Hogan Lovells

Overview of Selected Provisions of the Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule for Calendar Year 2021

On August 12, 2020, the Centers for Medicare & Medicaid Services (CMS) published the Medicare Hospital Outpatient Prospective Payment (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems and Quality Reporting Programs proposed rule for calendar year (CY) 2021 (the "Proposed Rule").[1] The Proposed Rule also includes proposals relating to new categories for hospital outpatient department prior authorization processes; clinical laboratory fee schedule laboratory date of service policies; overall hospital quality star rating methodology; and physician-owned hospitals. CMS will accept comments on it until October 5, 2020.[2]

CMS proposes to increase payment rates under the OPPS by an outpatient department (OPD) fee schedule increase factor of 2.6 percent.[3] CMS estimates that total payments to OPPS providers for CY 2021 would be approximately $83.9 billion, an increase of approximately $7.5 billion compared to estimated CY 2020 OPPS payments.[4] 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 0.9805 to the OPPS payments and copayments for all applicable services.[5]

The addenda containing relative weights, payment rates, wage indices, and other payment information are available only on the CMS website.

- Addenda relating to the OPPS are available at: https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientppshospital-outpatient-regulations-and-notices/cms-1736-p.
- Addenda relating to the ASC payment system are available at: https://www.cms.gov/medicaremedicare-fee-service-paymentascpaymentasc-regulations-and-notices/cms-1736-p.

This Summary Addresses the Following Topics in the CY 2021 Proposed Rule:

(1) Updates Affecting OPPS Payments
   a. Recalibration of Ambulatory Payment Classification (APC) relative payment weights
   b. Conversion factor update
   c. Wage index changes

[1] 85 Fed. Reg. 48,772 (Aug. 12, 2020). Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-owned Hospitals; CMS-1736-P, available at: https://www.govinfo.gov/content/pkg/FR-2020-08-12/pdf/2020-17086.pdf ("Proposed Rule").

[2] In conjunction with the Proposed Rule release, CMS also published a fact sheet, available at: https://www.cms.gov/newsroom/fact-sheets/cy-2021-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center, and a press release, available at: https://www.cms.gov/newsroom/press-releases/trump-administration-proposes-policies-provide-seniors-more-choices-and-lower-costs-surgeries.

[3] 85 Fed. Reg. at 48,774.

[4] *Id.*

[5] *Id.*

d. Statewide average default Cost-to-Charge Ratios (CCRs)
e. Payment adjustment for certain cancer hospitals
f. Hospital outpatient outlier payments
g. Calculation of an adjusted Medicare payment from the national unadjusted Medicare payment

(2) OPPS APC Group Policies
a. Treatment of new and revised Healthcare Common Procedure Coding System (HCPCS) Codes
b. Exceptions to the "2 times rule"
c. New technology APCs

(3) Proposed New C-APCs

(4) OPPS Payment for Devices
a. Transitional pass-through payment status
b. Device intensive procedures

(5) OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals
a. Drugs and biologicals with expiring pass-through payment status
b. Drugs, biologicals, and radiopharmaceuticals with new or continuing pass-through payment status in CY 2021

(6) 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. Payment methodology for 340B purchased drugs
d. CY 2021 packaging of skin substitutes
e. Allowing synthetic skin graft sheet products to be reported with graft skin substitute procedure codes

(7) Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

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

(9) Payment Rates
a. Drug administration rates
b. Radiation therapy services
c. Payment for CAR-T therapies

(10) Phased Elimination of the Inpatient-Only (IPO) List
a. Effect of elimination of IPO List on medical review, two-midnight rule

(11) Comment Solicitation on OPPS Payment for Specimen Collection for COVID-19 Tests

(12) Medicare Payment Advisory Committee (MedPAC) Recommendations

(13) Updates to the ASC Payment System
a. Designation of HCPCS codes as office-based or ASC covered
b. Device-intensive procedures performed in the ASC
c. Adjustment to ASC Payments for no cost/full credit and partial credit devices
d. Additions to list of ASC covered surgical procedures
e. Update and payment for ASC covered surgical procedures and covered ancillary services
f. ASC payment and comment indicators for CY 2021

g. ASC conversion factor update

(14) Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

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

(16) Addition of New Service Categories for Hospital Outpatient Department (OPD) Prior Authorization Process

(17) Overall Hospital Quality Star Rating Methodology for Public Release in CY 2021 and Subsequent Years

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

(19) Waiver of the 60-day Delayed Effective Date for the Final Rule

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

a. *Drugs and biologicals without pass-through status*. CMS proposes to continue its policy of packaging drugs and biologicals with a per day cost less than or equal to $130 and to identify drugs and biologicals with a per day cost greater than $130 as separately payable unless they are policy-packaged.[6] Policy packaged drugs include: (i) anesthesia, certain drugs, biologicals, and other pharmaceuticals; medical and surgical supplies and equipment; surgical dressings; and devices used for external reduction of fractures and dislocations; (ii) intraoperative items and services; (iii) drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including but not limited to, diagnostic radiopharmaceuticals, contrast agents, and pharmacologic stress agents); and (iv) drugs and biologicals that function as supplies when used in a surgical procedure (including, but not limited to, skin substitutes and similar products that aid wound healing and implantable biologicals).[7] For drugs and biologicals without pass-through status that are not packaged (and which are not 340B covered drugs), CMS proposes to continue its policy to reimburse at Average Sales Price (ASP) plus six (ASP+6) percent.[8]

b. *OPPS payment for hospital outpatient visits and critical care services.* CMS proposes "to continue with [its] current clinic and emergency department (ED) hospital outpatient visits payment policies," the payment policy for critical care services, which was laid out in the CY 2016 OPPS final rule.[9] CMS also is retaining its policy on volume control of outpatient services, described in detail in the CY 2020 final rule, for CY 2021.[10] This policy pays for clinic visits furnished at non-excepted off-campus departments at the same rate that applies to excepted off-campus departments, which is 40 percent of the OPPS rate.

c. *Comprehensive APC (C-APC) policy.* For CY 2021 and subsequent years, CMS proposes to continue to apply its C-APC policy.[11] 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 will 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.[12] CMS will continue its policy that payment for services assigned to a New Technology

[6] *Id.* at 48,877.
[7] *Id.* at 48,878.
[8] *Id.* at 48,880.
[9] *Id*. at 48,900.
[10] *Id*.
[11] *Id.* at 48,786. (CMS does propose to create two new C-APCs as discussed later in this document.)
[12] *Id.*

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.[13]

d. *OPPS payment policies for non-opioid pain management alternatives*. For CY 2021, CMS proposes to continue to conditionally package the costs of selected newly identified ancillary services into payment for a primary service where CMS believes the packaged item or service is integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by the primary service HCPCS code.[14] CMS proposes to continue 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 2021.[15] 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 were necessary for CY 2020 and that conducting a similar CY 2021 review was not necessary.[16]

e. *Establishing payment rates for low-volume new technology services.* For CY 2021, CMS proposes to continue establishing payment rates for low-volume new technology services using the policy adopted in the CY 2019 OPPS/ASC final rule, under which CMS utilizes its equitable adjustment authority to calculate the geometric mean, arithmetic mean, and median using multiple years of claims data to select the appropriate payment rate for purposes of assigning services with fewer than 100 claims per year to a New Technology APC.

f. *Pass-through payment eligibility for biosimilar biological products.* CMS proposes to continue its policy to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product, and to pay for biosimilars at the biosimilar's ASP instead of the biosimilar's reference product's ASP.[17]

Details about select topics and proposed changes are provided below.

(1) *Updates Affecting OPPS Payments*

a. Recalibration of APC relative payment weights

CMS proposes to recalibrate relative payment weights for each APC based on claims and cost report data for HOPD services using the most recent available data to construct a database for calculating APC group weights.[18] CMS proposes to continue to use hospital-specific overall ancillary and departmental cost-to-charge ratios (CCRs) to convert charges to estimated costs through application of a revenue code-to-cost center crosswalk.[19] CMS proposes to continue to use single procedure APC criteria-based costs for blood and blood products and brachytherapy sources.[20]

For unclassified blood products, CMS proposes to package the cost reported by HCPCS code P9099 (Blood component or product not otherwise classified) into the cost of the associated primary procedure, and to change the status indicator for this code from "E2"

[13] *Id.*
[14] *Id.* at 48,796.
[15] *Id.* at 48,797 and 48,979.
[16] *Id.*
[17] *Id.* at 48,881.
[18] *Id.* at 48,779.
[19] *Id.*
[20] *Id.* at 48,781-83.

(not payable by Medicare in the OPPS) to "N" (payment is packaged into other services in the OPPS).[21] CMS is inviting comment on the alternative proposal to make HCPCS code P9099 separately payable with a payment rate equivalent to the payment rate for the lowest cost blood product, HCPCS code P9403 (Infusion, plasma protein fraction (human), 5 percent, 50 ml), with a proposed CY 2021 payment rate of $8.02 per unit. If this alternative proposal is adopted, CMS would also change the status indicator for this code from "E2" to "R" (blood and blood products, paid under OPPS).[22]

For brachytherapy sources, CMS proposes to use costs derived from CY 2019 claims data to set the proposed CY 2021 payment rates and to base the payment rates for brachytherapy sources on the geometric mean unit costs for each source, with the exception of the proposed payment rate for C2645 (Brachytherapy planar source, palladium-103, per square millimeter).[23] This methodology is consistent with the methodology that CMS uses for other items and services paid under the OPPS.[24] 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.[25]

CMS proposes to exclude cancer-related protein-based Multianalyte Assays with Algorithmic Analyses (MAAAs) from the OPPS packaging policy and to pay for them separately under the Clinical Laboratory Fee Schedule (CLFS).[26] CMS identifies six cancer-related protein-based MAAAs (Current Procedural Terminology (CPT®)[27] codes 81500, 81503, 81535, 81536, 81538 and 81539) and proposes to assign status indicator "A" (Not paid under OPS; paid by Medicare Administrative Contractors (MACs) under a fee schedule or payment system other than OPPS) for the identified codes (excluding 81538, which as a designated advanced diagnostic laboratory tests (ADLTs), already is paid under the CLFS).[28] For additional discussion about CMS's proposals regarding MAAAs, see Section 18 of this summary.

For CY 2021, 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.[29] CMS proposes to calculate APC relative weight scales by dividing the CY 2020 estimated aggregate weight by the proposed unscaled CY 2021 estimated aggregate weight.[30] CMS further proposes to adjust the estimated CY 2021 unscaled relative payment weights by multiplying them by a proposed weight scalar of 1.4443 to ensure the proposed CY 2021 relative payment weights are budget neutral.[31]

b. Conversion factor update

Section 1833(t)(3)(C)(ii) of the Social Security Act requires the Secretary to update the conversion factor used to determine the payment rates under the OPPS on an annual

[21] *Id.* at 48,783.
[22] *Id.*
[23] *Id.*
[24] *Id.*
[25] *Id.* at 48,784.
[26] *Id.* at 48,799.
[27] CPT Copyright 2019 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.
[28] 85 Fed. Reg. at 48,799.
[29] *Id.*
[30] *Id.* at 48,800.
[31] *Id.*

basis by applying the OPD fee schedule increase factor. For CY 2021, CMS proposes to amend its regulation at 42 CFR § 419.32(b)(1)(iv)(B) by adding a new paragraph to provide that, for CY 2020 and subsequent years, the OPD fee schedule increase factor will be reduced by the private nonfarm business multifactor productivity (MFP) adjustment (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period) as determined by CMS.[32] CMS clarifies that it neglected to make this change in CY 2020, even though it is required by law.

For CY 2021, CMS proposes to increase the OPD fee schedule increase factor in order to satisfy certain statutory requirements. Specifically, CMS proposes a conversion factor of $83.697 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs.[33] The conversion factor of $83.697 (up from $80.793 in CY 2020) results from the proposed OPD fee schedule increase factor of 2.6 percent, the required proposed wage index budget neutrality adjustment of approximately 1.0017, the proposed cancer hospital payment adjustment to 1.0000, and the proposed adjustment of 0.05 percentage point of projected OPPS spending for the difference in pass-through spending.[34] CMS proposes to use a reduced conversion factor of $82.065 to calculate payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of -1.632 relative to hospitals that meet the requirements).[35]

c. Wage index changes

CMS proposes to use the FY 2021 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 2021.[36] 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.[37]

d. 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 for which the most recent cost report reflects an all-inclusive rate status.[38] CMS proposes to update the statewide default CCRs for CY 2021 using the most recent cost report data.[39] The statewide average CCRs are available on the CMS website at:

---

[32] *Id.*
[33] *Id.* at 48,801.
[34] *Id.*
[35] *Id.*
[36] *Id.* at 48,803.
[37] *Id*. at 48,803-04.
[38] *Id.* at 48,804.
[39] *Id.*

https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientppshospital-outpatient-regulations-and-notices/cms-1736-p.[40]

e. Payment adjustment for certain cancer hospitals

CMS proposes to use a target payment-to-cost ratio (PCR) of 0.89 (which is the same as CY 2020) to determine the CY 2021 cancer hospital payment adjustment.[41] 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.[42] Table 5 in the Proposed Rule provides the estimated percentage increase in OPPS payments for CY 2021 due to payment adjustment for these eleven cancer hospitals.[43]

f. 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.[44] To meet this estimate, CMS proposes to increase the fixed-dollar amount threshold by $225 from $5,075 in CY 2020 to a proposed $5,300 for CY 2021.[45] CMS does not propose changes to the multiplier threshold of 1.75.

g. Calculation of an adjusted Medicare payment from the national unadjusted Medicare payment

In the Proposed Rule, CMS provides the formula for providers to use to calculate the payment amount that they will receive for a specific service from the national unadjusted payment rates presented in Addenda A and B of the Final Rule.[46] The formula incorporates factors related to the wage index area in which the hospital is located, whether the hospital failed to meet the Hospital OQR Program requirements and therefore receives the "reduced" national unadjusted payment rate of 0.9805 of the "full" national unadjusted payment rate, and whether the provider is a Rural Sole Community Hospital (SCH) among other factors. The formula is unchanged from prior years, though the wage index has been updated.

(2) OPPS APC Group Policies

a. Treatment of new and revised HCPCS Codes

CMS is soliciting comments on the proposed APC and status indicator assignments for 13 new HCPCS codes that were made effective on April 1, 2020, and on over 100 new HCPCS codes that were made effective on July 1, 2020. The codes and their long descriptors are listed in Tables 6 and 7 of the Proposed Rule and we have included a select number of these codes here:

---

[40] *Id.*
[41] *Id.* at 48,805-06.
[42] *Id.* at 48,805.
[43] *Id.* at 48,807.
[44] *Id.*
[45] *Id.*
[46] *Id.* at 48,808.

HCPCS Code	Long Descriptor	Proposed CY 2021 Comment Indicator	Proposed CY 2021 Status Indicator	Proposed CY 2021 APC
C1849	Skin substitute, synthetic, resorbable, per square centimeter	NP	N	N/A
C9061	Injection, teprotumumab-trbw, 10 mg	NP	G	9355

The proposed APC and status indicator assignments appear in Addendum B and are assigned to comment indicator "NP" to indicate that the codes are assigned to an interim APC assignment and that comments will be accepted on their interim APC assignments. CMS will solicit comments on the new CPT and Level II HCPCS codes that will be effective October 1, 2020, and on the new Level II HCPCS codes that will be effective January 1, 2021, in the CY 2021 OPPS/ASC final rule with comment period.[47]

In addition, CMS received the CY 2021 CPT codes from the American Medical Association (AMA) that will be effective January 1, 2021, in time for inclusion in the Proposed Rule. These codes appear in Addendum B and are assigned to 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 CY 2021 OPPS/ASC final rule with comment period. CMS proposes to continue its policy of assigning comment indicator "NI" in Addendum B to the OPPS/ASC final rule with comment period to the new codes effective October 1, 2020, and January 1, 2021, to indicate that CMS is assigning them an interim status indicator, which is subject to public comment.[48]

b. 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 2021, CMS proposes exceptions from the 2 times rule for the following 18 APCs.[49]

Proposed CY 2021 APC	Proposed CY 2021 APC title
5051	Level 1 Skin Procedures
5055	Level 5 Skin Procedures
5071	Level 1 Excision/ Biopsy/ Incision and Drainage
5112	Level 2 Musculoskeletal Procedures
5301	Level 1 Upper GI Procedures
5311	Level 1 Lower GI Procedures

[47] *Id.* at 48,812–823.
[48] *Id.* at 48,823-24.
[49] *Id.* at 48,826-27.

Proposed CY 2021 APC	Proposed CY 2021 APC title
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
5627	Level 7 Radiation Therapy
5691	Level 1 Drug Administration
5721	Level 1 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5821	Level 1 Health and Behavior Services
5823	Level 3 Health and Behavior Services

c. New technology APCs

Consistent with its current policy, CMS proposes to retain services within new technology APC groups until it obtains sufficient claims data to justify reassignment to a clinically appropriate APC. Selected proposed procedures assigned to new technology APCs for CY 2021 are described below. The proposed payment rates for all codes reportable under the OPPS are available in Addendum B of the Proposed Rule.

- **Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS) (APCs 1575, 5114, and 5414)**. CMS proposes to reassign the service described by CPT code 0398T (Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed) to the proposed new Level 3 APC for Neurostimulator and Related Procedures (Proposed APC 5463) for CY 2021, with a proposed payment rate of $12,780.91 for CY 2021.[50] The current APC assignment for CPT code 0398T is APC 1575 (New Technology—Level 38 ($10,001-$15,000)), with a payment rate of $12,500.50 for CY 2020.[51]
- **Administration of Subretinal Therapies Requiring Vitrectomy.** CMS proposes to establish a new HCPCS code C97X1 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent) for the subretinal injection procedure used to administer a certain gene therapy, and to assign new HCPCS code C97X1 to APC 1561 (New Technology - Level 24 ($3001-$3500)).[52]
- **Bronchoscopy with Transbronchial Ablation of Lesion(s) by Microwave Energy.** Due to the low volume of claims for the service in CY 2019, CMS proposes to change the assignment of the HCPCS code C9751 (Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including

[50] *Id.* at 48,829.
[51] 2021 NPRM OPPS "Data Addendum B" and "2 Times Rule" File (Aug. 4, 2020), available at: https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientppshospital-outpatient-regulations-and-notices/cms-1736-p.
[52] 85 Fed. Reg. at 48,829.

fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (for example, aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures an therapeutic intervention(s)) to APC 1563 (New Technology - Level 26 ($4001-$4500)), with a proposed payment rate of $4,250.50 for CY 2021.[53] The current APC assignment for HCPCS code C9751 is APC 1571 (New Technology—Level 34 ($8,001–$8,500)), with a payment rate of $8,250.50 for CY 2020.

- **Pathogen Test for Platelets/Rapid Bacterial Testing.** CMS proposes to reassign HCPCS code P9100 (Pathogen(s) test for platelets) from New Technology APC 1494 to clinical APC 5732 for CY 2021, with a proposed payment rate of $34.42 for CY 2021.[54] The current APC assignment for HCPCS code P9100 is APC 1494 (New Technology—Level 1D ($31–$40)), with a payment rate of $35.50.[55]

(3) Proposed New C-APCs

For CY 2021, CMS proposes two new C-APCs: C-APC 5378 (Level 8 Urology and Related Services) and C-APC 5465 (Level 5 Neurostimulator and Related Procedures).[56] With respect to proposed C-APC 5465, CMS states that in reviewing the claims data available it believes that it is appropriate to create an additional Neurostimulator and Related Procedures level.[57] Therefore, CMS proposes to establish a five-level APC structure for the Neurostimulator and Related Procedure series and to assign CPT code 0398T (Magnetic resonance image guided high intensity focused ultrasound (MRgFUS), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed) to the new Level 3 APC.[58]

(4) OPPS Payment for Devices

a. Transitional pass-through payment status

The following list of device categories with existing pass-through payment status will continue through CY 2021:[59]

HCPCS Codes	Descriptor	Effective Date	Pass-Through Expiration Date
C1823	Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads	1/1/2019	12/31/2021

[53] *Id.* at 48,833.
[54] *Id.* at 48,836.
[55] 2021 NPRM OPPS "Data Addendum B" and "2 Times Rule" File.
[56] 85 Fed. Reg. at 48,775.
[57] *Id.* at 48,838.
[58] *Id.* at 48,838-39.
[59] *Id*. at 48,844.

HCPCS Codes	Descriptor	Effective Date	Pass-Through Expiration Date
C1824	Generator, cardiac contractility modulation (implantable)	1/1/2020	12/31/2022
C1982	Catheter, pressure-generating, one-way valve, intermittently occlusive	1/1/2020	12/31/2022
C1839	Iris prosthesis	1/1/2020	12/31/2022
C1734	Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable)	1/1/2020	12/31/2022
C2596	Probe, image-guided, robotic, waterjet ablation	1/1/2020	12/31/2022
C1748	Endoscope, single-use (that is, disposable), Upper GI, imaging/illumination device (insertable)	7/1/2020	6/30/2023

In addition, CMS is seeking feedback on whether the following device pass-through payment applications for devices with an FDA Breakthrough Device designation (and which therefore are not evaluated under the substantial clinical improvement criterion) qualify for transitional pass-through payment status:

- CUSTOM *FLEX*® ARTIFICIAL *IRIS*, "intended to serve as an artificial iris prosthesis, inserted at the time of cataract surgery or during a subsequent stand-alone procedure."[60]

- EXALT™ Model D Single-Use Duodenoscope, which "is used during [endoscopic retrograde Cholangiopancreatography] procedures that are performed to examine bile and pancreatic ducts" and "enables passage and manipulation of accessory devices in the pancreaticobiliary system for diagnostic and therapeutic purposes, as necessary."[61]

- BAROSTIM NEO™ System, which "triggers the body's main cardiovascular reflex to regulate blood pressure and address the underlying causes of the progression of heart failure."[62]

CMS also is seeking feedback on the following traditional device pass-through payment applications:

- *Hemospray® Endoscopic Hemostat*, "indicated by the FDA for hemostasis of nonvariceal gastrointestinal bleeding." CMS seems particularly concerned about whether this device meets the substantial clinical improvement criterion.[63]

- *SpineJack® Expansion Kit*, "an implantable fracture reduction system, which is indicated for use in the reduction of painful osteoporotic vertebral compression

[60] *Id*. at 48,846-47.
[61] *Id*. at 48,847-49.
[62] *Id*. at 48,849-50.
[63] *Id*. at 48,850-55.

> fractures (VCFs) and is intended to be used in combination with Stryker VertaPlex and VertaPlex High Viscosity (HV) bone cement." CMS seems particularly concerned about whether this device meets the substantial clinical improvement criterion.[64]

CMS also is "clarifying [with respect to the Breakthrough Device approval pathway for pass-through payments] that under the OPPS, in order to be eligible for the alternative pathway, the device must receive marketing authorization for the indication covered by the Breakthrough Devices Program designation and [is] making a conforming change to the regulations at 419.66(c)(2)."[65]

Finally, CMS is issuing a comment solicitation "on whether [it] should adjust future payments for devices currently eligible to receive transitional pass-through payments that may have been impacted by the [COVID-19 public health emergency], and if so, how we should implement that adjustment and for how long the adjustment should apply."[66] Specifically, CMS is considering using its equitable adjustment authority to make separate payment for some period of time after pass-through status expires. CMS would then propose any necessary changes as part of the CY 2022 rulemaking.[67] CMS has not proposed a similar extension for pass-through drugs.

b. Device intensive procedures

CMS is not proposing any changes to its device-intensive policy or its device edit policy.[68] CMS is proposing confirming edits to the regulatory text with respect to its no cost/full credit or partial credit device policy to codify changes made for CY 2014 "of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit by the lesser of the device offset amount for the APC or the amount of the credit."[69] Specifically, CMS is proposing to:

> [R]evis[e its] regulations at § 419.45(b)(1) to state that, for situations in which a beneficiary has received an implanted device that is replaced without cost to the provider or the beneficiary, or where the provider receives full credit for the cost of a replaced device, the amount of reduction to the APC payment is calculated by reducing the APC payment amount by the lesser of the amount of the credit or the device offset amount that would otherwise apply if the procedure assigned to the APC had transitional pass-through status under § 419.66. . . . [and] revis[e its] regulation at § 419.45(b)(2) to state that, for situations in which the provider receives partial credit for the cost of a replaced device, but only where the amount of the device credit is greater than or equal to 50 percent of the cost of the replacement device being implanted, the amount of the reduction to the APC payment is calculated by reducing the APC payment amount by the lesser of the amount of the credit or the device offset amount that would otherwise apply if the procedure assigned to the APC had transitional-pass through status under § 419.66.[70]

---

64 *Id*. at 48,855-61.
65 *Id*. at 48,862.
66 *Id*.
67 *Id*.
68 *Id*. at 48,865.
69 *Id*. at 48,866.
70 *Id*.

CMS is proposing to continue its device intensive low-volume payment policy for CY 2020 for CY 2021, specifically that "of establishing the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC using the median cost instead of the geometric mean cost."[71] Finally, CMS is proposing "CY 2021 device offset percentage for CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis) is based on the CY 2020 OPPS final rule device offset percentage of 82.21 percent for CPT code 0308T" as part of this policy.[72]

(5) *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 28 drugs and biologicals listed below (and found in Table 21 of the Proposed Rule) would expire, or already have expired, in the second, third, or fourth quarter of 2020.[73] With the exception of seven drugs, all of the drugs listed below will have received at least two years, but no more than three years, of pass-through status.

There are two groups of drugs that will have received pass-through status for more than three years. The first group includes five drugs and biologicals that already have had three years of pass-through payment status, but for which pass-through payment status was extended for an additional two years from October 1, 2018, until September 30, 2020, under Section 1833(t)(6)(G) of the Social Security Act (SSA). The drugs covered by this provision include: HCPCS code A9586 (Florbetapir f18, diagnostic, per study dose, up to 10 millicuries); HCPC code J1097 (Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml); HCPCS code Q4195 (Puraply, per square centimeter); HCPCS code Q4196 (Puraply am, per square centimeter); and HCPCS code Q9950 (Injection, sulfur hexafluoride lipid microspheres, per ml).[74] The second group includes two diagnostic radiopharmaceuticals, HCPCS code Q9982 (Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries) and HCPCS code Q9983 (Florbetaben F18, diagnostic, per study dose, up to 8.1 millicuries) whose pass-through payment status was extended for an additional nine months from January 1, 2020, to September 30, 2020, under section 1833(t)(6)(J) of the SSA.

CY 2020 HCPCS CODE	CY 2020 LONG DESCRIPTOR	CY 2020 STATUS INDICATOR	CY 2020 APC	Pass-Through Payment End Date
C9488	Injection, conivaptan hydrochloride, 1 mg	G	9488	03/31/2020
J1428	Injection, eteplirsen, 10 mg	G	9484	03/31/2020
J1627	Injection,, granisetron extended release, 0.1mg	G	9486	03/31/2020
J3358	Usetkinumab, for intravenous injection, 1 mg	G	9487	03/31/2020
J7328	Hyaluronan or derivative, gelsyn-3, for intra-articular injection, 0.1 mg	G	1862	03/31/2020
J9285	Injection, olaratumab, 10 mg	G	9485	03/31/2020

[71] *Id.* at 48,866-67.
[72] *Id.* at 48,867.
[73] *Id.* at 48,867-68.
[74] *Id.* at 48,868.

CY 2020 HCPCS CODE	CY 2020 LONG DESCRIPTOR	CY 2020 STATUS INDICATOR	CY 2020 APC	Pass-Through Payment End Date
Q5103	Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg	G	1847	03/31/2020
J0565	Injection, bezlotoxumab, 10 mg	G	9490	06/30/2020
J2326	Injection, nusinersen, 01. mg	G	9489	06/30/2020
A9586	Florbetapir fl8, diagnostic, per study does, up to 10 millicuries	G	9084	09/30/2020
J1097	Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml	G	9324	09/30/2020
J1301	Injection, edaravone, 1 mg	G	9493	09/30/2020
J2350	Injection, ocrelizumab, 1 mg	G	9494	09/30/2020
J9023	Injection, avelumab, 10 mg	G	9491	09/30/2020
J9173	Injection, durvalumab, 10 mg	G	9492	09/30/2020
Q4195	Puraply, per square centimeter	G	9175	09/30/2020
Q4196	Puraply am, per square centimeter	G	9176	09/30/2020
Q9950	Injection, sulfur hexafluoride lipid microsphere, per ml	G	9085	09/30/2020
Q9982	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries	G	9459	09/30/2020
Q9983	Florbetaben F18, diagnostic, per study does, up to 8.1 millicuries	G	9458	09/30/2020
J0567	Injection, cerliponase alfa, 1 mg	G	9014	12/31/2020
J0599	Injection, c-1 esterase inhibitor (human), (haegarda), 10 units	G	9015	12/31/2020
J1628	Injection, guselkumab, 1 mg	G	9029	12/31/2020
J3316	Injection, triptorelin, extended-release, 3.75 mg	G	9016	12/31/2020
J7345	Aminolevulinic acid hcl for topical administration, 10% gel, 10 mg	G	9301	12/31/2020
J9153	Injection, liposomal, 1 mg daunorubicin and 2.27 mg cytarabine	G	9302	12/31/2020
J9203	Injection, gemtuzumab ozogamicin, 0.1 mg	G	9495	12/31/2020
J9229	Injection, inotuzumab ozogamicin, 0.1 mg	G	9028	12/31/2020

CMS proposes that the pass-through payment status of the 26 drugs and biologicals listed below (and found in Table 22 of the Proposed Rule) would expire in CY 2021.[75]

CY 2021 HCPCS CODE	CY 2021 LONG DESCRIPTOR	CY 2021 STATUS INDICATOR	CY 2021 APC	Pass-Through Payment End Date
C9462	Injection, delafloxacin, 1 mg	G	9462	03/31/2021
J0185	Injection, aprepitant, 1 mg	G	9463	03/31/2021
J0517	Injection, benralizumab, 1 mg	G	9466	03/31/2021
J2797	Injection, rolapitant, 0.5 mg	G	9464	03/31/2021

[75] *Id.* at 48,870.

CY 2021 HCPCS CODE	CY 2021 LONG DESCRIPTOR	CY 2021 STATUS INDICATOR	CY 2021 APC	Pass-Through Payment End Date
J3304	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg	G	9469	03/31/2021
J7203	Injection factor ix, (antihemophilic factor, recombinant), glycopegylated, (rebinyn), 1 iu	G	9468	03/31/2021
J7318	Hyaluronan or drerivative, durolane, for intra-articular injection, 1 mg	G	9714	03/31/2021
J79311	Injection, rituximab 10 mg and hyaluronidase	G	9467	03/31/2021
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	03/31/2021
Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9194	03/31/2021
Q5104	Injection, infliximab-abda, biosimilar, (renflexis), 10 mg	G	9036	03/31/2021
A9513	Lutetium lu 177, dotatate, therapeutic, 1 millicurie	G	9067	06/30/2021
J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes	G	9070	06/30/2021
J7170	Injection, emicizumab-kxwh, 0.5 mg	G	9257	06/30/2021
J9057	Injection, copanlisib, 1 mg	G	9030	06/30/2021
Q9991	Injection, buprenorphine extended-release (sublocade), less than or equal to 100 mg	G	9073	06/30/2021
Q9992	Injection, buprenorphine extended-release (sublocade), greater than 100 mg	G	9239	06/30/2021
J1454	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg	G	9099	09/30/2021
Q5105	Injection, epoetin alfa-epbx, biosimilar (Retacrit) (for esrd on dialysis), 100 units	G	9096	09/30/2021
Q5106	Injection, epoetin alfa-epbx, biosimilar (Retacrit) (for non-esrd use), 1000 units	G	9097	09/30/2021
A9590	Iodine i-131 iobenguane, therapeutic, 1 millicurie	G	9339	12/31/2021
J0222	Injection, Patisiran, 0.1 mg	G	9180	12/31/2020
J0291	Injection, plazomicin, 5 mg	G	9183	12/31/2021
J1943	Injection, aripiprazole lauroxil, (aristada initio), 1 mg	G	9179	12/3/12021
J2798	Injection, risperidone (perseris), 0.5 mg	G	9181	12/31/2021
J9204	Injection, mogamulizumab-kpkc, 1 mg	G	9182	12/31/2021

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 2021).[76] CMS proposes that if the estimated per day cost for the drug or biological is less than or equal to the applicable OPPS drug packaging threshold, the agency would package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimated per day cost of the drug or biological is greater than the OPPS drug packaging threshold, CMS proposes to provide separate payment at ASP+6 percent for CY 2021.[77]

b. *Drugs, biologicals, and radiopharmaceuticals with new or continuing pass-through payment status in CY 2021*

CMS proposes to continue pass-through payment status in CY 2021 for 46 drugs and biologicals that were approved for pass-through payment status between April 1, 2019, and April 1, 2020. These drugs and biologicals are included in the table below (and at Table 23 of the Proposed Rule).[78]

CY 2021 HCPCS CODE	CY 2021 LONG DESCRIPTOR	PROPOSED CY 2021 STATUS INDICATOR	PROPOSED CY 2021 APC	PASS-THROUGH PAYMENT EFFECTIVE DATE	PASS-THROUGH PAYMENT EXPIRATION DATE
C9041	Injection, coagulation factor Xa (recombinant), inactivated (andexxa), 10mg	G	9198	04/01/2019	3/31/2022
C9046	Cocaine hydrochloride nasal solution for topical administration, 1 mg	G	9307	04/01/2019	3/31/2022
J0642	Injection, levoleucovorin (khapzory), 0.5 mg	G	9334	01/01/2020	03/31/2022
J1095	Injection, dexamethaxone 9 percent, intraocular, 1 microgram	G	9172	04/01/2019	03/31/2022
J3031	Injection, fremanezumab-vfrm, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)	G	9197	04/01/2019	03/31/2022
J3245	Injection, tildrakizumab, 1 mg	G	9306	04/01/2019	03/31/2022
J7208	Injection, factor viii, (antihemophilic factor, recombinant), pgylated-aucl (jivi) 1 i.u.	G	9299	04/01/2019	03/31/2022
J9119	Injection, cemiplimab-rwlc, 1 mg	G	9304	04/01/2019	03/31/2022
J9313	Injection, moxetumomab pasudotox-tdfk, 0.01 mg	G	9305	04/01/2019	03/31/2022

[76] *Id.* at 48,868.
[77] *Id.*
[78] *Id.* at 48,872.

CY 2021 HCPCS CODE	CY 2021 LONG DESCRIPTOR	PROPOSED CY 2021 STATUS INDICATOR	PROPOSED CY 2021 APC	PASS-THROUGH PAYMENT EFFECTIVE DATE	PASS-THROUGH PAYMENT EXPIRATION DATE
Q5108	Injection, pegfilgrastim-jmdb, biosimilar, (fulphila), 0.5 mg	G	9173	04/01/2019	03/31/2022
Q5110	Injection, filgrastim-aafi, biosimilar (nivestym), 1 microgram	G	9193	04/01/2019	03/31/2022
Q5111	Injection, Pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg	G	9195	04/01/2019	03/31/2022
C9047	Injection, caplacizumab-yhdp, 1 mg	G	9199	07/01/2019	06/30/2022
J0121	Injection, omadacycline, 1 mg	G	9311	07/01/2019	06/30/2022
J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	G	9308	07/01/2019	06/30/2022
J1303	Injection, ravulizumab-cwvz, 100 mg	G	9312	07/01/2019	06/30/2022
J9036	Injection, bendamustine hydrochloride (belrapzo/bendamustine), 1 mg	G	9313	07/01/2019	06/30/2022
J9210	Injection, emapalumab-lzsg, 1 mg	G	9310	07/01/2019	06/30/2022
J9269	Injection, tagraxofusp-erzs, 10 micrograms	G	9309	07/01/2019	06/30/2022
J3111	Injection, romosozumab-aqqg, 1 mg	G	9327	10/01/2019	09/30/2022
J9356	Injection, trastuzumab, 10 mg and hyaluronidase-oysk	G	9314	10/01/2019	09/30/2022
C9054	Injection, lefamulin (xenleta), 1 mg	G	9332	01/01/2020	12/31/2022
C9055	Injection, brexanolone, 1 mg	G	9333	01/01/2020	12/31/2022
J9309	Injection, polatuzumab vedotin-piiq, 1 mg	G	9331	01/01/2020	12/31/2022
Q5107	Injection, bevacizumab-awwb, biosimilar, (mvasi), 10 mg	G	9329	01/01/2020	12/31/2022
Q5117	Injection, trastuzumab-anns, biosimilar, (kanjinti), 10 mg	G	9330	01/0/1/2020	12/31/2022
J0179	Injection, brolucizumab-dbll, 1 mg	G	9340	04/01/2020	03/31/2023
J0223	Injection, givosiran, 0.5 mg	G	9343	04/01/2020	03/31/2023
J0791	Injection, crizanlizumab-tmca, 1 mg	G	9342	04/01/2020	03/31/2023
J1201	Injection, cetirizine hydrochloride, 1 mg	G	9344	04/01/2020	03/31/2023

CY 2021 HCPCS CODE	CY 2021 LONG DESCRIPTOR	PROPOSED CY 2021 STATUS INDICATOR	PROPOSED CY 2021 APC	PASS-THROUGH PAYMENT EFFECTIVE DATE	PASS-THROUGH PAYMENT EXPIRATION DATE
J7331	Hyaluronan or derivative, synojoynt, for intra-articular injection, 1 mg	G	9337	04/01/2020	03/31/2023
Q5114	Injection, Trastuzumab-dkst, biosimilar, (ogivri), 10 mg	G	9341	04/01/2020	03/31/2023
Q5115	Injection, rituximab-abbs, biosimilar (truxima), 10 mg	G	9336	04/01/2020	03/31/2023
Q5120	Injection, pegfilgrastim-bmez, biosimilar, (ziextenzo), 0.5 mg	G	9345	04/01/2020	03/31/2023
C9059	Injection, meloxicam, 1 mg	G	9357	07/01/2020	06/30/2023
C9061	Injection, teprotumumab-trbw, 10 mg	G	9355	07/01/2020	06/30/2023
C9063	Injection, eptinezumab-jjmr, 1 mg	G	9357	07/01/2020	06/30/2023
C9122	Mometasone furoate sinus implant, 10 micrograms (Sinuva)	G	9346	07/01/2020	06/30/2023
J0742	Injection, imipenem 4 mg, cilastatin 4 mg and relebactam 2 mg	G	9362	07/01/2020	06/30/2023
J0896	Injection, luspatercept-aamt, 0.25 mg	G	9347	07/01/2020	06/30/2023
J1429	Injection, golodirsen, 10 mg	G	9356	07/01/2020	06/30/2023
J7204	Injection, factor VIII, antihemophilic factor (recombinant), (esperoct), glycopegylated-xei, per iu	G	9354	07/01/2020	06/30/2023
J9177	Injection, enfortumab vedotin-ejfv, 0.25 mg	G	9364	07/01/2020	06/30/2023
J9358	Injection, fam-trastuzumab deruxtecan-nxki, 1 mg	G	9353	07/01/2020	06/30/2023
Q5116	Injection, trastuzumab-qyyp, biosiilar, (trazimera), 10 mg	G	9350	07/01/2020	06/30/2023
Q5119	Injection, rituximab-pvvr, biosimilar, (Ruxience), 0 mg	G	9367	07/01/2020	06/30/2023

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.[79]

Consistent with the agency's CY 2020 policy for diagnostic and therapeutic radiopharmaceuticals, CMS proposes to provide CY 2021 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

[79] *Id.* at 48,873.

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).[80]

CMS proposes to continue to make the payment offset applicable to the APCs for pass-through diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents, and pass-through skin substitutes.[81]

(6) *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, the same as the current level.[82] 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.[83]

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 2020 and that are proposed for separate payment in CY 2021, and that then have per day costs equal to or less than the CY 2021 final rule drug packaging threshold, based on the updated ASP and hospital claims data used for the CY 2021 final rule, would continue to receive separate payment in CY 2021.

- HCPCS codes for drugs and biologicals that were packaged in CY 2020 and that are proposed for separate payment in CY 2021, and that then have per day costs equal to or less than the CY 2021 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2021 final rule, would remain packaged in CY 2021.

- HCPCS codes for drugs and biologicals for which we proposed packaged payment in CY 2021 but that then have per-day costs greater than the CY 2021 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2021 final rule, would receive separate payment in CY 2021.[84]

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

[80] *Id.*
[81] *Id.* at 48,875-76.
[82] *Id.* at 48,876.
[83] *Id*.
[84] *Id.* at 48,877.

HCPCS code over the other. Table 25 in the Proposed Rule provides a list of the HCPCS codes to which the CY 2020 drug-specific packaging determination methodology applies.[85]

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:

- Pay for all separately payable drugs and biologicals, including specified covered outpatient drugs (SCODs), at ASP+6 percent.[86]

- Use a three percent add-on, rather than a six percent add-on, for WAC-based SCOD drugs and non-SCOD separately payable drugs.[87]

- Use WAC+3 percent, rather than WAC+6 percent, whenever WAC-based pricing is used for a drug or biological during the initial period when ASP data are not available.[88]

c. Payment methodology for 340B purchased drugs

With respect to nonpass-through drugs and biological products acquired with a 340B discount, CMS proposes to revise the payment to a net rate of ASP minus 28.7 (ASP-28.7) percent (as opposed to the CY 2020 rate of ASP minus 22.5 (ASP-22.5) percent), based on a payment of ASP minus 34.7 (ASP-34.7) percent, plus an add-on of six percent of the product's ASP.[89]

CMS explains that beginning in CY 2018, the Secretary of Department of Health and Human Services (HHS) adjusted the 340B drug payment rate to ASP-22.5 percent (as compared to ASP+6 percent) to approximate a minimum average discount for 340B drugs, based on findings of the Government Accountability Office (GAO) and Medicare Payment Advisory Committee (MedPAC) that hospitals were acquiring drugs at a significant discount under the 340B Drug Pricing Program. The United States District Court for the District of Columbia in the case of *American Hospital Association, et al. v. Azar et al.*, concluded that the Secretary lacks the authority to bring the default rate in line with average acquisition cost unless the Secretary obtains survey data from hospitals on their acquisition costs. On July 31, 2020, the D.C. Circuit Court of Appeals entered an opinion reversing the lower court's decision, holding that HHS's interpretation of the statute was reasonable. The American Hospital Association has until August 31, 2020 to file a petition for rehearing to the Court of Appeals (which we understand it

---

[85] *Id.* at 48,879.

[86] *Id.* at 48,880. Under Section 1833(t)(14)(B)(i) of the SSA, a "specified covered outpatient drug (known as a SCOD) is defined as a covered outpatient drug, as defined in section 1927(k)(2) of the Act, for which a separate APC has been established and that either is a radiopharmaceutical agent or is a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002.

[87] 85 Fed. Reg. at 48,880.

[88] *Id.*

[89] *Id.* at 48,880-82, and 48,889.

intends to do), the Court has stayed the case until after disposition of the petition for rehearing.

Although HHS disagreed with the district court's ruling and appealed the decision, from April 24, 2020 to May 15, 2020, CMS gathered survey data from 340B hospitals using data for the fourth quarter of CY 2018 and the first quarter of CY 2019.[90] CMS limited the survey to hospitals that are eligible to acquire drugs under the 340B program and limited the data requested from 340B hospitals to acquisition costs for 340B-acquired drugs, rather than for drugs purchased outside the 340B program for 340B participating hospitals.[91] The survey was administered to 1,422 340B entities and requested that the entities supply their average acquisition cost for each SCOD purchased under the 340B program during the last quarter of CY 2018 (October 1, 2018 through December 31, 2018) and/or first quarter of 2019 (January 1, 2019 through March 31, 2019), which could be the 340B ceiling price, a 340B sub-ceiling price, or another amount, depending on the discounts the hospital received when it acquired a particular drug.[92] Where the acquisition price for a particular drug was not available or submitted in response to the survey, CMS used the 340B ceiling price for that drug as a proxy for the hospitals' acquisition cost.

CMS gave respondents to survey response options: (1) a Detailed Survey which provided acquisition costs for each individual SCOD; or (2) a Quick Survey in which the hospital indicated that it preferred that CMS utilize the 340B ceiling prices obtained from HRSA as reflective of their hospital acquisition costs. Additionally, where a hospital did not affirmatively respond to the Detailed or Quick Survey within the open period of response, CMS used the 340B ceiling prices in lieu of their responses because the ceiling price represents the highest possible price that a 340B hospital could permissibly be required to pay for a 340B-acquired drug.

Of the surveyed hospitals, 38 percent did not respond, 7 percent responded via the Detailed Survey option, and 55 percent responded via the Quick Survey Option. This means the data CMS used overwhelmingly relied upon the 340B ceiling prices rather than actual acquisition costs. CMS acknowledged this noting that the survey results may be skewed towards the minimum average discount (that is, the ceiling price), that a 340B hospital would receive on a drug.[93]

According to CMS, the survey data confirmed that the ASP minus 22.5 percent rate is generous to 340B hospitals, and the survey data supports an even lower payment rate.[94] In support of its proposal to revise the payment to a net rate of ASP minus 28.7 (ASP-28.7) percent (as opposed to the CY 2020 rate of ASP minus 22.5 (ASP-22.5) percent), based on a payment of ASP minus 34.7 (ASP-34.7) percent, plus an add-on of six percent of the product's ASP, CMS explains that it believes it is within the Secretary's authority under Section 1833(t)(14)(A)(iii) of the SSA to distinguish between hospital groups based on whether or not they are covered entities under section 340B(a)(4) of the

[90] *Id.* at 48,884-85.
[91] *Id.* at 48,885.
[92] *Id.*
[93] *Id.* at 48,885-86.
[94] *Id.* at 48,882-83.

Public Health Services Act (PHSA) that are eligible to receive drugs and biologicals at discounted rates under the 340B program. CMS believes that the significant drug acquisition cost discounts that 340B covered entity hospitals receive enable these hospitals to acquire drugs at much lower costs than non-340B hospitals incur for the same drugs, and therefore impacts hospital acquisition cost and overhead for separately payable drugs.[95]

In order to calculate the proposed ASP reduction amount based on the survey data, CMS applied various statistical methodologies to determine an appropriate average or typical amount by which to reduce ASP that would approximate hospital acquisition costs for 340B drugs and biologicals. CMS states that it chose methodologies that yield the most conservative reduction to ASP when establishing the payment rate, and thus would be most generous to hospitals.[96] CMS says that using this methodology, which included using the geometric mean of the survey data, volume weighting the average based upon utilization of the drug in the OPPS, using the highest priced national drug code (NDC) when multiple NDCs were available for a single HCPCS code, eliminating penny priced drugs from the average, and applying trimming methodologies to remove anomalous or outlier data outside of three standard deviations, the agency estimates that the typical acquisition cost for 340B drugs for hospitals paid under the OPPS is ASP-34.7 percent.[97]

Thus, for CY 2021 and subsequent years, CMS proposes to pay for drugs acquired under the 340B program at ASP-34.7 percent, plus an add-on of six percent of the product's ASP consistent with CMS's Part B payment policy for separately payable drugs and biologicals.[98] This results in a net proposed payment of ASP-28.7 percent.[99] CMS proposes that each drug would receive the same add-on payment regardless of whether it is paid at the 340B rate or at the traditional ASP rate for drugs not purchased under the 340B program. CMS states that this add-on percentage would be more generous to hospitals than adding six percent of the reduced 340B rate.[100] Biosimilars would be reimbursed at ASP-28.7 percent of the biosimilar's ASP. In the alternative, CMS proposes to continue payment for 340B-acquired drugs at ASP-22.5 percent.[101]

For drugs for which ASP data are unavailable, CMS proposes that the 340B payment adjustment for WAC-priced drugs mirror that of ASP payment with payment being WAC minus 34.7 (WAC-34.7) percent plus six percent of the drug's WAC (WAC-28.7), except for during the initial period when ASP data are not available and the WAC+3 percent policy applies, in which case CMS proposes a payment rate of WAC-34.7 percent plus three percent of the drug's WAC (WAC-31.7).[102]

CMS proposes to continue to exempt children's hospitals, PPS-exempt cancer hospitals, and rural sole community hospitals (SCHs) from the alternative 340B drug payment

---

95 *Id.* at 48,886.
96 *Id.*
97 *Id.* at 48,886-87.
98 *Id.* at 48,889.
99 *Id.*
100 *Id.*
101 *Id.* at 48,890.
102 *Id.* at 48,889.

methodology and to permit them to continue to be paid ASP+6 percent for 340B-acquired drugs.[103] CMS states that it may revisit its policy to exempt rural SCHs, as well as other hospital designations for exemption from the 340B drug payment reduction in future rulemaking.[104]

d. CY 2021 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.[105] 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 $47/cm^2 (reduced from $49 in CY 2020) or the PDC threshold of $936 (increased from the CY 2020 PDC threshold of $789).[106] 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 2020, irrespective of whether the product exceeds the CY 2021 MUC or PDC threshold.[107] New skin substitutes without pricing information would be assigned to the low cost category until pricing information is available to compare to the CY 2021 MUC threshold. Table 27 of the Proposed Rule displays the final CY 2021 cost category assignment for each skin substitute product.

e. Allowing synthetic skin graft sheet products to be reported with graft skin substitute procedure codes

CMS proposes to include synthetic products in addition to biological products in its description of skin substitutes for CY 2021.[108] The new proposed description would define skin substitutes as a category of biological and synthetic products that are most commonly used in outpatient settings for the treatment of diabetic foot ulcers and venous leg ulcers. This modifies previous policy that described skin substitutes as a class of products that are treated as biologicals (thereby excluding synthetic products). CMS states that its revised description is supported by a paper referenced in a report cited in the CY 2014 OPPS/ASC final rule titled "Skin Substitutes for Treating Chronic Wounds Technology Assessment Report at ES-2", which is available on the Agency for Healthcare Research and Quality (AHRQ) website at: https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/ta/skinsubs/HCPR0610_skinsubst-final.pdf.[109]

(7) Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

---

[103] *Id.* at 48,890.
[104] *Id.*
[105] *Id.* at 48,891.
[106] *Id.* at 48,894.
[107] *Id.*
[108] *Id.* at 48,898.
[109] *Id.*

CMS proposes to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2021.[110] For CY 2021, CMS estimates that total pass-through spending for devices, drugs and biologicals that are continuing to receive pass-through payment in CY2021 and those that first become eligible for pass-through payment during CY 2021 is approximately $783.2 million.[111] This represents 0.934 percent of total projected OPPS payments for CY 2021 (approximately $84 billion) and therefore is less than 2.0 percent of total projected OPPS CY 2020 program spending. This impacted the proposed conversion factor update by adjusting the proposed conversion factor by the difference between the 0.88 percent estimate of pass-through spending for CY 2020 and the 0.93 percent estimate of proposed pass-through spending for CY 2021, which resulted in a proposed decrease to the conversion factor for CY 2021 of 0.05 percent.[112]

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

CMS proposes to make permanent changes in the level of supervision for non-surgical extended duration therapeutic services (NSEDTS)[113] and pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services that were implemented in response to the COVID-19 public health emergency (PHE) that were adopted on an interim final basis on March 31, 2020.[114] Specifically, CMS proposes to allow general supervision of outpatient hospital therapeutic services currently assigned to the NSEDTS level of supervision.[115] NSEDTS are "hospital or [critical access hospital] outpatient therapeutic services that can last a significant period of time, have a substantial monitoring component that is typically performed by auxiliary personnel, have a low risk of requiring the physician's or appropriate nonphysician practitioner's immediate availability after the initiation of the service, and are not primarily surgical in nature[.]" These services currently require direct supervision during the imitation of the service, which may be followed by general supervision at the discretion of the supervising physician or the appropriate nonphysician practitioner.

CMS also proposes to allow direct supervision of pulmonary rehabilitation services, cardiac rehabilitation services, and intensive cardiac rehabilitation services using interactive telecommunications technology.[116] CMS proposes that the virtual presence required for direct supervision using audio/video real-time communications technology would not be limited to mere availability, but rather real-time presence via interactive audio and video technology throughout the performance of the procedure.[117]

(9) *Payment Rates*

a. Drug administration rates

A chart comparing the current 2020 drug administration payment rates to the proposed CY 2021 drug administration payment rates is provided below.

---

[110] *Id.* at 48,899.
[111] *Id.* at 48,900.
[112] *Id.* at 48,801.
[113] 42 C.F.R. § 410.27(a)(1)(iv)(E).
[114] 85 Fed. Reg. at 48,935.
[115] *Id.*
[116] *Id.* at 48,936.
[117] *Id*.

Comparison of Hospital OPPS Drug Administration Rates, July 2020 to Proposed CY 2021

HCPCS Code	Short Descriptor	Proposed 2021 Rates			Q3 2020 Rates			% Change 2020-2021
		SI	APC	Payment Rate	SI	APC	Payment Rate	
90461	Im admin each addl component	B		$0.00	B		$0.00	
90471	Immunization admin	Q1	5692	$62.68	Q1	5692	$60.47	3.65%
90472	Immunization admin each add	N		$0.00	N		$0.00	
90473	Immune admin oral/nasal	Q1	5692	$62.68	Q1	5692	$60.47	3.65%
90474	Immune admin oral/nasal addl	N		$0.00	N		$0.00	
96360	Hydration iv infusion init	S	5693	$205.39	S	5693	$183.74	11.78%
96361	Hydrate iv infusion add-on	S	5691	$40.41	S	5691	$38.11	6.04%
96365	Ther/proph/diag iv inf init	S	5693	$205.39	S	5693	$183.74	11.78%
96366	Ther/proph/diag iv inf addon	S	5691	$40.41	S	5691	$38.11	6.04%
96367	Tx/proph/dg addl seq iv inf	S	5692	$62.68	S	5692	$60.47	3.65%
96368	Ther/diag concurrent inf	N		$0.00	N		$0.00	
96369	Sc ther infusion up to 1 hr	S	5693	$205.39	S	5693	$183.74	11.78%
96370	Sc ther infusion addl hr	S	5691	$40.41	S	5691	$38.11	6.04%
96371	Sc ther infusion reset pump	Q1	5692	$62.68	Q1	5692	$60.47	3.65%
96372	Ther/proph/diag inj sc/im	Q1	5692	$62.68	Q1	5692	$60.47	3.65%
96373	Ther/proph/diag inj ia	S	5693	$205.39	S	5693	$183.74	11.78%
96374	Ther/proph/diag inj iv push	S	5693	$205.39	S	5693	$183.74	11.78%
96375	Tx/pro/dx inj new drug addon	S	5691	$40.41	S	5691	$38.11	6.04%
96376	Tx/pro/dx inj same drug adon	N		$0.00	N		$0.00	
96379	Ther/prop/diag inj/inf proc	Q1	5691	$40.41	Q1	5691	$38.11	6.04%
96401	Chemo anti-neopl sq/im	Q1	5692	$62.68	Q1	5692	$60.47	3.65%
96402	Chemo hormon antineopl sq/im	Q1	5692	$62.68	Q1	5692	$60.47	3.65%
96405	Chemo intralesional up to 7	Q1	5692	$62.68	Q1	5692	$60.47	3.65%
96406	Chemo intralesional over 7	S	5693	$205.39	S	5693	$183.74	11.78%
96409	Chemo iv push sngl drug	S	5693	$205.39	S	5693	$183.74	11.78%
96411	Chemo iv push addl drug	S	5692	$62.68	S	5692	$60.47	3.65%
96413	Chemo iv infusion 1 hr	S	5694	$315.93	S	5694	$309.60	2.04%
96415	Chemo iv infusion addl hr	S	5692	$62.68	S	5692	$60.47	3.65%
96416	Chemo prolong infuse w/pump	S	5694	$315.93	S	5694	$309.60	2.04%
96417	Chemo iv infus each addl seq	S	5692	$62.68	S	5692	$60.47	3.65%
96420	Chemo ia push tecnique	S	5694	$315.93	S	5694	$309.60	2.04%
96422	Chemo ia infusion up to 1 hr	S	5693	$205.39	S	5693	$183.74	11.78%
96423	Chemo ia infuse each addl hr	S	5691	$40.41	S	5691	$38.11	6.04%

HCPCS Code	Short Descriptor	Proposed 2021 Rates			Q3 2020 Rates			% Change 2020-2021
		SI	APC	Payment Rate	SI	APC	Payment Rate	
96425	Chemotherapy infusion method	S	5694	$315.93	S	5694	$309.60	2.04%
96440	Chemotherapy intracavitary	S	5694	$315.93	S	5694	$309.60	2.04%
96446	Chemotx admn prtl cavity	S	5694	$315.93	S	5694	$309.60	2.04%
96450	Chemotherapy into cns	S	5694	$315.93	S	5694	$309.60	2.04%
96521	Refill/maint portable pump	S	5693	$205.39	S	5693	$183.74	11.78%
96522	Refill/maint pump/resvr syst	S	5693	$205.39	S	5693	$183.74	11.78%
96523	Irrig drug delivery device	Q1	5733	$56.50	Q1	5733	$55.01	2.71%
96542	Chemotherapy injection	S	5693	$205.39	S	5693	$183.74	11.78%
96549	Chemotherapy unspecified	Q1	5691	$40.41	Q1	5691	$38.11	6.04%

b. Radiation therapy services

A chart comparing the current 2020 radiation therapy payment rates to the proposed CY 2021 radiation therapy payment rates is provided below.

Comparison of Hospital OPPS Radiation Therapy Rates, July 2020 to Proposed CY 2021

HCPCS Code	Short Descriptor	Proposed 2021 Rates			Q3 2020 Rates			% Change 2020-2021
		SI	APC	Payment Rate	SI	APC	Payment Rate	
76873	Echograp trans r pros study	S	5522	$111.39	S	5522	$112.08	-0.62%
77280	Set radiation therapy field	S	5611	$129.86	S	5611	$126.59	2.58%
77285	Set radiation therapy field	S	5612	$346.33	S	5612	$335.16	3.33%
77290	Set radiation therapy field	S	5612	$346.33	S	5612	$335.16	3.33%
77295	3-d radiotherapy plan	S	5613	$1,290.83	S	5613	$1,245.34	3.65%
77300	Radiation therapy dose plan	S	5611	$129.86	S	5611	$126.59	2.58%
77301	Radiotherapy dose plan imrt	S	5613	$1,290.83	S	5613	$1,245.34	3.65%
77321	Special teletx port plan	S	5612	$346.33	S	5612	$335.16	3.33%
77331	Special radiation dosimetry	S	5611	$129.86	S	5611	$126.59	2.58%
77332	Radiation treatment aid(s)	S	5611	$129.86	S	5611	$126.59	2.58%
77333	Radiation treatment aid(s)	S	5611	$129.86	S	5611	$126.59	2.58%
77334	Radiation treatment aid(s)	S	5612	$346.33	S	5612	$335.16	3.33%
77336	Radiation physics consult	S	5611	$129.86	S	5611	$126.59	2.58%
77338	Design mlc device for imrt	S	5612	$346.33	S	5612	$335.16	3.33%
77370	Radiation physics consult	S	5611	$129.86	S	5611	$126.59	2.58%
77371	Srs multisource	J1	5627	$7,938.28	J1	5627	$7,942.41	-0.05%
77372	Srs linear based	J1	5627	$7,938.28	J1	5627	$7,942.41	-0.05%

HCPCS Code	Short Descriptor	Proposed 2021 Rates				Q3 2020 Rates			% Change 2020-2021
		SI	APC	Payment Rate		SI	APC	Payment Rate	
77373	Sbrt delivery	S	5626	$1,760.32		S	5626	$1,768.45	-0.46%
77401	Radiation treatment delivery	S	5621	$124.88		S	5621	$122.71	1.77%
77470	Special radiation treatment	S	5623	$554.43		S	5623	$538.83	2.90%
77520	Proton trmt simple w/o comp	S	5623	$554.43		S	5623	$538.83	2.90%
77522	Proton trmt simple w/comp	S	5625	$1,308.19		S	5625	$1,246.76	4.93%
77523	Proton trmt intermediate	S	5625	$1,308.19		S	5625	$1,246.76	4.93%
77525	Proton treatment complex	S	5625	$1,308.19		S	5625	$1,246.76	4.93%
77750	Infuse radioactive materials	S	5622	$247.58		S	5622	$236.36	4.75%
77761	Apply intrcav radiat simple	S	5623	$554.43		S	5623	$538.83	2.90%
77762	Apply intrcav radiat interm	S	5623	$554.43		S	5623	$538.83	2.90%
77763	Apply intrcav radiat compl	S	5624	$734.80		S	5624	$740.52	-0.77%
77778	Apply interstit radiat compl	S	5624	$734.80		S	5624	$740.52	-0.77%
77789	Apply surf ldr radionuclide	S	5621	$124.88		S	5621	$122.71	1.77%
77799	Radium/radioisotope therapy	S	5621	$124.88		S	5621	$122.71	1.77%

c. *Payment for CAR-T therapies*

A chart comparing the current 2020 CAR-T therapy payment rates to the proposed CY 2021 CAR-T therapy payment rates is provided below.

Comparison of Hospital OPPS CAR-T Therapy Rates, July 2020 to Proposed CY 2021

HCPCS Code	Short Descriptor	Proposed 2021 Rates			Q3 2020 Rates			% Change 2020-2021
		SI	APC	Payment Rate	SI	APC	Payment Rate	
Q2042	Tisagenlecleucel car-pos t	K	9194	$427,836.49	G	9194	$427,836.49	0.00%
Q2041	Axicabtagene ciloleucel car+'	K	9035	$395,380.00	G	9035	$395,380.00	0.00%
0537T	Bld drv t lymphcyt car-t cll	B	0	$0.00	B		$0.00	
0538T	Bld drv t lymphcyt prep trns	B		$0.00	B		$0.00	
0539T	Receipt&prep car-t cll admn	B		$0.00	B		$0.00	
0540T	Car-t cll admn autologous	S	5694	$315.93	S	5694	$309.60	2.04%

(10) Phased Elimination of the Inpatient-Only (IPO) List

CMS proposes to eliminate, over a transitional period, the IPO List that historically has identified services (currently 1,740 services) that would not be paid by Medicare under the OPPS because they require inpatient care due to the invasive nature of the procedure, the need for at least 24 hours of postoperative recovery time, or the underlying physical condition of the patient who would require the surgery.[118] CMS cites to the evolving nature of the practice of medicine, "in addition to physician judgment, state and local licensure requirements, accreditation requirements, hospital conditions of participation (CoPs), medical malpractice laws, and CMS quality and monitoring initiatives and programs" as measures that will continue to ensure the safety of beneficiaries in both the inpatient and outpatient settings in the absence of the IPO list.[119]

Recognizing that providers may need time to prepare and update their billing systems to take this change into account, CMS proposes to transition services off the IPO list over a three-year period, beginning with the proposed removal of 266 musculoskeletal-related services from the IPO list.[120] CMS further proposes to revise its regulations to require the phased removal of the IPO list over three years, with the full list eliminated in its entirety by January 1, 2024.[121] CMS solicits comments on whether three years is an appropriate time frame for the transition, whether there are other services that would be ideal candidates for removal from the IPO list in the near term given known technological and other advances in care, and the order of removal of additional clinical families and/or specific services for each of the CY 2022 and CY 2023 rulemakings, until the IPO list is completely eliminated.[122]

CMS also seeks comment on whether it should restructure or create any new APCs to allow for OPPS payment for services that are removed from the IPO list, and whether any of the musculoskeletal codes proposed for removal may meet the criteria to be added to the ASC Covered Procedures List.

a. Effect of elimination of IPO List on medical review, two-midnight rule

CMS proposes to continue a policy finalized last year to exempt procedures that have been removed from the IPO list from site-of-service claim denials, Beneficiary and Family-Centered Care Quality Improvement Organization (BFCC-QIO) referrals to Recovery Audit Contractors (RACs), and RAC reviews for "patient status" for a period of two years after removal. CMS solicits comments on whether a two-year exemption continues to be appropriate, or if a longer or shorter period may be more warranted, in particular given that many more services will be removed from the IPO list as a part of the transition towards elimination.[123]

Current policy regarding IPO list procedures is that they are appropriate for inpatient hospital admission and payment under Part A regardless of the expected length of stay (i.e., without regard to the two-midnight rule). CMS clarifies that the elimination of the

[118] *Id.* at 48,909.
[119] *Id.* at 48,910.
[120] *See Id.* at 48,912-934, Table 31 for a full list of proposed musculoskeletal-related services proposed for removal from the IPO List for CY 2021.
[121] *Id.* at 48,911.
[122] *Id.*
[123] *Id.* at 48,909.

IPO list would mean that any service that was once on the IPO list would be subject to the two-midnight benchmark and two-midnight presumption.[124] Specifically, for services removed from the IPO list, under the two-midnight presumption, inpatient hospital claims with lengths of stay greater than two midnights after admission would be presumed to be appropriate for Medicare Part A payment and would not be the focus of medical review efforts, except under unusual circumstances. Additionally, under the two-midnight benchmark, services formerly on the IPO list would be 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 two midnights and admits the patient to the hospital based upon that expectation.[125]

(11) Comment Solicitation on OPPS Payment for Specimen Collection for COVID-19 Tests

CMS solicits comments on whether to keep active the COVID-19 specimen collection HCPCS code C9803 beyond the end of the COVID-19 public health emergency (PHE).

CMS implemented the code via interim final rule on May 8, 2020, because the agency was not aware of an alternative code that would describe the standalone services of symptom assessment and specimen collection that HOPDs were undertaking to facilitate widespread testing for COVID-19. Under CMS's interim final policy, when HCPCS code C9803 is billed without another separately payable primary service, CMS will make a separate payment for the specimen collection service under OPPS.

In the Proposed Rule, CMS asks for comment on whether to continue its interim final policy after the COVID-19 PHE ends, including the reasoning and timeframe for such extension.[126]

(12) MedPAC Recommendations

MedPAC was established under Section 1805 of the SSA to advise the Congress on issues affecting Medicare. In the March 2020 report to Congress, MedPAC made recommendations related to the OPPS and ASC payment systems.[127]

MedPAC recommended Congress update OPPS payment rates by two percent, with the difference between that update and the current statutory update amount to be used to increase payments under a new quality value incentive program. CMS cannot act on this recommendation without an act of Congress, so it is not proposing a rule based on this recommendation.[128]

MedPAC found that the number of ASCs had increased, beneficiaries' use of ASCs had increased, and ASC access to capital has been adequate.[129] Therefore, MedPAC determined that payments to ASCs are adequate and recommended that absent cost report data, no payment update should be given for CY 2021. CMS is maintaining its CY 2019 policy codified at 42 CFR 416.171(a)(2) to apply the multifactor productivity (MFP)-adjusted

[124] *Id.* at 48,938-39.
[125] *Id.*
[126] *Id.* at 48,940 (CMS also solicits comments on whether to continue to assign HCPCS code C9803 to APC 5731 - Level 1 Minor Procedures with a proposed status indicator of "Q1").
[127] *Id.* at 48,940-41.
[128] *Id.*
[129] *Id.* at 48,941.

hospital market basket update to ASC payment system rates for five years. CMS proposes to apply a 2.6 MFP-adjusted hospital market basket update factor to the CY 2020 ASC conversion factor for ASCs meeting quality reporting requirements to determine the CY 2021 ASC payment amounts.[130]

MedPAC recommended that Congress require ASCs to report cost data to better analyze ASCs' costs over time. CMS recognizes the administrative burden required to submit additional cost data. CMS is not proposing any cost reporting requirements for ASCs in this proposed rule, but it is interested in methods that would mitigate the burden of reporting costs while collecting adequate data to reliably use it in determining ASC costs.[131]

(13) Updates to the Ambulatory Surgical Center (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 2020 and July 2020.[132] CMS also solicits comments on the proposed CY 2021 payment indicators for the new and revised Category I and III CPT codes that will be effective January 1, 2021.[133] A list of HCPCS codes for which CMS seeks comment can be found in ASC Addendum AA and Addendum BB on the CMS website, and are identified by comment indicator "NP" to indicate that the code is new for the next calendar year or is an existing code with substantial revision to its code descriptor in the next calendar year as compared to current calendar year.[134] A selection of the new HCPCS codes on which CMS requests comment is listed below:

HCPCS Code	Long Descriptor	Proposed CY 2021 Payment Indicator	Proposed CY 2021 Payment Rate
0600T	Ablation, irreversible electroporation; 1 or more tumors per organ, including imaging guidance, when performed, percutaneous	J8	$3,037.63
0601T	Ablation, irreversible electroporation; 1 or more tumors per organ, including imaging guidance, when performed, percutaneous; 1 or more tumors per organ, including fluoroscopic and ultrasound guidance, when performed, open	J8	$3,037.63
558XX	Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance	G2	$2,069.56

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

130 *Id.*
131 *Id.*
132 *Id.* at 48,943-47.
133 *Id.* at 48,948.
134 *Id.*

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.[135]

Of the 18 procedures designated as temporarily office-based in the CY 2020 OPPS, CMS proposes to maintain the temporary office-based designation for 11 procedures[136], permanently assign an office-based designation for 5 of the procedures[137], and to assign a non-office based payment indicator to 2 for CY 2020.[138] CMS is proposing to designate two new CY 2021 CPT codes for ASC covered surgical procedures as temporarily office-based.[139]

CMS reviewed CY 2019 volume and utilization data for CPT codes 36902 and 36905 (dialysis vascular access procedures) and determined these procedures do not meet the criteria for office-based procedures and therefore did not propose to designate these CPT codes as office-based procedures for CY 2021.[140]

b. Device-intensive procedures performed in the ASC

In the CY 2019 OPPS final rule, CMS modified its criteria for device-intensive procedures to better capture costs for procedures with significant device costs.[141] Based on this modified device-intensive criteria, for CY 2021, CMS is proposing to update the ASC covered procedures list to indicate procedures that are eligible for payment according to its device-intensive procedure payment methodology, based on the proposed individual HCPCS code device-offset percentages using CY 2018 OPPS claims and cost report data.[142] The ASC-covered surgical procedures that CMS proposes to designate as device-intensive – and therefore subject to the device-intensive procedure payment methodology – are listed in Addendum AA to the ASC proposed rule, with payment indicator "J8."[143] Some procedures that are proposed to be added to the list in CY 2021 are identified in the chart in Section (12) above (indicated by the J8 payment indicator).

With respect to the addition of HCPCS codes C9765 and C9767 (revascularization with intravascular lithotripsy) to the device-intensive list, it is unclear why C9764 and C9766 are not also proposed to have a J8 designation and are instead proposed to have a G2 designation (non office-based surgical procedure added in CY2008 or later; payment based on OPPS relative payment weight), since these procedures involve the same equipment.

---

[135] *Id.* at 48,949-50 (CPT codes 11760, 21208, 23077, 44408, 53854, and 53854, relating to nail bed repair, osteoplasty, radical tumor resection, colonoscopy, transurethral destruction of prostate tissue, and retrobulbar injection).

[136] *Id*. at 48,951 (CPT codes 64454, 64624, 65785, 67229, 0402T, 0512T, 0551T, 0566T, 0588T, 93985, and 93986, relating to anesthetic and steroid injections, neurolytic agent destruction, corneal ring implantation, cryotherapy to treat retinopathy, collagen cross-linking of cornea, extracorporeal shock wave therapy, transperineal balloon continence device, autologous cellular implants for the treatment of knee osteoarthritis, revision or removal of integrated single device neurostimulation systems, complete bilateral duplex scans prior to creation of hemodialysis access, and complete unilateral duplex scans prior to creation of hemodialysis access).

[137] *Id.* at 48,951-52 (CPT codes 10007, 10011, 11102, 11104, and 11106, relating to bone marrow biopsies and aspirations).

[138] *Id.* at 48,952 (CPT codes 10005 and 10009, relating to bone marrow biopsies and aspirations).

[139] *Id.* at 48,953 (CPT codes 0596T, and 0579T, relating to temporary female intraurethral valve-pump insertion and replacement).

[140] *Id.*

[141] *Id.* at 48,954.

[142] *Id.*

[143] *Id.*

c. Adjustment to ASC payments for no cost/full credit and partial credit devices

For CY 2021 and subsequent calendar years, CMS proposes to continue to apply its policy for partial credits, specified in the CY 2019 OPPS final rule, that reduces the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit (if the credit to the ASC is 50 percent or more, but less than 100 percent, of the cost of the device).[144]

d. Additions to list of ASC covered surgical procedures

For CY 2021 and subsequent years, CMS proposes to continue to apply the revised definition of "surgery" adopted in the CY 2019 OPPS final rule, which includes certain "surgery-like" procedures that are assigned codes outside of the CPT surgical range.[145]

For CY 2021, CMS proposes to include in its list of ASC covered surgical procedures those procedures that are described by Category I CPT codes that are not in the surgical range but directly crosswalk or are clinically similar to procedures in the Category I CPT code surgical range, which CMS has determined: (i) do not pose a significant safety risk; (ii) would not be expected to require an overnight stay when performed in an ASC; and (iii) are separately paid under the OPPS.[146]

In addition, CMS proposes two alternative options for modifying its approach to adding surgical procedures to its list of ASC covered surgical procedures:

- A nomination process for adding new procedures for CY 2021, allowing CMS to propose to add nominated procedures through annual rulemaking, beginning in CY 2022[147], and
- A broader approach under which CMS would revise its regulatory criteria at 42 CFR 416.166 to evaluate potential additions by retaining the general standard criteria and eliminating five of the general exclusion criteria.[148]

CMS proposes to finalize only one of these alternative proposals, and expects that either of these options, if adopted, will have the effect of expanding the ASC covered list of procedures, while maintaining the balance between safety and access for Medicare beneficiaries.[149] CMS is requesting comment on both of these alternative proposals.[150] Under the second alternative proposal, approximately 270 potential surgery or surgery-like codes would be added that are not on the CY 2020 IPO list and that meet the revised criteria.[151] If the second alternative is adopted, CMS solicits comments on potential revisions to the ASC Conditions for Coverage (CfCs).[152]

---

144 *Id.* at 48,955.
145 *Id.* at 48,955-56.
146 *Id.* at 48,957.
147 *Id.* at 48,957-60.
148 *Id.* at 48,957, 48,960-63.
149 *Id.*
150 *Id.* at 48,958-63.
151 *Id.* at 48,963-75 (Table 41 provides the approximately 270 CY 2021 CPT codes and long descriptors that CMS would be added if the second alternative proposal is adopted).
152 *Id.* at 48,961-62.

Regardless of which alternative proposal is adopted, CMS proposes to add the following to the list of ASC covered surgical procedures among others:[153]

CY 2021 CPT Code	CY 2021 Long Descriptor
0404T	Transcervical uterine fibroid(s) ablation with ultrasound guidance, radiofrequency

CMS solicits comments on the proposed addition of these procedures, including any medical evidence or literature to support the commenters' views on whether or not CMS should add these procedures for CY 2021.[154]

e. *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.[155] 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 for the device portion based upon the proposed CY 2021 OPPS device offset percentages that have been calculated using the standard OPPS APC rate setting methodology.[156] CMS proposes that payment for office-based procedures would be at the lesser of the proposed CY 2021 PFS non-facility practice expense (PE) relative value unit (RVU)-based amount, or the proposed CY 2021 ASC payment amount, calculated according to the ASC standard rate setting methodology.[157]

For low-volume device-intensive procedures, CMS continues to apply the policy it finalized in the CY 2020 OPPS final rule to limit the ASC payment rate to an amount equal to the OPPS payment rate for that procedure.[158] For CY 2020, this only affected HCPCS code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis).[159] For CY 2021, CMS proposes to apply a payment rate under the ASC payment system equal to the OPPS payment rate for CPT code 0308T, which is $20,994.57 (increased slightly from the CY 2020 ASC payment rate of $20,673.31) and to continue the CY 2020 final rule device offset percentage of 90.18 percent for CPT code 0308T.[160]

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 CY 2021 OPPS and ASC payment system regarding the packaged or separately payable status or services, and the payment rates.[161]

---

153 *Id.* at 48,963.
154 *Id.* at 48,958.
155 *Id.* at 48,976.
156 *Id.*
157 *Id.*
158 *Id.* at 48,976-77.
159 *Id.* at 48,977.
160 *Id.*
161 *Id.* at 49,978.

f. ASC payment and comment indicators for CY 2021

For CY 2021 and subsequent calendar years, CMS proposes new and revised Category I and III CPT codes as well as new and revised Level II HCPCS codes. CMS proposes to add ASC payment indicator "K5" (Items, Codes, and Services for which pricing information and claims data are not available; No payment made) to ASC Addendum DD1 of the proposed rule to indicate those services and procedures that CMS anticipates will become payable when claims data or payment information becomes available.[162]

g. ASC conversion factor update

For CY 2021, CMS proposes to adjust the CY 2020 ASC conversion factor ($47.747) by the proposed wage index budget neutrality factor of 0.9999 in addition to the private annual economy-wide nonfarm business MFP-adjusted hospital market basket update factor of 2.6 percent, which results in a proposed CY 2021 ASC conversion factor of $48.984 for ASCs meeting the quality reporting requirements.[163] For ASCs not meeting the quality reporting requirements, CMS proposes to adjust the CY 2020 ASC conversion factor ($47.747) by the proposed wage index budget neutrality factor of 0.9999 in addition to the quality reporting/MFP-adjusted hospital market basket update factor of 0.6 percent, which results in a proposed CY 2021 ASC conversion factor of $48.029.[164]

(14) Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

Under the Hospital OQR Program, hospital outpatient facilities face a 2.0 percentage point reduction in their annual payment update if they fail to meet quality reporting requirements.

CMS does not propose major changes to the Hospital OQR Program. Among other things, CMS does not propose any changes to the previously finalized measure set,[165] nor does CMS propose to amend its criteria for retaining[166] or removing measures.[167] CMS does, however, propose certain technical changes to the requirements associated with the OQR Program.[168]

(15) Requirements for the Ambulatory Surgical Center Quality Reporting (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.

---

[162] *Id.* at 48,981.
[163] *Id.* at 48,983.
[164] *Id.* at 48,983-84.
[165] *Id.* at 48,985.
[166] *Id.*
[167] *Id.*
[168] *See, e.g., id.* at 48,987 (proposing to revise its regulation to replace "security official" with "security administrator"); *id.* (proposing to update to remove "submit a new participation form" from a regulation and update internal cross-references to align with a previously finalized policy). Likewise, CMS proposes a technical amendment to its OQR submission deadlines to clarify that, consistent with the statute, deadlines on non-work days for federal employees carry-over to the next to the next day that is not a non-work day. *Id.* at 48,987-88, *see also id.* at 48,990. (also proposing said clarification to CMS's extraordinary circumstances exception process). In addition, CMS proposes to expand its policy of giving hospitals an opportunity to review and correct measure data to apply to web-based measures, s*ee id.* at 48,989 (also proposing to codify this change), and to codify a previously finalized policy about the educational review process for chart-abstracted measures, *id.*

As with the Hospital OQR Program, CMS does not propose major changes to the ASCQR Program. Among other things, CMS does not propose any changes to the previously finalized measure set,[169] nor does CMS propose to amend its criteria for retaining[170] or removing measures.[171] CMS does, however, propose certain technical changes to the requirements associated with the ASCQR Program.[172] CMS also solicits comment on new measures for consideration that address care quality in the ASC settings, as well as additional measures that could facilitate comparisons of care provided in ASCs and hospitals.[173]

(16) Addition of New Service Categories for Hospital Outpatient Department (OPD) Prior Authorization Process

In the CY 2020 OPPS/ASC final rule, CMS established a prior authorization process for certain hospital OPD services.[174] CMS proposes adding two new services categories for services on or after July 1, 2021: Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators.[175] These additions are proposed based on CMS's determination that there has been an unnecessary increase in the volume of the services.

The ICR associated with prior authorization requests is the required documentation submitted by providers including all relative documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules, and the request must be submitted before the service is provided to the beneficiary and before the claim is submitted for processing.

(17) Overall Hospital Quality Star Rating Methodology for Public Release in CY 2021 and Subsequent Years

CMS's Overall Star Ratings are intended to provide a summary of hospital quality information based on certain publicly available quality measures. The purpose of the Overall Star Ratings is to help the public to more easily compare differences in hospital quality.

Beginning with CY 2021, CMS proposes to update the methodology used to calculate Overall Hospital Quality Star Ratings. Under the proposal, CMS would retain the current measures used in the Overall Star Ratings[176] and method for standardizing scores across

---

169 *Id.* at 48,992.
170 *Id.* at 48,991.
171 *Id.* at 48,992.
172 *See, e.g.*, *id.* at 48,993 (proposing to revise its regulation to replace "security official" with "security administrator"); *id.* (proposing to remove the phrase "data collection time period" from various regulations and replace with the phrase "data collection period," "period," or "time period"); *id.* at 48,994 (clarifying submission deadlines when a deadline falls on a non-work day for federal employees).
173 *Id.* at 48,993.
174 84 Fed. Reg. 61,142 (Nov. 12, 2019); 42 CFR §§ 419.80-89.
175 85 Fed. Reg. at 49,028.
176 *See id.* at 49,003 (specifically, CMS uses publicly reported measures from the Hospital IQR Program, Hospital OQR Program, HRRP, HAC Reduction Program, and Hospital VBP Program, to calculate the Overall Star Ratings). CMS also largely proposes to retain its measures for exclusions from the Overall Star Ratings, with relatively minor updates. *See id.* at 49,001-02.

measures,[177] but significantly revise the methodology for how those measures are used in the calculation of Overall Star Ratings beginning with CY 2021.

CMS's proposal includes numerous refinements, many of which are highly technical in nature. At a summary level, however, CMS is proposing to replace its current Latent Variable Model for calculating Overall Star Ratings with a new and simplified methodology where CMS calculates the simple average of the measures in each Star Rating measure group,[178] standardizes measure group scores across groups,[179] and then calculates a final summary score (largely in accordance with its existing approach, whereby CMS calculates the overall summary score through a weighted average of measure group scores).[180]

Among other refinements, CMS also proposes to consolidate three of its measures groups (Effectiveness of Care, Timeliness of Care, and Efficient Use of Medical Imaging) into a single new process measure group (Time and Effective Care).[181] In addition, CMS proposes to add Veterans Health Administration (VHA) hospitals to its Overall Star Ratings beginning in CY 2023.[182]

(18) *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 ADLTs that satisfy certain requirements.

---

[177] *See id.* at 49,004.
[178] *Id.* at 49,010 (proposing to use a simple average of measure scores to calculate measure group scores).
[179] *Id.* at 49,014. CMS also proposes to stratify readmission measure group scores (but no other measure group) based on the proportion of dual-eligible patients, in order to create consistency between the stratification method used for the HRRP and the proposed new Overall Star Rating methodology. *See id.* at 49,015-16.
[180] *Id.* at 49,018. The proposed modifications to CMS's methodology also include numerous other adjustments and refinements in light of the proposed change to the agency's basic underlying methodology, many of which are very technical. For example, CMS proposes to begin standardizing measure group scores by calculating a standard deviation score (known as a Z-score) for each measure group. *Id.* at 49,014. In addition, CMS proposes to stop removing extreme outliers from its measure data (a process known as Winsorization). *Id.* at 49,005-06.
[181] *Id.* at 49,006.
[182] *Id.* at 48,999. In prior years, Overall Star Ratings were calculated for subsection (d) hospitals (which include most general, acute-care hospitals). In addition, Overall Star Ratings were calculated for critical access hospitals (CAHs) that voluntarily submit quality measures data. CMS proposes to continue its existing policies with respect to subsection (d) hospitals, *see id.* at 48,997-98, and voluntarily participating CAHs, *see id.* at 48,998 (also proposing that CAHs that wish voluntarily to be included must have elected to submit the requisite quality measures and publicly report their quality measure data on one of CMS's public websites).

With respect to the third exception for molecular pathology tests and certain ADLTs, CMS proposes to add cancer-related protein-based Multianalyte Assays with Algorithmic Analyses (MAAAs) to the exception.[183] Under the proposed revision, the DOS for a cancer-related protein-based MAAA would be the date the test was performed (and therefore billed by the performing laboratory and not the hospital) if: (1) the test was performed following a hospital outpatient's discharge from the hospital outpatient department; (2) the specimen was collected from a hospital outpatient during an encounter; (3) it was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter; (4) the results of the test do not guide treatment provided during the hospital outpatient encounter; and (5) the test was reasonable and medically necessary for the treatment of an illness.[184] CMS explains that the reason for the proposed change is that it believes cancer-related protein-based MAAAs have a pattern of clinical use that make them relatively unconnected to the primary hospital outpatient service during which the specimen was collected because the results of these tests are typically used to determine post-hospital care.[185] CMS has identified six cancer-related protein-based MAAAs to which this policy would apply: CPT codes 81500, 81503, 81535, 81536, 81538, and 81539.[186]

(19) *Waiver of the 60-day Delayed Effective Date for the Final Rule*

CMS anticipates that it will rely on its authority under 5 U.S.C. § 808(2) to revise the effective date for the Final Rule to 30 days after publication (instead of the usual 60 days) due to CMS prioritizing efforts in support of containing and combatting the COVID-19 PHE.[187] This means that the Final Rule may not be published until December 1, 2020.

[183] *Id.* at 49,036.
[184] *Id.*
[185] *Id.* at 49,035-36.
[186] *Id.* at 49,036.
[187] *Id.* at 49,042-43.