NCHA Financial Feature

November 9, 2018

CMS Releases Final Updates to the CY 2019 Hospital Outpatient and ASC Prospective Payment Systems

The Centers for Medicare and Medicaid Services (CMS) has issued a rule that updates payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments (HOPDs) and in ambulatory surgical centers (ASCs) beginning Jan. 1, 2019 (CY 2019). A copy of the 1,182-page document is available online at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-24243.pdf.

Publication is scheduled in the Federal Register for Nov. 21. The link above will change upon publication. The Addenda relating to the OPPS are available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

The Addenda relating to the ASC payment system are available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

Comment

As in the proposed CY 2019 OPPS proposed rule, two major controversial issues remain. That is, CMS is adopting its proposed changes.

First, CMS will "exercise its authority under law to control unnecessary increases in the volume of covered hospital outpatient department services by applying a Physician Fee Schedule (PFS) - equivalent payment rate for the clinic visit service when provided at an off-campus provider-based department (PBD) that is paid under the OPPS." This change will be phased in over two years. This policy would result in savings for the Medicare program of an estimated $380 million for 2019.

Second, CMS will extend its 340B drug payment policy at the average sales price (ASP) minus 22.5 percent. This will affect not only hospital outpatient departments, but excepted off-campus PBDs of a hospital. Note, critical access hospitals are not subject to this policy since they are paid on a cost basis. CMS also excepted rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals.

For 2019, CMS is also finalizing policies that will:

- Expand the number of surgical procedures payable at ASCs to include additional procedures that can safely be performed in that setting;
- Ensure ASC payment for procedures involving certain high-cost devices generally parallel the payment amount provided to hospital outpatient departments for these devices; and
- Help ensure that ASCs remain competitive by addressing the differential between how ASC payment rates and hospital outpatient department payment rates are updated for inflation.

As noted many times in the past, CMS does not help the reader easily locate pertinent sections. It is very difficult to locate cited material. In fact, CMS' table of contents in most recent rulemaking, including this one, is abridged. The table of contents only cites major sections. Sub-heads are no longer being shown.

To help the reader, we have added selected page numbers (in red) of the display copy of the rule.

I. UPDATES AFFECTING OPPS PAYMENTS

A. OPPS Update: ***(Page 19)***

For CY 2019, CMS is increasing the payment rates by an outpatient department (OPD) fee schedule increase factor of 1.35 percent. This increase factor is based on the final FY 2019 hospital inpatient market basket percentage increase of 2.9 percent, minus a multifactor productivity (MFP) adjustment of 0.8 percentage point, and minus a 0.75 percentage point adjustment required by the ***Affordable Care Act*** (ACA).

CMS is continuing to implement the statutory 2.0 percentage point reduction in payments for hospital OPDs failing to meet quality reporting requirements by applying a factor of 0.980 to the OPPS payments and copayments for all applicable services.

CMS says it estimates that total payments to OPPS providers (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2019 will be approximately $74.1 billion, an increase of approximately $5.8 billion compared to estimated CY 2018 OPPS payments.

Comment

CMS estimates that "total OPPS payments for CY 2019, including beneficiary cost-sharing, to the approximately 3,840 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and CMHCs) will increase by approximately $360 million compared to CY 2018 payments, excluding our estimated changes in enrollment, utilization, and case-mix."
(refer page 29)

CMS also states that it "estimates that the total increase in Federal government expenditures under the OPPS for CY 2019, compared to CY 2018, due only to the changes to the OPPS in this final rule with comment period, will be approximately $440 million. ***(refer page 1117)***

B. Conversion Factor ***(Page 141)***

The OPD fee schedule increase factor of 1.35 percent for CY 2019, a required wage index budget neutrality adjustment of approximately 0.9984, and an adjustment of -0.10 percentage point of projected OPPS spending for the difference in pass-through spending results in a conversion factor for CY 2019 of **$79.490**.

[2018 CF $78.636 x 1.0135 percent rate increase X 0.9984 wage index budget neutrality X pass through adjustment 0.999 = $79.49]

C. Wage Index Changes ***(Page 147)***

The OPPS labor-related share will remain at 60 percent of the national OPPS payment.

CMS is finalizing its proposal not to extend the area wage index imputed floor policy beyond December 31, 2018.

CMS is finalizing its proposal, without modification, to use the FY 2019 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 2019.

CMS will continue its policy of allowing non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county. CMS is including the out-migration adjustment information in the rule's Addendum L. Table 2 associated with the FY 2019 IPPS/LTCH PPS final rule identifies counties eligible for the out-migration adjustment and IPPS hospitals that will receive the adjustment for FY 2019. Read more online here: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.

CMS will continue to implement the frontier State area wage floor applicable in the same manner as it has since CY 2011.

For Community Mental Health Centers (CMHC), CMS will continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located.

D. Statewide Average Default CCRs ***(Page 162)***

CMS has updated the default ratios for CY 2019 using the most recent cost report data. The statewide values are presented in the rule's table 9.

E. Rural Adjustment ***(Page 166)***

CMS will continue its current policy of a 7.1 percent payment adjustment that is done in a budget neutral manner for rural SCHs and Essential Access Community Hospitals, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs.

F. Payment Adjustment for Certain Cancer Hospitals for CY 2019 ***(Page 170)***

Section 16002(b) of the ***21st Century Cures Act*** requires that the payment adjustment for certain cancer hospitals (11 hospitals), for services furnished on or after Jan. 1, 2018, the target payment-to-cost ratio (PCR) adjustment be reduced by 1.0 percentage point less than what would otherwise apply.

Estimated CY 2019 Hospital-Specific Payment Adjustment for Cancer Hospitals to Be Provided at Cost Report Settlement

Provider Number	Hospital Name	Estimated Percentage Increase in OPPS Payments for CY 2019 due to Payment Adjustment
050146	City of Hope Comprehensive Cancer Center	37.1%
050660	USC Norris Cancer Hospital	13.4%
100079	Sylvester Comprehensive Cancer Center	21.0%
100271	H. Lee Moffitt Cancer Center & Research Institute	22.3%
220162	Dana-Farber Cancer Institute	43.7%
330154	Memorial Sloan-Kettering Cancer Center	46.4%
330354	Roswell Park Cancer Institute	16.2%
360242	James Cancer Hospital & Solove Research Institute	22.6%
390196	Fox Chase Cancer Center	8.4%

Provider Number	Hospital Name	Estimated Percentage Increase in OPPS Payments for CY 2019 due to Payment Adjustment
450076	M.D. Anderson Cancer Center	53.6%
500138	Seattle Cancer Care Alliance	54.3%

G. Hospital Outpatient Outlier Payments ***(Page 177)***

CMS will continue its policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS. A portion of that 1.0 percent, an amount equal to less than 0.01 percent of outlier payments (or 0.0001 percent of total OPPS payments) will be allocated to CMHCs for the Partial Hospital Program outlier payments.

CMS is proposing an outlier threshold that exceeds 1.75 times the APC payment amount and exceeds the APC payment amount plus **$4,825**. The proposed amount was $4,600. The current threshold is $4,150.

For CMHCs, the threshold would be 3.40 times the payment rate, and the outlier payment will be calculated as 50 percent of the amount by which the cost exceeds 3.40 times APC 5853.

H. Calculation of an Adjusted Medicare Payment from the National Unadjusted Medicare Payment ***(Page 185)***

The national unadjusted payment rate for most APCs contained in Addendum A and for most HCPCS codes to which separate payment under the OPPS has been assigned in Addendum B and was calculated by multiplying the CY 2019 scaled weight for the APC by the CY 2019 conversion factor.

I. Proposed Beneficiary Copayments ***(Page 191)***

The national unadjusted copayment amounts for services payable under the OPPS that will be effective Jan. 1, 2019 are included in Addenda A and B.

Final Comment to the Payment Updates Above

For many of the changes shown above, it is both interesting and surprising that CMS says it received “no” comments to these proposals.

II. OPPS AMBULATORY PAYMENT CLASSIFICATION (APC) GROUP POLICIES ***(Page 197)***

A. OPPS Treatment of New CPT and Level II HCPCS Codes

CPT and Level II HCPCS codes are used to report procedures, services, items, and supplies under the hospital OPPS. Specifically, CMS recognizes the following codes on OPPS claims:

- Category I CPT codes, which describe surgical procedures and medical services;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures; and
- Level II HCPCS codes, which are used primarily to identify products, supplies, temporary procedures, and services not described by CPT codes.

1. Treatment of New HCPCS Codes That Were Effective April 1, 2018

As proposed, the final rule adds,

- Nine (9) new level II HCPCS codes that were effective April 1, 2018. ***(Refer rule's Table 12)***

- Twelve (12) new laboratory CPT Multianalyte Assays with Algorithmic Analyses (MAAA) codes (M codes) and Proprietary Laboratory Analyses (PLA) codes and (U codes) that were effective April 1, 2018. ***(Refer rule's Table 13)***

2. Treatment of New HCPCS Codes that were effective July 1, 2018.

The final rule adds:

The treatment of 14 new HCPCS codes that were effective July 1, 2018. ***(Refer rule's Table 14)***

CMS notes that the status indicators, APC assignments, and payment rates for the new CPT codes can be found in Addendum B. The status indicator meanings can be found in Addendum D1 (OPPS Payment Status Indicators for CY 2019)

B. OPPS Changes – Variations within APCs ***(Page 217)***

The Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest cost for an item or service in the group is more than 2 times greater than the lowest cost for an item or service within the same group (referred to as the "2 times rule"). The statute authorizes the Secretary to make exceptions to the 2 times rule in unusual cases, such as low volume items and services.

The following table lists the APCs that CMS will exempt from the 2 times rule for CY 2019.

APC Exceptions to the 2 Times Rule for CY 2019

CY 2019 APC	CY 2019 APC Title
5071	Level 1 Excision/ Biopsy/ Incision and Drainage
5113	Level 3 Musculoskeletal Procedures
5193	Level 3 Endovascular Procedures
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5524	Level 4 Imaging without Contrast
5571	Level 1 Imaging with Contrast
5612	Level 2 Therapeutic Radiation Treatment Preparation
5691	Level 1 Drug Administration
5692	Level 2 Drug Administration
5721	Level 1 Diagnostic Tests and Related Services
5724	Level 4 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5732	Level 2 Minor Procedures
5735	Level 5 Minor Procedures

CY 2019 APC	CY 2019 APC Title
5822	Level 2 Health and Behavior Services
5823	Level 3 Health and Behavior Services

C. New Technology APCs ***(Page 224)***

CMS is finalizing its proposed policy to establish payment rates for low-volume procedures with fewer than 100 claims per year that are assigned to New Technology APCs. CMS points out it may use up to 4 years of claims data to establish a payment rate for each applicable service both for purposes of assigning a service to a New Technology APC and for assigning a service to a regular APC at the conclusion of payment for the service through a New Technology APC.

a. Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS) (APCs 1537, 5114, and 5414) ***(Page 233)***

Currently, there are four CPT/HCPCS codes that describe magnetic resonance image guided high intensity focused ultrasound (MRgFUS) procedures, three of which CMS proposed to continue to assign to standard APCs, and one that CMS proposed to reassign to a different New Technology APC for CY 2019.

CPT codes 0071T, 0072T, and 0398T, and HCPCS code C9734. CPT codes 0071T and 0072T describe procedures for the treatment of uterine fibroids, CPT code 0398T describes procedures for the treatment of essential tremor, and HCPCS code C9734 describes procedures for pain palliation for metastatic bone cancer.

The table below lists the final CY 2019 status indicator and APC assignments for MRgFUS procedures.

CY 2019 Status Indicator (SI), APC Assignment, and Payment Rate for the Magnetic Resonance Image Guided High Intensity Focused Ultrasound (MRgFUS) Procedures

CPT/ HCPCS Code	Long Descriptor	CY 2018 OPPS SI	CY 2018 OPPS APC	CY 2018 OPPS Payment Rate	CY 2019 OPPS SI	CY 2019 OPPS APC	CY 2019 OPPS Payment Rate
0071T	Focused ultrasound ablation of uterine leiomyomata, including mr guidance; total leiomyomata volume less than 200 cc of tissue.	J1	5414	$2,272.77	J1	5414	Refer to OPPS Addendum B.
0072T	Focused ultrasound ablation of uterine leiomyomata, including mr guidance; total leiomyomata volume greater or equal to 200 cc of tissue.	J1	5414	$2,272.77	J1	5414	Refer to OPPS Addendum B.
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.	S	1576	$17,500.50	S	1575	Refer to OPPS Addendum B.

CPT/ HCPCS Code	Long Descriptor	CY 2018 OPPS SI	CY 2018 OPPS APC	CY 2018 OPPS Payment Rate	CY 2019 OPPS SI	CY 2019 OPPS APC	CY 2019 OPPS Payment Rate
C9734	Focused ultrasound ablation/therapeutic intervention, other than uterine leiomyomata, with magnetic resonance (mr) guidance.	J1	5115	$5,606.42	J1	5115	Refer to OPPS Addendum B.

b. Retinal Prosthesis Implant Procedure ***(Page 242)***

CMS is reassigning the Argus® II procedure (CPT code 0100T) to APC 1908 (New Technology - Level 52 ($145,001-$160,000)) with a payment rate of $152,500.50 for CY 2019.

c. Bronchoscopy with Transbronchial Ablation of Lesion(s) by Microwave Energy ***(Page 248)***

CMS is assigning the procedure described by HCPCS code C9751 to New Technology APC 1571 (New Technology - Level 34 ($8001-$8500)), with a payment rate of $8,250.50 for CY 2019.

D. OPPS APC-Specific Policies **(Page 250)**

CMS discusses specific policies regarding the following:

1. Benign Prostatic Hyperplasia Treatments (APCs 5373 and 5374)
2. Cardiac Contractility Modulation (CCM) Therapy (APC 5231)
3. Cardiac Resynchronization Therapy (APCs 5221, 5222, 5231, 5731, and 5741)
4. Chimeric Antigen Receptor T-Cell (CAR T) Therapy (APCs 5694, 9035, and 9094)
5. Drug-Eluting Implant (APC 5733)
6. Endovascular Procedures (APCs 5191 through 5194)
7. Fine Needle Aspiration Biopsy (APC 5071)
8. Fluorescence In Situ Hybridization (FISH) Assays (APCs 5672 and 5673)
9. Immediate Breast Implant Following Mastopexy/Mastectomy (C-APC 5092)
10. Intracardiac Ischemia Monitoring (APCs 5221, 5222, 5223, and 5741)
11. Intraocular Retinal Electrode Programming and Reprogramming (APCs 5742 and 5743)
12. Kidney Dilation of Tract (C-APC 5373)
13. Intraocular Procedures (APC 5494)
14. Magnetocardiography
15. Musculoskeletal Procedures (APCs 5111 through 5116)
16. Nasal Airway Obstruction Treatment (APC 5164)
17. Nerve Procedures and Services (APCs 5431 through 5432)
18. Radiology and Procedures and Services
    a. Imaging Procedures and Services (APCs 5521 through 5524 and 5571 through 5573)
    b. Non-Ophthalmic Fluorescent Vascular Angiography (APC 5572)
19. Remote Physiologic Monitoring (APCs 5012 and 5741)
20. Sclerotherapy (APC 5054)

III. OPPS PAYMENT FOR DEVICES ***(Page 338)***

A. Pass-Through Payments for Devices ***(Page 340)***

There currently are no device categories eligible for pass-through payment.

New Device Pass-Through Applications ***(Page 340)***

CMS received seven applications for new device pass through applications. Only one is now approved – remedē® System Transvenous Neurostimulator. ***(Page 379)***

B. Device-Intensive Procedures ***(Page 399)***

CMS is adopting that device-intensive procedures would be subject to the following revised criteria:

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

CMS also is specifying for CY 2019 and subsequent years, that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

- Has received FDA marketing authorization, has received an FDA investigational device exemption (IDE), and has been classified as a Category B device by the FDA in accordance with 42 CFR 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;
- Is an integral part of the service furnished;
- Is used for one patient only;
- Comes in contact with human tissue;
- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not any of the following:

  (a) Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1); or

  (b) A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker).

The full listing of the CY 2019 device-intensive procedures is included in Addendum.

IV. OPPS PAYMENT CHANGES FOR DRUGS, BIOLOGICALS, AND RADIOPHARMACEUTICALS ***(Page 425)***

- *Drugs and Biologicals <u>with</u> Expiring Pass-Through Payment Status in CY 2018 (**Page 428**)*

CMS is adopting, as proposed, that the pass-through payment status of 23 drugs and biologicals as listed in the table below will expire on December 31, 2018.

Drugs and Biologicals for which Pass-Through Payment Status Expires December 31, 2018

CY 2019 HCPCS Code	CY 2019 Long Descriptor	Final CY 2019 Status Indicator	Final CY 2019 APC	Pass-Through Payment Effective Date
A9515	Choline C 11, diagnostic, per study dose	G	9461	04/01/2016
C9460	Injection, cangrelor, 1 mg	G	9460	01/01/2016

CY 2019 HCPCS Code	CY 2019 Long Descriptor	Final CY 2019 Status Indicator	Final CY 2019 APC	Pass-Through Payment Effective Date
C9482	Injection, sotalol hydrochloride, 1 mg	G	9482	10/01/2016
J1942	Injection, aripiprazole lauroxil, 1 mg	G	9470	04/01/2016
J2182	Injection, mepolizumab, 1 mg	G	9473	04/01/2016
J2786	Injection, reslizumab, 1 mg	G	9481	10/01/2016
J2840	Injection, sebelipase alfa, 1 mg	G	9478	07/01/2016
J7202	Injection, Factor IX, albumin fusion protein (recombinant), Idelvion, 1 i.u.	G	9171	10/01/2016
J7207	Injection, Factor VIII (antihemophilic factor, recombinant) PEGylated, 1 I.U.	G	1844	04/01/2016
J7209	Injection, Factor VIII (antihemophilic factor, recombinant) (Nuwiq), per i.u.	G	1846	04/01/2016
J7322	Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg	G	9471	04/01/2016
J7342	Instillation, ciprofloxacin otic suspension, 6 mg	G	9479	07/01/2016
J7503	Tacrolimus, extended release, (envarsus xr), oral, 0.25 mg	G	1845	04/01/2016
J9022	Injection, atezolizumab, 10 mg	G	9483	10/01/2016
J9145	Injection, daratumumab, 10 mg	G	9476	07/01/2016
J9176	Injection, elotuzumab, 1 mg	G	9477	07/01/2016
J9205	Injection, irinotecan liposome, 1 mg	G	9474	04/01/2016
J9295	Injection, necitumumab, 1 mg	G	9475	04/01/2016
J9325	Injection, talimogene laherparepvec, 1 million plaque forming units (PFU)	G	9472	04/01/2016
J9352	Injection, trabectedin, 0.1 mg	G	9480	07/01/2016
Q5101	Injection, filgrastim-sndz, biosimilar, (zarxio), 1 microgram	G	1822	07/01/2015
Q9982	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries	G	9459	01/01/2016
Q9983	Florbetaben F18, diagnostic, per study dose, up to 8.1 millicuries	G	9458	01/01/2016

The proposed packaged or separately payable status of each of these drugs or biologicals is listed in Addendum B

- *Drugs, Biologicals, and Radiopharmaceuticals with New or Continuing Pass-Through Payment Status in CY 2019* ***(Page 434)***

CMS will continue pass-through payment status in CY 2019 for 45 drugs and biologicals, as proposed. They are listed in the rule's table 38. ***(Page 437)*** The APCs and HCPCS codes for these drugs and biologicals are assigned status indicator "G" in Addenda A and B. In addition, there are four drugs and biologicals that have already had 3 years of pass-through payment status but for which pass-through payment status is required to be extended for an additional 2 years under section 1833(t)(6)(G) of the Act. Thus, 49 drugs and biologicals will have continuing pass-through payment status and are reflected in table 38.

CMS will continue to pay for pass-through drugs and biologicals at ASP+6 percent, equivalent to the payment rate these drugs and biologicals would receive in the physician's office setting in CY 2019.

- *Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Status as a Result of Section 1301 of the Consolidated Appropriations Act of 2018* ***(Page 443)***

The ***Consolidated Appropriations Act*** provides that drugs or biologicals whose period of pass-through payment status ended on December 31, 2017 and for which payment was packaged into a covered hospital outpatient service furnished beginning January 1, 2018, such pass-through payment status shall be extended for a 2-year period beginning on October 1, 2018 through September 30, 2020.

The drugs are: Florbetapir f18, diagnostic, perstudy dose, up to 10 millicuries; Injection, phenylephrine and ketorolac, 4 ml vial; Puraply, per square centimeter; Puraply AM, per square centimeter; and, Injection, sulfur hexafluoride lipid microsphere, per ml.

- *Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs, Biologicals, and Radiopharmaceuticals to Offset Costs Packaged into APC Groups* ***(Page 450)***

For CY 2019, CMS will continue to apply the same packaged offset policy to payment for pass-through diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents, and pass-through skin substitutes.

- *OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals without Pass-Through Payment Status* ***(Page 453)***

CMS is finalizing a packaging threshold for CY 2019 of **$125**, an increase from the current packaging threshold of $120.

- *High Cost/Low Cost Threshold for Packaged Skin Substitutes* ***(Page 463)***

Under the OPPS, payment for skin substitutes – products used to aid in wound healing – is packaged into the payment for their associated surgical procedures. These products are assigned to either a "high cost group" or a "low cost group" depending on how costly they are relative to certain cost thresholds.
Skin substitutes assigned to the high cost group are described by HCPCS codes 15271 through 15278.
Skin substitutes assigned to the low cost group are described by HCPCS codes C5271 through C5278.

The final CY 2019 geometric mean unit cost (MUC) threshold is $49 per cm2 (rounded to the nearest $1) (proposed at $49 per cm2) and the final CY 2019 product's per day cost (PDC) threshold is $872 (rounded to the nearest $1) (proposed at $895).

The rule's table 41 ***(Page 474)*** displays the CY 2019 high cost or low cost category assignment for each skin substitute product.

- *Payment for Drugs and Biologicals without Pass-Through Status That Are Not Packaged* ***(Page 480)***

CMS will pay for separately payable non-pass-through drugs acquired with a 340B discount at a rate of ASP minus 22.5 percent.

CMS will utilize a 3.0 percent add-on instead of a 6.0 percent add-on for drugs that are paid based on WAC.

- *Biosimilar Biological Products* ***(Page 493)***

CMS is finalizing its proposed payment policy for biosimilar products, without modification, to continue the policy in place from CY 2018 to make all biosimilar biological products eligible for pass-through payment and not just the first biosimilar biological product for a reference product.

CMS also is finalizing its proposal to pay non-pass-through biosimilars acquired under the 340B Program at the biosimilar's ASP minus 22.5 percent.

V. OPPS PAYMENT FOR HOSPITAL OUTPATIENT VISITS AND CRITICAL CARE SERVICES *(Page 520)*

CMS is not making any changes to its current clinic and emergency department (ED) hospital outpatient visits payment policies.

VI. PAYMENT FOR PARTIAL HOSPITALIZATION SERVICES *(Page 521)*

A partial hospitalization program (PHP) is an intensive outpatient program of psychiatric services provided as an alternative to inpatient psychiatric care for individuals who have an acute mental illness, which includes, but is not limited to, conditions such as depression, schizophrenia, and substance use disorders.

CMS is continuing to use CMHC APC 5853 (Partial Hospitalization (3 or More Services Per Day)) and hospital-based PHP APC 5863 (Partial Hospitalization (3 or More Services Per Day)).

The following table provides the CY 2019 values. Note the current amount for APC 5853 is $143.22 and for APC 5863 it is $208.09.

CY 2019 PHP APC Geometric Mean Per Diem Costs

CY 2019 APC	Group Title	PHP APC Geometric Mean Per Diem Costs
5853	Partial Hospitalization (3 or more services per day) for CMHCs	$121.62
5863	Partial Hospitalization (3 or more services per day) for hospital-based PHPs	$222.76

VII PROCEDURES THAT WOULD BE PAID ONLY AS INPATIENT PROCEDURES *(Page 571)*

The rule's table 49 *(Page 585)* contains the five final changes CMS is making to the IPO list for CY 2019.

The complete list of codes (the IPO list) is included as Addendum E.

VIII NONRECURRING POLICY CHANGES *(Page 586)*

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

CMS will create a HCPCS modifier (ER—Items and services furnished by a provider-based off-campus emergency department) that is to be reported with every claim line for outpatient hospital services furnished in an off-campus provider-based emergency department effective January 1, 2019. CAH hospitals are exempt.

- *Proposal and Comment Solicitation on Method to Control for Unnecessary Increases in the Volume of Outpatient Services* ***(Pages 589-629)***

CMS is finalizing its proposal to apply an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate) for the clinic visit service, as described by HCPCS code G0463. In addition, CMS is finalizing its proposal to implement this policy in a non-budget neutral manner. The final payment rates are available in Addendum B

The PFS-equivalent amount paid to nonexcepted off-campus PBDs is 40 percent of OPPS payment (that is, 60 percent less than the OPPS rate) for CY 2019. Based on a 2-year phase-in of this policy, half of the total 60-percent payment reduction, a 30-percent reduction, will apply in CY 2019.

CMS says this policy results in an estimated CY 2019 savings of approximately $380 million, with approximately $300 million of the savings accruing to Medicare, and approximately $80 million saved by Medicare beneficiaries in the form of reduced copayments.

- *Proposal to Apply the 340B Drug Payment Policy to Nonexcepted Off-Campus Departments of a Hospital* ***(Pages 630-658)***

CMS refers to an "off-campus outpatient department of a provider," which is the term used in section 603 of the ***Bipartisan Budget Act of 2015***, as an "off-campus outpatient provider-based department" or an "off-campus PBD."

Because separately payable drugs and biologicals acquired under the 340B Program and furnished in nonexcepted off-campus PBDs are no longer covered outpatient department services, as of CY 2018, these drugs and biologicals are currently paid in the same way Medicare Part B drugs are paid in the physician office and other nonhospital settings – typically at ASP+6 percent – regardless of whether they are acquired under the 340B Program.

For CY 2019, CMS will now pay under the PFS the adjusted payment amount of ASP minus 22.5 percent for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program when they are furnished by nonexcepted off-campus PBDs of a hospital.

- Expansion of Clinical Families of Services at Excepted Off-Campus Departments of a Provider ***(Pages 658-679)***

CMS says that it continues "to be concerned that if excepted off-campus PBDs are allowed to furnish new types of services that were not provided at the excepted off-campus PBDs prior to the date of enactment of the ***Bipartisan Budget Act of 2015*** and can be paid OPPS rates for these new types of services, hospitals may be able to purchase additional physician practices and add those physicians to existing excepted off-campus PBDs."

However, CMS has decided not to make any changes that would limit expansion of clinical families for CY 2019.

IX. CY 2018 OPPS PAYMENT STATUS AND COMMENT INDICATORS *(Page 679)*

Payment status indicators (SIs) that CMS assigns to HCPCS codes and APCs indicate whether a service represented by a HCPCS code is payable under the OPPS or another payment system and also whether particular OPPS policies apply to the code. For CY 2019, CMS is not making any changes to the definitions of status indicators that were listed in Addendum D1 to the CY 2018 OPPS/ASC final rule.

The complete list of the payment status indicators and their definitions that will apply for CY 2019 is displayed in Addendum D1.

X. UPDATES TO THE AMBULATORY SURGICAL CENTER (ASC) PAYMENT SYSTEM *(Page 683)*

a. Calculation of the ASC Payment Rates and the ASC Conversion Factor ***(Page 808)***

ASC payments were annually updated by the percentage increase in the Consumer Price Index for all urban consumers (CPI-U). CMS is revising and updating ASC payment rates using the hospital market basket and to revise its regulations under 42 CFR 416.171(a)(2), which address the annual update to the ASC conversion factor, to reflect this change. The change from CPI to MB is a five-year test.

For CY 2019, CMS is utilizing the hospital market basket update of 2.9 percent minus the MFP adjustment of 0.8 percentage point, resulting in an MFP adjusted hospital market basket update factor of 2.1 percent for ASCs meeting the quality reporting requirements. Those not meeting the quality requirement are subject to a 2.0 percent reduction or an increase of 0.1 percent. ***(Page 822)***

For CY 2019, CMS is adjusting the CY 2018 ASC conversion factor ($45.575) by a wage index budget neutrality factor of 1.0004 in addition to the MFP-adjusted hospital market basket update factor of 2.1. This results in a CY 2019 ASC conversion factor of **$46.551** for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, CMS is adjusting the CY 2018 ASC conversion factor ($45.575) by the wage index budget neutrality factor of 1.0004 in addition to the quality reporting/MFP-adjusted hospital market basket update factor of 0.1 percent, which results in a CY 2019 ASC conversion factor of $45.639. ***(Page 828)***

Addenda AA and BB contain the updated ASC payment rates for CY 2019.

b. Treatment of New and Revised Codes ***(Page 683)***

Category I CPT, Category III CPT, and Level II HCPCS codes are used to report procedures, services, items, and supplies under the ASC payment system. Specifically, CMS recognizes the following codes on ASC claims:

- Category I CPT codes, which describe surgical procedures and vaccine codes;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures; and
- Level II HCPCS codes, which are used primarily to identify items, supplies, temporary procedures, and services not described by CPT codes.

- *Treatment of New and Revised Level II HCPCS Codes Implemented in April 2018* ***(Page 683)***

The rule's table 53 ***(Page 699)*** lists the new Level II HCPCS codes that were implemented April 1, 2018, along with their payment indicators for CY 2019.

- *Treatment of New and Revised Level II HCPCS Codes Implemented in July 2018*

The rule's table 54 ***(Page 701)*** lists the HCPCS codes that were effective July 1, 2018.

- *Process for New and Revised Level II HCPCS Codes that Will Be Effective Oct. 1, 2018 and Jan. 1, 2019*

The Level II HCPCS codes effective Oct. 1, 2018, and Jan. 1, 2019, will be flagged with comment indicator "NI" in Addendum B to indicate that CMS has assigned the codes an interim OPPS payment status for CY 2019. ***(Page 702)***

- *Process for Recognizing New and Revised Category I and Category III CPT Codes that will be Effective January 1, 2019*

The new and revised CY 2019 Category I and III CPT codes that will be effective on Jan. 1, 2019, can be found in ASC Addendum AA and Addendum BB. These codes are assigned to comment indicator "NP" to indicate that the code is new for the next calendar year. ***(Page 703)***

c. Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services ***(Page 705)***

CMS proposed to permanently designate as office-based 4 covered surgical procedures for CY 2019. They involved CPT codes 31573, 36513, 36902 and 36905. CMS is only designating codes 31573 and 36513 as

office based. Codes 36902 and 36905 will retain the same payment indicator, “G2.”

CMS proposed to designate 8 new CY 2019 CPT codes for ASC covered surgical procedures as temporary office-based. CMS is adopting the codes as proposed and are displayed in the rule’s table 58. ***(Page 716)***

d. Changes to List of ASC Covered Surgical Procedures Designated as Device-Intensive for CY 2019 ***(Page 717)***

CMS is finalizing its proposal to allow procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures. In addition, CMS is finalizing its proposal to lower the device offset percentage threshold from 40 percent to 30 percent. ***(Page 730)***

e. Additions to the List of ASC Covered Surgical Procedures ***(Page 735)***

CMS is updating the list of ASC covered surgical procedures by adding 12 cardiac catheterization procedures and 5 others. The list for CY 2019 is shown the rule’s table 60.

XI. REQUIREMENTS FOR THE HOSPITAL OUTPATIENT QUALITY REPORTING (OQR) PROGRAM ***(Page 831)***

CMS proposed to remove a total of 10 measures from the Hospital OQR Program measure set; one in CY 2020 and nine in CY 2021.

For CY 2020, CMS would remove (1) OP-27: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431).

For CY 2021, CMS would remove (2) OP-5: Median Time to ECG (NQF #0289); (3) OP 31: Cataracts - Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536); (4) OP-29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658); (5) OP-30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use (NQF #0659); (6) OP-9: Mammography Follow-up Rates (no NQF number); (7) OP-11: Thorax Computed Tomography (CT) – Use of Contrast Material (NQF #0513); (8) OP-12: The Ability for Providers with HIT (Health Information Technology) to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data (NQF endorsement removed); (9) OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT (no NQF number); and (10) OP-17: Tracking Clinical Results between Visits (NQF endorsement removed). ***(Page 852)***

CMS is removing 8 of the 10 proposed. The 2 that will not be removed are OP-29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658) ***(Page 876)****;* and, OP 31: Cataracts - Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536) ***(Page 891)***.

CMS will also: (1) Extend the performance period from one to three years for OP-32: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy; (2) Update the factors to be considered when removing measures from the program; (3) Change the frequency of the Hospital OQR Program Specifications Manual release beginning with CY 2019 and for subsequent years; (4) Update requirements related to participation status, including removal of the Notice of Participation form.

The table below outline the Hospital OQR Program measure set CMS is adopting for the CY 2020 payment determination and subsequent years:

Hospital OQR Program Measure Set for the CY 2020 Payment Determination

NQF #	Measure Name
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival
0290	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention
0289	OP-5: Median Time to ECG†
0514	OP-8: MRI Lumbar Spine for Low Back Pain
None	OP-9: Mammography Follow-up Rates
None	OP-10: Abdomen CT – Use of Contrast Material
0513	OP-11: Thorax CT – Use of Contrast Material
None	OP-12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
None	OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)
0491	OP-17: Tracking Clinical Results between Visits†
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
0499	OP-22: Left Without Being Seen†
0661	OP-23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival
0658	OP-29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients*
0659	OP-30: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use*
1536	OP-31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery**
2539	OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
1822	OP-33: External Beam Radiotherapy for Bone Metastases
None	OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
2687	OP-36: Hospital Visits after Hospital Outpatient Surgery
None	OP-37a: OAS CAHPS – About Facilities and Staff***
None	OP-37b: OAS CAHPS – Communication About Procedure***
None	OP-37c: OAS CAHPS – Preparation for Discharge and Recovery***
None	OP-37d: OAS CAHPS – Overall Rating of Facility***
None	OP-37e: OAS CAHPS – Recommendation of Facility***

† CMS notes that NQF endorsement for this measure was removed.
* OP-26: Procedure categories and corresponding HCPCS codes are located at: https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1196289981244.
** CMS notes that measure name was revised to reflect NQF title.
*** Measure voluntarily collected as set forth in section XIII.D.3.b. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66946 through 66947).
**** Measure reporting delayed beginning with CY 2018 reporting and for subsequent years as discussed in section XIII.B.5. of the CY 2018 OPPS/ASC final rule with comment period (82 FR 59432 through 59433).

Comment

Quality is always a complex topic. The final rule devotes over 100 pages to the OQR subject.

XII. REQUIREMENTS FOR THE AMBULATORY SURGICAL CENTER QUALITY REPORTING (ASCQR) PROGRAM *(Page 937)*

CMS is finalizing policies to:

1. Remove one quality measure beginning with the CY 2020 payment determination and one quality measure beginning with the CY 2021 payment determination. CMS is not finalizing proposals to remove the Mammography Follow-up Rates (ASC-9) and Thorax Computed Tomography (CT) Use of Contrast Material (ASC-11);
2. Extend the reporting period from one to three years for ASC-12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy beginning with the CY 2020 payment determination and for subsequent years; and
3. Update the factors to be considered when removing measures from the program and update the Code of Federal Regulations to better reflect measure removal policies.

CMS is not finalizing its proposals to remove the following four ASCQR patient safety measures (1) (ASC-1) Patient Burns; (2) (ASC-2) Patient Falls; (3) (ASC-3) Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and (4) (ASC-4) All-Cause Hospital Transfer/Admission.

CMS is retaining these measures in the ASCQR Program and suspending their data collection beginning with the CY 2021 payment determination until further action in rulemaking with the goal of updating the measures.

The table below summarize the ASCQR Program measure sets as finalized in this final rule with comment period for the CY 2020: *(Page 1013)*

ASCQR Program Measure Set for the CY 2020 Payment Determination and Subsequent Years		
ASC #	**NQF #**	**Measure Name**
ASC-1	0263†	Patient Burn
ASC-2	0266	Patient Fall
ASC-3	0267†	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
ASC-4	0265†	All-Cause Hospital Transfer/Admission
ASC-9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
ASC-10	0659	Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps-Avoidance of Inappropriate Use
ASC-11	1536	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery*
ASC-12	2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
ASC-13	None	Normothermia Outcome
ASC-14	None	Unplanned Anterior Vitrectomy
ASC-15a	None	OAS CAHPS – About Facilities and Staff**
ASC-15b	None	OAS CAHPS – Communication About Procedure**
ASC-15c	None	OAS CAHPS – Preparation for Discharge and Recovery**
ASC-15d	None	OAS CAHPS – Overall Rating of Facility**
ASC-15e	None	OAS CAHPS – Recommendation of Facility**

† NQF endorsement was removed.
* Measure voluntarily collected effective beginning with the CY 2017 payment determination as set forth in section XIV.E.3.c. of the CY 2015 OPPS/ASC final rule with comment period (79 FR 66984 through 66985).
**Measure finalized for delay in reporting beginning with the CY 2020 payment determination (CY 2018 data collection) until further action in future rulemaking as discussed in section XIV.B.4. of the CY 2018 OPPS/ASC final rule with comment period (82 FR 59450 through 59451).

Comment

Like the OQR, the ASCQR discussion is approximately 100 pages. Combined, these two quality sections are more than 200 pages in length, or nearly 20 percent of the total rulemaking.

XIII. REQUESTS FOR INFORMATION (RFIS) ***(Page 1044)***

In the proposed rule, CMS sought comments on three items as follows:

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

B. Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

C. Request for Information on Leveraging the Authority for the Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model
CMS has not discussed comments received.

Final Thoughts

While this is a fairly well written rule and easy to read through, it is full of repetitive history that simply adds to the overall length of the document and does not clearly focus on final outcomes. There is no highlighted final decision section. Most final actions are headed in paragraphs as "after consideration of the public comments we received." These actions may or may not be presented as separate paragraphs. Many are part of previous discussions.

As noted before, the quality issue is overbearing and complex. CMS cannot assume that these requirements come without major burden and cost.

In many cases, and as noted previously, CMS has indicated that "We did not receive any public comments on these proposals." This note is not infrequent. One wonders why no comments were received on these items since CMS received numerous comments on most issues.

Our Washington liaison, Larry Goldberg of Larry Goldberg Consulting, has provided us with this summary. Please contact Jeff Weegar, NCHA, at 919-677-4231, jweegar@ncha.org or Ronnie Cook, NCHA, at 919-4225, rcook@ncha.org if you have questions.