Hogan Lovells

Overview of Selected Provisions of the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule for Calendar Year 2020

On August 9, 2019, 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) 2020 (the "Proposed Rule"). The Proposed Rule also includes proposals relating to price transparency of hospital standard charges, revisions of organ procurement organizations conditions of coverage, the prior authorization process and requirements for certain covered outpatient department services, the laboratory date of service policy, and grandfathered children's hospitals-within-hospitals. Comments on the Proposed Rule are due September 27, 2019.[1]

CMS proposes to increase payment rates under the OPPS by an outpatient department (OPD) fee schedule increase factor of 2.7 percent. This increase factor is based on the proposed hospital inpatient market basket percentage increase of 3.2 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS), minus the proposed multifactor productivity (MFP) adjustment of 0.5 percentage points. CMS estimates that total payments to OPPS providers for CY 2020 would be approximately $79 billion, an increase of approximately $6 billion compared to estimated CY 2019 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-1717-P.html.

- 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-1717-P.html.

In conjunction with the Proposed Rule release, CMS also published a fact sheet, available at: https://www.cms.gov/newsroom/fact-sheets/cy-2020-medicare-hospital-outpatient-prospective-

[1] 84 Fed. Reg. 39,398. Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Proposed Revisions of Organ Procurement Organizations Conditions of Coverage; Proposed Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Proposed Changes to Grandfathered Children's Hospitals-Within-Hospitals (Aug. 9, 2019), *available at* https://www.govinfo.gov/content/pkg/FR-2019-08-09/pdf/2019-16107.pdf ("Proposed Rule").

[2] *Id.* at 39,401.

payment-system-and-ambulatory-surgical-center, and a press release, available at: https://www.cms.gov/newsroom/press-releases/cms-takes-bold-action-implement-key-elements-president-trumps-executive-order-empower-patients-price.

This Summary Addresses the Following Topics in the CY 2020 Proposed Rule:

(1) Proposed Updates Affecting OPPS Payments
   a. Proposed recalibration of Ambulatory Payment Classification (APC) relative payment weights
   b. Proposed conversion factor update
   c. Proposed wage index changes
   d. Proposed statewide average default Cost-to-Charge Ratios (CCRs)
   e. Proposed changes to the Inpatient Only (IPO) list
   f. Short inpatient hospital stays
   g. Payment adjustment for certain cancer hospitals
   h. Hospital outpatient outlier payments

(2) Proposed OPPS APC Group Policies
   a. Proposed treatment of new and revised CY 2020 Category I and III Current Procedural Terminology (CPT®)[3] codes
   b. Proposed treatment of new CY 2020 CPT and Level II Healthcare Common Procedure Coding System (HCPCS) codes
   c. Proposed APC exceptions to the 2 Times Rule

(3) Proposed OPPS Payment for Devices
   a. Substantial clinical improvement criterion for pass-through payment status Request for Information (RFI)
   b. Food and Drug Administration (FDA) Breakthrough Device alternative pathway to pass-through payment status
   c. Devices with pass-through payment status

(4) Proposed OPPS Payment Changes for 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 2020
   c. Estimate of OPPS transitional pass-through spending for drugs, biologicals, radiopharmaceuticals, and devices

(5) Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals without Pass-through Payment Status
   a. Packaging policies
   b. Payment for drugs and biologicals without pass-through status that are not packaged
   c. Proposed payment methodology for 340B purchased drugs
   d. Packaging of skin substitutes
   e. Response to CY 2019 RFI on alternative reimbursement methodologies for skin substitutes

(6) Proposed Payment Rates
   a. Drug administration services

[3] CPT Copyright 2018 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.

b. Radiation therapy services
c. Payment for Chimeric Antigen Receptor T-cell (CAR-T) therapies

(7) Proposed Changes in the Level of Supervision of Outpatient Therapeutic Services in Hospitals and Critical Access Hospitals (CAHs)

(8) Method to Control Unnecessary Increases in the Volume of Clinic Visit Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs)

(9) Medicare Payment Advisory Commission (MedPAC) Recommendations

(10) Proposed Updates to the ASC Payment System
a. Designation of HCPCS codes as office-based or ASC covered
b. Proposed update and payment for ASC covered surgical procedures and covered ancillary services
c. ASC conversion factor

(11) Proposed Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

(12) Proposed Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

(13) Proposed Requirements for Hospitals to Make Public a List of Their Standard Charges
a. Proposed definitions
b. Proposed public display requirements for hospital standard charge lists
c. Proposed monitoring and enforcement of requirements for public standard charge lists

(14) RFI: Quality Measurement to Price Transparency for Improving Beneficiary Access to Provider and Suppler Charge Information

(15) Clinical Laboratory Fee Schedule: Potential Revisions to the Laboratory Date of Service Policy

(16) Proposed Prior Authorization Process and Requirements for Certain Hospital OPD Services

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

a. *Comprehensive APC (C-APC) payment methodology*.[4]
b. *Biosimilar pass-through payment eligibility.* CMS does not propose changes to the CY 2019 policy that all biosimilar biological products are eligible for pass-through payment.[5]
c. *Therapeutic radiopharmaceuticals payment.* CMS does not propose changes to continue its current policy of paying all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP plus six (ASP+6) percent. The agency's proposed CY 2020 payment rates for nonpass-through, separately payable therapeutic radiopharmaceuticals are in Addenda A and B of the Proposed Rule.[6]
d. Payment for services furnished by certain *off-campus* PBDs.[7]
e. *Blood clotting factors payment.* For CY 2020, 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.[8]

[4] Proposed Rule at 39,412.
[5] *Id.* at 39,501.
[6] *Id.* at 39,489.
[7] *Id.* at 39,528.
[8] *Id*. at 39,502.

f. *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.[9]
g. *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.[10]
h. *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.[11]
i. *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.[12]

Details about the proposed changes are provided below.

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(1) *Proposed Updates Affecting OPPS Payments*

a. Proposed recalibration of APC relative payment weights

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 a database for calculating APC group weights.[13] CMS proposes to continue to use single procedure APC criteria-based costs for blood and blood products and brachytherapy sources.[14]

For brachytherapy sources, CMS proposes to use costs derived from CY 2018 claims data to set the proposed CY 2020 payment rates and to base the payment rates for brachytherapy sources on the geometric mean unit costs for each source.[15] This methodology is consistent with the methodology that CMS uses for other items and services paid under the OPPS.[16] CMS also proposes to continue the other, previously finalized payment policies for brachytherapy sources.[17] CMS solicited recommendations for new codes to describe new brachytherapy sources and stated that it would continue to add new brachytherapy source codes and descriptors to its systems for payment on a quarterly basis.[18]

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9 *Id.*
10 *Id.*
11 *Id.*
12 *Id.* at 39,503.
13 *Id.* at 39,406.
14 *Id.* at 39,409-11.
15 *Id.* at 39,411.
16 *Id.*
17 *Id.*
18 *Id.* at 39,412.

For CY 2020 and subsequent years, CMS proposes to continue to apply the C-APC policy, with the proposed addition of two new C-APCs: 5182 (Level 2 Vascular Procedures) and 5461 (Level 1 Neurostimulator and Related Procedures).[19] To ensure that there are sufficient claims data for new services to enable CMS to assign these new services to an appropriate clinical APC, CMS proposes to continue 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 C-APC.[20] CMS proposes that payment for services assigned to a New Technology APC when included on a claim for a service assigned status indicator "J2" assigned to a C-APC would be packaged into the payment for the comprehensive service; though CMS solicited comments on the clinical appropriateness of this proposal.[21]

CMS proposes to continue composite APC payment policies for mental health services and multiple imaging services.[22] With respect to multiple imaging services, CMS proposes to continue to pay for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology (APCs 8004, 8005, 8006, 8007, and 8008).[23]

In the CY 2019 OPPS, CMS finalized its proposal to unpackage and pay separately for the cost of non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting for CY 2019.[24] Since then, CMS has continued to analyze the issue of access to non-opioid alternatives in the HOPD setting and in the ASC setting.[25] After reviewing data from stakeholders and Medicare claims data, CMS concluded that it had not found compelling evidence to suggest that revisions to the OPPS payment policies for non-opioid pain management alternatives are necessary for CY 2020.[26] CMS is inviting comments on whether there are other non-opioid pain management alternatives for which its payment policy should be revised to allow separate payment.[27]

For CY 2020, CMS proposes to continue to apply the policy established in CY 2013 of calculating relative payment weights for each APC using geometric mean-based APC costs.[28] CMS proposes to calculate APC relative weight scales by dividing the CY 2019 estimated aggregate weight by the proposed unscaled CY 2020 estimated aggregate weight.[29] CMS further proposes to adjust the estimated CY 2020 unscaled relative payment weights by multiplying them by a proposed weight scalar of 1.4401 to ensure the proposed CY 2020 relative payment weights are budget neutral.[30]

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[19] *Id.* at 39,414.
[20] *Id.* at 39,417.
[21] *Id.* at 39,417-18.
[22] *Id.* at 39,418.
[23] *Id.* at 39,419.
[24] *Id.* at 39,425.
[25] *Id.* at 39,425-26.
[26] *Id.* at 39,427.
[27] *Id.*
[28] *Id.*
[29] *Id.*
[30] *Id.* at 39,428.

b. Proposed conversion factor update

For CY 2020, 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 $79.770 to calculate payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of -1.628 relative to hospitals that meet the requirements).[31] CMS proposes to use a conversion factor of $81.398 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs.[32]

The conversion factor of $81.398 results from the proposed OPD fee schedule increase factor of 2.7 percent, the required proposed wage index budget neutrality adjustment of approximately 0.9993, the proposed cancer hospital payment adjustment to 0.9998, and the proposed adjustment of -0.20 percentage point of projected OPPS spending for the difference in pass-through spending.[33]

c. Proposed wage index changes

CMS proposes to use the FY 2020 hospital IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment standardized amount for CY 2020.[34] For hospitals that are paid under the OPPS, but not under the IPPS, CMS also proposes to continue its policy of assigning the wage index that would be applicable if the hospital were paid under the IPPS, based on its geographic location and any applicable wage index adjustments.[35]

d. Proposed statewide average default CCRs

CMS uses the statewide average default CCR to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPPS for hospitals in certain circumstances, including for hospitals that are new, have not yet accepted assignment of an existing hospital's provider agreement, hospitals that have not yet submitted a cost report, hospitals whose CCR falls outside the predetermined ceiling threshold for a valid CCR, and hospitals in which the most recent cost report reflects an all-inclusive rate status.[36] CMS proposes to update the statewide default CCRs for CY 2020 using the most recent cost report data.[37] Beginning with CY 2020, CMS will no longer publish the statewide average CCRs in the OPPS proposed and final rules.[38] Instead, these CCRs will be available on the CMS website.

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[31] *Id.* at 39,429.
[32] *Id.*
[33] *Id.*
[34] *Id.* at 39,431.
[35] *Id*.
[36] *Id.* at 39,432.
[37] *Id.*
[38] *Id.*

e. Proposed changes to the IPO list

CMS proposes to remove CPT code 27130 (Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty) with or without autograft or allograft) from the IPO list for CY 2020 and subsequent years.[39] CMS proposes to assign CPT code 27130 to C-APC 5115 with status indicator "J1."[40]

CMS is soliciting comments on the potential removal of the following CPT codes from the IPO list:[41]

CPT Code	Long Descriptor
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar;
22634	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar; each additional interspace and segment
63265	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; cervical
63266	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; cervical
63267	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; cervical
63268	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; cervical

f. Short inpatient hospital stays

The "2-Midnight Rule" provides that surgical procedures, diagnostic tests, and other treatments are generally considered appropriate for inpatient hospital admission and payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights and admits the patient to the hospital based upon that expectation.[42] Services that are designated as IPO procedures under the OPPS are not subject to the 2-Midnight Rule – that is, these procedures are appropriate for inpatient hospital admission and payment under Medicare Part A regardless of the expected length of stay, due to intrinsic risk, recovery impacts, and/or complexities associated with these services.[43] The 2-Midnight Rule becomes applicable once a procedure is removed from the IPO list, however.[44]

Starting in CY 2020, CMS proposes to establish a 1-year exemption from certain medical review activities for procedures removed from the IPO list under the OPPS.[45] Specifically, Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIOs) could not consider these procedures in determining whether a provider

[39] *Id.* at 39,523.
[40] *Id.* at 39,524.
[41] *Id.*
[42] *Id.* at 39,526-27.
[43] *Id.* at 39,527.
[44] *Id.*
[45] *Id.*

exhibits persistent noncompliance with the 2-Midnight Rule for purposes of referral to the Recovery Audit Contractor (RAC), nor would those procedures be reviewed by RACs for "patient status."[46] During this 1-year period, however, BFCC-QIOs could review claims for these services to provide education to providers, but claims identified as noncompliant would not be denied with respect to site-of-service.[47]

g. Payment adjustment for certain cancer hospitals

CMS proposes to use a target payment-to-cost ratio (PCR) of 0.89 to determine the CY 2020 cancer hospital payment adjustment, which is 0.01 higher than for CY 2019.[48] 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.[49] Table 6 in the Proposed Rule provides the estimated percentage increase in OPPS payments for CY 2020 due to payment adjustment for these eleven cancer hospitals.[50]

h. 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 meet this estimate, CMS proposes to increase the fixed-dollar amount threshold by $125 from $4,825 to a proposed $4,950 for CY 2020.[51] CMS does not propose changes to the multiplier threshold of 1.75.

(2) <u>Proposed OPPS APC Group Policies</u>

a. Proposed treatment of new and revised CY 2020 Category I and III CPT codes

CMS received the CY 2020 CPT codes from the American Medical Association (AMA) that will be effective January 1, 2020 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.[52]

b. Proposed treatment of new CY 2020 CPT and Level II HCPCS codes

CMS solicits comments on the proposed CY 2020 status indicators, APC assignments, and payment rates for 66 Level II HCPCS codes and four Category III CPT codes that

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[46] *Id*.
[47] *Id.* at 39,527-28.
[48] *Id.* at 39,433-34.
[49] *Id.* at 39,433.
[50] *Id.* at 39,434.
[51] *Id.* at 39,435.
[52] *Id*. at 39,450.

were made effective April 1, 2018 and July 1, 2018. These codes are listed in Tables 7 and 8 of the Proposed Rule.[53]

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 2020, CMS proposes exceptions from the 2 times rule for the following 18 APCs.[54]

Proposed CY 2020 APC	Proposed CY 2020 APC title
5112	Level 2 Musculoskeletal Procedures
5161	Level 1 ENT Procedures
5181	Level 1 Vascular Procedures
5311	Level 1 Lower GI Procedures
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5524	Level 4 Imaging without Contrast
5571	Level 1 Imaging with Contrast
5612	Level 2 Therapeutic Radiation Treatment Preparation
5672	Level 2 Pathology
5691	Level 1 Drug Administration
5721	Level1 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5733	Level 3 Minor Procedures
5734	Level 4 Minor Procedures
5822	Level 2 Health and Behavior Services
5823	Level 3 Health and Behavior Services

(3) Proposed OPPS Payment for Devices

a. Substantial clinical improvement criterion for pass-through payment status RFI

Consistent with the IPPS proposed rule for FY 2020, CMS issued an RFI asking for public comment on "the type of additional detail and guidance that the public and applicants for device pass-through transitional payment would find useful" and "on specific changes or clarifications to the . . . OPPS substantial clinical improvement criterion that CMS might consider making" for CY 2020.[55]

b. FDA Breakthrough Device alternative pathway to pass-through payment status

Consistent with the proposed alternative New Technology Add-On Payment (NTAP) Pathway for FDA Breakthrough Devices in the IPPS proposed rule for FY 2020, CMS

[53] *Id*. at 39,439-50.
[54] *Id.* at 39,452.
[55] *Id*. at 39,482.

proposes an alternative pathway to pass-through payment status for devices with FDA Breakthrough Device status beginning January 1, 2020.[56] According to CMS, "[u]nder this proposed alternative pathway, a medical device that has received FDA marketing authorization . . . and that is part of the FDA's Breakthrough Devices Program would still need to meet the eligibility criteria under § 419.66(b), the other criteria for establishing device categories under § 419.66(c), and the cost criterion under § 419.66(d)."[57]

Unlike CMS's proposal for pass-through payment status under the OPPS, CMS's proposed abbreviated pathway for NTAP based on FDA Breakthrough Device status would have considered such devices as having satisfied the newness criterion in addition to the substantial clinical improvement criterion.[58] Under the NTAP abbreviated pathway, FDA Breakthrough Devices only would have needed to satisfy the cost criterion.[59] The proposed alternative pathway in the OPPS therefore does not fully align with the proposed alternative pathway in the IPPS as CMS suggests.[60]

c. Devices with pass-through payment status

Currently, there are two device categories with pass-through payment status:

- HCPCS code C1822 (*Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system*), which the Proposed Rule indicates was established effective January 1, 2019.[61] CMS's current list of devices with pass-through payment status indicates that status for C1822 expired on December 31, 2017, however. CMS likely meant to list HCPCS code C1823 (*Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads*) instead, which is listed as having pass-through payment status effective January 1, 2019, to expire December 31, 2021, on CMS's website.[62]

- HCPCS code C2624 (*Implantable wireless pulmonary artery pressure sensor with delivery catheter, including all system components*), which CMS indicates is set to expire December 31, 2022.[63] Pass-through payment status for HCPCS code C2624 expired on December 31, 2016, so this listing may be incorrect.

CMS received the following seven applications for transitional pass-through payment status for devices.

- Surefire® Spark™ Infusion System[64]
- TracPatch[65]

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[56] *Id*. at 39,482-83.
[57] *Id*. at 39,483.
[58] 84 Fed. Reg. 19,158, 19,372 (May 3, 2019).
[59] *Id*.
[60] Proposed Rule at 39,483.
[61] *Id*. at 39,461.
[62] The list of HCPCS codes with pass-through payment status is available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Complet-list-DeviceCats-OPPS.pdf.
[63] Proposed Rule at 39,461.
[64] *Id*. at 39,462-64.

- Vagus Nerve Stimulation® Therapy System for Treatment Resistant Depression[66]
- Optimizer® System[67]
- AquaBeam® System (a resubmission from last year)[68]
- Eluvia™ Drug-Eluting Vascular Stent System[69]
- AUGMENT® Bone Graft[70]

None of the applications were approved during the quarterly process. In the Proposed Rule, CMS invites public on whether the applicants satisfy the pass-through status criteria.[71]

(4) *Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals*

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

CMS proposes that the pass-through payment status of the six drugs and biologicals listed below would expire on December 31, 2019. All of these drugs and biologicals will have received OPPS pass-through payment for at least two years and no more than three years by December 31, 2019.[72]

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

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 $130 for CY 2020).[73] 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

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[65] *Id*. at 39,464-66.
[66] *Id*. at 39,466-71.
[67] *Id*. at 39,471-73.
[68] *Id*. at 39,473-75.
[69] *Id*. at 39,475-80.
[70] *Id*. at 39,480-82.
[71] *Id*. at 39,462.
[72] *Id.* at 39,488.
[73] *Id.*

would package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimate 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 2020.[74]

b. *Proposed drugs, biologicals, and radiopharmaceuticals with new or continuing pass-through payment status in CY 2020*

CMS proposes to continue pass-through payment status in CY 2020 for 61 drugs and biologicals that were approved for pass-through payment status between April 1, 2017 and April 1, 2019. These drugs and biologicals are included in the table below.[75]

CY 2020 HCPCS CODE	CY 2020 LONG DESCRIPTOR	PROPOSED CY 2020 STATUS INDICATOR	PROPOSED CY 2020 APC	PASS-THROUGH PAYMENT EFFECTIVE DATE	PASS-THROUGH PAYMENT EXPIRATION DATE
A9513	Lutetium lu 177, dotatate, therapeutic, 1 millicurie	G	9067	07/01/2018	6/30/2021
A9586	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries	G	9084	10/01/2018	9/30/2020
C9035	Injection, aripiprazole lauroxil (aristada initio), 1 mg	G	9179	01/01/2019	12/31/2021
C9036	Injection, patisiran, 0.1 mg	G	9180	01/01/0219	12/31/2021
C9037	Injection, risperidone (perseris), 0.5 mg	G	9181	01/01/2019	12/31/2021
C9038	Injection, mogamulizumab-kpkc, 1 mg	G	9182	01/01/2019	12/31/2021
C9039	Injection, plazomicin, 5 mg	G	9183	01/01/2019	12/31/2021
C9040	Injection, fremanezumab-vfrm, 1 mg	G	9197	04/01/2019	3/31/2022
C9041	Injection, coagulation factor Xa(recombinant), inactivated (andexxa), 10mg	G	9198	04/01/2019	3/31/2022
C9043	Injection, levoleucovorin	G	9303	04/01/2019	3/31/2022
C9044	Injection, cemiplimab-rwlc, 1 mg	G	9304	04/01/2019	3/31/2022
C9045	Injection, moxetumomab pasudotox-tdfk, 0.01 mg	G	9305	04/01/2019	3/31/2022
C9046	Cocaine hydrochloride nasal solution for topical administration, 1 mg	G	9307	04/01/2019	3/31/2022
C9141	Injection, factor viii, (antihemophilic factor,	G	9299	04/01/2019	3/31/2022

[74] *Id.*
[75] *Id.* at 39,488-94.

CY 2020 HCPCS CODE	CY 2020 LONG DESCRIPTOR	PROPOSED CY 2020 STATUS INDICATOR	PROPOSED CY 2020 APC	PASS-THROUGH PAYMENT EFFECTIVE DATE	PASS-THROUGH PAYMENT EXPIRATION DATE
	recombinant), pegylated-aucl (jivi) 1 i.u.				
C9407	Iodine i-131 iobenguane, diagnostic, 1 millicurie	G	9184	01/01/2019	12/31/2021
C9408	Iodine i-131 iobenguane, therapeutic, 1 millicure	G	9185	01/01/2019	12/31/2021
C9447	Injection, phenylephrine and ketorolac, 4 ml vial	G	9083	10/01/2018	9/30/2020
C9462	Injection, delafloxacin, 1 mg	G	9462	04/01/2018	3/31/2021
C9488	Injection, conivaptan hydrochloride, 1 mg	G	9488	04/01/2017	3/31/2020
J0185	Injection, aprepitant, 1 mg	G	9463	04/01/2018	3/31/2021
J0517	Injection, benralizumab, 1 mg	G	9466	04/01/2018	3/31/2021
J0565	Injection, bezlotoxumab, 10 mg	G	9490	07/01/2017	6/30/2020
J0567	Injection, cerliponase alfa, 1 mg	G	9014	01/01/2018	12/31/2021
J0599	Injection, c-1 esterase inhibitor (human), (haegarda), 10 units	G	9015	01/01/2018	12/31/2021
J1095	Injection, dexamethasone 9%, intraocular, 1 microgram	G	9172	10/01/2018	9/30/2021
J1301	Injection, edaravone, 1 mg	G	9493	10/01/2017	9/30/2020
J1428	Injection, eteplirsen, 10 mg	G	9484	04/01/2017	3/31/2020
J1454	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg	G	9099	10/01/2018	9/30/20201
J1627	Injection, granisetron extended release, 0.1 mg	G	9486	04/01/2017	3/31/2020
J1628	Injection, guselkumab, 1 mg	G	9029	01/01/2018	12/31/2020
J2326	Injection, nusinersen, 0.1 mg	G	9489	07/01/2017	6/30/2020
J2350	Injection, ocrelizumab, 1 mg	G	9494	10/01/2017	9/30/2020
J2797	Injection, rolapitant, 0.5 mg	G	9464	04/01/2018	3/31/2021
J3245	Injection, tildrakizumab, 1 mg	G	9306	04/01/2019	3/31/2022
J3304	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	G	9469	04/01/2018	3/31/2021
J3316	Injection, triptorelin, extended-release, 3.75 mg	G	9016	01/01/2018	12/31/2020
J3358	Ustekinumab, for	G	9487	04/01/2017	3/31/2020

CY 2020 HCPCS CODE	CY 2020 LONG DESCRIPTOR	PROPOSED CY 2020 STATUS INDICATOR	PROPOSED CY 2020 APC	PASS-THROUGH PAYMENT EFFECTIVE DATE	PASS-THROUGH PAYMENT EXPIRATION DATE
	intravenous injection, 1 mg				
J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes	G	9070	07/01/2018	6/30/2021
J7170	Injection, emicizumab-kxwh, 0.5 mg	G	9257	07/01/2018	6/30/2021
J7203	Injection factor ix, (antihemophilic factor, recombinant), glycopegylated, (rebinyn), 1 iu	G	9468	04/01/2018	3/31/2021
J7318	Hyaluronan or derivative, durolane, for intra-articular injection, 1 mg	G	9174	04/01/2018	3/31/2021
J7328	Hylauronan or derivative, gelsyn-3, for intra-articular injection, 0.1 mg	G	1862	04/01/2017	3/31/2020
J7345	Aminolevulinic acid hcl for topical administration, 10% gel, 10 mg	G	9301	01/01/2018	12/31/2020
J9023	Injection, avelumab, 10 mg	G	9491	10/01/2017	9/30/2020
J9057	Injection, copanlisib, 1 mg	G	9030	07/01/2018	6/30/2121
J9153	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine	G	9302	01/01/2018	12/31/2020
J9173	Injection, durvalumab, 10 mg	G	9492	10/01/2017	9/30/2020
J9203	Injection, gemtuzumab ozogamicin, 0.1 mg	G	9495	01/01/2018	12/31/2020
J9229	Injection, inotuzumab ozogamicin, 0.1 mg	G	9028	01/01/2018	12/31/2020
J9285	Injection, olaratumab, 10 mg	G	9485	04/01/2017	3/31/2020
J9311	Injection, rituximab 10 mg and hyaluronidase	G	9467	04/01/2018	3/31/2021
Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9035	04/01/2018	3/31/2021
Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose	G	9194	04/01/2018	3/31/2021

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

CMS also proposes to continue pass-through status for the following four drugs and biologicals that have already had three years of pass-through payment status but are eligible for an extended pass-through status 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. (Please note that HCPCS codes Q4195 and Q4196 represent one drug and were previously described by a single HCPCS code).

CY 2020 HCPCS CODE	CY 2020 LONG DESCRIPTOR	PROPOSED CY 2020 STATUS INDICATOR	PROPOSED CY 2020 APC	PASS-THROUGH PAYMENT EFFECTIVE DATE	PASS-THROUGH PAYMENT EXPIRATION DATE
A9586	Florbetapir f18, diagnostic, per study dose, up to 10 millicuries	G	9084	10/1/2018	9/30/2020
C9447	Injection, phenylephrine and ketorolac, 4 ml vial	G	9083	10/1/2018	9/30/2020
Q4195	Puraply, per square centimeter	G	9175	10/1/2018	9/30/2020
Q4196	Puraply AM, per square centimeter	G	9176	10/1/2018	9/30/2020
Q9950	Injection, sulfur hexafluoride lipid microsphere, per ml	G	9085	10/1/2018	9/30/2020

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.[76]

Consistent with the agency's CY 2019 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).[77]

CMS proposes to continue to make payment offset applicable to the APCs for pass-through diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents, and pass-through skin substitutes.[78]

c. *Proposed estimate of OPPS transitional pass-through spending for drugs, biologicals, radiopharmaceuticals, and devices*

CMS proposes to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2020.[79] For CY 2020, CMS estimates that total pass-through spending for devices, drugs and biologicals that are continuing to receive pass-through payment in CY2020 and those that first become eligible for pass-through payment during CY 2020 is approximately $269.8 million.[80] This represents 0.34 percent of total projected OPPS payments for CY 2020

[76] *Id.* at 39,489.
[77] *Id.*
[78] *Id.* at 39,495.
[79] *Id.* at 39,511-12.
[80] *Id.* at 39,512.

(approximately $80 billion) and is therefore less than 2.0 percent of total projected OPPS CY 2020 program spending.

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

a. Packaging policies

CMS is proposing a packaging threshold for CY 2020 of $130, an increase from the current level of $125. The agency would package items with a per-day cost less than or equal to $130, and identify items with a per day cost greater than $130 as separately payable unless they are policy-packaged.[81]

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 2019 and that are proposed for separate payment in CY 2020, and that then have per day costs equal to or less than the CY 2020 final rule drug packaging threshold, based on the updated ASP and hospital claims data used for the CY 2020 final rule, would continue to receive separate payment in CY 2020.
- HCPCS codes for drugs and biologicals that were packaged in CY 2019 and that are proposed for separate payment in CY 2020, and that then have per day costs equal to or less than the CY 2020 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2020 final rule, would remain packaged in CY 2020.

- HCPCS codes for drugs and biologicals for which we proposed packaged payment in CY 2020 but that then have per-day costs greater than the CY 2020 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2020 final rule, would receive separate payment in CY 2020.[82]

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 18 in the Proposed Rule provides a list of the HCPCS codes to which the CY 2020 drug-specific packaging determination methodology applies.[83]

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

With respect to payment for drugs and biologicals without pass-through status that are not packaged, CMS proposes to continue to:

[81] *Id*. at 39,496.
[82] *Id.* at 39,497.
[83] *Id.* at 39,499.

- Pay for all separately payable drugs and biologicals, including specified covered outpatient drugs (SCODs), at ASP+6 percent.[84]
- Use a three percent add-on, rather than a six percent add-on, for WAC-based SCOD drugs and non-SCOD separately payable drugs.[85]
- Use WAC+3 percent, rather than WAC+6 percent, whenever WAC-based pricing is used for a drug or biological.
- Pay nonpass-through biosimilars acquired under the 340B Program at ASP-22.5 percent of the biosimilar's ASP instead of the biosimilar's reference product's ASP.[86]

CMS also is soliciting comment on whether payment for 340B-acquired biosimilars at ASP+3 percent of the reference product's ASP would be an appropriate alternative, depending on the outcome of the litigation discussed in the next section of this summary.[87]

c. Proposed payment methodology for 340B purchased drugs

For CY 2020, CMS is proposing to continue to pay ASP-22.5 percent for 340B-acquired drugs including when furnished in nonexcepted off-campus PBDs paid under the Medicare Physician Fee Schedule (PFS).[88]
In CY 2018 and CY 2019, CMS implemented a policy 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. This payment policy is the subject of ongoing litigation in the case of *American Hospital Association et al. v. Azar et al.*, in the United States District Court for the District of Columbia, as discussed by CMS in the Proposed Rule.[89] On December 27, 2018, the district court concluded in the context of reimbursement requests for CY 2018 that the Secretary of the Department of Health and Human Services (HHS) exceeded his statutory authority by adjusting the Medicare payment rates for drugs acquired under the 340B Program to ASP-22.5 percent for that year.[90] The district court asked the government and the hospitals to provide ideas about how to adjust payments to hospitals to remedy the past payment cuts. On May 6, 2019, the court issued an opinion that reiterated that the 2018 rate reduction exceeded the Secretary's authority and declared that the rate reduction for 2019 also exceeded his authority. However, with regard to the remedy, the court remanded to HHS to devise an appropriate remedy. CMS notes in the Proposed Rule that it intends to appeal the district court's decision, but is also taking the steps necessary to craft an appropriate remedy in the event of an unfavorable decision on appeal.[91] Accordingly, in the Proposed Rule, CMS solicits comment on several proposed solutions to remedy underpayments for CY 2018 and CY 2019 (assuming

[84] *Id.* at 39,500.
[85] *Id.*
[86] *Id.* at 39,501.
[87] *Id.* at 39,502.
[88] *Id.* at 39,504.
[89] *Id.*
[90] *American Hosp. Ass'n, et al. v. Azar, et al.*, No. 1:18-cv-2084 (D.D.C. Dec. 27, 2018).
[91] Proposed Rule at 39,504.

the policy for those years is found to be unlawful) as well as future payment policy for CY 2020 and beyond.

CMS also seeks comment on whether a rate of ASP+3 percent could be an appropriate remedial payment amount for these drugs, both for CY 2020 and for purposes of determining the remedy for CYs 2018 and 2019. Despite making this proposal, CMS states that it believes these amounts would be "well above the actual costs hospitals incur in purchasing 340B drugs, and it is being proposed solely because of the court decision."[92] CMS also states that, interpreting the court's decision, it could be appropriate to apply a payment reduction of between 0.2 percent and 2.9 percent.[93]

With regard to remediation for CY 2018 and CY 2019, CMS seeks comment on whether such a remedy should be retrospective in nature (e.g., made on a claim-by-claim basis), whether such remedy could be prospective in nature (for example, an upward adjustment to 340B claims in the future to account for any underpayments in the past), and whether there is some other mechanism that could produce a result equitable to hospitals that do not acquire drugs through the 340B program while respecting the budget neutrality mandate.[94] One potential remedy that CMS sets forth would involve making additional payments to parties who have demonstrated harm from the alleged underpayments (which could be defined as hospitals that submitted a claim for drug payment with the "JG" modifier in CYs 2018 and 2019) outside the normal claims process. Under this approach, CMS would calculate the amount that such hospitals should have been paid and would use Medicare contractors to make one payment to each affected hospital.

d. CY 2020 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.[95] 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 $789 (reduced from the CY 2019 PDC threshold of $895).[96] 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 2019, irrespective of whether the product exceeds the CY 2020 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 2020 MUC threshold.

Notwithstanding that CMS proposes to continue its current payment policies for skin substitutes, for CY 2020, CMS also considers eliminating the high cost and low cost categories for skin substitutes and having only one payment category and set of procedure codes for the application of all graft skin substitute products.[97] If finalized,

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92 *Id.* at 39,505.
93 *Id.*
94 *Id.*
95 *Id.* at 39,506.
96 *Id.* at 39,506, 39,508.
97 *Id.* at 39,507.

the only available procedure codes to bill for skin substitute graft procedures would be CPT codes 15271 through 15278 (HCPCS codes C5271 through C5278 would be eliminated). There would be only one APC for the graft skin substitute application procedures, and the payment rate would be the geometric mean of all graft skin substitutes procedures for a given CPT code that are covered under the OPPS. If this policy option was implemented, only CPT code 15271 would be available in the OPPS, and the geometric mean cost for the procedure code in CY 2020 would be $1,465.18.[98]

Based on the comments received in response to the CY 2019 comment solicitation on this topic, CMS believes that a single payment category potentially could provide a more equitable payment for many products used with graft skin substitute procedures, while recognizing that procedures performed with costly skin substitute products would likely receive substantially lower payment. CMS solicits comment on this proposal and notes that it may consider modifying the skin substitute payment policy in the CY 2020 OPPS/ASC final rule. CMS also solicits comment on ways that CMS should transition from the current low cost/high cost payment methodology to a single payment category.[99]

e. Response to CY 2019 RFI on alternative reimbursement methodologies for skin substitutes

CMS discusses the public comment it received on potential alternative methodologies for reimbursement of skin substitutes under the OPPS for future years. According to CMS, the methodology that commenters discussed most in response to the comment solicitation in CY 2019 and that stakeholders have raised in subsequent meetings held with the wound care community has been a lump-sum "episode-based" payment for a wound care episode.

Commenters both expressed support for the episode-based payment option (citing that they believed it would allow health care professionals to choose the best skin substitute for a given patient, reduce incentives to use high-cost products, and encourage the development of products that require fewer applications), as well as concerns (noting that wound care is too complex and variable to be covered through such a payment methodology, and that it would be too difficult to risk-stratify and specialty-adjust an episode-based payment given the diversity of patients receiving wound care).

Given the wide array of views on episode-based payment for skin substitute products and the unforeseen issues that may arise from the implementation of such a policy, CMS states that it is reluctant to present a proposal for episode-based payments in the CY 2020 proposed rule. CMS seeks further comments from stakeholders and other interested parties on potential payment policies that could be applied in future years to address concerns about excessive utilization and spending on skin substitute products, while avoiding administrative issues such as establishing additional HCPCS codes to describe different treatment situations.

One possible policy construct on which CMS seeks comment would be to establish a payment period for skin substitute application services between 4 weeks and 12

98 *Id.*at 39,507-08.
99 *Id.* at 39,508.

weeks, or to assign the CPT codes to comprehensive APCs with the option for a complexity adjustment that would allow for an increase in the standard APC payment for more resource-intensive cases.

(6) Proposed Payment Rates

a. Drug administration rates

A chart comparing the current 2019 drug administration payment rates to the proposed CY 2020 drug administration payment rates is provided below.

Comparison of Hospital OPPS Drug Administration Rates, July 2019 to Proposed CY 2020

HCPCS Code	Short Descriptor	Proposed 2020 Rates			Q3 2019 Rates			% Change 2019-2020
		SI	APC	Payment Rate	SI	APC	Payment Rate	
90461	Im admin each addl component	B			B			
90471	Immunization admin	Q1	5692	$60.85	Q1	5692	$59.75	1.84%
90472	Immunization admin each add	N			N			
90473	Immune admin oral/nasal	Q1	5692	$60.85	Q1	5692	$59.75	1.84%
90474	Immune admin oral/nasal addl	N			N			
96360	Hydration iv infusion init	S	5693	$185.68	S	5693	$187.18	-0.80%
96361	Hydrate iv infusion add-on	S	5691	$38.48	S	5691	$37.88	1.58%
96365	Ther/proph/diag iv inf init	S	5693	$185.68	S	5693	$187.18	-0.80%
96366	Ther/proph/diag iv inf addon	S	5691	$38.48	S	5691	$37.88	1.58%
96367	Tx/proph/dg addl seq iv inf	S	5692	$60.85	S	5692	$59.75	1.84%
96368	Ther/diag concurrent inf	N			N			
96369	Sc ther infusion up to 1 hr	S	5693	$185.68	S	5693	$187.18	-0.80%
96370	Sc ther infusion addl hr	S	5691	$38.48	S	5691	$37.88	1.58%
96371	Sc ther infusion reset pump	Q1	5692	$60.85	Q1	5692	$59.75	1.84%
96372	Ther/proph/diag inj sc/im	Q1	5692	$60.85	Q1	5692	$59.75	1.84%
96373	Ther/proph/diag inj ia	S	5693	$185.68	S	5693	$187.18	-0.80%
96374	Ther/proph/diag inj iv push	S	5693	$185.68	S	5693	$187.18	-0.80%
96375	Tx/pro/dx inj new drug addon	S	5691	$38.48	S	5691	$37.88	1.58%
96376	Tx/pro/dx inj same drug adon	N			N			
96379	Ther/prop/diag inj/inf proc	Q1	5691	$38.48	Q1	5691	$37.88	1.58%
96401	Chemo anti-neopl sq/im	Q1	5692	$60.85	Q1	5692	$59.75	1.84%
96402	Chemo hormon antineopl sq/im	Q1	5692	$60.85	Q1	5692	$59.75	1.84%
96405	Chemo intralesional up to 7	Q1	5692	$60.85	Q1	5692	$59.75	1.84%
96406	Chemo intralesional over 7	S	5693	$185.68	S	5693	$187.18	-0.80%
96409	Chemo iv push sngl drug	S	5693	$185.68	S	5693	$187.18	-0.80%
96411	Chemo iv push addl drug	S	5692	$60.85	S	5692	$59.75	1.84%
96413	Chemo iv infusion 1 hr	S	5694	$314.54	S	5694	$288.38	9.07%
96415	Chemo iv infusion addl hr	S	5692	$60.85	S	5692	$59.75	1.84%

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

b. Radiation therapy services

A chart comparing the current 2019 radiation therapy payment rates to the proposed CY 2020 radiation therapy payment rates is provided below.

Comparison of Hospital OPPS Radiation Therapy Rates, July 2019 to Proposed CY 2020

HCPCS Code	Short Descriptor	Proposed 2020 Rates			Q3 2019 Rates			% Change 2019-2020
		SI	APC	Payment Rate	SI	APC	Payment Rate	
76873	Echograp trans r pros study	S	5522	$111.04	S	5522	$112.51	-1.31%
77280	Set radiation therapy field	S	5611	$128.45	S	5611	$123.77	3.78%
77285	Set radiation therapy field	S	5612	$339.20	S	5612	$321.82	5.40%
77290	Set radiation therapy field	S	5612	$339.20	S	5612	$321.82	5.40%
77295	3-d radiotherapy plan	S	5613	$1,260.81	S	5613	$1,191.92	5.78%
77300	Radiation therapy dose plan	S	5611	$128.45	S	5611	$123.77	3.78%
77301	Radiotherapy dose plan imrt	S	5613	$1,260.81	S	5613	$1,191.92	5.78%
77321	Special teletx port plan	S	5612	$339.20	S	5612	$321.82	5.40%
77331	Special radiation dosimetry	S	5611	$128.45	S	5611	$123.77	3.78%
77332	Radiation treatment aid(s)	S	5611	$128.45	S	5611	$123.77	3.78%
77333	Radiation treatment aid(s)	S	5611	$128.45	S	5611	$123.77	3.78%
77334	Radiation treatment aid(s)	S	5612	$339.20	S	5612	$321.82	5.40%
77336	Radiation physics consult	S	5611	$128.45	S	5611	$123.77	3.78%
77338	Design mlc device for imrt	S	5612	$339.20	S	5612	$321.82	5.40%

HCPCS Code	Short Descriptor	Proposed 2020 Rates			Q3 2019 Rates			% Change 2019-2020
		SI	APC	Payment Rate	SI	APC	Payment Rate	
77370	Radiation physics consult	S	5611	$128.45	S	5611	$123.77	3.78%
77371	Srs multisource	J1	5627	$8,037.04	J1	5627	$7,644.24	5.14%
77372	Srs linear based	J1	5627	$8,037.04	J1	5627	$7,644.24	5.14%
77373	Sbrt delivery	S	5626	$1,790.84	S	5626	$1,690.57	5.93%
77401	Radiation treatment delivery	S	5621	$123.88	S	5621	$116.99	5.89%
77470	Special radiation treatment	S	5623	$547.14	S	5623	$519.85	5.25%
77520	Proton trmt simple w/o comp	S	5623	$547.14	S	5623	$519.85	5.25%
77522	Proton trmt simple w/comp	S	5625	$1,202.61	S	5625	$1,078.97	11.46%
77523	Proton trmt intermediate	S	5625	$1,202.61	S	5625	$1,078.97	11.46%
77525	Proton treatment complex	S	5625	$1,202.61	S	5625	$1,078.97	11.46%
77750	Infuse radioactive materials	S	5622	$239.51	S	5622	$224.46	6.70%
77761	Apply intrcav radiat simple	S	5623	$547.14	S	5623	$519.85	5.25%
77762	Apply intrcav radiat interm	S	5623	$547.14	S	5623	$519.85	5.25%
77763	Apply intrcav radiat compl	S	5624	$754.19	S	5624	$704.72	7.02%
77778	Apply interstit radiat compl	S	5624	$754.19	S	5624	$704.72	7.02%
77789	Apply surf ldr radionuclide	S	5621	$123.88	S	5621	$116.99	5.89%
77799	Radium/radioisotope therapy	S	5621	$123.88	S	5621	$116.99	5.89%

c. Payment for CAR-T therapies

A chart comparing the current 2019 CAR-T therapy payment rates to the proposed CY 2020 CAR-T therapy payment rates is provided below.

Comparison of Hospital OPPS CAR-T Therapy Rates, July 2019 to Proposed CY 2020

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

(7) *Proposed Changes in the Level of Supervision of Outpatient Therapeutic Services in Hospitals and CAHs*

CMS proposes to amend the existing regulation at 42 C.F.R. § 410.27(a)(1)(iv) to change the generally applicable minimum required level of supervision for hospital outpatient therapeutic

services from direct supervision to general supervision for services furnished by all hospitals and CAHs.[100]

Since 2010, there have been two different levels of supervision required for hospital outpatient therapeutic services: (1) direct supervision for hospital outpatient therapeutic services covered and paid by Medicare that are furnished in hospitals and PBDs of hospitals (other than CAHs) and small rural hospitals); and (2) general supervision for CAHs and small rural hospitals with 100 or fewer beds. The exception to the direct supervision requirement for CAHs and small rural hospitals was implemented via a 2010 exceptions policy indicating non-enforcement of the direct supervision requirement that was extended through December 31, 2019. Because of the enforcement instruction, there has essentially been a two-tiered system of physician supervision requirements for hospital outpatient therapeutic services. CMS states in the Proposed Rule that it believes it is time to end this two-tiered system, particularly given the additional burden on providers that reduces their flexibility to provide medical care, that there have been no reported issues with general supervision in CAHs and small rural hospitals, and that hospitals still need to comply with Conditions of Participation which may require a higher level of supervision for specific situations.

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

CMS proposes to complete its two-year phase-in of payment reductions for clinic visit services furnished at excepted off-campus PBDs (in general, these are locations that billed as off-campus PBDs prior to November 2, 2015). In the CY 2019 OPPS/ASC final rule, CMS indicated that it would phase-in over two years (CYs 2019 and 2020) a policy whereby payment for excepted off-campus PBDs would gradually be reduced to the same level as that applied to nonexcepted off-campus PBDs for clinic visit services (HCPCS code G0463).[101]

For CY 2020, CMS proposes to complete implementation of the two year phase-in as contemplated under the CY 2019 OPPS/ASC final rule. For CY 2020 (i.e., the second year of the phase-in), CMS proposes to apply the total reduction in payment for excepted off-campus PBDs: The proposed PFS-equivalent rate for CY 2020 would therefore be 40 percent of the proposed OPPS payment rate (that is, 100 percent of the proposed OPPS rate minus the 60 percent payment reduction that is applied in CY 2020).[102]

Consistent with the policy announced in the CY 2019 OPPS/ASC final rule, CMS proposes that the CY 2020 payment reduction would be implemented in a non-budget neutral fashion, such that the reductions in payment for clinic visit services would not be offset by increases in the payment rate for other services paid under OPPS.[103]

(9) *MedPAC Recommendations*

CMS discusses three MedPAC recommendations pertaining to OPPS payment rate updates, ASC conversion factor updates, and ASC cost reporting requirements. CMS did not take action on any of discussed recommendations stating that the recommendations either

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[100] *Id.* at 39,526.

[101] Under the CY 2019 policy, the CY 2019 payment reduction was 50 percent of the ultimate reduction. Thus, for CY 2019, the payment rate for G0463 was 70 percent of the OPPS rate for clinic visit services. *See* 83 Fed. Reg. 58,818, 58,822 (Nov. 21, 2018).

[102] Proposed Rule at 39,528.

[103] *Id.*

required legislative action, were misaligned with CMS's policies, or could be too administratively burdensome.[104]

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

CMS seeks comment on proposed payment indicators and payment rates for the Category III CPT code and Level II HCPCS codes newly recognized as ASC covered procedures or covered ancillary services effective April 2019 and July 2019.[105] CMS also solicits comments on the proposed CY 2020 payment indicators for the new and revised Category I and III CPT codes that will be effective January 1, 2020.[106]

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

CMS is proposing to permanently designate several CPT codes as office-based, based on data indicating that these procedures are performed more than 50 percent of the time in physicians' offices, and CMS's belief that the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices.[107]

Of the 12 procedures designated as temporarily office-based in the CY 2019 OPPS, CMS proposes to maintain the temporary office-based designation for 11 procedures[108] and to assign a non-office based payment indicator to one for CY 2020.[109]

CMS is proposing to designate seven new CY 2020 CPT codes for ASC covered surgical procedures as temporarily office-based.[110] CMS will reevaluate these procedures when utilization data becomes available.[111]

b. Proposed update and payment for ASC covered surgical procedures and covered ancillary services

CMS is proposing to calculate payment rates for office-based procedures (i.e., those with payment indicators PT, P3, and R2) and device intensive procedures (i.e., payment indicator J8) according to its established policies, and for device intensive procedures, using the modified definition of device-intensive procedures.[112] Therefore, CMS is proposing to update the payment amount for the service portion of the device-intensive procedures using the ASC standard rate setting methodology and the payment amount

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[104] *Id.* at 39,529.
[105] *Id.* at 39,531-33.
[106] *Id.* at 39,534.
[107] *Id.* at 39,536-37 (CPT codes 31298, 31634, 31647, 36465, 36466, 36482, 50727, 59414, 61880, relating to balloon dilation, surgical endoscopy, bronchoscopy, ultrasound compression maneuvers to guide injections, ablation therapy, urostomy, placenta delivery, and electrode removal or revision).
[108] *Id*. at 39,537-39 (CPT codes 10005, 10007, 10009, 10011, 11102, 11104, 11106, 65785, 67229, 0402T, and 0512T, relating to aspiration biopsies, skin biopsies, bone marrow biopsies and aspirations, corneal ring implantation, photocoagulation or cryotherapy to treat retinopathy, collagen cross-linking of cornea, and extracorporeal shock wave therapy).
[109] *Id.* (CPT code 38222, relating to bone marrow biopsies and aspirations).
[110] *Id.* (CPT codes 64XX0, 64XX1, 93X00, 93X01, 0551T, 05X4T, and 0X71T, relating to genicular nerve branch injections, neurolytic agent destruction, duplex scans for preoperative vessel assessment, transperineal periurethral balloon continence devices, autologous cellular implants for the treatment of knee osteoarthritis, and well-being coaching).
[111] *Id.* at 39,539.
[112] *Id.* at 39,547.

for the device portion based upon the proposed CY 2020 OPPS device offset percentages that have been calculated using the standard OPPS APC rate setting methodology.[113] CMS proposes that payment for office-based procedures would be at the lesser of the proposed CY 2020 PFS non-facility practice expense (PE) relative value unit (RVU)-based amount, or the proposed CY 2020 ASC payment amount, calculated according to the ASC standard rate setting methodology.[114]

For low-volume device-intensive procedures, CMS is proposing to limit the ASC payment rate to an amount equal to the OPPS payment rate for that procedure.[115] For CY 2020, this would only affect HCPCS code 0308T.[116]

For covered ancillary services, CMS proposes to update the ASC payment rates, and to make changes to ASC payment indicators, as necessary, to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status or services, and the payment rates.[117]

c. ASC conversion factor

For CY 2020, CMS proposes to adjust the CY 2019 ASC conversion factor ($46.532) by the proposed wage index budget neutrality factor of 1.0008 in addition to the private annual economy-wide nonfarm business multifactor productivity (MFP)-adjusted hospital market basket update factor of 2.7 percent, which results in a proposed CY 2020 ASC conversion factor of $47.827 for ASCs meeting the quality reporting requirements.[118] For ASCs not meeting the quality reporting requirements, CMS proposes to adjust the CY 2019 ASC conversion factor ($46.532) by the proposed wage index budget neutrality factor of 1.0008 in addition to the quality reporting/MFP-adjusted hospital market basket update factor of 0.7 percent, which results in a proposed CY 2020 ASC conversion factor of $46.895.[119]

(11) <u>Proposed Requirements for the Hospital OQR Program</u>

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 quality reporting requirements.[120] CMS does not propose major changes to the Hospital OQR Program: Among other things, no changes are proposed to the form, manner, and timing of data submitted for the Hospital OQR Program,[121] and CMS does not propose any new measures for the Program.[122]

CMS does propose the removal of one measure from the Hospital OQR Program beginning with October 2020 encounters used for the CY 2022 payment determination, on the grounds that the costs of continuing collection outweigh the benefit of continued use:

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113 *Id.*
114 *Id.*
115 *Id.* at 39,547-48.
116 *Id.*
117 *Id.* at 39,549.
118 *Id.* at 39,552.
119 *Id.* at 39,552-53.
120 *See id.* at 39,560–61 (proposing to continue existing policies related to reporting ratio application and associated adjustment policies).
121 *Id.* at 39,559.
122 *Id.*

- *OP-33: External Beam Radiotherapy (EBRT) (NQF# 1822)* (percentage patients with painful bone metastases and no prior history of radiation who receive acceptable EBRT).[123]

CMS also requests comment on four potential new Hospital OQR Program patient safety measures[124] that may be proposed in a future rulemaking: (1) patient burn;[125] (2) patient fall;[126] (3) wrong site, wrong side, wrong procedure, wrong implant;[127] and (4) all-cause hospital.[128]

(12) *Proposed Requirements for the ASCQR Program*

Under the ASCQR Program, ASCs face a 2.0 percentage point reduction in their annual payment update if they fail to meet certain quality reporting requirements. CMS does not propose major changes to the Hospital ASCQR Program. Among other things, no changes are proposed to the form, manner, and timing of data submitted for the Hospital ASCQR Program.[129]

CMS does propose one new measure for the ASCQR Program set for the CY 2024 payment determination and subsequent years:

- *ASC-19: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (NQF #3357)* (risk-adjusted measure of acute, unplanned hospital visits within 7 days of a general surgery procedure performed at an ASC among Medicare FFS patients age 65+).[130]

If the new measure is finalized, CMS proposes to conduct a "dry run" before the official data collection period (or any public reporting) where there would be a period of confidential reporting and opportunity to ask questions or obtain feedback on measure results.[131] CMS also requests comments about a potential proposal for future rulemaking, where the agency is considering updating the data submission method for four ASCQR Program patient safety measures to be through CMS's QualityNet online data submission tool: (1) ASC 1: Patient Burn; (2) ASC 2: Patient Fall; (3) ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and (4) ASC 4: All-Cause Hospital Transfer/Admission.[132]

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123 *Id.* at 39,555.

124 *Id.* at 39,557 (the four measures were previously adopted in the ASCQR program). CMS also generally solicits public comment on potential future outcome measure topics that the agency could consider proposing in future rulemakings. *Id.* at 39,559.

125 *Id.* at 39,557.

126 *Id.* at 39,557-58 (assessing the percentage of admissions experiencing a fall).

127 *Id.* at 39,558 (assessing the percentage of admissions receiving treatment affecting the wrong site/side, wrong patient, wrong procedure, or wrong implant).

128 *Id.* (assessing the rate of admissions requiring a hospital transfer or hospital admission upon discharge).

129 *Id.* at 39,569.

130 *Id.* at 39,563-64. CMS proposes to require public reporting for facilities with a sufficient number of cases to meet moderate reliability standards. *Id.* at 39,566.

131 *Id.*

132 *Id.* at 39,568.

(13) *Proposed Requirements for Hospitals to Make Public a List of Their Standard Charges*

CMS proposes expansive new public disclosure requirements under section 2718(e) of the Public Health Service Act (PHSA) that would, among other things, require all non-federally owned or operated hospitals to publicly display gross *and payer-specific* negotiated charges for all items and services. CMS would also be required to provide, in a more "consumer friendly" fashion, pricing information related to 300 "shoppable" services as defined by CMS.

Specifically, CMS proposes that all entities that meet CMS's new proposed definition of "hospital" (except for federally-owned or operated hospitals)[133] make public a list of the hospital's "standard charges" for "items and services" provided by the hospital, including for Diagnosis Related Groups (DRGs). CMS proposes to interpret this new requirement in a broad manner that would require hospitals to develop substantial (and likely costly) new processes for public disclosure and display of both gross charges and payer-negotiated rates and pricing information.

CMS proposes to operationalize this new requirement as follows:

a. *Proposed definitions*

- CMS proposes to define "hospital" in a manner that would subject virtually all (non-federally owned or operated) hospitals to the new requirement. Specifically, CMS proposes to define "hospital" to mean any institution in any state in which state or applicable local law provides for licensing of hospitals that is licensed as a hospital pursuant to such law (or approved by the responsible state or local agency as meeting such hospital licensure requirements).[134]

- CMS proposes that "items and services" would be defined expansively to mean all items and services provided by the hospital (including individual items and services and service packages that would be provided by a hospital in connection with an inpatient admission or outpatient visit) for which the hospital has established a standard charge.[135]

    - *Items and Services Furnished by Hospital Employees*. CMS's proposed definition includes items or services furnished by physicians and non-physician practitioners that are employed by the hospital.[136]

    - *Items and Services Furnished by Non-Employees*. CMS solicits comments on whether to add to its proposed definition those items and services furnished by physicians and non-physician practitioners that are <u>not</u> employed by the hospital but that provide services at a hospital location.[137]

- CMS proposes to define "standard charges" to include two sets of charges: Gross

[133] Federally-owned or operated hospitals are proposed to include Indian Health Service (IHS) facilities (including Tribally-owned and operated facilities), Veterans Affairs (VA) facilities, and Department of Defense Military Treatment Facilities (MTFs). *Id.* at 39,575.
[134] CMS also proposes to define "state" to include the 50 states, the District of Columbia, and American territories. *Id.*
[135] *Id.* at 39,576.
[136] *Id.* at 39,577.
[137] *Id.*

charges and payer-specific negotiated charges.[138]

- *Gross Charges*. CMS proposes to define "gross charges" to mean the regular rate established by the hospital for the items and services provided to a specific group of paying patients—i.e., the hospital's "list price" absent any discounts.[139]

- *Payer-Specific Negotiated Charges*. CMS defines "payer-specific negotiated charges" to mean the charge that the hospital has negotiated with a third party payer for an item or service.[140] CMS further proposes to define third party payer to mean an entity that is, by statute, contract, or agreement, legally responsible for payment of a claim for a health care item or service.[141]

CMS also solicits comments on potential alternative or additional definitions of standard charges, such as including the "modal negotiated charges" (the most frequently charged rate); the minimum, medium, and maximum negotiated charges; or all charges (whether or not negotiated).[142] CMS also solicits comments on various alternative or additional standard charge definitions relevant to self-pay individuals, such as the discounted cash price or the median discounted cash price.[143]

b. Proposed public display requirements for hospital standard charge lists

CMS proposes to require hospitals to make public their standard charges for all items and services in two ways: (1) a comprehensive machine readable file and (2) a narrower consumer-friendly "shoppable" services list.[144]

- *Proposed comprehensive machine readable file requirements*

  CMS proposes to require hospitals to make public a comprehensive machine-readable file that makes public all standard charge information—including payer-specific negotiated rates—for all hospital items and services.[145] CMS proposes to define machine readable format as a digital representation of data or information in a file that can be imported or read into a computer system for further processing.[146]

  In addition, CMS solicits public comment on technologies and standards that could facilitate public access to real-time updates in a format to make consumer access to such information easier.[147] In particular, CMS is interested in application programming interface (API) standards that could facilitate access to real-time hospital charge information through "apps."[148] CMS specifically requests comment on whether to require hospitals to make public their standard

[138] *Id.* at 39,578.
[139] *Id.*
[140] *Id.* at 39,579.
[141] *Id.*
[142] *Id.* at 39,580-81.
[143] *Id.*
[144] *Id.* at 39,581-82
[145] *Id.* at 39,582.
[146] *Id.* at 39,583.
[147] *Id.*
[148] *Id.*

charges through "openly charged" or "open" APIs.[149]

- *Proposed Standardized Data Elements*. CMS proposes that the comprehensive machine-readable list must incorporate various standardized data elements to promote uniformity across hospitals—including a description of each item or service; corresponding gross and payer-specific negotiated charges for each item or services; associated CPT, HCPCS, DRG, and/or National Drug Codes (NDCs).[150]

- *Proposed Location and Accessibility Requirements*. CMS proposes to give each hospital discretion to choose the internet location it uses to post its list of standard charges so long as the file is displayed on a publicly-available webpage and the following proposed requirements are satisfied:

    - *Displayed Prominently*. CMS proposes to require that the file be "displayed prominently," meaning clearly identified and communicated without reliance on "breadcrumbs" to help with navigation and the link to the standard charge file is visually distinguished on the webpage.[151]

    - *Easily Accessible*. CMS proposes to require the file be "easily accessible," which CMS proposes to mean in a single machine readable file that is searchable and posted on a website that can be accessed with "the fewest number of clicks."[152]

    - *Available Without Barriers*. CMS proposes to require the file be available "without barriers," which CMS proposes to define to mean free of charge and without requiring users to input information (e.g., name, e-mail address) or to register to access for such information.[153]

    CMS also solicits comments on a potential alternative policy where hospitals would be required to submit a link to the standard charge file to a CMS-specified central website (or otherwise submit a link to the standard charge file to CMS that would be made public on a CMS webpage).[154]

- *Proposed Frequency of Updates*. CMS proposes to require hospitals to make public and update their file of all standard charges at least once annually. CMS also proposes to require that hospitals clearly indicate the date of last update to the standard charge data.[155]

- *Proposed Requirements for Different Hospital Locations*. If a hospital has two different locations operating under a consolidated or single license, CMS proposes to require that each hospital make public a separate identifiable list of

[149] *See id.* at 39,583-84.
[150] *Id.* at 39,582 (note that CMS proposes to *require* that each standard charge be associated with a relevant CPT or HCPCs code, DRG, NDC, or other common payer identifier).
[151] *Id.* at 39,584.
[152] *Id.*
[153] *Id.*
[154] *Id.* CMS also seeks public comment on potential additional requirements, including easily-searchable file naming conventions and whether CMS should specify the website location for posting rather than its current proposal that would permit hospitals some flexibility in choosing an appropriate website.
[155] *Id.* at 39,584-85.

standard charges.[156]

- *Proposed consumer-friendly "shoppable" services list requirements*

  CMS proposes to require hospitals to display in a "consumer-friendly" fashion a list of payer-specific negotiated charges for a set of CMS-defined "shoppable" services. Specifically, CMS proposes that the shoppable services list must include as many of 70 CMS-selected shoppable services that are provided by the hospital—and as many additional shoppable services selected by the hospital as is necessary for a combined total of 300 shoppable services on the list.[157]

  CMS indicates that it plans to increase the number of required shoppable services to be listed over time.[158] CMS also solicits comments on whether the 300 total shoppable services should be increased or decreased as a reasonable starting point.[159]

  In addition, CMS proposes the following requirements related to the shoppable services list:

- *Proposed Definition of "Shoppable Service."* CMS proposes to define "shoppable service" as a service package that can be scheduled by a health care consumer in advance (e.g., typically routine or non-urgent services).[160]

- *Proposed Grouping of Shoppable and Ancillary Services*. CMS proposes that the charges for shoppable services be displayed as a grouping of related services—meaning the charge for the shoppable service is displayed along with commonly associated ancillary services.[161] CMS proposes to define "ancillary services" to mean an item or service that a hospital customarily provides as part of or in conjunction with a shoppable primary service.[162]

- *Proposed Required Data Elements*. CMS proposes that the shoppable services list must incorporate various standardized data elements to promote uniformity across hospitals—including a plain-language description of each item or service and their payer-specific negotiated charges; a list of all associated ancillary services for each shoppable service (including payer-specific negotiated charges); the location at which each shoppable service is provided by the hospital; and any primary codes used for accounting or billing of the shoppable service.[163]

- *Proposed "Consumer Friendly" Format of Display*. CMS proposes to give hospitals flexibility with respect to how best to display the data elements of the

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156 *Id.* at 39,585.
157 *Id.* at 39,586-89.
158 *Id.* CMS also solicits comments on a possible alternative, where CMS would propose a larger set of shoppable services and allow hospitals to select up to 70 CMS-selected shoppable services from the larger list. Then the hospital would select an additional 230 shoppable services for a total of 300 shoppable services.
159 *Id.*
160 *Id.*
161 *Id.*
162 *Id.*
163 *Id.* at 39,589-90.

shoppable service list—so long as it is displayed on a website that is consumer friendly and easily accessible to the public.[164] CMS also indicates that it is considering (but not proposing) requiring hospitals to make such data available in API format to enable app-based consumer access to information.[165]

Further, CMS proposes to require that all required data elements be made available in a consumer-friendly offline format within 72 hours of a request.[166]

- *Proposed Location and Accessibility Requirements*. CMS proposes to apply the same proposed location and accessibility requirements described above in the comprehensive machine readable file section to the consumer-friendly shoppable services list.[167]

- *Proposed Frequency of Updates*. CMS proposes to require hospitals to make public and update their shoppable services list at least one annually. CMS also proposes to require that hospitals clearly indicate the date of last update to the list.[168]

c. *Proposed monitoring and enforcement of requirements for public standard charge lists*

CMS proposes to establish regulations allowing it to employ methods to monitor and assess hospital compliance with CMS's proposed public standard charge disclosure requirements. CMS anticipates predominately monitoring compliance through complaints made to CMS regarding potential non-compliance.[169] If a hospital is found to be in non-compliance, CMS proposes that it will give the hospital an opportunity to take corrective actions to come into compliance by submitting a corrective action plan (CAP) and implementing program improvements within specified timeframes while subject to CMS review and approval.[170]

- *Proposed Civil Monetary Penalties (CMPs)*. CMS proposes a new CMP for non-compliance with its proposed public standard charge disclosure requirements of up to $300 per day.[171] CMS also proposes to publicize on CMS's website notices of the imposition of CMPs.[172]

- *Proposed Appeal Right*. CMS proposes that generally a hospital upon which a CMP is imposed may request a hearing before an Administrative Law Judge

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[164] *Id.* To be consumer-friendly, CMS proposes that the information must be displayed in a way that is understandable to patients (e.g., plain-language descriptions of services). CMS also proposes to require that the shoppable service charge be displayed along with charges for ancillary services customarily provided with the primary shoppable service. CMS further proposes to require that the consumer be able to easily search and find charges for the shoppable services based on the service description, associated codes, or payer. *See id.* at 39,585.

[165] *Id.* at 39,590.

[166] *Id.*

[167] *Id.*

[168] *Id.* at 39,591.

[169] *Id.* at 39,591-92.

[170] *Id.* at 39,592.

[171] *Id.* (CMS also proposes to adjust by applying a cost-of-living adjustment multiplier determined by OMB for adjusting CMPs).

[172] *Id.* at 39,593.

(ALJ) to challenge the penalty. The Administrator would then have discretionary review of an adverse ALJ decision. A hospital against which a final CMP order was imposed could then obtain judicial review.[173]

(14) *RFI: Quality Measurement to Price Transparency for Improving Beneficiary Access to Provider and Suppler Charge Information*

CMS seeks stakeholder input on the following quality health care issues:

- "Improving availability and access to existing quality of health care information for third parties and health care entities to use when developing price transparency tools and when communicating charges for health care services."[174]

- "Improving incentives and assessing the ability of health care providers and suppliers to communicate and share charge information with patients."[175]

(15) *Clinical Laboratory Fee Schedule: Potential Revisions to the Laboratory Date of Service Policy*

For clinical laboratory tests performed on specimens obtained during a hospital outpatient encounter, the entity that will bill Medicare for the test (either the hospital as part of the hospital stay or the laboratory) depends on the date of service (DOS) of the test (which is an attempt by CMS to determine whether the test performed as part of post-hospital care or care that the beneficiary receives in the hospital).

The default rule is that tests performed on specimens collected during a hospital stay have a DOS of the date of specimen collection, payment is bundled with the hospital service, and the hospital therefore would bill Medicare for the test and would then pay the laboratory that performed the test (if the laboratory provided the test under arrangement). There are currently three different "exceptions", set forth at 42 C.F.R. § 414.510 to determine whether the DOS of a laboratory test is instead the date the test is performed and therefore billable by the clinical laboratory and separately payable under Medicare Part B: (i) tests that satisfy the "14-day rule"; (ii) chemotherapy sensitivity tests performed on live tissue; and (iii) molecular pathology tests and certain advanced diagnostic laboratory tests (ADLTs) that satisfy certain requirements.

For CY 2020, CMS is considering three options for potential changes to the molecular pathology and ADLT DOS exception.[176] Currently, the molecular pathology and ADLT exception provides that the date of service of the test is the date the test is performed (and therefore billable by the laboratory and separately payable under Medicare Part B) if: (i) the test was performed following a hospital outpatient's discharge from the hospital outpatient department; (ii) the specimen was collected from a hospital outpatient during an encounter; (iii) it was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter; (iv) the results of the test do not guide treatment provided during the hospital outpatient encounter; and (v) the test was reasonable and

[173] *Id.* at 39,593-94.
[174] *Id*. at 39,595.
[175] *Id*.
[176] *Id.* at 39,601.

medically necessary for the treatment of an illness.[177] With regard to ADLTs, this exception does not apply to ADLTs that are cleared or approved by the FDA.

CMS proposes the following three changes to the exception for CY 2020:

- Revising criterion (iv) to determine whether a molecular pathology test or ADLT is separable from a hospital service by specifying that the ordering physician would determine whether the results of the ADLT or molecular pathology test are intended to guide treatment provided during a hospital outpatient encounter.[178] If implemented, this would mean that a molecular pathology or ADLT would be considered a hospital service unless the ordering physician determines that the test does not guide treatment during a hospital outpatient encounter, even if all of the other exception criteria are met. CMS solicits comments regarding its position that when the results of molecular pathology testing and applicable ADLTs are intended to guide treatment during a future hospital outpatient encounter, the test is a hospital service and regarding the administrative aspect of requiring the ordering physician to determine when the test results are not intended to guide the treatment during a hospital outpatient encounter.

- Removing molecular pathology tests from the exception at 42 C.F.R. § 414.510(b)(5) such that only tests designated by CMS as an ADLT under paragraph (1) of the definition of an ADLT at 42 C.F.R. § 414.502 would be included in the exception.[179] CMS explains that it believes such a policy is supported by the fact that, unlike ADLTs, molecular pathology tests are not required by statute to be furnished by a single laboratory, and that hospital laboratories are more easily able to perform molecular pathology tests.[180]

- Finally, CMS proposes to exclude blood banks and centers from the exception at 42 C.F.R. § 414.510(b)(5), and would define a blood bank and center as an entity whose primary function is the collection, storage and dissemination of blood products.[181] Under this potential revision, the DOS for laboratory testing performed by blood banks and centers on specimens collected from a hospital outpatient during a hospital outpatient encounter would, depending on the underlying service, be the date of specimen collection (and therefore the hospital would bill for the laboratory test under arrangements and the blood bank or center would seek payment from the hospital).[182] CMS's rationale for this potential change is that molecular pathology testing, when performed by blood banks or centers has a different use than other molecular pathology testing; it enables hospitals to prevent adverse conditions associated with blood transfusions, rather than performing molecular pathology testing for diagnostic purposes. Thus, molecular pathology testing, when performed by blood banks or centers, is inherently tied to a hospital service because hospitals receive payment for and/or use the blood and/or blood products provided by blood banks and blood centers to treat patients in the hospital setting. We note that if CMS were to finalize its proposal to remove molecular pathology tests from the exception

[177] 42 C.F.R. § 414.510(b)(5).
[178] Proposed Rule at 39,601.
[179] *Id.* at 39,602.
[180] *Id.*
[181] *Id.* at 39,603.
[182] *Id.*

at 42 C.F.R. § 414.510(b)(5), then it would seem unnecessary for it to also exclude blood banks and centers from the exception.

CMS solicits comments on these proposals.

(16) *Proposed Prior Authorization Process and Requirements for Certain HOPD Services*

CMS recently completed an analysis of the volume of covered OPD services furnished and determined that CMS has experienced significant increases in the utilization volume of some of these services.[183] To further the goals of managing the growth in Medicare spending for OPD services, and to control unnecessary increases in the volume of OPD services, CMS proposes to implement a prior authorization requirement for five categories of services: Blepharoplasty, Botulinum Toxin Injections, Panniculectomy, Rhinoplasty, and Vein Ablation.[184]

CMS explains that a prior authorization process for certain OPD services would ensure that Medicare beneficiaries continue to receive medically necessary care while protecting the Medicare Trust Funds from improper payments, and at the same time keeping the medical necessity documentation requirements unchanged for providers.[185]

CMS proposes to use its authority under section 1833(t)(2)(F) of the SSA to establish a process through which providers would submit a prior authorization request for a provisional affirmation of coverage for designated services before a the OPD service is furnished to the beneficiary and before the claim is submitted for processing. CMS defines the relevant terms as follows:[186]

- "Prior authorization" means a process through which a request for provisional affirmation of coverage is submitted to CMS or its contractors for review before the service is provided to the beneficiary and before the claim is submitted.

- "Provisional affirmation" means a preliminary finding that a future claim for the service will meet Medicare's coverage, coding, and payment rules.

- "List of hospital outpatient department services requiring prior authorization" as the list of OPD services that CMS publishes.

CMS proposes that a provider must submit a prior authorization request for services on the list of HOPD services requiring prior authorization to CMS and that claims submitted for services that require prior authorization that have not received a provisional affirmation of coverage from CMS or its contractors would be denied, unless the provider is exempt.[187] CMS notes, however, that even when a provisional affirmation is provided, a claim for services could be later denied based on either technical requirements that can only be evaluated after the claim has been submitted for formal processing or information not available at the time the prior authorization request is received.[188] Providers receiving a non-

183 *Id.* at 39,603.
184 *Id.* at 39,604.
185 *Id.*
186 *Id.* at 39,604-05.
187 *Id.* at 39,605.
188 *Id.*

affirmation decision would be allowed to resubmit a prior authorization request with any applicable additional relevant documentation.[189]

CMS proposes that the list of covered OPD services that would require prior authorization include 40 CPT codes that are identified in Table 38 of the Proposed Rule.[190]

[189] *Id.*

[190] *Id.* at 39,607-09 (CPT codes relating to blepharoplasty, eyelid surgery, brow lift, botulinum toxin injection, panniculectomy, excision of excess skin and subcutaneous tissue (including lipectomy), rhinoplasty, vein ablation, and related services).