693	$191.09	1.7%
96522	Refill/maint pump/resvr syst	S	5693	$187.87	S	5693	$191.09	1.7%
96523	Irrig drug delivery device	Q1	5733	$56.60	Q1	5733	$55.96	-1.1%
96542	Chemotherapy injection	S	5693	$187.87	S	5693	$191.09	1.7%
96549	Chemotherapy unspecified	Q1	5691	$37.89	Q1	5691	$37.03	-2.3%

b. Radiation Therapy Services

A chart comparing the current 2018 radiation therapy payment rates to the proposed CY 2019 radiation therapy payment rates is provided below.

Comparison of Hospital OPPS Radiation Therapy Rates, July 2018 to Proposed CY 2019

HCPCS Code	Short Descriptor	Proposed 2019 Rates			Q3 2018 Rates			% Change 2018-2019
		SI	APC	Payment Rate	SI	APC	Payment Rate	
76873	Echograp trans r pros study	S	5522	$113.80	S	5522	$114.46	0.6%
77280	Set radiation therapy field	S	5611	$125.68	S	5611	$125.35	-0.3%
77285	Set radiation therapy field	S	5612	$327.18	S	5612	$323.09	-1.3%
77290	Set radiation therapy field	S	5612	$327.18	S	5612	$323.09	-1.3%
77295	3-d radiotherapy plan	S	5613	$1,208.10	S	5613	$1,186.68	-1.8%
77300	Radiation therapy dose plan	S	5611	$125.68	S	5611	$125.35	-0.3%
77301	Radiotherapy dose plan imrt	S	5613	$1,208.10	S	5613	$1,186.68	-1.8%
77321	Special teletx port plan	S	5612	$327.18	S	5612	$323.09	-1.3%
77331	Special radiation dosimetry	S	5611	$125.68	S	5611	$125.35	-0.3%
77332	Radiation treatment aid(s)	S	5611	$125.68	S	5611	$125.35	-0.3%
77333	Radiation treatment aid(s)	S	5611	$125.68	S	5611	$125.35	-0.3%
77334	Radiation treatment aid(s)	S	5612	$327.18	S	5612	$323.09	-1.3%
77336	Radiation physics consult	S	5611	$125.68	S	5611	$125.35	-0.3%
77338	Design mlc device for imrt	S	5612	$327.18	S	5612	$323.09	-1.3%
77370	Radiation physics consult	S	5611	$125.68	S	5611	$125.35	-0.3%
77371	Srs multisource	J1	5627	$7,784.59	J1	5627	$7,565.69	-2.9%
77372	Srs linear based	J1	5627	$7,784.59	J1	5627	$7,565.69	-2.9%
77373	Sbrt delivery	S	5626	$1,702.73	S	5626	$1,677.22	-1.5%
77401	Radiation treatment delivery	S	5621	$127.79	S	5621	$124.73	-2.5%
77470	Special radiation treatment	S	5623	$530.43	S	5623	$522.31	-1.6%
77520	Proton trmt simple w/o comp	S	5623	$530.43	S	5623	$522.31	-1.6%
77522	Proton trmt simple w/comp	S	5625	$1,081.08	S	5625	$1,053.52	-2.6%
77523	Proton trmt intermediate	S	5625	$1,081.08	S	5625	$1,053.52	-2.6%
77525	Proton treatment complex	S	5625	$1,081.08	S	5625	$1,053.52	-2.6%
77750	Infuse radioactive materials	S	5622	$226.97	S	5622	$219.83	-3.2%
77761	Apply intrcav radiat simple	S	5623	$530.43	S	5623	$522.31	-1.6%

77762	Apply intrcav radiat interm	S	5623	$530.43	S	5623	$522.31	-1.6%
77763	Apply intrcav radiat compl	S	5624	$714.95	S	5624	$714.11	-0.1%
77778	Apply interstit radiat compl	S	5624	$714.95	S	5624	$714.11	-0.1%
77789	Apply surf ldr radionuclide	S	5621	$127.79	S	5621	$124.73	-2.5%
77799	Radium/radioisotope therapy	S	5621	$127.79	S	5621	$124.73	-2.5%

c. Payment for CAR-T Therapies

For CY 2019, CMS proposes four new HCPCS codes for CAR-T therapies. None of these new HCPCS codes is proposed to be payable under the OPPS, however. A chart with the proposed CY 2019 payment rates for the existing and proposed HCPCS codes for CAR-T therapies is provided below.

HCPCS Code	Short Descriptor	SI[71]	APC	Payment Rate
Q2040	Tisagenlecleucel car-pos t	G	9081	$500,838.643
Q2041	Axicabtagene ciloleucel car+	G	9035	$395,380.000
05X1T	Bld drv t lymphcyt car-t cll	B	N/A	N/A
05X2T	Bld drv t lymphcyt prep trns	B	N/A	N/A
05X3T	Receipt&prep car-t cll admn	B	N/A	N/A
05X4T	Car-t cll admn autologous	B	N/A	N/A

d. Partial Hospitalization Services

CMS proposes to continue to apply established policies to calculate the partial hospitalization program (PHP) APC per diem payment rates based on geometric mean per diem costs. For PHP services provided in a community mental health center (CMHC), CMS proposes a payment rate of $119.51. For hospital-based PHPs, CMS proposes a payment rate of $220.52.[72] CMS will continue to designate approximately less than 0.01 percent of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs.[73] CMS proposes to continue to set the cutoff point for outlier payments for CY 2018 at 3.4 times the payment rate for CMHC APC 5853.[74] Overall, CMS estimates a 17.9 percent decrease in CY 2019 payments to CMHCs relative to their CY 2018 payments.[75]

[71] A status indicator (SI) of "G" means "Pass-Through Drugs and Biologicals; Paid under OPPS; separate APC payment." A SI of "B" means "Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x); Not paid under OPPS; May be paid by MACs when submitted on a different bill type, for example, 75x (CORF), but not paid under OPPS; An alternate code that is recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x) may be available."
[72] *Id.* at 37,131.
[73] *Id.* at 37,135.
[74] *Id.*
[75] *Id.* at 37,051.

CMS also proposes to create a separate PHP-only Revenue-Code-to-Cost-Center crosswalk to provide a more accurate and operationally simple method of matching hospital-based PHP charges to the correct hospital-based PHP cost center CCR without affecting non-PHP ratesetting.[76]

(10) *Collecting Data on Services Furnished in Off-Campus Provider-Based Emergency Departments*

The Medicare Payment Advisory Commission (MedPAC) and other entities have expressed concern that higher payment rates for services performed in off-campus provider-based emergency departments compared to similar services provided in other settings (e.g. physician offices or urgent care clinics) and the exemption for services provided in an emergency department included under section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114-25) may be a key contributing factor to the growth in the number of emergency departments located off-campus from a hospital.

CMS agrees with MedPAC that there is a need to develop data to assess the extent to which current policies and payment incentives may be causing a shift of OPPS services to off-campus provider-based emergency departments. Beginning January 1, 2019, CMS proposes to implement a new HCPCS modifier, "ER—Items and services furnished by a provider-based off-campus emergency department" that is to be reported with every claim line for outpatient hospital services furnished in an off-campus provider-based emergency department.[77]

(11) *Payment for Clinical Families of Services Furnished by Certain Off-Campus Provider Based Departments (PBDs)*

For CY 2019, CMS proposes to decrease reimbursement at certain off-campus departments for services provided in what it considers to be "new clinical families" to 40 percent of the OPPS rate.[78] CMS made a similar proposal in the 2017 OPPS rulemaking cycle but did not implement it. At the time, stakeholders raised concerns about the effect of the proposal on access to care, the burdens it would impose on hospitals to implement payment under different systems for services provided in the same visit, and the proposal's compliance with the statutory requirements for payment.

CMS makes its proposal under section 603 of the Balanced Budget Act of 2015, which requires services at most off-campus hospital outpatient departments that began billing Medicare under the OPPS after November 2, 2015, to be paid under a different payment system. CMS has determined that the payment system for these "nonexcepted" departments is the Medicare Physician Fee Schedule (MPFS). Because CMS cannot process claims submitted by hospitals under the MPFS, it applies a "PFS-adjuster" of 40 percent to calculate what the agency considers to be "PFS-equivalent" rates under the OPPS.

[76] *Id.*at 37,135.
[77] *Id.* at 37,138.
[78] *Id.* at 37,148-49.

Currently, “excepted” off-campus departments – departments that are not subject to the section 603 requirements – are paid under the OPPS. An off-campus PBD is “excepted” if it billed Medicare under the OPPS prior to November 2, 2015, if it meets specific criteria for having been under construction as of November 2, 2015, or if it is an off-campus PBD of a PPS-exempt cancer hospital. Under CMS’s current rules, these departments could expand their service lines and continue to be paid under the OPPS. If they changed ownership or moved, however, they would no longer be excepted and would be paid at 40 percent of the OPPS rates.

CMS proposes that beginning in CY 2019, if an excepted off-campus PBD furnishes services from any “clinical family” of services from which it did not previously furnish services during a baseline period, the services from the new clinical family will not be paid under OPPS, and will instead be paid under the MPFS. CMS defines the following 19 clinical families of services that also appear in Table 32 of the Proposed Rule.[79]

Proposed Clinical Families of Services	APCs
Airway Endoscopy	5151–5155
Blood Product Exchange	5241–5244
Cardiac/Pulmonary Rehabilitation	5771; 5791
Diagnostic/Screening Test and Related Procedures	5721–5724; 5731–5735; 5741–5743
Drug Administration and Clinical Oncology	5691–5694
Ear, Nose, Throat (ENT)	5161–5166
General Surgery and Related Procedures	5051–5055; 5061; 5071–5073; 5091–5094; 5361–5362
Gastrointestinal (GI)	5301–5303; 5311–5313; 5331; 5341
Gynecology	5411–5416
Major Imaging	5523–5525; 5571–5573; 5593–5594
Minor Imaging	5521–5522; 5591–5592
Musculoskeletal Surgery	5111–5116; 5101–5102
Nervous System Procedures	5431–5432; 5441–5443; 5461–5464; 5471
Ophthalmology	5481, 5491–5495; 5501–5504
Pathology	5671–5674
Radiation Oncology	5611–5613; 5621–5627; 5661

[79] *Id.* at 37,150.

Proposed Clinical Families of Services	APCs
Urology	5371–5377
Vascular/Endovascular/Cardiovascular	5181–5184; 5191–5194; 5200; 5211–5213; 5221–5224; 5231–5232
Visits and Related Services	5012; 5021–5025; 5031–5035; 5041; 5045; 5821–582

If CMS implements this proposal, hospitals would be required to identify the clinical families for services they billed under the OPPS in the baseline period, and determine which services they provide in 2019 belong to those families. If a service does not belong to a clinical family that the department billed under the OPPS in the baseline period, then the hospital would be required to report the "PN" modifier to ensure that it is reimbursed at 40 percent the OPPS rate.

(12) *Proposal to Apply the 340B Drug Payment Policy to Nonexcepted Off-Campus Departments of a Hospital*

CMS notes that under the CY 2018 OPPS Final Rule, CMS adopted a policy of paying for drugs purchased through the 340B program at ASP-22.5 percent instead of ASP+6 percent.[80] Nonexcepted off-campus PBDs were not subject to this payment adjustment because the items and services they furnish they were no longer considered to be outpatient department services.[81] As a result, drugs furnished by nonexcepted off-campus PBDs currently are paid using the methodologies in effect for physicians' offices, including ASP+6 percent, not the methodologies under the OPPS.

For CY 2019, CMS is proposing to apply the ASP-22.5 percent payment cuts for 340B acquired drugs to nonexcepted off-campus provider-based departments, excepting sole community hospitals, children's hospitals, and OPPS-exempt cancer hospitals.[82] This proposal extends last year's cuts for 340B acquired drugs to more sites. CMS states that it is proposing this policy to address the incongruity between payments in excepted and nonexcepted off-campus PBDs under the CY 2018 Final Rule.[83] To explain its change in approach, CMS notes that although nonexcepted off-campus PBDs are paid under the MPFS, the PFS-adjuster methodology used to set the "PFS-equivalent" rates for these departments is based on the OPPS, therefore CMS believes it can apply the OPPS payment policies to these sites.

[80] *Id*. at 37,145.
[81] *Id*.
[82] *Id*. at 37,146.
[83] *Id*.

(13) *Proposal and Comment Solicitation on Method to Control Unnecessary Increases in the Volume of Outpatient Services*

a. Proposed payment modification for clinic visits provided by excepted off-campus PBDs

CMS notes its concern about increases in the volume of hospital outpatient services overall, and clinic visits in particular, as described in several MedPAC reports. CMS asserts that this increase is "unnecessary" because it appears to have been incentivized by differences in payment between the OPPS and the MPFS. CMS proposes to use its authority under SSA section 1833(t)(2)(F) to "develop a method for controlling unnecessary increases in the volume of covered outpatient department (OPD) services" to address this concern.

Starting in CY 2019, CMS proposes to set payment for excepted off-campus PBDs at the same level as that applied to nonexcepted off-campus PBDs for clinic visit services (HCPCS code G0463). Under this proposal, both excepted and nonexcepted off-campus PBDs would be reimbursed at 40 percent of the OPPS when billing HCPCS code G0463. In addition, CMS proposes *not* to implement this change in a budget neutral fashion.[84] CMS estimates that this change would reduce total payments to hospitals by $760 million, or 1.2 percent.

b. Solicitation for comments on methods to control unnecessary increases in the volume of hospital outpatient department services

CMS says it is developing a method to systematically control for unnecessary increases in the volume of other hospital outpatient department services. CMS solicits comment on how to maintain access to new innovations while controlling for unnecessary increases in the volume of covered hospital OPD services.

CMS also solicits public comment on how to expand the application of the Secretary's statutory authority under SSA section 1833(t)(2)(F) to additional items and services paid under the OPPS that may represent unnecessary increases in OPD utilization. Specifically, CMS asks:[85]

- How might Medicare define the terms "unnecessary" and "increase" for services (other than the clinic visit) that can be performed in multiple settings of care?
- Should prior authorization be considered as a method for controlling overutilization of services?
- For what reasons might it ever be appropriate to pay a higher OPPS rate for services that can be performed in lower cost settings?
- How might Medicare use the authority at section 1833(t)(2)(F) to implement an evidence-based, clinical support process to assist physicians in evaluating the use of medical services based on medical necessity, appropriateness, and efficiency? Could utilization management help reduce the overuse of inappropriate or unnecessary services?

[84] *Id.* at 37,142.
[85] *Id.* at 37,143.

- How should CMS account for providers that serve Medicare beneficiaries in provider shortage areas, which may include certain rural areas? With respect to rural providers, should there be exceptions from this policy, such as for providers who are at risk of hospital closure or that are sole community hospitals?
- What impact on beneficiaries and the health care market would such a method to control for unnecessary increases in the volume of covered OPD services have?
- What exceptions, if any, should be made if additional proposals to control for unnecessary increases in the volume of outpatient services are made?

(14) *Proposed Updates to the ASC Payment System*

CMS proposes to revise the definition of surgery for the ASC prospective payment system. The agency requests comments on whether the definition should be expanded to include procedures that fall outside the CPT surgical range but fall within the definition of "surgery" developed by the AMA for use in the MPFS professional liability insurance relative values, that CMS determines do not pose a significant safety risk, would not be expected to require an overnight stay when performed in an ASC, and are separately paid under the OPPS.[86]

In addition, CMS seeks comment on proposed payment indicators and proposed payment rates for new HCPCS codes recognized as ASC covered procedures and ancillary services and proposes to finalize its payment indicators and payment rates in the final rule.[87] The agency also solicits comments on the proposed CY 2019 payment indicators for the new and revised Category I and III CPT codes effective January 1, 2019.

a. Designation of HCPCS code as office-based or ASC covered

CMS is proposing to permanently designate certain CPT codes (31573, 36513, 36902 and 36905) as office-based.[88]

CMS proposed to designate eight new CY 2019 CPT codes for ASC covered surgical procedures as temporary office-based (O6X1T, 10X12, 10X14, 10X16, 10X18, 11X02, 11X02, 11X04, 11X06).[89]

b. Device-intensive procedures performed in the ASC

CMS proposes to modify its criteria for device-intensive procedures to better capture costs for procedures with significant device costs. Specifically, CMS proposes to allow procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures. The agency also proposes to modify the criteria to decrease the device offset percentage threshold from 40 to 30 percent. Specifically, CMS proposes that device-intensive procedures would be subject to the following

[86] *Id.* at 37,153.
[87] *Id.* at 37,154.
[88] *Id.* at 37,155-56.
[89] *Id.* at 37,158.

criteria:

- All procedures must involve implantable devices assigned a CPT or HCPCS code;
- Required devices must be surgically inserted or implanted; and
- The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost.[90]

Corresponding to the cost change, CMS proposes that the default device offset for new codes that describe procedures involving the implantation of medical devices would be 31 percent beginning in CY 2019.[91]

CMS proposes to reduce the payment for a device-intensive procedure for which ASC receives partial credit by a half of the device offset amount that would be applied if a device was provided at no cost with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the new device.[92]

c. Definition of surgical procedure in ASC

As discussed above, CMS further proposes to revise the definition of surgery to include "surgery-like" procedures that are assigned codes outside the CPT surgical range. In addition to those discussed, CMS proposes to update the list of ASC covered surgical procedures by adding 12 cardiac catheterization procedures to the list for CY 2019.[93]

CMS also proposes to review all 38 procedures added to the ASC Covered Procedures List (CPL) in CYs 2015, 2016, and 2017 to assess whether these procedures continue to meet CMS criteria including whether they continue to not be expected to pose a significant safety risk to Medicare beneficiaries and if they continue to be expected to require active medical monitoring and care of a beneficiary at midnight following the procedure.[94]

CMS proposes to update ASC Covered Surgical Procedure Payment Rates for CY 2019 by applying the device offset percentage based on the standard OPPS APC ratesetting methodology to the OPPS national unadjusted payment to determine the device cost included in the OPPS ratesetting for a device-intensive ASC covered surgical procedure, which is then set as equal to the device portion of the national unadjusted ASC payment rate for the procedure.[95]

Additionally, CMS proposes to update the payment amount for the service portion of the device-intensive procedures using the ASC standard rate setting methodology and payment amount for the device portion based on the proposed CY 2019 OPPS device

[90] *Id.*
[91] *Id.*
[92] *Id.* at 37,159.
[93] *Id.* at 37,160.
[94] *Id*. at 37,161.
[95] *Id.* at 37,163.

offset percentages that have been calculated using the standard OPPS APC ratesetting methodology.[96]

d. Temporary hospital market basket update for ASCs

CMS proposes to apply a hospital market basket update to ASCs for an interim period of five years and is seeking public comment on ASC costs to assess whether the hospital market basket is an appropriate proxy for ASC costs.[97] The hospital market basket update would be derived from using the same hospital inpatient market basket percentage increase that CMS is proposing to use to derive the OPD fee increase factor and is adjusted for multi factor productivity. CMS proposes to use this methodology for five years.[98]

Specifically, CMS proposes to utilize the hospital market basket update of 2.8 percent minus the MFP adjustment of 0.8 percentage point, resulting in an MFP-adjusted hospital market basket update factor of 2.0 percent for ASCs meeting quality reporting requirements.[99]

e. ASC conversion factor

For CY 2019, CMS proposes to adjust the CY 2018 ASC conversion factor ($45.575) by the proposed wage index budget neutrality factor of 1.0003 in addition to the MFP-adjusted hospital market basket update factor of 2.0 percent, as discussed above, resulting in a proposed CY 2019 ASC conversion factor of $46.500 for ASC's meeting the quality reporting requirements.[100] For those ASC's not meeting quality reporting requirements, CMS proposes a conversion factor of $45.589.

(15) Requirements for the Hospital OQR Program

Under the Hospital OQR Program, hospital outpatient facilities face a 2.0 percentage point reduction in their annual payment update if they fail to meet certain quality reporting requirements. CMS proposes a series of updates to its Hospital OQR policies, factors, and measures. CMS states that its proposals were developed under its new Meaningful Measures Initiative, which is intended to promote improved health outcomes for beneficiaries while minimizing costs. By including Meaningful Measures in its programs, CMS believes it can address the following cross-cutting measure criteria:

- Eliminating disparities;
- Tracking measurable outcomes and impact;
- Safeguarding public health;
- Achieving cost savings;
- Improving access for rural communities; and

[96] *Id.*
[97] *Id.* at 37,173.
[98] *Id.* at 37,168.
[99] *Id.* at 37,175.
[100] *Id.*

- Reducing burden.

a. Proposed updates to hospital OQR removal factors

For CY 2019, CMS proposes to update or introduce new factors that CMS relies on in determining whether to remove existing quality measures from the Hospital OQR Program.

First, CMS clarifies Removal Factor 1, which authorizes removal of a measure when performance among hospitals has "topped out" and is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made. CMS previously has said that a measure is topped out (1) when there is statistically indistinguishable performance at the 75th and 90th percentiles of national facility performance; and (2) when the measure's truncated coefficient of variation (TCOV) is less than or equal to 0.10. In the Proposed Rule, CMS clarifies that it calculates the TCOV by calculating the truncated standard deviation (SD) divided by the truncated mean.

Second, CMS proposes to update Removal Factor 7 that currently allows CMS to consider "collection or public reporting of a measure leads to negative unintended consequences *such as* patient harm." CMS proposes to revise the wording of the factor to state that CMS may consider "collection or public reporting of a measure leads to negative unintended consequences *other than* patient harm." CMS explains the revision by noting that it would already remove a measure that led to unintended patient harm immediately (outside of rulemaking) under a separate policy.[101]

Third, CMS proposes the adoption of a new removal factor (Removal Factor 8) when evaluating Hospital OQR measures for removal. The new factor considers whether the costs associated with a measure outweigh the benefits of continued use.[102]

b. Proposed removal of hospital OQR measures

CMS proposes to remove a total of 10 measures from the Hospital OQR Program measure set across the CY 2020 and CY 2021 payment determinations. For CY 2020, CMS proposes to remove the following measure based on its newly proposed Removal Factor 8 (the burden associated with the measure outweighs the benefit of its continued use):

- OP-27: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431).[103]

For CY 2021, CMS proposes to remove the following measures based on Removal Factors 1, 2, 3, and the newly proposed Removal Factor 8:[104]

[101] *Id.* at 37,178.
[102] *Id.* at 37,178-79.
[103] *Id.* at 37,179.

- OP-5: Median Time to ECG (NQF #0289),
- OP 31: Cataracts - Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536),
- OP-29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658),
- OP-30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use (NQF #0659),
- OP-9: Mammography Follow-up Rates (no NQF number),
- OP-11: Thorax Computed Tomography (CT) – Use of Contrast Material (NQF #0513),
- OP-12: The Ability for Providers with HIT (Health Information Technology) to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data (NQF endorsement removed),
- OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT (no NQF number), and
- OP-17: Tracking Clinical Results between Visits (NQF endorsement removed).[105]

c. Possible hospital OQR program measures and topics for future consideration

CMS solicits public comment on future measure topics for the Hospital OQR Program that could be introduced in subsequent rulemakings. CMS specifically requests comment on any outcome measures that would be useful to add to as well as any process measures that should be eliminated from the Hospital OQR Program.[106]

d. Proposals related to QualityNet Security Administrator administrative requirements

CMS proposes the following updates to its QualityNet Security Administrator administrative requirements:

- Beginning with the CY 2018 reporting period (CY 2020 payment determination), CMS proposes that submission of the Notice of Participation (NOP) form would no longer be required. In order to participate in the Hospital OQR Program, hospitals would instead need to: (1) register on the QualityNet website before beginning to report data; (2) identify and register a QualityNet security administrator; and (3) submit data.[107]
- Beginning with CY 2019, CMS proposes to release Hospital Outpatient Quality Reporting Specifications Manuals every 6 to 12 months—as opposed to the current policy of releasing the manuals every 6 months.[108]
- Beginning with the CY 2018 reporting period (CY 2020 payment determination), CMS proposes to extend the reporting period for OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy from one year to three years.[109]

---

[104] *Id.* at 37,181, 37,185.
[105] *Id.* at 37,179.
[106] *Id.* at 37,188.
[107] *Id.* CMS also proposes to revise its regulation at 42 CFR 419.46(a) to reflect the proposed change.
[108] *Id.* at 37,189.
[109] *Id.* at 37,189-90.

(16) *Requirements for the ASCQR Program*

Under the ASCQR Program, ambulatory surgical centers (ASCs) face a 2.0 percentage point reduction in their annual payment update if they fail to meet certain quality reporting requirements. CMS proposes a series of updates to its ASCQR policies, factors, and measures. CMS states that its proposals were developed under its new Meaningful Measures Initiative.

a. Proposed updates to ASCQR removal factors

For CY 2019, CMS proposes to introduce, remove, or update the following removal factors that CMS relies on in determining whether to remove existing quality measures from the ASCQR Program. First, CMS proposes to clarify Removal Factor 1, which authorizes removal of a measure when performance among hospitals has "topped out" and is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made. CMS has previously explained that a measure is "topped-out" under the ASCQR Program: (1) when there is statistically indistinguishable performance at the 75th and 90th percentiles of national facility performance; and (2) when the measure's TCOV is less than or equal to 0.10. In the Proposed Rule, CMS clarifies that—when calculating the TCOV for four of the measures (ASC-1, ASC-2, ASC-3, and ASC-4) proposed for removal for CY 2019—CMS will use the mean of *non-adverse* events in calculating the TCOV. CMS explains that this is because, by design, these measures have very low rates (and, unlike the vast majority of measures, a low rate reflects a preferred outcome for these measures).[110]

Second, beginning with CY 2019, CMS proposes to eliminate the current Removal Factor 2 (availability of alternative measures with a stronger relationship to patient outcomes). CMS indicates that the removal factor appears to be redundant with Removal Factor 6 (the availability of a measure that is more strongly associated with desired patient outcomes for the particular topic).[111]

Third, CMS proposes to adopt the following two new removal factors:

- Newly Proposed Removal Factor 2: Performance or Improvement on a Measure Does Not Result in Better Patient Outcomes,[112] *and*
- Newly Proposed Removal Factor 8: The costs associated with a measure outweigh the benefit of its continued use in the program.[113]

Fourth, CMS proposes to revise 42 CFR 416.320(c) (retention and removal of quality measures under the ASCQR Program) to better reflect CMS's considerations for

[110] *Id.* at 37,196-97.
[111] *Id.* at 37,195.
[112] *Id.*
[113] *Id.* at 37,195-96.

removing measures policy in light of its proposals to eliminate the current Removal Factor 2 and adopt the newly proposed Removal Factors 2 and 8.[114]

b. Proposed removal of ASCQR measures

CMS proposes to remove a total of eight measures from the ASCQR Program measure set across the CY 2020 and CY 2021 payment determinations. For CY 2020, CMS proposes to remove the following measure based on its newly proposed Removal Factor 8 (the burden associated with the measure outweighs the benefit of its continued use):

- ASC-8: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431).[115]

For CY 2021, CMS proposes to remove the following measures based on Removal Factors 1 and the newly proposed Removal Factor 8:[116]

- ASC-1: Patient Burn (NQF #0263),
- ASC-2: Patient Fall (NQF #0266),
- ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267),
- ASC-4: All-Cause Hospital Transfer/Admission (NQF #0265),
- ASC-9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658),
- ASC-10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use (NQF #0659), and
- ASC-11: Cataracts - Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536).

c. Possible ASCQR program measures and topics for future consideration

CMS solicits public comment on the possible future validation of ASCQR Program measures. CMS notes that no validation of ASCQR measure data currently exists (unlike the Hospital OQR Program). CMS states that it believes that ASCs may benefit from the opportunity to better understand their data and examine potential discrepancies.

CMS specifically requests comment on whether Hospital OQR Program's validation policies could be an appropriate model for the ASCQR Program, the possible ASC sample size, sampling methodology, number of cases to sample, validation score methodology, and reduced annual payment updates for facilities that do not pass validation requirements. CMS also requests comment on possibly starting with only one measure, specifically ASC-13, before expanding to more measures.[117]

---

[114] *Id.* at 37,196.
[115] *Id.* at 37,197.
[116] *Id.* CMS proposes to remove ASC-1, ASC-2, ASC-3, and ASC-4 based on Removal Factor 1, as clarified by CMS in the Proposed Rule. CMS proposes to remove ASC-8, ASC-9, ASC-10, and ASC-11 based on CMS's newly proposed Removal Factor 8.
[117] *Id.* at 37,204.

d. Proposals related to requirements for non-QDC based, claims-based measure data

CMS does not propose any changes to its requirements for non-QDC based, claims-based measures, but CMS does propose to change the reporting period for the previously adopted measure, ASC-12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy. Under CMS's proposal, beginning with the CY 2020 payment determination, CMS would extend the reporting period for ASC-12: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy from one year to three years.[118]

(17) RFIs

a. RFI on Promoting Interoperability and Electronic Healthcare Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers

In the Proposed Rule, the agency notes that, given the widespread adoption of electronic health records (EHRs) and the increased availability of health information exchange infrastructure, it seeks information from stakeholders regarding how CMS health and safety standards that are required of providers and suppliers participating in the Medicare and Medicaid programs may be used to advance electronic exchange of information that supports safe, effective transitions of care between hospitals and community-based providers. The agency includes a broad RFI on changes that CMS might make to the following standards in support of this goal: Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation (RfPs) for Long-Term Care (LTC) Facilities.[119]

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

- Should CMS propose new CoPs/CfCs/RfPs for hospitals and other participating providers and suppliers to ensure a patient's or resident's (or his or her caregiver's or representative's) right and ability to electronically access his or her health information without undue burden?
- Are new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information necessary to ensure patients/residents and their treating providers routinely receive relevant electronic health information from hospitals on a timely basis or will this be achieved in the next few years through existing Medicare and Medicaid policies, the implementing regulations related to the privacy and security standards of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104-91), and implementation of relevant policies in the 21st Century Cures Act?

[118] *Id.* at 37,206-07.
[119] *Id*. at 37,209-11.

- Do stakeholders believe that new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information would help improve routine electronic transfer of health information as well as overall patient/resident care and safety?
- Are there any other operational or legal considerations (for example, implementing regulations related to the HIPAA privacy and security standards), obstacles, or barriers that hospitals and other providers and suppliers would face in implementing changes to meet new or revised interoperability and health information exchange requirements under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future?
- What types of exceptions, if any, to meeting new or revised interoperability and health information exchange requirements should be allowed under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future? Should exceptions under the QPP, including CEHRT hardship or small practices, be extended to new requirements? Would extending such exceptions impact the effectiveness of these requirements?[120]

CMS further invites public comment on items such as:

- How best to accomplish the goal of fully interoperable health information technology (IT) and EHR systems for Medicare- and Medicaid-participating providers and suppliers,
- How best to help advance the MyHealthEData initiative for patients, *and*
- How to encourage adoption of certified health IT and interoperability among Medicare- and Medicaid-participating providers and suppliers.[121]

b. *RFI on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information*

CMS notes that it continues to consider "ways to improve the accessibility and usability of current charge information" so as to "promote greater price transparency for patients."[122] To that end, CMS is asking for comment from providers and suppliers on the following issues and related questions:

- How should CMS define 'standard charges' in provider and supplier settings?[123]
- What types of information would be most beneficial to patients, how can health care providers and suppliers best enable patients to use charge and cost information in their decision-making, and how can CMS and providers and suppliers help third parties create patient-friendly interfaces with these data?[124]

[120] *Id*.
[121] *Id*. at 37,211.
[122] *Id*. at 37,212.
[123] *Id*.
[124] *Id*.

- Should providers and suppliers be required to inform patients how much their out-of-pocket costs for a service will be before those patients are furnished that service?
- Can CMS require providers and suppliers to provider patients with information on what Medicare pays for a particular services performed by that provider or supplier?[125]

CMS also requests comment related to patients' understanding of Medigap and how that impacts patients' understanding of their out-of-pocket costs, among related questions.[126]

c. Leveraging the Authority for the CAP for Part B Drugs and Biologicals for a Potential CMMI Model

CMMI is exploring leveraging the authority for the CAP to test whether allowing private-sector model vendors to enter into and administer value-based arrangements with manufacturers of separately payable Medicare Part B drugs and biologicals improves beneficiary access and quality of care while reducing Medicare expenditures.[127]

CMS explains that a potential CAP-like model is one that could:

- Include competitively selected private-sector vendors that would establish vendor-administered payment arrangements with the manufacturers of separately payable Part B drugs and biologicals included in the model
- Start with a subset of therapies, with an increasing number of included drugs and biologicals over time
- Test how to structure a potential vendor role and whether a CAP-like demonstration could include a former CAP-like or MedPAC's Drug Value Program (DVP) approach where providers and suppliers purchase and receive drugs and biologicals through pricing arrangements
- Eventually include other payers including Medicare Advantage organizations, State Medicaid agencies, as well as Medicaid Managed Care Organizations (MCOs)

CMS is soliciting public comments on the above design considerations and poses questions in the following key areas:

1. Included providers and suppliers;
2. Included drugs and biologicals;
3. Beneficiary cost-sharing, protections, and fiscal considerations;
4. Model vendors;
5. Regulatory barriers and transparency issues;
6. Manufacturer participation; *and*
7. Model scope.

[125] *Id*.
[126] *Id*.
[127] *Id.* at 37,215.

(18) *Proposed Additional Hospital IQR Program Policies*

In the CY 2007 OPPS final rule with comment period, CMS adopted the Hospital Consumer Assessment of Healthcare Providers and System (HCAHPS) Survey (OMB Control Number 0938-0981) in the Hospital IQR Program. The HCAHPS Survey is the first national, standardized, publicly reported survey of patients' experience of hospital care and asks discharged patients questions about their recent hospital stay. In the FY 2018 Hospital Inpatient Prospective Payment System and Long-Term Care Hospital (IPPS/LTCH) final rule, CMS adopted three survey questions within the HCAHPS Survey that collectively were known as the Communication About Pain questions.

Effective with January 2022 discharges (FY 2024 payment determination), CMS proposes to update the HCAHPS Survey by removing the Communication About Pain questions from the survey. CMS explains that, after adopting the Communication About Pain questions, it received stakeholder feedback expressing concern that the questions could potentially pressure hospital staff to prescribe more opioids. CMS does not propose to change how performance scores are calculated on the remaining 29 questions on the HCAHPS Survey.[128]

[128] *Id.* at 37,219.