Issue Brief

FEDERAL ISSUE BRIEF • July 26, 2018

KEY POINTS

- CMS has issued a proposed rule that would update payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments and in ambulatory surgical centers beginning Jan. 1, 2019 (CY 2019).
- In addition, CMS is proposing to modify the HCAHPS Survey measure by removing the Communication about Pain questions from the HCAHPS Survey for the Hospital IQR Program, which are used to assess patients' experiences of care, effective with January 2022 discharges for the FY 2024 payment determination.

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

The Centers for Medicare & Medicaid Services has issued a proposed rule that would update 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 761-page document is available at https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-15958.pdf.

Publication is scheduled in the *Federal Register* for July 31. The above link will change upon publication. A comment period ending Sept. 24 is provided.

In addition, CMS is proposing to modify the HCAHPS Survey measure by removing the Communication about Pain questions from the HCAHPS Survey for the Hospital IQR Program, which are used to assess patients' experiences of care, effective with January 2022 discharges for the FY 2024 payment determination.

CMS also is including three Requests for Information (RFI) on: (1) promoting interoperability and electronic health care information exchange through possible revisions to the CMS patient health and safety requirements for hospitals and other Medicare-participating and Medicaid-participating providers and suppliers; (2) improving beneficiary access to provider and supplier charge information; and (3) leveraging the authority for the Competitive Acquisition Program (CAP) for Part B drugs and biologicals for a potential CMS Innovation Center model.

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

There are two major items which are bound to stir controversy. First, CMS is proposing to "exercise its authority under the 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."

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This proposed change would result in lower copayments for beneficiaries and savings for the Medicare program which are estimated to be $760 million for 2019. For an individual Medicare beneficiary, current Medicare payment for the clinic visit is approximately $116 with $23 (20 percent) being the average beneficiary copayment. The proposal to adjust this payment to the PFS equivalent rate would reduce the OPPS payment rate for the clinic visit by the PFS relativity adjuster of 40 percent to an amount of $46 and a beneficiary copayment of $9.

Second, CMS would apply the 340B drug payment policy to nonexcepted off-campus provider-based departments (PBDs). Section 340B of the Public Health Service Act (Section 340B) allows participating hospitals and other providers to purchase certain covered outpatient drugs at discounted prices from manufacturers. Beginning Jan. 1, 2018, Medicare pays an adjusted amount of the ASP minus 22.5 percent for certain separately payable drugs or biologicals that are acquired through the 340B program by a hospital paid under the OPPS that is not excepted from the payment adjustment policy. For CY 2018, rural sole community hospitals (SCHs), children's hospitals, and PPS-exempt cancer hospitals are excepted from the 340B payment adjustment.

CMS is now proposing to adopt a policy to pay ASP minus 22.5 percent for 340B-acquired drugs furnished by non-excepted off-campus provider-based departments.

I. PROPOSED OPPS PAYMENT POLICY CHANGES

A. OPPS Payment Update (Page 18)

CMS would increase the OPPS payment rates by 1.25 percent. The amount is based on a hospital marketbasket increase of 2.8 percent minus a 0.8 percentage point adjustment for the multi-factor productivity (MPF) and a 0.75 percentage point adjustment required by law.

CMS will continue to implement the statutory 2.0 percentage point reduction in payments for hospitals failing to meet the hospital outpatient quality reporting requirements.

CMS estimates that total payments to OPPS providers (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2019 would be approximately $74.6 billion, an increase of approximately $4.9 billion compared to estimated CY 2018 OPPS payments. However, CMS also estimates that the proposed total increase in Federal government expenditures under the OPPS for CY 2019, compared to CY 2018, due only to the proposed changes to OPPS in this proposed rule, would be approximately $90 million.

Further, CMS says it estimates that "the proposed rates for CY 2019 would decrease Medicare OPPS payments by an estimated 0.1 percent."

B. Conversion Factor (Pages 28 and 102)

To set the OPPS conversion factor for this CY 2019 OPPS/ASC proposed rule, CMS is proposing to increase the CY 2018 conversion factor of $78.636 by 1.25 percent. CMS is proposing to calculate an overall proposed area wage index budget neutrality factor of 1.0004. CMS is making additional adjustments that result in a CY 2019 conversion factor of $79.546.

C. Proposed Wage Index Changes (Page 108)

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

CMS will, as in previous years, use the fiscal year IPPS post-reclassified wage index, inclusive of any adjustments, as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment standardized amount.

continued

CMS would continue to implement the frontier State floor under the OPPS in the same manner as it has since CY 2011.

For CY 2019, CMS also 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 (section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)). CMS is including the out-migration adjustment information in Addendum L

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

D. Proposed Statewide Average Default CCRs (Page 119)

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 5.

E. Proposed Rural Adjustment (Page 123)

CMS will continue the 7.1 percent adjustment to the OPPS payments to certain rural sole community hospitals (SCHs), including essential access community hospitals (EACHs). This adjustment applies to all services 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 cost.

F. Proposed Payment Adjustment for Certain Cancer Hospitals for CY 2019 (Page 125)

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.

Proposed 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	46.9%
330354	Roswell Park Cancer Institute	16.2%
360242	James Cancer Hospital & Solove Research Institute	22.6%
390196	Fox Chase Cancer Center	8.4%
450076	M.D. Anderson Cancer Center	53.6%
500138	Seattle Cancer Care Alliance	54.3%

continued

G. Proposed Hospital Outpatient Outlier Payments (Page 130)

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 $4,600. 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. Proposed Calculation of an Adjusted Medicare Payment from the National Unadjusted Medicare Payment (Page 135)

The proposed 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 was calculated by multiplying the proposed CY 2019 scaled weight for the APC by the proposed CY 2019 conversion factor.

I. Proposed Beneficiary Copayments (Page 141)

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

II. PROPOSED OPPS AMBULATORY PAYMENT CLASSIFICATION (APC) GROUP POLICIES (PAGE 148)

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.

The proposal identifies:

- The treatment of 9 new level II HCPCS codes that were effective April 1, 2018. Refer rule's table 8.
- Twelve (12) new laboratory CPT Multianalyte Assays with Algorithmic Analyses (MAAA) codes (M codes) and Proprietary Laboratory Analyses (PLA) codes (U codes) that were effective April 1, 2018. Refer rule's table 9.
- The treatment of 14 new HCPCS codes that were effective July 1, 2018. See the rule's table 10.

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continued

The proposed status indicators, APC assignments, and payment rates for the new CPT codes that are can be found in Addendum B.

B. OPPS Changes – Variations within APCs (Page 163)

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 proposes to exempt from the 2 times rule for CY 2019.

Proposed APC Exceptions to the 2 Times Rule for CY 2018	
Proposed CY 2019 APC	**Proposed CY 2019 APC Title**
5071	Level 1 Excision/ Biopsy/ Incision and Drainage
5113	Level 3 Musculoskeletal Procedures
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5571	Level 1 Imaging with Contrast
5612	Level 2 Therapeutic Radiation Treatment Preparation
5691	Level 1 Drug Administration
5692	Level 2 Drug Administration
5721	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
5822	Level 2 Health and Behavior Services
5823	Level 3 Health and Behavior Services

C. Proposed New Technology APCs (Page 175)

CMS is proposing that services assigned to New Technology Ambulatory Payment Classifications (APCs) with fewer than 100 claims annually would be paid under one of several alternative payment methodologies. Specifically, CMS is proposing to use up to four years of data to calculate the geometric mean, the median, and the arithmetic mean and is soliciting comments on which method should be used to establish payment for the new technology service for the upcoming year.

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

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

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Proposed 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	Proposed CY 2019 OPPS SI	Proposed CY 2019 OPPS APC	Proposed 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.
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

For CY 2019, CMS is proposing to reassign the Argus® II procedure from APC 1904 (New Technology—Level 50 ($115,001-$130,000)) to APC 1906 (New Technology—Level 51 ($130,001-$145,000)), which would result in a proposed payment rate for the Argus® II procedure of $137,500.50.

D. OPPS APC-Specific Policies (Page 187)

CMS discusses specific policies regarding the following:

1. Endovascular Procedures (APCs 5191 through 5194)
2. Imaging Procedures and Services (APCs 5521 through 5524, and 5571 through 5573)
3. Musculoskeletal Procedures (APCs 5111 through 5116)
4. Level 5 Intraocular Procedures (APC 5495)

III. PROPOSED OPPS PAYMENT FOR DEVICES (PAGE 196)

Pass-Through Payments for Devices

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

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New Device Pass-Through Applications

CMS received seven applications for new device pass through applications. None of the seven applications are yet to be approved.

Device-Intensive Procedures

CMS is proposing 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 proposing to specify, 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 proposed CY 2019 device-intensive procedures is included in Addendum P.

IV. PROPOSED OPPS PAYMENT CHANGES FOR DRUGS, BIOLOGICALS, AND RADIOPHARMACEUTICALS (PAGE 254)

Drugs and Biologicals with Expiring Pass-Through Payment Status

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

Proposed Drugs and Biologicals for which Pass-Through Payment Status Expires Dec. 31, 2018				
CY 2018 HCPCS Code	CY 2018 Long Descriptor	CY 2018 Status Indicator	CY 2018 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
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

Proposed Drugs, Biologicals, and Radiopharmaceuticals with New or Continuing Pass-Through Payment Status in CY 2019

CMS is proposing to continue pass-through payment status in CY 2019 for 45 drugs and biologicals. They are listed in the rule's table 20. **(Page 263)** 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 would have continuing pass-through payment status.

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CMS is proposing to 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.

Proposed Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs, Biologicals, and Radiopharmaceuticals to Offset Costs Packaged into APC Groups

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

Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals without Pass-Through Payment Status

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

Proposed High Cost/Low Cost Threshold for Packaged Skin Substitutes

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.

For CY 2019, CMS is proposing to continue to determine the high cost/low cost status for each skin substitute product based on either a product's geometric mean unit cost (MUC) exceeding the geometric MUC threshold or the product's per day cost (PDC) (the total units of a skin substitute multiplied by the mean unit cost and divided by the total number of days) exceeding the PDC threshold. The proposed CY 2019 MUC threshold is $49 per cm2 (rounded to the nearest $1) and the proposed CY 2019 PDC threshold is $895 (rounded to the nearest $1).

The rule's table 23 **(Page 286)** displays the proposed CY 2019 high cost or low cost category assignment for each skin substitute product.

Biosimilar Biological Products

CMS is proposing changes to its Medicare Part B drug payment methodology for biosimilars acquired under the 340B Program. Specifically, CMS is proposing to pay nonpass-through biosimilars acquired under the 340B Program at ASP minus 22.5 percent.

V. PROPOSED OPPS PAYMENT FOR HOSPITAL OUTPATIENT VISITS AND CRITICAL CARE SERVICES (PAGE 315)

CMS is not proposing any changes to its current clinic and emergency department hospital outpatient visits payment policies.

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VI. PROPOSED PAYMENT FOR PARTIAL HOSPITALIZATION SERVICES (PAGE 316)

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 proposed values. Note the current amount for APC 5853 is $143.22 and for APC 5863 it is $208.09.

CY 2019 Proposed PHP APC Geometric Mean Per Diem Costs		
CY 2019 APC	**Group Title**	**Proposed PHP APC Geometric Mean Per Diem Costs**
5853	Partial Hospitalization (3 or more services per day) for CMHCs	$119.51
5863	Partial Hospitalization (3 or more services per day) for hospital-based PHPs	$220.52

VII PROPOSED PROCEDURES THAT WOULD BE PAID ONLY AS INPATIENT PROCEDURES (PAGE 347)

The complete list of codes (the IPO list) that are proposed to be placed on the IPO list for CY 2019 are included as Addendum E

VIII PROPOSED NONRECURRING POLICY CHANGES (PAGE 352)

Collecting Data on Services Furnished in Off-Campus Provider-Based EDs

CMS will create a HCPCS modifier (ER—Items and services furnished by a provider-based off-campus ED) that is to be reported with every claim line for outpatient hospital services furnished in an off-campus provider-based ED.

Proposal and Comment Solicitation on Method to Control for Unnecessary Increases in the Volume of Outpatient Services (Pages 355-375)

CMS is proposing to use its authority under section 1833(t)(2)(F) of the Act 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, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier "PO" on claim lines). Off-campus PBDs that are not excepted (departments that bill the modifier "PN") already receive a PFS-equivalent payment rate for the clinic visit.

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Proposal to Apply the 340B Drug Payment Policy to Nonexcepted Off-Campus Departments of a Hospital (Pages 375-387)

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."

CMS is proposing to 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 388-401)

CMS states 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."

CMS is proposing that if an excepted off-campus PBD furnishes services from any clinical family of services (as clinical families of services as defined in the table 32 **(Page 401)** of this proposed rule) from which it did not furnish an item or service during a baseline period from Nov. 1, 2014 through Nov. 1, 2015 (and subsequently bill under the OPPS for that item or service), items and services from these new clinical families of services would not be excepted items and services and, thus, would not be covered OPD services, and instead would be paid under the PFS.

IX. PROPOSED CY 2018 OPPS PAYMENT STATUS AND COMMENT INDICATORS (PAGE 401)

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 proposing to make 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 would apply for CY 2019 is displayed in Addendum D1.

X. PROPOSED UPDATES TO THE AMBULATORY SURGICAL CENTER (ASC) PAYMENT SYSTEM (PAGE 403)

a. Calculation of the Proposed ASC Payment Rates and the Proposed ASC Conversion Factor (Page 484)

ASC payments are annually updated by the percentage increase in the Consumer Price Index for all urban consumers (CPI-U). CMS is proposing to update ASC payment rates using the hospital marketbasket 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 proposal.

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CPI-U, U.S. city average, as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved, is currently projected to be 2.1 percent (based on IGI's first quarter 2018 forecast). If CMS was to derive the MFP adjustment that aligns with this payment update under current policy (ending with the midpoint of the year involved), the MFP adjustment is projected to be 0.8 percent, which would lead to a proposed update amount of 1.3 percent. (Page 496)

For CY 2019, CMS is proposing to utilize the hospital marketbasket update of 2.8 percent minus the MFP adjustment of 0.8 percentage point, resulting in an MFP adjusted hospital marketbasket update factor of 2.0 percent for ASCs meeting the quality reporting requirements. **(Page 497)**

CMS is proposing to adjust the CY 2018 ASC conversion factor ($45.575) by the proposed wage index budget neutrality factor of 1.0003 in addition to the MFP-adjusted hospital marketbasket update factor of 2.0 percent which results in a proposed CY 2019 ASC conversion. factor of $46.500 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, the CY 2018 ASC conversion factor would be $45.575.

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

b. Proposed Treatment of New and Revised Level II HCPCS Codes Implemented in April 2018

The rule's table **(Page 416)** lists the new Level II HCPCS codes that were implemented April 1, 2018, along with their proposed payment indicators for CY 2019. The proposed payment rates, where applicable, for these April codes can be found in Addendum AA and Addendum BB.

c. Proposed Treatment of New and Revised Level II HCPCS Codes Implemented in July 2018

The rule's table 35 **(Page 417)** lists the new HCPCS codes that are effective July 1, 2018. The proposed payment rates, where applicable, for these July codes can be found in Addendum BB.

d. Proposed Process for New and Revised Level II HCPCS Codes that Will Be Effective October 1, 2018 and Jan. 1, 2019

CMS is proposing that the Level II HCPCS codes that will be effective Oct. 1, 2018, and Jan. 1, 2019, would be flagged with comment indicator "NI" in Addendum B to the CY 2019 OPPS/ASC final rule to indicate that CMS has assigned the codes an interim OPPS payment status for CY 2019.

e. Proposed Process for Recognizing New and Revised Category I and Category III CPT Codes that Will Be Effective Jan. 1, 2019

The new and revised CY 2019 Category I and III CPT codes that will be effective on Jan. 1, 2019, and can be found in ASC Addendum AA and Addendum BB to this proposed rule.

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f. Proposed Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services (Page 421)

CMS is proposing to permanently designate as office-based 4 covered surgical procedures for CY 2019. They are CPT codes 31573, 36513, 36902 and 36905. They are further defined in the rule's table 37.

Further, CMS is proposing to designate eight new CY 2019 CPT codes for ASC covered surgical procedures as temporary office-based, as displayed in the rule's table 39. **(Page 428)**

g. Proposed Changes to List of ASC Covered Surgical Procedures Designated as Device-Intensive for CY 2019

CMS is proposing to allow procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures. The ASC covered surgical procedures that CMS is proposing to designate as device-intensive, and therefore subject to the device-intensive procedure payment methodology for CY 2019, are assigned payment indicator "J8" and are included in Addendum AA.

h. Proposed Additions to the List of ASC Covered Surgical Procedures (Page 436)

CMS is proposing to update the list of ASC covered surgical procedures by adding 12 cardiac catheterization procedures to the list for CY 2019, as shown in the rule's table 40.

i. New Technology Intraocular Lenses (NTIOLs)

CMS received no requests for new technology intraocular lenses.

XI. REQUIREMENTS FOR THE HOSPITAL OUTPATIENT QUALITY REPORTING (OQR) PROGRAM (PAGE 500)

CMS is proposing 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 Health care 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 515)**

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CMS would 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 following table outlines the Hospital OQR Program measure set CMS is adopting for the CY 2020 payment determination and subsequent years.

Proposed 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***

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Proposed Hospital OQR Program Measure Set for the CY 2020 Payment Determination	
NQF #	**Measure Name**
None	OP-37d: OAS CAHPS – Overall Rating of Facility***
None	OP-37e: OAS CAHPS – Recommendation of Facility***

† CMS notes that the 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 and its related requirements is always a complex topic. The proposed rule devotes nearly 70 pages to the OQR subject.

XII. REQUIREMENTS FOR THE AMBULATORY SURGICAL CENTER QUALITY REPORTING (ASCQR) PROGRAM (PAGE 568)

CMS is proposing to remove a total of eight measures from the ASCQR Program measure set across the CY 2020 and CY 2021.

For CY 2020, CMS would remove (1) ASC-8: Influenza Vaccination Coverage Among Health care Personnel (NQF #0431). For CY 2021, CMS would remove (1) ASC-1: Patient Burn (NQF #0263); (2) ASC-2: Patient Fall (NQF #0266); (3) ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant (NQF #0267); (4) ASC-4: All-Cause Hospital Transfer/Admission (NQF #0265); (5) ASC-9: Endoscopy/Polyp Surveillance Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658); (6) ASC-10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use (NQF #0659); and (7) ASC-11: Cataracts - Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536). **(Page 583)**

Proposed 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

continued

Proposed ASCQR Program Measure Set for the CY 2020 Payment Determination and Subsequent Years		
ASC #	**NQF #**	**Measure Name**
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).*

XIII. REQUESTS FOR INFORMATION (RFIS) (PAGE 626)

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

CMS states it is "interested in hearing from stakeholders on how we could use the CMS health and safety standards that are required for providers and suppliers participating in the Medicare and Medicaid programs (that is, the Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation (RfPs) for Long-Term Care (LTC) Facilities) to further advance electronic exchange of information that supports safe, effective transitions of care between hospitals and community providers.

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

CMS is asking whether providers and suppliers can and should be required to inform patients about charges and payment information for health care services and out-of-pocket costs, what data elements the public would find most useful, and what other changes are needed to empower patients.

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

Analysis provided for MHA by Larry Goldberg, Goldberg Consulting

CMS is soliciting public comment on how best to develop a model leveraging authority provided to the agency under the Competitive Acquisition Program (CAP) to reduce expenditures while maintaining or improving the quality of care furnished to beneficiaries. CMS seeks feedback on ways to design a potential model that tests private-sector vendor-administered payment arrangements for certain separately payable Part B drugs and biologicals, including high cost therapies. The RFI solicits public comments on potential model parameters such as a potential model's scope, which types of providers and suppliers should be included or excluded from a potential model, the types of Medicare Part B drugs and biologicals that should be included or excluded from a model, the role of private-sector vendors selected to negotiate and administer vendor-based payment arrangements with manufacturers under the model, the defined population of beneficiaries to be addressed by a potential model, appropriate beneficiary protections, possible inclusion of other payers, options for model payments, and other design features.