SUMMARY OF FINAL RULE — DECEMBER 2019

CY 2020 Medicare Outpatient Prospective Payment System

Overview

The Centers for Medicare & Medicaid Services (CMS) issued Part I of its final rule addressing rate updates and policy changes to the Medicare outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) prospective payment system for calendar year (CY) 2020 on November 1. Policies in the final rule are generally effective January 1, 2020, unless otherwise specified. The final rule was published in the *Federal Register* on November 12.

Resources related to the OPPS final rule are available on the CMS website.

Notably, CMS issued a separate final rule finalizing provisions related to price transparency requirements for hospitals that were originally included in the CY 2020 OPPS proposed rule. The provisions of this final rule are effective January 1, 2021. This final rule is summarized under separate cover.

For Additional Information

The following summary provides a comprehensive overview of Part I of the CY 2020 OPPS final rule. A separate summary of the final rule on price transparency requirements is available on CHA's Federal Regulatory Tracker. A summary of the final rule's ASC provisions is available upon request. With questions or for additional information related to the final rule summary, please contact Alyssa Keefe, vice president federal regulatory affairs, at (202) 488-4866 or akeefe@calhospital.org. With questions related to the CY 2020 OPPS final rule DataSuite reports, please contact Alenie Reth at areth@calhospital.org or (916) 552-7682.

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Summary of Key Provisions

The final rule includes annual updates to the Medicare fee-for-service (FFS) outpatient payment rates, as well as regulations that implement new policies. The final rule includes policies that will:

- Adopt FFY 2020 inpatient prospective payment system (IPPS) final rule area wage indices for CY 2020 OPPS
- Continue phasing in payment changes for clinic services furnished in excepted off-campus provider-based departments
- Establish a process for prior authorization for certain covered outpatient department services
- Change the requirements by which a medical device may qualify for device pass-through status
- Revise conditions for coverage for organ procurement organization
- Make changes to the inpatient-only list
- Change the two-midnight policy for inpatient stays for procedures removed from the inpatient-only list
- Change the minimum level of supervision required for hospital outpatient therapeutic services from direct supervision to general supervision

CY 2020 OPPS Payment Rate Updates and Impact

The tables below summarize the final CY 2020 conversion factor compared to CY 2019 and the components of the update factor.

	Final CY 2019	Final CY 2020	Percent Change
OPPS Conversion Factor	$79.490	$80.784	+1.63%

Final CY 2020 Update Factor Component	Value
Market Basket (MB) Update	+3.0%
Affordable Care Act-Mandated Productivity MB Reduction	-0.4%
Wage Index 5% Stop Loss BN	-0.09%
Wage Index BN Adjustment	-0.10%
Pass-through Spending / Outlier BN Adjustment	-0.74%*
Cancer Hospital BN Adjustment	-0.01%
Overall Rate Update	**+1.63%**

*In the CY 2020 final rule, CMS states that the pass-through spending adjustment is 0.88 PPT. However, when combined with the final adjustments to the CY 2019 OPPS rate, the result does not equal the final CY 2020 rate. It seems as though 0.88 PPT is the estimate of pass-through spending for CY 2020, and the pass-through adjustment to the conversion factor should be negative 0.74%, as stated in table above. Clarification from CMS has not yet been received.

CMS estimates the update to the conversion factor and other adjustments — not including the effects of outlier payments, pass-through payment estimates, the application of the frontier state wage adjustment, and controlling for unnecessary increases in the volume of covered hospital outpatient

department (HOPD) services — will increase total OPPS payments by 2.6% in 2020. Considering all other factors, CMS estimates a 1.3% increase in payments between 2019 and 2020.

The update equals the market basket of 3%, reduced by a multifactor productivity adjustment of 0.04%. The net update is 2.6%. Hospitals that satisfactorily report quality data will qualify for the full update of 2.6%, while hospitals that do not will be subject to a statutory reduction of two percentage points. All other adjustments are the same for the two sets of hospitals. CMS determined that 14 hospitals will not receive the full OPPS increase factor.

CMS notes the following estimated impacts in Table 68 of the final rule.

Facility Type	Estimated 2020 Impact
All Hospitals	1.3%
Urban – All	1.3%
Urban – Pacific Region	2.1%
Rural – All	1.1%
Rural – Pacific Region	1.0%

Site-Neutral Payment Policy for Off-Campus Provider-Based Departments

As required by Section 603 of the Bipartisan Budget Act of 2015 (BBA), CMS restricts OPPS payments for services provided by certain off-campus provider-based departments (PBDs) that opened after November 2, 2015, with limited exceptions. CMS generally refers to off-campus PBDs subject to Section 603 as "non-excepted off-campus PBDs." Off-campus PBDs not subject to Section 603 are referred to as "excepted off-campus PBDs." PBDs on a hospital campus are not subject to Section 603, and are simply referred to as "on-campus PBDs" or "on-campus" departments of a hospital.

All excepted off-campus PBDs may bill for excepted services under the OPPS using the claim line indicator "PO." Excepted services include those furnished in a dedicated emergency department (ED), in an on-campus PBD, or within 250 yards of a remote location of a hospital facility. The Medicare Physician Fee Schedule (PFS) is the "applicable payment system" for the majority of nonexcepted items and services furnished in an off-campus PBD. These services are paid under established rates — 40% of the amount paid under OPPS — and continue to be billed on the institutional claim. For 2020, CMS requires the new claim line modifier "PN," which flags the service as nonexcepted. Exceptions to this process include:

- Items and services assigned status indicator "A" that are reported on an institutional claim and paid under the Medicare PFS, Clinical Laboratory Fee Schedule (CLFS), or the Ambulance Fee Schedule, as appropriate, do not receive reduced payments.
- Drugs and biologicals that are separately payable under the OPPS (status indicators "G" and "K") are paid at average sales price (ASP) plus 6%. Those that are always packaged (status indicator "N") are bundled into the Medicare PFS payment and are not paid separately.

In CY 2019, CMS expanded the Medicare PFS payment methodology to excepted off-campus PBDs, for Healthcare Common Procedure Coding System (HCPCS) code G0463, with a two-year phase-in (70% of

the OPPS rate for CY 2019 and fully reduced for CYs 2020 and beyond). These excepted PBDs continue to bill HCPCS code G0463 with modifier "PO."

Despite a recent district court decision that found the cuts unlawful, CMS finalized its proposal to fully implement the Medicare PFS payment methodology for excepted off-campus PBDs (40% of the OPPS rate) for the clinic visit service for CY 2020, implemented in a non-budget-neutral manner.

Recalibration of APC Relative Payment Weights

As required by law, CMS must review and revise the APC relative payment weights annually. CMS must also revise the APC groups each year to account for drugs and medical devices that no longer qualify for pass-through status, new and deleted HCPCS or Current Procedural Terminology (CPT) codes, advances in technology, new services, and new cost data.

The final payment weights and rates for CY 2020 are available in Addenda A and B of the final rule at https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1717-FC-2020-OPPS-Addenda.zip.
CMS finalizes the removal of the following five HCPCS codes from the CY 2020 bypass list:

- HCPCS G0436: Tobacco-use counsel 3-10 min.
- HCPCS 71010: Chest x-ray 1 view frontal
- HCPCS 71015: Chest x-ray stereo frontal
- HCPCS 71020: Chest x-ray 2 view frontal & lateral
- HCPCS 93965: Extremity study

The table below shows the shift in the number of APCs per category from CY 2019 to CY 2020 (Addendum A):

APC Category	Status Indicator	Final CY 2019	Final CY 2020
Pass-Through Drugs and Biologicals	G	60	78
Pass-Through Device Categories	H	1	6
OPD Services Paid through a Comprehensive APC	J1	63	66
Observation Services	J2	1	1
Non-Pass-Through Drugs/Biologicals	K	330	329
Partial Hospitalization	P	2	2
Blood and Blood Products	R	36	36
Procedure or Service, No Multiple Reduction	S	79	79
Procedure or Service, Multiple Reduction Applies	T	31	29
Brachytherapy Sources	U	17	17
Clinic or Emergency Department Visit	V	11	11
New Technology	S/T	112	112
Total		**743**	**766**

Calculation and Use of Cost-to-Charge Ratios

CMS adopts its proposal to sunset the transition policy to remove claims from providers that use a "square footage" cost allocation method in order to calculate cost-to-charge ratios (CCRs) to estimate costs for the CT and MRI APCs identified below:

- APC 5521: Level 1 Imaging without Contrast
- APC 5522: Level 2 Imaging without Contrast
- APC 5523: Level 3 Imaging without Contrast
- APC 5524: Level 4 Imaging without Contrast
- APC 5571: Level 1 Imaging with Contrast
- APC 5572: Level 2 Imaging with Contrast
- APC 5573: Level 3 Imaging with Contrast
- APC 8005: CT and CTA without Contrast Composite
- APC 8006: CT and CTA with Contrast Composite
- APC 8007: MRI and MRA without Contrast Composite
- APC 8008: MRI and MRA with Contrast Composite

To address concerns from commenters about the decrease in imaging payment in CY 2020 due to the transition period ending, CMS finalizes an additional two-year phased-in approach. For CY 2020, CMS will calculate costs for the CT and MRI APCs listed above using both the standard method (all claims with valid CT and MRI cost center CCRs).

Comprehensive APCs for 2020

A comprehensive APC (C-APC) is defined as a classification for a primary service and all adjunctive services provided to support the delivery of the primary service. When such a primary service is reported on a hospital outpatient claim, Medicare makes a single payment for that service and all other items and services reported on the hospital outpatient claim that are provided during the delivery of the comprehensive service and that are integral, ancillary, supportive, dependent, and adjunctive to the primary service.

CMS also assigns a C-APC to specific services performed in combination. Applying C-APC policies to these code combinations means that other OPPS-payable services and items reported on the claim are treated as adjunctive to the comprehensive service. A single prospective payment is made for the comprehensive service based on the costs of all reported services on the claim.

Certain combinations of comprehensive services are recognized for higher payment through complexity adjustments. Qualifying services are reassigned from the originating C-APC to a higher-paying C-APC in the same clinical family. Currently, code combinations that satisfy the complexity criteria are moved to the next higher cost C-APC within the clinical family, unless the APC reassignment is not clinically appropriate or the primary service is already assigned to the highest-cost APC within the C-APC clinical family. CMS does not create new APCs with a geometric mean cost that is higher than the highest-cost

C-APC in a clinical family just to accommodate potential complexity adjustments.

For CY 2020, CMS creates two new C-APCs, bringing the total number of C-APCs to 67:

- APC 5182: Level 2 Vascular Procedures
- APC 5461: Level 1 Neurostimulator and Related Procedures

Table 5 in the final rule lists all C-APCs for CY 2020.

Exclusion of Procedures Assigned to New Technology APCs from C-APC Packaging

In the CY 2019 OPPS final rule, CMS excluded procedures assigned to new technology APCs from being packaged into C-APCs because of a concern that packaging payment reduces claims for the new technology that is available for APC pricing. Since publication of the final rule, some stakeholders asked whether CMS' policy applies to the "Comprehensive Observation Services" C-APC just as it would to a procedural C-APC. CMS considered the issue and does not believe the policy needs to be extended because the criteria for billing to the "Comprehensive Observation Services" C-APC make it highly unlikely that a new technology service will be billed in conjunction with it.

Several commenters objected to CMS packaging payment for procedures assigned to a new technology APC into the C-APC for "Comprehensive Observation Services." The commenters stated that there were instances in which beneficiaries receiving observation services may require the types of procedures that are assigned to new technology APCs. CMS agreed with these comments and is modifying its policy to exclude procedures assigned to new technology APCs from being packaged under the C-APC policy including for the "Comprehensive Observation Services" C-APC.

The full list of C-APCs, the data CMS used to evaluate APCs for C-APC status, and C-APC complexity adjustments are found in Addendum J. C-APCs with a status indicator of "J1" or "J2" (only for the Comprehensive Observation Services C-APC) can be found in other addenda as well.

Blood and Blood Products

For 2020, CMS continues, without change, to set payment rates for blood and blood products using the blood-specific CCR methodology that it has used since 2005. CMS is also continuing to include blood and blood products in the C-APCs, which provide all-inclusive payments covering all services on the claim. HCPCS codes and their associated APCs for blood and blood products are identified with a status indicator of "R" (Blood and Blood Products) in Addendum B of the final rule.

Pathogen-Reduced Platelets and Rapid Bacterial Testing for Platelets

Although pathogen reduction is a costlier service than rapid bacterial testing, a single code was created for both services. CMS was concerned that the OPPS relative weight for pathogen reduction would be too low, as evidence suggested a single code was being used to bill for two different services that vary significantly in costs. Until this concern could be addressed, CMS created a code for pathogen reduction

only and crosswalked its relative weight until claims data were available to price code P9073 under the normal claim's methodology. For 2020, CMS indicates that it now has 4,700 claims for code P9073 (pathogen reduction), and the rate based on claims data will be $585 — $60 less than the crosswalked payment rate to P9037 (irradiated platelets). CMS finalized its proposal to price code P9073 under its normal methodology, using data from 2018 claims, rather than through a crosswalk to code P9037.

Brachytherapy Sources

CMS makes no changes to its brachytherapy policy for 2020. The payment rates appear in Addendum B to the final rule and are identified with status indicator "U."

Composite APCs

Since 2008, CMS has used composite APCs to make a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. CMS continues, without changes, composite policies for mental health services and multiple imaging services for 2020.

Changes to Packaged Items and Services

Drugs that function as a supply are packaged under the OPPS and the ASC payment system, regardless of cost. CMS examined this policy for 2019 in response to the President's Commission on Combating Drug Addiction and the Opioid Crisis. As a result of this review, CMS decided to pay separately for one product (Exparel, a post-surgical analgesia injection) only in the ASC setting. It remains a packaged product in the OPPS. However, despite recommendations from CHA and other stakeholders, CMS determined it would not pay separately for these drugs in hospital outpatient departments.

In the proposed rule, CMS reevaluated this issue under Section 6082 of the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act, which requires the Secretary to review payments under the OPPS for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) so that there are not financial incentives to use opioids instead of non-opioid alternatives. CMS reiterated its previous analysis, reviewed external data from stakeholders, and referenced the Medicare Payment Advisory Commission's (MedPAC) March 2019 report to Congress, concluding there was no compelling evidence to propose revisions to its OPPS payment policies for 2020.

In the final rule, CMS states that it received a number of comments that urged CMS to pay separately for a number of specific products including Exparel, Omidria, MKO Melt, continuous peripheral nerve blocks, spinal cord stimulators, and other products that function as a surgical supply in the hospital outpatient setting. However, CMS disagrees, saying that it observed increasing utilization despite its packaging policies and that studies provided did not demonstrate a reduction in opioid use. As a result, CMS will continue to package all drugs that function as supplies under the OPPS and pay separately for

the cost of non-opioid pain management drugs that function as surgical supplies in the ASC setting.

Area Wage Index

CMS continues its policy of using the fiscal year IPPS post-reclassified wage index for urban and rural areas as the OPPS calendar year wage index. The FFY 2020 IPPS final rule outlined the following area wage index policies (detailed in CHA's FFY 2020 IPPS final rule summary) that will be applied for the CY 2020 OPPS:

1. Calculate the rural floor without including the wage data of urban hospitals that have reclassified as rural.
2. Remove the wage data of urban hospitals that have reclassified as rural from the calculation of "the wage index for rural areas in the state."
3. Increase the wage index values below the 25th percentile by half the difference between the otherwise applicable final wage index value and the 25th percentile wage index value.
4. Apply a budget neutrality adjustment for the increase in the 25th percentile wage indexes as well as a 5% cap on reductions in the wage index.

There are two differences between the proposed and finalized adjustments. In the proposed rule, CMS applied a uniform adjustment for budget neutrality to hospitals with wage indexes in the top quartile to offset the costs for increasing the wage indexes for hospitals in the bottom quartile. For the final rule, CMS does not apply the reduction in the wage indexes for hospitals in the top quartile. Budget neutrality for the increase in the lowest 25th percentile wage indexes will be achieved through a uniform reduction to all OPPS rates.

Notably, CHA opposed the area wage index policies in the FFY 2020 IPPS final rule and the application of those policies to the OPPS. CHA is currently pursuing litigation on behalf of CHA members to challenge the policy. Additional information is available on CHA's Area Wage Index Litigation resource page.

CMS retains the OPPS labor-related share of 60% for purposes of applying the wage index for 2020 and notes that the wage index adjustment is made in a budget-neutral manner. It will use the latest Office of Management and Budget statistical area delineations and continue past adjustments required by the Affordable Care Act (ACA) (e.g., the "frontier state" adjustment that requires a wage index floor of 1).

For non-IPPS hospitals paid under the OPPS for 2020, CMS will continue past policies of assigning the wage index that would be applicable if the hospital were paid under the IPPS and allowing the hospital to qualify for the out-migration adjustment.

For community mental health clinics (CMHCs), CMS will continue to calculate the wage index by using the post-reclassification IPPS wage index based on the core-based statistical area where the CMHC is located. CMS notes that consistent with its current policy, the wage index that applies to CMHCs

includes the rural floor adjustment. It does not include the out-migration adjustment, which only applies to hospitals.

Payment Increase for Rural Sole Community, Essential Access Community Hospitals

For 2020, CMS continues a 7.1% payment increase for rural sole community hospitals and essential access community hospitals. This payment add-on excludes separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to costs. The adjustment is budget neutral and is applied before calculating outliers and copayments.

Cancer Hospital Payment Adjustment and Budget Neutrality Effect

The ACA requires an adjustment to the 11 IPPS-exempt cancer hospitals' outpatient payments, sufficient to bring each hospital's payment-to-cost ratio (PCR) up to the level of the PCR for all other hospitals — the target PCR. The change in these additional payments from year to year is budget neutral. The 21st Century Cures Act reduced the target PCR by one percentage point and excludes the reduction from OPPS budget neutrality. The cancer hospital adjustment is applied at cost report settlement rather than on a claim-by-claim basis.

For 2020, CMS updated its calculations using the latest available cost data resulting in a target PCR of 0.9. CMS reduced the proposed target PCR from 0.9 to 0.89, as required by the 21st Century Cures Act. Table 7 in the final rule shows the estimated hospital-specific payment adjustment for each of the 11 cancer hospitals, with increases in OPPS payments for 2020 ranging from 7.1% to 50.2%. As indicated in the conversion factor update section, the revised cancer hospital adjustment requires a negative 0.01% adjustment to OPPS rates for budget neutrality.

Outlier Payments

To maintain total outlier payments at 1% of total OPPS payments, CMS finalizes a CY 2020 outlier fixed-dollar threshold of $5,075, an increase over the current threshold of $4,825. Outlier payments will continue to be paid at 50% of the amount by which the hospital's cost exceeds 1.75 times the APC payment amount, when both the 1.75 multiple threshold and the fixed-dollar threshold are met.

To model hospital outlier payments and set the outlier threshold for the final rule, CMS applied the hospital-specific overall ancillary CCRs available in the October 2019 update to the Outpatient Provider-Specific File after adjustment using a CCR inflation adjustment factor of 0.97517 to approximate 2020 CCRs, and a charge inflation factor of 1.11100 to approximate 2020 charges from 2018 claims.

New Technology APCs

For CY 2020, CMS will continue its CY 2019 policy that created a different payment methodology for services assigned to new technology APCs with fewer than 100 claims. This methodology may use up to four years of claims data to establish a payment rate (based on either the geometric mean, median, or arithmetic mean) for assigning services to a new technology APC.

Payment for Devices

Alternative Pathway for Device Pass-through Status

To address barriers to health care innovation and ensure access to new critical and life-saving cures and technologies, CMS finalizes that a new medical device that is part of the Food and Drug Administration Breakthrough Devices Program would no longer need to demonstrate the substantial clinical improvement criterion to qualify for device pass-through status. CMS had proposed that this policy would begin with applications received on or after January 1, 2020, but, due to public comments, instead finalizes its application to devices that will receive pass-through payments effective on or after January 1, 2020. As a result, CMS will include device pass-through applications received by the September 2019 quarterly application submission deadline.

Device-Intensive Procedure Policy

CMS defines device-intensive APCs as procedures that require the implantation of a device and are assigned an individual HCPCS code-level device offset of more than 30%, regardless of APC assignment.

For new HCPCS codes describing device implantation procedures that do not yet have associated claims data, CMS applies a device offset of 31% until claims data are available to establish an offset for the procedure. In addition, CMS applies the CY 2016 device coding requirements to newly defined device-intensive procedures. Any device code would satisfy this edit when it is reported on a claim with a device-intensive procedure, regardless of whether the device remains in the patient's body post-procedure.

For CY 2020, CMS did not adopt any changes to the device-intensive policy. The full listing of the 2020 device intensive procedures is included in Addendum P to the final rule.

Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices

For outpatient services that include certain medical devices, CMS reduces the APC payment if the hospital received a credit from the manufacturer. The offset can be 100% of the device amount when a hospital attains the device at no cost or receives a full credit from the manufacturer, or 50% when a hospital receives partial credit of 50% or more.

CMS determines the procedures to which this policy applies using three criteria:

- All procedures must involve implantable devices that would be reported if device insertion procedures were performed.
- The required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedure, even if temporarily.
- The procedure must be device-intensive, defined as devices exceeding 30% of the procedure's average cost.

For CY 2020, CMS did not adopt any changes to the no cost/full credit and partial credit device policies.

Payment Policy for Low-Volume Device-Intensive Procedures

For CY 2020, CMS continues its policy where, for any device-intensive procedure assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC, the payment rate for that procedure will be calculated using the median cost. CMS finalizes that, for CY 2020, the only procedure to which this policy will apply continues to be CPT 0308T (insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis), which CMS assigns to APC 5495.

Payment for Drugs, Biologicals, and Radiopharmaceuticals

CMS pays for drugs and biologicals that do not have pass-through status in one of two ways: either packaged into the APC for the associated service or assigned to their own APC and paid separately. The determination is based on the packaging threshold. CMS allows for a quarterly expiration of pass-through payment status of drugs and biologicals approved since CY 2017. This allows a pass-through period as close to a full three years as possible and eliminates the variability of the pass-through payment eligibility period, without exceeding the statutory three-year limit.

For CY 2020, CMS finalizes a packaging threshold of $130. Drugs, biologicals, and radiopharmaceuticals that are above the $130 threshold are paid separately using individual APCs, and those below the threshold are packaged; the baseline payment rate for CY 2020 is the ASP plus 6%. Separately payable drugs and biological products that do not have pass-through status and are not acquired under the 340B program are paid at wholesale acquisition cost (WAC) plus 3%, instead of WAC plus 6%.

For CY 2020, CMS will continue paying for therapeutic radiopharmaceuticals with pass-through payments status based on ASP plus 6%. If ASP data are not available, CMS will pay based on WAC plus 3%, or 95% of average wholesale price (AWP) if WAC data are also unavailable. Finally, CMS finalizes a pass-through status expiration date of December 31, 2019, for six drugs and biologicals listed in Table 40 of the final rule (page 61303), and continues or establishes pass-through status in CY 2020 for 80 others, shown in Table 41 of the final rule (pages 61305-61310).

OPPS Payment Methodology for 340B Purchased Drugs

In the CY 2018 OPPS final rule, CMS adopted a policy to pay for separately payable drugs acquired through the 340B program at ASP minus 22.5% instead of ASP plus 6%. In 2019, CMS continued this policy and extended it to apply to non-excepted off-campus PBDs. For 2020 — despite ongoing litigation described below — CMS adopts its proposal to continue to pay ASP minus 22.5% for 340B-acquired drugs under the OPPS, as well as 340B-acquired drugs furnished in non-excepted off-campus PBDs paid under the PFS-equivalent rate equal to 40% of the OPPS payment amount. Rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals are exempt from the 340B adjustment and receive drug payments based on ASP plus 6%. Because this is an OPPS policy, the payment reduction does not apply to critical access hospitals (CAHs).

To implement this payment adjustment, CMS established modifiers "JG" and "TB," effective January 1, 2018. Modifier "JG" is used by non-exempt hospitals to report separately payable drugs that were

acquired through the 340B program and thus paid the reduced rate. Modifier "TB" is used by hospitals exempt from the 340B payment adjustment to report separately payable drugs that were acquired through the 340B program.

In the proposed rule, CMS sought public comments on potential remedies related to the continuing lawsuit *American Hospital Association et al. v. Azar et al.* On December 27, 2018, United States District Court for the District of Columbia concluded the Secretary exceeded his statutory authority by adjusting the Medicare payment rates for drugs acquired under the 340B program to ASP minus 22.5% for 2018. On May 6, 2019, the district court ruled that the rate reduction for 2019 also exceeded his authority. The district court remanded the issue to the Secretary to devise an appropriate remedy while also retaining jurisdiction. CMS asked the district court to enter final judgment so as to permit an immediate appeal. On July 10, 2019, the district court granted the government's request and entered a final judgment. CMS has since appealed the district court decision.

In the final rule, CMS states it is taking the steps necessary to craft an appropriate remedy in the event of an unfavorable decision on appeal, including the agency's intention to conduct a 340B hospital survey to collect drug acquisition costs for 2018 and 2019. The survey data may be used in setting the Medicare payment amount for drugs acquired under the 340B program going forward and as a remedy for prior years if the district court decision is upheld on appeal.

CMS further states that devising a remedy will be complex because of the OPPS budget neutrality requirements and the transfer of payments between separately payable drugs acquired under the 340B program and all other services — an estimated $1.6 billion for 2018 alone. The payment transfer will affect approximately 3,900 facilities that are reimbursed for outpatient items and services covered under the OPPS as well as the 20% coinsurance paid by millions of Medicare beneficiaries.

In the final rule, CMS states that it will consider this public input in the event the 340B hospital survey data are not used to devise a remedy. Public input will inform the steps that are required under the Administrative Procedure Act (i.e., hospitals will be provided with sufficient notice of the impact of the remedy on their rates to enable them to comment meaningfully on a proposed rule). CMS anticipates proposing the specific remedy for 2018 and 2019, as well as changes to the 2020 rates, in the 2021 OPPS proposed rule in the event the agency loses on appeal and it does not use 340B hospital survey data to craft the remedy.

High-Cost/Low-Cost Threshold for Packaged Skin Substitutes

CMS divides skin substitutes into a high-cost group and a low-cost group in terms of packaging. CMS assigns skin substitutes with a geometric mean unit cost (MUC) or a products-per-day cost (PDC) that exceeds either the MUC threshold or the PDC threshold to the high-cost group.
CMS will continue to assign skin substitutes that did not exceed the thresholds but were assigned to the high-cost group in CY 2019 to the high-cost group in CY 2020 as well. CMS will also assign those with

pass-through payment status to the high-cost category. Table 45 of the final rule lists the packaged skin substitutes and their group assignments.

Partial Hospitalization Program Services

Partial hospitalization programs (PHPs) are intensive outpatient psychiatric programs that provide outpatient services in place of inpatient psychiatric care. PHP services may be provided in either a hospital outpatient setting or a freestanding CMHC. PHP providers are paid on a per diem basis with payment rates calculated using CMHC-specific or hospital-specific data.

The table below compares the final CY 2019 and CY 2020 PHP payment rates.

	Final Payment Rate 2019	Final Payment Rate 2020	Percent Change
APC 5853: Partial Hospitalization (3+ services) for CMHCs	$120.58	$124.29	+3.1%
APC 5863: Partial Hospitalization (3+ services) for Hospital-Based PHPs	$220.86	$238.64	+8.1%

CMS had proposed, for both CMHCs and hospital-based PHPs, to use the CY 2020 APC geometric mean per diem cost, calculated using the existing methodology, but with a cost floor equal to the CY 2019 final geometric mean per diem cost, as the basis for developing CY 2020 APC per diem rates. However, in the final rule, CMS used the most recent updated data to calculate the CY 2020 geometric mean per diem costs and found that use of the cost floor was only needed for CMHCs. This was due to outliers in the data that heavily influenced the calculated geometric mean per diem and significantly lowered the value compared to CY 2019. This is solely for CY 2020 and will not apply in future years.

For CMHCs, CMS will continue to calculate a CMHC outlier payment equal to 50% of the difference between the CMHC's cost for the services and the product of 3.4 times the APC 5853 payment rate. Additionally, CMS will continue to apply an 8% outlier payment cap to the CMHC's total per diem payments.

Updates to the Inpatient-Only List

The inpatient-only list specifies services and procedures that Medicare will pay for only when provided in an inpatient setting. Despite opposition from CHA and other stakeholders, for CY 2020, CMS finalizes its proposal to the following service from the inpatient-only list: CPT code 27130— Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty (THA)) with or without autograft or allograft.

CMS continues to believe that THA meets criterion 2 (the simplest procedure described by the code may be performed in most outpatient departments) and criterion 3 (the procedure is related to codes already removed from the inpatient-only list). For appropriately selected patients, CMS believes

outpatient THA is appropriate. CMS removes THA from the inpatient-only list and assigns CPT code 27130 to C-APC 5115 with status indicator "J1," meaning that a single bundled payment will be made for both the surgical procedure and all ancillary services furnished in conjunction with it during the outpatient encounter. At this time, CMS will not remove partial hip replacement (PHA) from the inpatient-only list because it does not believe it meets the criteria for removal.

In addition, CMS responded to comments from CHA and others raising concerns that the removal of THA from the inpatient-only list will have detrimental impacts on the Comprehensive Care for Joint Replacement (CJR) and Bundled Payments for Care Improvement (BPCI) Advanced models. CMS states that the Center for Medicare & Medicaid Innovation may consider making future changes to the CJR and BPCI Advanced models to address the removal of THA from the inpatient-only list.

In addition, CMS finalizes the removal of the following CPT codes from the inpatient-only list, listed in Table 49 of the final rule:

- CPT code 22633— Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar
- CPT code 22634— Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar; each additional interspace and segment
- CPT code 63265— Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; cervical
- CPT code 63266— Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; thoracic
- CPT code 63267— Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; lumbar
- CPT code 63268— Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; sacral
- CPT code 00670— Anesthesia for extensive spine and spinal cord procedures (for example, spinal instrumentation or vascular procedures);
- CPT code 00802— Anesthesia for procedures on lower anterior abdominal wall; panniculectomy;
- CPT code 00865— Anesthesia for extraperitoneal procedures in lower abdomen, including urinary tract; radical prostatectomy (suprapubic, retropubic);
- CPT code 00944— Anesthesia for vaginal procedures (including biopsy of labia, vagina, cervix or endometrium); vaginal hysterectomy; and
- CPT code 01214— Anesthesia for open procedures involving hip joint; total hip arthroplasty.

CMS did not add any items to the inpatient-only list for CY 2020.

Two-Midnight Policy for Inpatient Stays

Hospital stays that are expected to span two midnights or longer are presumed appropriate for inpatient admission and are not subject to medical necessity reviews. Currently, procedures on the inpatient-only list are not subject to the two-midnight policy for purposes of inpatient payment and, therefore, are not subject to medical necessity reviews. However, once the procedures are removed from the inpatient only list, the two-midnight rule applies and the procedures are subject to review.

CMS modifies its proposal, establishing a two-year exemption (rather than one year as proposed) from medical review activities for procedures removed from the inpatient-only list for CY 2020 and forward. Specifically, these procedures will not be eligible for referral to recovery audit contractors (RACs) for noncompliance with the two-midnight rule and RAC "patient status" review within the two calendar years of removal from the list. Information gathered when reviewing procedures that are newly removed from the inpatient-only list during the two-year exemption period could be used for education purposes but would not result in claim denial.

Supervision Level for Outpatient Therapeutic Services

Currently, CMS requires direct supervision for hospital outpatient therapeutic services covered by Medicare that are furnished in hospitals as well as in hospital PBDs, including CAHs. Due to the difficulty of meeting this standard, CMS had created an interim nonenforcement ("enforcement instruction") for CAHs and small rural hospitals with 100 beds or fewer that allowed Medicare administrative contractors to not evaluate or enforce the supervision requirements; this is set to expire after CY 2019.

CMS now believes that Medicare providers will provide a similar quality of services, regardless of whether the minimum level of supervision required is direct or general. Also, CMS believes the direct supervision requirement places an additional burden on providers and reduces flexibility to provide medical care, especially for CAHs and small rural hospitals.

Therefore, CMS adopts its proposal to change the minimum level of supervision required for hospital outpatient therapeutic services from direct supervision to general supervision for hospitals and CAHs beginning January 1, 2020. The procedure still must be furnished under the physician's overall direction and control, but the physician's presence is not required during the procedure.

Prior Authorization for Certain Hospital Outpatient Department Services

In an effort to control for what CMS deems "unnecessary increases in the volume of certain covered outpatient services," CMS adopts a prior authorization requirement for five categories of services: blepharoplasty, botulinum toxin injections, panniculectomy rhinoplasty, and vein ablation. CMS notes that these are primarily cosmetic procedures and the prior authorization process would ensure these services are only billed when medically necessary.

In the final rule, CMS establishes a process through which providers will request prior authorization for provisional affirmation of coverage before the service is furnished to the beneficiary and before the claim is submitted for processing. CMS adds regulations that establish the conditions of payment for covered outpatient department services that require prior authorization, establish requirements for the submission of prior authorization requests (including expedited review request), and permit suspension of the prior authorization process generally or for particular services. CMS will implement the process for dates of service on or after July 1, 2020.

A full list of the services that would require prior authorization can be found in Table 64 of the final rule.

Grandfathered Children's Hospitals-within-Hospitals (HwHs)

A hospital-within-a-hospital (HwH) is one that occupies space in the same building as another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital. On October 1, 1995, CMS created separateness and control rules governing HwHs to ensure that the HwH is separate and distinct from the hospital it is within. HwHs that were in existence on or before September 30, 1995, are grandfathered from the separateness and control regulations established on October 1, 1995, so long as they continue to operate under the same terms and conditions, including not increasing the number of beds. The HwH rules initially only applied to long-term care hospitals but were later expanded to all hospitals excluded from the IPPS (including children's hospitals).

CMS believes there is no Medicare payment policy rationale for prohibiting grandfathered children's HwHs from increasing their number of beds. Because these hospitals receive a minimal level of Medicare reimbursement relative to other payers, CMS believes that such a regulatory change would allow these hospitals to address changing community needs for services without any increased incentive for inappropriate patient shifting to maximize Medicare payments. Additionally, CMS does not believe that allowing a grandfathered children's HwH to increase its number of beds would impart an economic advantage relative to other hospitals. As a result, CMS adopts its proposal to allow grandfathered children's HwHs to increase the number of beds within the hospital without resulting in the loss of their grandfathered status.

Revisions to Laboratory Date of Service Policy

Date of service (DOS) is a required field on all Medicare claims for laboratory services. The DOS is used to determine whether a hospital bills Medicare for a clinical diagnostic laboratory test or whether the laboratory performing the test bills Medicare directly. If the DOS occurs while the patient is an inpatient of a hospital, Medicare will bundle payment for the test into hospital service. If the DOS is on the same date as a hospital outpatient encounter, payment for the laboratory test is either packaged into the OPPS service payment or, if separately payable, must be billed by the hospital.

If a test was ordered more than 14 days after a patient's discharge date, **the DOS is the date the test was performed;** the laboratory would bill Medicare directly for the test, and the laboratory would be

paid directly by Medicare. If the test is ordered fewer than 14 days after a patient's discharge date, **the DOS is the date the specimen was collected from the patient;** the hospital (not the laboratory) would bill Medicare for the test, and then the hospital would pay the laboratory.

In the CY 2018 final rule, CMS adopted an exception to the current DOS regulations so that the DOS of molecular pathology tests and advanced diagnostic laboratory tests (ADLTs) is the date that the test was performed only if:

- The test was performed following the date of a hospital outpatient's discharge from the hospital outpatient department.
- The specimen was collected from a hospital outpatient during an encounter.
- It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter.
- The results of the test do not guide treatment provided during the hospital outpatient encounter.
- The test was reasonable and medically necessary for the treatment of an illness.

Many hospitals and laboratories had administrative difficulties implementing the DOS exception. Therefore, CMS applied a six-month enforcement discretion for the DOS exception to provide additional time for providers and suppliers to make necessary changes to their systems to bill for tests subject to the exception. CMS extended the enforcement discretion until January 2, 2020, because many providers needed additional time. The latest enforcement discretion announcement can be found at www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Lab-DOS-Policy.html.

The industry has informed CMS that many hospitals are still struggling to make the necessary system changes to provide the performing laboratory with several data elements that are needed for the laboratory to bill Medicare directly for the test. In addition, molecular tests are often performed by blood banks and blood centers that are not enrolled in Medicare and do not have an established mechanism to bill Medicare directly.

In response, CMS finalized its proposal to — beginning with CY 2020 — exclude molecular pathology tests performed by a laboratory that is a blood bank or center from the laboratory DOS exception. Notably, CMS did not finalize its proposals, which were opposed by CHA, to change the test results requirement to specify that if the other four requirements are met, the ordering physician can decide whether the results of the test guide treatment provided during a hospital outpatient encounter, and to limit the laboratory DOS exception to solely ADLTs and not molecular pathology tests.

Notice of Teaching Hospital Closures and Opportunity to Apply for Available Slots

The ACA authorizes the redistribution of residency slots after a hospital that trained residents in an approved medical residency program closes. The final rule is being used to notify hospitals of two such

closures, and the opportunity to obtain additional residency slots. Hospitals that wish to apply for these slots must submit their applications by January 30, 2020. The closed teaching hospitals are:

CCN	Provider Name	City and State	CBSA Code	Terminating Date	IME FTE Resident Cap (including +/- MMA Sec. 422 Adjustments)	Direct GME FTE Resident Cap (including +/- MMA Sec. 422 Adjustments)
390290	Hahnemann University Hospital	Philadelphia, PA	37964	9/6/2019	556.81	574.82
510039	Ohio Valley Medical Center	Wheeling, WV	48540	9/20/2019	22.93	22.93

Hospital Outpatient Quality Reporting Program

CMS finalizes its proposal to remove one measure from the Outpatient Quality Reporting (OQR) Program beginning with the 2022 payment determination. No changes are adopted for other policies, including those regarding priorities for measure selection, retention of measures, considerations in removing measures, data submission deadlines, public display of measures, QualityNet account and security administrator requirements, data submission requirements, data validation, extraordinary circumstances exceptions, or reconsiderations and appeals.

A table in the appendix of this summary shows the previously adopted and OQR Program measures for payment determinations 2018 through 2022.

Measure Removal for the 2022 Payment Determination

CMS removes the measure OP-33: External Beam Radiotherapy for Bone Metastases (NQF #1822) from the OQR Program beginning with 2022 payment. CMS will remove the measure under its measure removal Factor 8 (costs outweigh the benefit of continued use of the measure).

CMS notes that it receives more questions about how to report this measure than any other in the program. CMS recently finalized the removal of this measure from the PPS-Exempt Cancer Hospital Quality Reporting Program because it is burdensome and because the measure steward is no longer maintaining the measure. Because the measure is no longer being maintained, CMS states that it cannot ensure the measure aligns with clinical guidelines and standards.

In response to comments from CHA and other stakeholders, CMS clarifies that it will no longer require reporting on the measure beginning with January 1, 2020 encounters. CMS had erroneously proposed to no longer require reporting on the measure beginning with October 2020 encounters.

Organ Procurement Organizations Conditions for Coverage

Organ procurement organizations (OPOs) are required to meet two of three outcome measures in order to receive payments from Medicare and Medicaid, one being that the observed donation rate must not be significantly lower than the expected donation rate for more than 18 of 36 months of data.

Beginning with the 2022 recertification cycle, CMS will revise the definition of "expected donation rate" to match the definition established by the Secretary's Advisory Committee on Organ Transplantation. The finalized definition is "the expected donation rate per 100 eligible deaths is the rate expected for an OPO based on the national experience for OPOs serving similar eligible donor populations and donation services areas," which differs from the current definition. CMS adopts its proposal to adjust this rate for age, sex, race, and cause of death, which also differs from the adjustments to current definition of Level I or Level II trauma center, metropolitan statistical area (MSA) size, MSA case-mix index, total bed size, number of intensive care unit beds, primary service, presence of a neurosurgery unit, and hospital control/ownership.

To allow time for OPOs to comply with the definition, CMS had proposed to adjust the time period of the expected donation rate for the 2022 recertification cycle to 12 months, from January 1, 2020, through December 31, 2021. CMS is not finalizing the proposal, as it may have unintended consequences. In response to comments and to ensure fairness for OPOs, CMS is modifying its proposal to require OPOs to meet the standards of one of the two other outcome measures (the donation rate of eligible donors measure or the aggregate donor yield measure) for the 2022 recertification cycle only.

Appendix

Table 1 – OQR Measures for Payment Determination Years 2018-22

NQF	Measure Title	2018	2019	2020	2021	2022
0287+	OP-1: Median Time to Fibrinolysis	X	X	Removed		
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED arrival	X	X	X	X	X
0290	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention	X	X	X	X	X
0286+	OP-4: Aspirin at Arrival	X	X	Removed		
0289+	OP-5: Median Time to ECG	X	X	X	Removed	
0514	OP-8: MRI Lumbar Spine for Low Back Pain	X	X	X	X	X
	OP-9: Mammography Follow-up Rates	X	X	X	Removed	
	OP-10: Abdomen CT – Use of Contrast Material	X	X	X	X	X
0513	OP-11: Thorax CT – Use of Contrast Material	X	X	X	Removed	
	OP-12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC Certified EHR System as Discrete Searchable Data	X	X	X	Removed	
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low-Risk Surgery	X	X	X	X	X
	OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)	X	X	X	Removed	
0491+	OP-17: Tracking Clinical Results between Visits	X	X	X	Removed	
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients	X	X	X	X	X
	OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional	X	X	Removed		
0662	OP-21: ED- Median Time to Pain Management for Long Bone Fracture	X	X	Removed		
0499+	OP-22: ED- Left Without Being Seen	X	X	X	X	X
0661	OP-23: ED- Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan Interpretation Within 45 minutes of Arrival	X	X	X	X	X

	OP-25: Safe Surgery Checklist Use	X	X	Removed		
	OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures	X	X	Removed		
0431	OP-27: Influenza Vaccination Coverage among Healthcare Personnel	X	X	Removed		
0658	OP-29: Appropriate Follow- up Interval for Normal Colonoscopy in Average Risk Patients	X	X	X	X	X
0659	OP-30: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use	X	X	X	Removed	
1536	OP-31: Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	Voluntary				
2539	Op-32: Facility Seven Day Risk Standardized Hospital Visit Rate After Outpatient Colonoscopy	X	X	X	X	X
1822	OP-33: External Beam Radiotherapy for Bone Metastases	X	X	X	X	Remove
	OP-35 Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy			X	X	X
2687	OP-36 Hospital Visits After Hospital Outpatient Surgery			X	X	X
	OP 37a OAS CAHPS – About Facilities and Staff*					
	OP-37b: OAS CAHPS – Communication About Procedure*					
	OP-37c: OAS CAHPS – Preparation for Discharge and Recovery*					
	OP-37d: OAS CAHPS – Overall Rating of Facility*					
	OP-37e: OAS CAHPS – Recommendation of Facility*					

+NQF endorsement removed

* Mandatory reporting on these measures, once scheduled to begin in 2018 for the 2020 payment determination, was indefinitely delayed (82 FR 59432). CMS implemented a voluntary national reporting program for the OAS CAHPS Survey in January 2016. Voluntary reporting is not discussed in this final rule. More information is available at https://oascahps.org/General-Information/National-Implementation.