SUMMARY OF PROPOSED RULE — AUGUST 2019

CY 2020 Medicare Outpatient Prospective Payment System

Overview

The Centers for Medicare & Medicaid Services (CMS) issued its proposed 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 July 29. The proposed rule was published in the *Federal Register* on August 9.

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

Member Forum

CHA will host a member forum on September 11 at 1 p.m. (PT) to review the proposed rule and solicit member input for draft comments. Register for this forum by noon (PT) on September 10. For additional information on CHA member forums, please contact Nicole Hoffman at (202) 488-3740 or nhoffman@calhospital.org, or visit our website.

To Comment

Comments are due to CMS on September 27 by 2 p.m. (PT). Comments can be submitted electronically at www.regulations.gov by using the website's search feature to search for file code "CMS-1717-P." Approximately one week prior to the comment deadline, CHA will provide a draft comment letter in *CHA News* for members' use in submitting their own comments. CHA encourages members to comment on any provision that is of interest to their hospital or health system.

For Additional Information

The following summary provides a comprehensive overview of the CY 2020 OPPS proposed rule. A summary of the ASC rule is available upon request. For questions or additional information related to the proposed rule summary, please contact Alyssa Keefe, vice president federal regulatory affairs, at (202) 488-4866 or akeefe@calhospital.org. For questions related to the CY 2020 OPPS proposed rule DataSuite reports, please contact Ron Yaw, vice president, finance and economic analysis, at (916) 552-7695 or ryaw@calhospital.org.

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Summary of Key Provisions

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

- Adopt FFY 2020 IPPS final rule area wage indices for CY 2020 OPPS
- Continue the phase-in of 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
- Establish requirements for all hospitals to make hospital standard charges and negotiated rates for items and services available to the public
- Change the requirements for a medical device to 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 Proposed Payment Rate Updates and Impact

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

	Final CY 2019	Proposed CY 2020	Percent Change
OPPS Conversion Factor	$79.490	$81.398	+2.40%

Proposed CY 2020 Update Factor Component	Value
Market Basket (MB) Update	+3.2%
Affordable Care Act-Mandated Productivity MB Reduction	-0.5 %
Wage Index Transition Budget Neutrality (BN)	-0.12%
Wage Index BN Adjustment	+0.05%
Pass-through Spending / Outlier BN Adjustment	-0.20%
Cancer Hospital BN Adjustment	-0.02%
Overall Proposed Rate Update	**+2.40%**

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% in 2020. Considering all other factors, CMS estimates a 2.8% increase in payments between 2019 and 2020.

The update equals the market basket of 3.2%, reduced by a multifactor productivity adjustment of 0.05%. The net update is 2.7%. Hospitals that satisfactorily report quality data will qualify for the full update of 2.7%, 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 41 of the proposed rule.

Facility Type	Estimated 2020 Impact
All Hospitals	2.0%
Urban – All	2.0%
Urban – Pacific Region	2.4%
Rural – All	1.9%
Rural – Pacific Region	1.1%

California estimated impacts provided by CHA DataSuite are noted in the table below; impacts will vary by hospital.

Impact Analysis	Dollar Impact	Percent Change
Estimated CY 2019 OPPS Payments	*$5,207,301,500*	
Market Basket Update	$139,233,600	2.67%
ACA-Mandated Market Basket Reduction	($21,755,700)	-0.42%
Other BN Adjustments	($7,599,100)	-0.15%
Wage Index (based on FFY 2020 IPPS Final Rule Wage Index)	$54,403,900	1.04%
Reducing Wage Index Disparities (based on FFY 2020 IPPS Final Rule)	($11,023,600)	-0.21%
> Increasing Bottom Quartile Wage Index Values	$0	0.00%
> Application of 5% Stop Loss Adjustment	$721,200	0.01%
> Wage Index Transition Budget Neutrality	($11,744,800)	-0.23%
APC Factor/Updates	$10,072,000	0.19%
Estimated CY 2020 OPPS Payments	*$5,370,632,600*	
Total Estimated Change CY 2019 to CY 2020	***$163,331,100***	***3.14%***
The impact shown above does not include the impact of the 2.0% sequestration reduction to all lines of Medicare payment authorized by Congress through FFY 2027. It is estimated that the impact of sequestration on CY 2020 OPPS PPS-specific payments would be: -$107,412,600		

Source: CHA DataSuite Analysis, August 2019

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" 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 ASP +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 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."

For CY 2020, CMS proposes to fully implement the Medicare PFS payment methodology for excepted off-campus PBDs (40% of the OPPS rate) for the clinic visit service, implemented in a non-budget-neutral manner. CMS makes no additional proposals at this time, but remains steadfast in its commitment to expand these policies.

In the table below, CHA DataSuite estimates the impact for California.

Estimated Impact of Payment Change to Excepted Off-Campus Provider-Based Departments (PBDs) at 40% of OPPS Rate	*Portion of CY 2017 OPPS Revenue for Off-Campus PBDs*	*Estimated CY 2019 Payment for Excepted Off-Campus PBDs*	*Estimated CY 2020 Proposed Payment for Excepted Off-Campus PBDs*
	1.00%	*$53,780,200*	*$30,731,500*
Estimated Impact/Change to CY 2020 OPPS Revenue	*($23,048,700)*		*-42.9%*

Source: CHA DataSuite Analysis, August 2019

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 Healthcare Common Procedure Coding System/Current Procedural Terminology (HCPCS/CPT) codes, advances in technology, new services, and new cost data.

The proposed payment weights and rates for CY 2020 are available in Addenda A and B of the proposed rule at www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1717-P-2020-OPPS-Addenda.zip.

CMS proposes to remove 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 proposed shift in the number of APCs per category from CY 2019 to CY 2020 (Addendum A):

APC Category	Status Indicator	Final CY 2019	Proposed CY 2020
Pass-Through Drugs and Biologicals	G	60	72
Pass-Through Device Categories	H	1	1
OPD Services Paid through a Comprehensive APC	J1	63	66
Observation Services	J2	1	1
Non-Pass-Through Drugs/Biologicals	K	330	322
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**	**748**

Blood and Blood Products

For 2020, CMS proposes to continue, without change, to set payment rates for blood and blood products using the blood-specific cost-to-charge ratio (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 proposed 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). Therefore, CMS proposes to price code P9073 under its

normal methodology rather than through a crosswalk to code P9037.

Brachytherapy Sources

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

Comprehensive APCs for 2019

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 proposes to create 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 4 in the proposed rule lists all proposed 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 Observations Services" C-APC make it highly

unlikely that a new technology service will be billed in conjunction with it.

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.

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 proposes to continue, 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 the costs of the drugs. 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 postsurgical analgesia injection) only in the ASC setting, rather than as packaged. 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 reevaluates 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 reiterates its previous analysis, reviews external data from stakeholders, and references the Medicare Payment Advisory Commission's (MedPAC) March 2019 report to Congress — concluding there is no compelling evidence to propose revisions to its OPPS payment policies for 2020. 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 proposes to continue its policy of using the fiscal year inpatient prospective payment system (IPPS) post-reclassified wage index for urban and rural areas as the OPPS calendar year wage index. The FFY 2020 IPPS proposed rule outlined the following area wage index policies (detailed in CHA's FFY 2020 IPPS proposed rule summary) for consideration as part of 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, and reduce the wage index values above the 75th percentile wage index value by 4.3 percent.
4. Apply a 5 % cap on the reduction in any FFY 2020 wage index.

For the 5% cap, CMS had proposed to apply a budget neutrality adjustment to the standardized amount. CMS is now proposing an analogous budget neutrality adjustment for the OPPS that is reflected in the update to the OPPS conversion factor.

Notably, on August 1, CMS finalized its FFY 2020 IPPS payment policies related to the area wage index. They include:

- Increase the wage index values below the 25th percentile by half the difference between the otherwise applicable final wage index value, and adjust the standardized amount for all hospitals to account for the increased payments.
- Calculate the rural floor without including the wage data of urban hospitals that have reclassified as rural.
- Apply a 5% cap on the reduction in any FFY 2020 wage index.

Additional information will be forthcoming in CHA's FFY IPPS final rule summary.

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 also proposes to use the latest Office of Management and Budget statistical area delineations, and continue past adjustments required by the ACA (the "frontier state" adjustment that requires a wage index floor of 1.0).

For non-IPPS hospitals paid under the OPPS for 2020, CMS proposes to 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 proposes to continue 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 and proposes a target PCR of 0.9. CMS proposes to reduce the proposed target PCR from 0.9 to 0.89. Table 6 in the proposed 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 51.9%. As indicated in the conversion factor update section, the revised cancer hospital adjustment requires a negative 0.02% adjustment to OPPS rates for budget neutrality.

Outlier Payments

To maintain total outlier payments at 1% of total OPPS payments, CMS proposes a CY 2020 outlier fixed-dollar threshold of $4,950, an increase over the current threshold of $4,825. Outlier payments would 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 April 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 1.11189 to approximate 2020 charges from 2018 claims.

New Technology APCs

For CY 2020, CMS proposes to continue its policy established in CY 2019 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.

Proposed Payment for Devices

Payment for Medical Devices with Pass-Through Status

To address barriers to health care innovation and ensure access to new critical and life-saving cures and technologies, CMS proposes 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, beginning with applications received on or after January 1, 2020.

The Breakthrough Devices Program was established by the 21st Century Cures Act to expedite the development and review of medical devices and device-led combination products that provide for more effective treatment/diagnosis of life-threatening or irreversibly debilitating diseases or conditions. Even if a device waives the substantial clinical improvement criterion with this alternative pathway, the device would still need to meet the other requirements to qualify for pass-through payment status.

There is currently one device category eligible for pass-through payment: HCPCS C1822 – Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system. CMS has not yet approved any new device pass-through payment applications for CY 2020.

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 does not propose any changes to the device-intensive policy. The full listing of the proposed 2020 device intensive procedures is included in Addendum P to the proposed 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 does not propose 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 proposes to continue 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 proposes that, for CY 2020, the only procedure to which this policy would apply continues to be CPT 0308T (insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis), which CMS proposes to assign 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 proposes 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 average sales price (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 proposes to continue paying for therapeutic radiopharmaceuticals with pass-through payments status based on ASP plus 6%. If ASP data are not available, CMS proposes to pay based on WAC plus 3%, or 95% of average wholesale price (AWP) if WAC data are also not available. Finally, CMS proposes the pass-through status to expire on December 31, 2019, for six drugs and biologicals, listed in Table 14, and to continue/establish pass-through status in CY 2020 for 65 others, shown in Table 15.

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, CMS proposes to continue to pay ASP minus 22.5% for 340B-acquired drugs under the OPPS, as well as when 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.

CMS also addresses 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. In the proposed rule, CMS affirms its commitment to appeal the court's decision.

CMS seeks public comment on potential remedies for the CY 2018 and CY 2019 payments, and for use in CY 2020 payments in the event the agency receives an adverse ruling by the U.S. Court of Appeals. Notably, the American Hospital Association has outlined its proposed remedy in its detailed brief to the court. CMS notes that devising a remedy will be complex because of the OPPS budget neutrality requirements and seeks comments on the most appropriate way to maintain budget neutrality, either under a retrospective claim-by-claim approach, with a prospective approach, or any other proposed remedy — including whether to make the relevant budget neutrality adjustment across multiple years. CMS also seeks public comment on the appropriate OPPS payment rate for 340B acquired drugs, including whether a rate of ASP plus 3% could be an appropriate remedial payment amount both for 2020 and for determining the remedy for 2018 and 2019. In the event the agency loses on appeal, CMS anticipates proposing the specific remedy for 2018 and 2019, as well as changes to the 2020 rates, in the next available rulemaking vehicle — the CY 2021 OPPS proposed rule.

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 proposes to 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 also proposes to assign those with pass-through payment status to the high-cost category. Table 19 lists the proposed packaged skin substitutes and their group assignments.

In the CY 2019 proposed rule, CMS requested public comment about refinements to the existing payment methodology for packaged skin substitutes in order to stabilize payments for these products. CMS considered four potential methodologies and discusses the comments received about two of them in this proposed rule:

- Establish a lump-sum "episode-based" payment for a wound care episode.
- Eliminate the high-cost/low-cost categories for skin substitutes and have only one payment category and set of procedure codes for all skin substitute products.

CMS states it is reluctant to propose the episode-based payment methodology for CY 2020 due to the wide array of comments received. CMS also does not propose the single payment category methodology at this time but, based on comments in the CY 2019 proposed rule, believes there is potential for a single payment category to reduce the cost of wound care services for graft skin substitute procedures while providing a more equitable payment for products and lowering administrative burden. CMS seeks feedback on a single payment category and may include this as part of a skin substitute payment policy in the CY 2020 OPPS final rule.

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 proposed CY 2020 PHP payment rates.

	Final Payment Rate 2019	Proposed Payment Rate 2020	Percent Change
APC 5853: Partial Hospitalization (3+ services) for CMHCs	$120.58	$124.59	+3.3%
APC 5863: Partial Hospitalization (3+ services) for Hospital-Based PHPs	$220.86	$228.20	+3.3%

For both CMHCs and hospital-based PHPs, CMS proposes 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. This is due to an outlier in the data that heavily influenced the calculated geometric mean per diem and significantly lowered the value compared CY 2019. CMS states that its proposal applies specifically to CY 2020 and would not apply in future years. CMS proposes to use the most recently updated data to calculate the CY 2020 geometric mean per diem costs in the final rule.

For CMHCs, CMS proposes to 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 proposes to continue to apply an 8% outlier payment cap to the CMHC's total per diem payments.

Finally, CMS continues to be concerned that PHP providers may provide only three services per day when payment is heavily weighted to providing four or more services. Based on its review of 2018 claims, CMS believes that PHPs maintained an appropriately low utilization of three service days as compared to the three preceding years, but the agency will continue to monitor utilization of days with only three PHP services. CMS reiterates its expectation that days with only three services should be the exception and not the typical PHP day; it believes that the typical PHP day should generally consist of five or six units of service.

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. For CY 2020, CMS proposes to remove one 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.

After reviewing the clinical considerations of THA and considering public comments in response to past rules, CMS believes 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 proposes to remove THA from the inpatient-only list and to assign 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 does not propose to remove partial hip replacement (PHA) from the inpatient-only list because it does not believe it meets the criteria for removal.

In addition, CMS seeks comment on the future removal of the following CPT codes from the inpatient-only list:

- 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

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 is applicable, and the procedures are subject to the reviews.

CMS proposes to establish a one-year exemption from medical review activities for procedures removed from the inpatient-only list for CY 2020 and forward. Specifically, these procedures would not be eligible for referral to recovery audit contractors (RACs) for noncompliance with the two-midnight rule and RAC "patient status" review within their first calendar year of removal from the list. Information gathered when reviewing procedures that are newly removed from the inpatient-only list during the one-year exemption period could be used for education purposes, but would not result in a 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 or fewer beds that allowed Medicare administrative contractors not to evaluate or enforce the supervision requirements, 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 proposes 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 would be furnished under the physician's overall direction and control, but the physician's presence would not be 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 proposes to implement 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.

CMS proposes to establish a process through which providers would 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 proposes to add regulations that establish the conditions of payment for covered OPD 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 proposes to 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 38 of the proposed rule. These services are largely cosmetic eye procedures. Notably, CMS proposes a similar method for prior authorization that has been adopted for obtaining certain durable medical equipment and seeks comment on its proposals.

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.

Potential 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 is considering making the following changes and seeks comment on the following proposals:

- Changing the test results requirement to specify that if the other four requirements are met, the ordering physician can decide if the results of the test guide treatment provided during a hospital outpatient encounter
- Limiting the laboratory DOS exception to solely ADLTs and not molecular pathology tests
- Excluding blood banks and blood centers from the laboratory DOS

Hospital Outpatient Quality Reporting Program

CMS proposes to remove one measure from the Outpatient Quality Reporting (OQR) Program beginning with the 2022 payment determination. No changes are proposed to 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 proposed OQR Program measures for payment determinations 2018 through 2022.

Proposed Measure Removal for the 2022 Payment Determination

CMS proposes to remove the measure OP-33: External Beam Radiotherapy for Bone Metastases (NQF #1822) from the OQR Program beginning with 2022 payment. CMS proposes to 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 is in line with clinical guidelines and standards.

CMS proposes to no longer require reporting on the measure beginning with October 2020 encounters. Notably, it is unclear why the proposed date is not January 1, 2020, given that the reporting period for measures submitted via a web-based tool for 2021 payment is calendar year 2019. CMS considered proposing removal of the measure beginning with 2021 payment but decided not to do this out of concern about facilities' planning and operational procedures given that the reporting period for 2021 payment has already begun. Data submission for 2021 payment using a web-based tool will occur between January 1, 2020, and May 15, 2020.

OQR Program Measures and Topics for Future Consideration

CMS seeks comments on the potential addition of four patient safety measures previously adopted for the ASC quality reporting program to the OQR Program:

- ASC-1: Patient Burn, which assesses the percentage of admissions experiencing a burn prior to discharge
- ASC-2: Patient Fall, which assesses the percentage of admissions experiencing a fall
- ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant, which assesses the percentage of patients experiencing any of these events
- ASC-4: All-Cause Hospital Transfer/Admission, which assesses the rate of ASC admissions requiring a hospital transfer or admission upon discharge from the ASC

Data collection for these four ASC measures was suspended beginning in 2019 (for the 2021 payment determination) because of concerns about their reliance on data submission using quality data codes. CMS seeks comments on changing the data submission method for these measures in the future to an online tool, which would be utilized if these measures were proposed for the OQR Program in the future. In addition, the measures would need to be specified for the hospital OPD.

CMS believes these measures provide important data on events that should never occur, and would align the OQR and ASC quality reporting programs. CMS notes that NQF endorsement of these measures

was allowed to lapse by the measure steward; CMS intends to coordinate with the measure steward and seek NQF endorsement for the measures.

Proposed Price Transparency of Standard Charges

As required by Section 2718(e) of the Public Health Service (PHS) Act, effective January 1, 2019, CMS updated its guidelines to require hospitals to make a list of their current standard charges available via the internet in a machine-readable format and to update this information at least annually, or more often as appropriate. This could take the form of the chargemaster itself, or another form of the hospital's choice, as long as the information is in a machine-readable format. However, CMS does not believe the current policy is sufficient for consumers to make informed decisions based on prices of health care services, and the information needed is not currently available.

In accordance with President's Executive Order on "Improving Price and Quality Transparency in American Healthcare to Put Patients First" (June 24, 2019), CMS proposes an expansion of hospital charge display requirements to include charges and information based on negotiated rates and for common shoppable items and services, in a manner that is consumer-friendly. CMS also proposes to establish a mechanism for monitoring and the application of penalties for noncompliance.

Definition of "Hospital" and Special Requirements for Certain Types of Hospitals

CMS proposes to define a "hospital" – in terms of the price transparency requirements – by its licensure, either licensed by the state or approved as meeting hospital licensing standards, in order to ensure that the act applies to all hospitals operating within the United States, including those not considered hospitals for purposes of Medicare participation. Requirements would not apply to federally-owned or operated hospitals since these facilities do not serve the general public, and their payment rates are non-negotiable. CAHs, hospitals located in rural areas, and hospitals that treat special populations would be subject to the requirements because they treat the general public. CMS seeks comment on whether exceptions should be made for these hospitals.

Definition of "Items and Services" Provided by Hospitals

CMS proposes that "items and services" would include both individual and packaged items and services that can be provided in the inpatient or outpatient setting, including those furnished by physicians and non-physician practitioners who are employed by the hospital, for which a hospital has established a standard charge. Items and services furnished by physicians and non-physician practitioners who are not employed by the hospital would not be included. In addition, CMS would require hospitals to include all "service packages" (i.e., any form of bundling charges, such as a per diem rate or a diagnosis-related group (DRG) rate) negotiated with payers.

Definitions of Types of Standard Charges

CMS proposes to require that two types of standard charges — "gross charges" and "payer-specific negotiated charges" — be made publicly available at least annually, separately by each hospital location, on the internet in a single comprehensive machine-readable format. Gross charges would be those for individual items or services reflected on a hospital's chargemaster, without discounts. Payer-specific

negotiated charges would be those that the hospital has negotiated for an item or service with a third-party payer. CMS also seeks comment on other types of standard charges that should be made public, such as volume-driven negotiated charges; minimum, median, and maximum negotiated charges; all allowed charges; discounted cash price; and median cash price.

CMS is focusing on negotiated rates by third-party payers because many third-party payers do not reveal their negotiated rates, even to individuals on behalf of whom they pay. CMS strongly asserts that having insight into the charges that have been negotiated, however, is necessary for insured health care consumers to determine their potential out-of-pocket obligations prior to receipt of a health care service. Further, CMS notes that a negotiated charge is also important because a growing number of insured health care consumers are finding that some services are more affordable if they forego insurance and pay out of pocket.

CMS acknowledges that the impact of releasing negotiated rates is largely unknown. Some stakeholders have expressed concern with the public display of de-identified negotiated rates, which may have the unintended consequence of increasing health care costs of hospital services in highly concentrated markets.

Moreover, CMS recognizes that it may be requiring release of a large amount of data. However, CMS indicates that most (if not all) hospitals maintain such data electronically because these data are used routinely for billing. Therefore, CMS believes it presents little burden for a hospital to electronically pull and display these data online in a machine-readable format.

Hospitals would display all negotiated charges, including, for example, charges negotiated with Medicare Advantage (MA) plans. Hospitals would not include payment rates that are not negotiated, such as those set by Medicare fee-for-service. However, display of a non-negotiated rate would not be precluded.

Public Disclosure of All Hospital Standard Charges for All Items and Services

CMS proposes to require hospitals to post a list of all of their standard charges — both gross charges and rates negotiated with private payers — for all items and services in a machine-readable format on their websites. CMS would require that the information be "displayed prominently" on a publicly-available web page, without barriers, where the data are easily accessible and can be digitally searched.

Specifically, CMS would require that hospitals make public a list of each item or service they provide, along with:

- A description of each item or service (including both individual items and services and service packages)
- The gross charges that apply in the hospital inpatient or outpatient department settings
- The payer-specific negotiated charges that apply when provided in the hospital inpatient or outpatient department settings, clearly associated with the name of the third-party payer

- Any code used by the hospital for purposes of accounting or billing for the item or service, including, but not limited to, the HCPCS code, DRG, National Drug Code (NDC), or other common payer identifier
- Revenue code, as applicable

CMS proposes that hospitals associate each standard charge with a CPT or HCPCS code, DRG, NDC, or other common payer identifier, as applicable. When a hospital charges differently for the same item or service in a different department, CMS proposes that the hospital associate the charge with the department represented by the revenue code, providing the public with the charges they may expect for hospital services provided in different hospital departments.

CMS defines a machine-readable format as a digital representation of data or information in a file that can be imported or read into a computer system for further processing. Examples of machine-readable formats include .XML, JSON, and .CSV formats.

While this proposal would require the file to be updated annually, CMS seeks comment on alternatives that could allow public access to hospital standard charge data in real time, such as through portals established by third-party vendors where the vendor could access certain non-sensitive data elements directly from a hospital's accounting system. Specifically, CMS seeks comment on adopting a requirement that hospitals make public their standard charges via an open applications programming interface (API), through which they would disclose the standard charges and associated data elements. An open API would facilitate the technical and other information required for a third-party application to connect and obtain the data required to be disclosed under the proposed rule.

Consumer-Friendly Display of the Payer-Specific Negotiated Charges for Selected Shoppable Services

In addition to the posting of a machine-readable file for standard charges, CMS proposes to require that hospitals post the negotiated rates for "shoppable" services in a consumer-friendly way that is both easily understood and searchable. CMS proposes to define "shoppable service" as a service package that can be scheduled by a health care consumer in advance. Shoppable services are typically those that are routinely provided in non-urgent situations that do not require immediate action or attention to the patient, thus allowing patients to price shop and schedule a service at a convenient time. Additionally, CMS proposes that the charges for such services be displayed as a grouping of related services, meaning that the charge for the shoppable service is displayed along with charges for ancillary items and services the hospital customarily provides as part of or in addition to the primary shoppable service.

CMS proposes to require that make payer-specific negotiated charges public for a total of 300 shoppable services, with 70 of those selected by CMS. If a hospital does not provide one or more of the 70 CMS selected services, the hospital must make public a list of as many as possible selected services and self-select the additional services to total the 300 required. The list of the 70 CMS-identified shoppable services is included in the Appendix to this summary.

CMS proposes a consumer-friendly display of payer-specific negotiated charge information as follows:

- A plain-language description of each shoppable service (hospitals are invited to review and use the federal plain language guidelines at https://plainlanguage.gov/guidelines)
- The payer-specific negotiated charge that applies to each shoppable service ("N/A" if it is not a service the hospital provides)
- A list of all the associated ancillary items and services that the hospital provides with the shoppable service, including the payer-specific negotiated charge for each ancillary item or service
- The location at which each shoppable service is provided, including whether the payer-specific negotiated charge for the shoppable service applies at that location to the provision of that shoppable service in the inpatient setting or the outpatient department setting, or both
- Any primary code used by the hospital for purposes of accounting or billing for the shoppable service, including, but not limited to, the CPT or HCPCS code, DRG, or other commonly used service billing code

CMS does not propose a specific format for making such data public online in a consumer-friendly manner. Hospitals retain flexibility on how best to display the payer-specific negotiated charge data and proposed associated data elements, so long as the website is easily accessible to the public. Recognizing that not all consumers have access to the internet, CMS also proposes to require hospitals to make the data elements available in a consumer-friendly manner offline (for example, in a brochure or booklet) within 72 hours of a consumer's request.

Monitoring and Enforcement of Requirements for Making Standard Charges Public

CMS proposes to rely predominantly on complaints by individuals or entities regarding a hospital's potential noncompliance and its review of individuals' or entities' analysis of noncompliance. As it gains experience with compliance review of complaints, CMS may consider self-initiating audits of hospitals' websites as a monitoring method. CMS proposes that in the case of noncompliance, the agency would first issue a warning and, if the violation continues, require the hospital to submit and follow a corrective action plan. If a hospital does not submit or adhere to the corrective action plan, CMS proposes to impose a civil monetary penalty (CMP) of up to $300 a day.

Impact Analysis

CMS estimates that it would take hospitals 12 hours, translating to a cost of $1,017.24, to comply with these requirements. Specifically, it estimates that hospitals would need four hours to compile and post charge data for all items and services and eight hours to identify the 300 shoppable services and their corresponding ancillary services, collate the charge data, create a consumer-friendly approach to displaying the data, and post it on their websites. CHA seeks member input on these estimates, which we believe are significantly underestimated.

Request for Information: Price Transparency Quality Measurement

CMS seeks public comment on a number of additional price transparency topics in two broad categories: improving access to quality information by entities developing price transparency, and improving incentives for providers to share charge information with patients. Specifically, CMS seeks information on:

- Improving availability and access to quality data to aid in the development of price transparency tools and communicating charges for third parties and health care entities:
    - What type of quality data would be most beneficial?
    - How can health care providers and suppliers help patients use this data in conjunction with data on charges in decision making?
    - How can CMS help make patient-friendly interfaces for this information?
    - Would displaying volume and procedure complications with charge data be helpful to patients?
    - Should quality data be included with information about out-of-pocket costs to patients?
- Improving communication of health care providers and suppliers with regard to sharing charge information:
    - Should CMS create Hospital Consumer Assessment of Healthcare Providers and Systems questions regarding communication about cost of care with patients?
    - Do any existing measures help patients assess accuracy of charges in advance of service?
    - What value-based purchasing initiatives could be improved by including assessments of how well providers engage in communication with patients about cost of care?

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.

CMS proposes to, beginning with the 2022 recertification cycle, revise the definition of "expected donation rate" to match the definition established by the Secretary's Advisory Committee on Organ Transplantation. The proposed 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 proposes 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 proposed definition, CMS proposes to adjust the time period of the expected donation rate for the 2022 recertification cycle to January 1, 2020, through December 31, 2020.

Request for Information: Potential Changes to the OPO and Transplant Center Regulations

CMS is considering updating the Conditions for Coverage (CfCs) for OPOs and the Conditions of Participation (CoPs) for transplant center requirements. CMS seeks public comment on:

- The current OPO outcome measures' indication of OPO performance
- The implications of the current measures on OPO performance and availability of transplantable organs
- Impacts of certification/decertification processes for OPOs on organ procurement and transplantation
- Additional outcome measures or indicators of quality that could be used for OPOs
- Discrepancy between transplant center CoPs and OPO CfCs

CMS also seeks feedback on whether the following outcome measures would be valid for OPOs:

- Actual deceased donors as a percentage of inpatient deaths among patients age 75 or younger with a cause of death consistent with organ donation
- Actual organs transplanted as a percentage of inpatient deaths among patients age 75 or younger with a cause of death consistent with organ donation

Appendix

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

(Proposals in Italics)

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 proposed rule. More information is available at https://oascahps.org/General-Information/National-Implementation.

Table 2 – CMS-Specified Shoppable Services

Category/Service	2020 CPT/HCPCS Primary Code
Evaluation & Management Services	
Psychotherapy, 30 min	90832
Psychotherapy, 45 min	90834
Psychotherapy, 60 min	90837
Family psychotherapy, not including patient 50 min	90846
Family psychotherapy, including patient, 50 min	90847
Group psychotherapy	90853
New patient office or other outpatient visit, typically 30 min	99203
New patient office or other outpatient visit, typically 45 min	99204
New patient office or other outpatient visit, typically 60 min	99205
Patient office consultation, typically 40 min	99243
Patient office consultation, typically 60 min	99244
Initial new patient preventive medicine evaluation (18-39 years)	99385
Initial new patient preventive medicine evaluation (40-64 years)	99386
Laboratory & Pathology Services	
Basic metabolic panel	80048
Blood test, comprehensive group of blood chemicals	80053
Obstetric blood test panel	80055
Blood test, lipids (cholesterol and triglycerides)	80061
Kidney function panel test	80069
Liver function blood test panel	80076
Manual urinalysis test with examination using microscope	81000 or 81001
Automated urinalysis test	81002 or 81003
PSA (prostate specific antigen)	84153-84154
Blood test, thyroid stimulating hormone (TSH)	84443
Complete blood cell count, with differential white blood cells, automated	85025
Complete blood count, automated	85027
Blood test, clotting time	85610
Coagulation assessment blood test	85730
Radiology Services	
CT scan, head or brain, without contrast	70450
MRI scan of brain before and after contrast	70553
X-Ray, lower back, minimum four views	72110
MRI scan of lower spinal canal	72148
CT scan, pelvis, with contrast	72193
MRI scan of leg joint	73721
CT scan of abdomen and pelvis with contrast	74177
Ultrasound of abdomen	76700

Abdominal ultrasound of pregnant uterus (greater or equal to 14 weeks 0 days) single or first fetus	76805
Ultrasound pelvis through vagina	76830
Mammography of one breast	77065
Mammography of both breasts	77066
Medicine and Surgery Services	
Cardiac valve and other major cardiothoracic procedures with cardiac catheterization with major complications or comorbidities	216
Spinal fusion except cervical without major comorbid conditions or complications (MCC)	460
Major joint replacement or reattachment of lower extremity without major comorbid conditions or complications (MCC)	470
Cervical spinal fusion without comorbid conditions (CC) or major comorbid conditions or complications (MCC)	473
Uterine and adnexa procedures for non-malignancy without comorbid conditions (CC) or major comorbid conditions or complications (MCC)	743
Removal of 1 or more breast growth, open procedure	19120
Shaving of shoulder bone using an endoscope	29826
Removal of one knee cartilage using an endoscope	29881
Removal of tonsils and adenoid glands patient younger than age 12	42820
Diagnostic examination of esophagus, stomach, and/or upper small bowel using an endoscope	43235
Biopsy of the esophagus, stomach, and/or upper small bowel using an endoscope	43239
Diagnostic examination of large bowel using an endoscope	45378
Biopsy of large bowel using an endoscope	43580
Removal of polyps or growths of large bowel using an endoscope	43585
Ultrasound examination of lower large bowel using an endoscope	45391
Removal of gallbladder using an endoscope	47562
Repair of groin hernia patient age 5 years or older	49505
Biopsy of prostate gland	55700
Surgical removal of prostate and surrounding lymph nodes using an endoscope	55866
Routine obstetric care for vaginal delivery, including pre-and post- delivery care	59400
Routine obstetric care for cesarean delivery including pre-and post-delivery care	59510
Routine obstetric care for vaginal delivery after prior cesarean delivery including pre-and post-delivery care	59610
Injection of substance into spinal canal of lower back or sacrum using imaging guidance	62322-62323
Injections of anesthetic and/or steroid drug into lower or sacralspine nerve root using imaging guidance	64483
Removal of recurring cataract in lens capsule using laser	66821
Removal of cataract with insertion of lens	66984

Electrocardiogram, routine, with interpretation and report	93000
Insertion of catheter into left heart for diagnosis	93452
Sleep study	95810
Physical therapy, therapeutic exercise	97110

Source: Table 37 of the proposed rule
*The five codes listed with 3 digits are reproduced as presented in the proposed rule