SUMMARY OF PROPOSED RULE — AUGUST 2018

CY 2019 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 enter (ASC) prospective payment systems for calendar year (CY) 2019 on July 25, 2018. The proposed rule was published in the *Federal Register* on July 31.

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

Member Forum

CHA will host a member forum on **September 14** at 10 a.m. (PT) to review the proposed rule and solicit member input for draft comments. Register for this forum by noon on September 13. 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 September 24 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-1695-P." CHA will provide a draft comment letter for member use in submitting their own specific comments approximately one week prior to the comment deadline in *CHA News*. CHA members are encouraged 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 2019 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 2019 OPPS proposed rule DataSuite reports, please contact Ron Yaw, vice president, finance and economic analysis, at (916) 552-7695 or ryaw@calhospital.org.

Table of Contents

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 will:

- Make payment changes for excepted and non-excepted services furnished in off-campus provider-based departments (PBDs)
- Extend the 340B drug payment adjustment of average sales price (ASP) minus 22.5 percent to non-excepted PBDs
- Change the rate for biosimilars purchased by hospitals through the 340B program
- Change the inpatient-only list
- Change exceptions to the list of services to be packaged into ambulatory payment classifications (APCs), as opposed to separately paid

The rule also requests information on efforts to improve price transparency and interoperability, and create a competitive acquisition or value-based program for Part B drugs under the Center for Medicare and Medicaid Innovation.

CY 2019 OPPS Proposed Payment Rate Updates and Impact

The tables below summarize the proposed CY 2019 conversion factor compared to CY 2018 and the components of the update factor.

	Final CY 2018	Proposed CY 2019	Percent Change
OPPS Conversion Factor	$78.636	$79.546	+1.16%

Proposed CY 2019 Update Factor Component	Value
Market Basket (MB) Update	+2.80%
Affordable Care Act-Mandated Productivity MB Reduction	-0.8 %
ACA-Mandated Pre-Determined MB Reduction	-0.75 %
Wage Index Budget Neutrality Adjustment	+0.04%
Pass-through Spending / Outlier Budget Neutrality Adjustment	-0.13%
Cancer Hospital Budget Neutrality Adjustment	+0.00%
Overall Proposed Rate Update	**+1.16%**

CMS proposes a conversion factor increase of 1.25 percent, based on the hospital inpatient market basket percentage increase of 2.8 percent, minus the multifactor productivity adjustment of 0.8 percentage point minus an additional 0.75 percentage point adjustment required by the Affordable Care Act (ACA). Hospitals that satisfactorily report quality data will qualify for the full update of 1.25 percent, while hospitals that do not will be subject to a statutory reduction of two percentage points. CMS determined that 36 hospitals did not meet the requirements to receive the full outpatient department (OPD) fee schedule increase factor. One-half of these hospitals (18 of 36), chose not to participate in the Hospital Outpatient Quality Reporting (OQR) Program for the 2018 payment determination.

CMS estimates that, compared to 2018, its proposed policies will increase total payments under the OPPS by $90 million, including beneficiary cost-sharing and excluding estimated changes in enrollment, utilization and case mix. CMS estimates that OPPS expenditures for 2019 will be approximately $74.6 billion, an increase of approximately $4.9 billion compared to 2018 OPPS payments. CMS estimates the proposed update to the conversion factor and other adjustments — not including non-budget-neutral adjustments — will increase OPPS payments by 1.3 percent. With all adjustments — including CMS' 2019 proposal to control for "unnecessary increases" in the volume of the outpatient services by paying for clinic visits in off-campus PBDs at the physician fee schedule (PFS) equivalent rate — the proposed rule estimates that OPPS payments will decline by 0.1 percent.

CMS notes the following estimated impacts in Table 42 of the proposed rule.

Facility Type	Estimated Impact
All Hospitals	-0.1%
Urban - All	-0.1%
Urban – Pacific Region	0.05%
Rural – All	-0.1%
Rural – Pacific Region	-1.3%

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 2018 OPPS Payments	*$4,746,181,800*	
Marketbasket Update	$112,941,900	2.38%
ACA-Mandated Marketbasket Reductions	($62,521,200)	-1.32%
Other BN Adjustments	($3,742,200)	-0.08%
Wage Index	$36,025,200	0.76%
APC Factor/Updates	($43,563,000)	-0.92%
Estimated CY 2019 OPPS Payments	*$4,785,322,500*	
Total Estimated Change CY 2018 to CY 2019	***$39,140,700***	***0.82%***
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 2019 OPPS PPS-specific payments would be: -$95,707,000		

Source: CHA DataSuite Analysis, August 14, 2018

Proposed Changes to Site-Neutral Payment Policy for Off-Campus Provider-Based HOPDs

In the proposed rule, CMS details the history of Medicare inpatient and outpatient hospital payment systems and concerns about expenditure growth in the outpatient department. The proposed rule

references the Health and Human Services Secretary's authority under section 1833(t)(2)(F) of the Social Security Act to develop a method for controlling unnecessary increases in the volume of covered OPD services. To date, CMS has not established policy under this authority, instead attempting to address expenditure growth through policies such as increased packaging and the development of comprehensive APCs (C-APCs). Despite these policies, the proposed rule expresses concern about continued growth in program expenditures for hospital outpatient services, illustrated in the two tables below:

TABLE 30. GROWTH IN EXPENDITURES UNDER OPPS FROM CY 2010 THROUGH CY 2019*
(In millions)

Calendar Year	Incurred Cost	Percent Increase
2010	$36,774	-
2011	$39,781	8.2%
2012	$43,154	8.5%
2013	$46,462	7.7%
2014	$52,425	12.8%
2015	$56,274	7.3%
2016	$59,896	6.4%
2017	$64,770	8.1%
2018	$69,942	7.5%
2019 (estimated)	$75,315	8.1%

*Includes Medicare Part B Drug Expenditures.

TABLE 31. PERCENTAGE INCREASE IN VOLUME AND INTENSITY OF HOSPITAL OUTPATIENT SERVICES*

Calendar Year	Percentage Increase
2011	3.7%
2012	5.1%
2013	5.5%
2014	8.0%
2015	3.5%
2016	6.5%
2017	5.8%
2018	5.4%
2019 (Estimated)	5.3%

*Includes Medicare Part B Drug Expenditures.

The proposed rule argues that spending growth is a result of higher payments under the OPPS than the PFS for comparable services. CMS cites the Medicare Payment Advisory Commission's (MedPAC's) March 2018 report to Congress, which states, "A large source of growth in spending on services furnished in hospital outpatient departments (HOPDs) appears to be the result of the unnecessary shift of services from (lower cost) physician offices to (higher cost) HOPDs."

CMS considers these shifts in the sites of service unnecessary if the beneficiary can safely receive the same services in a lower cost setting but instead receives care in a higher cost setting. In its 2012 report to Congress, MedPAC recommended that the payment rates for evaluation and management visits provided in HOPDs be reduced so that total payment rates for these visits are the same, whether the service is provided in an HOPD or a physician office.

CMS expresses further concern about the implications of the higher payments in the HOPD for beneficiary cost sharing. For example, MedPAC estimates that, "Beneficiaries' cost-sharing was $260 million higher in 2009, $325 million higher in 2014, and $400 million higher in 2015 than it would have been because of the higher rates paid in HOPD settings." CMS believes this volume growth and the resulting increase in beneficiary cost sharing is unnecessary, because it appears due to the difference in payment for each setting rather than patient acuity.

Section 603 of the Bipartisan Budget Act of 2015 (BBA) partially addressed these concerns by precluding payment under the OPPS effective January 1, 2017, for new off-campus 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.

CMS indicates that the majority of hospital off-campus departments continue to receive full OPPS payment, which is often higher than the payment that would have been made if a similar service had been furnished in the physician office setting. CMS provides a comparison of payment for a clinic visit between the HOPD (G0463) and a physician office (Level 3 office visit, 99203 for new patient and 99213 for established patient) in 2017:

	HOPD	Physician Office
OPPS	$106.56	$0
PFS	$77.88 (New Patient) $51.68 (Established Patient)	$109.46 (New Patient) $73.93 (Established Patient)
Total	$184.44 (New Patient) $158.24 (Established Patient)	$109.46 (New Patient) $73.93 (Established Patient)

In these examples, the payment rate was approximately $75 to $85 more for the same service when furnished in the HOPD instead of a physician's office; 20 percent of that payment is the beneficiary's responsibility.

CMS believes capping the OPPS payment at the PFS-equivalent rate would remove the payment incentive that is increasing utilization in the HOPD and be an effective method to control the volume of unnecessary services. **Using its authority for controlling unnecessary increases in the volume of covered HOPD services under section 1833(t)(2)(F) of the Social Security Act, CMS proposes to pay**

the same amount — 40 percent of the OPPS rate — for clinic visits (G0463) at HOPDs, regardless of Section 603 exemption; this would take effect in 2019.

In 2019, the standard unadjusted Medicare OPPS proposed payment for the clinic visit is approximately $116; the average copayment is approximately $23. The proposed PFS equivalent rate for Medicare payment for a clinic visit would be approximately $46, and the copayment would be approximately $9, saving beneficiaries an average of $14 per visit. No changes to hospital billing practices would be required to implement this proposal. More specifically, hospitals currently bill for services in off-campus PBDs subject to Section 603 with a "PN" modifier that applies the PFS relativity adjuster of 0.4 to the OPPS payment amount. Excepted off-campus PBDs bill with modifier "PO" that indicates the service was provided in an off-campus PBD, but the PFS relativity adjuster does not apply. Under this proposal, CMS will make the system changes necessary to apply the PFS relativity adjuster when a clinic visit is billed in an excepted off-campus PBD with the "PO" modifier.

CMS does not believe that budget neutrality applies to Section 1833(t)(2)(F) of the Social Security Act and implements the proposal as a savings; its legal rationale is provided in the proposed rule. The estimated payment impact is displayed in Column 5 of Table 42 of the proposed rule. The President's fiscal year 2019 budget approximates the savings — including changes in enrollment, volume and case mix — at $760 million, with $610 million of the savings accruing to Medicare and $150 million saved by Medicare beneficiaries.

In the table below, CHA DataSuite estimates the impact for California, based on Medicare claims data from the CY 2016 Medicare 100 percent standard analytic file using indicator "PO" to identify appropriate claims **with the assumption that all are excepted sites**. The portion of CY 2016 OPPS revenue for off-campus PBDs is applied to CY 2019 OPPS estimated payments to determine impacts. Notably, the "PN" modifier to determine the excepted and non-excepted sites is not available in these claims files and will not be available for more complete analysis until the 2017 claims files are available for public use. Further, it is important to note that CMS uses a different claims file for rate setting and, therefore, hospital-specific impacts will vary.

Estimated Impact of CMS' Proposal to Pay Excepted Off-Campus Provider-Based Departments (PBDs) at 40% of OPPS Rate	*Portion of CY 2016 OPPS Revenue for Off-Campus PBDs*	*Estimated Current Payment for Excepted Off-Campus PBDs*	*Estimated Proposed Payment for Excepted Off-Campus PBDs*
	1.46%	*$69,928,100*	*$27,971,200*
Estimated Impact/Change to CY 2019 OPPS Revenue	*($41,956,900)*		*-60.0%*

Source: CHA DataSuite Analysis, August 14, 2018

CMS also solicits public comments on how to maintain access to new innovations while controlling for unnecessary increases in the volume of covered HOPD services, as well as how to expand the Secretary's statutory authority under section 1833(t)(2)(F) of the Social Security Act to additional

items and services paid under the OPPS that may represent unnecessary increases in OPD utilization. Specifically, CMS seeks public comment on:

- How might Medicare define the terms "unnecessary" and "increase" for services (other than the clinic visit) that can be performed in multiple settings of care? Should the method to control for unnecessary increases in the volume of covered OPD services include consideration of factors such as enrollment, severity of illness and patient demographics?
- Should prior authorization be considered as a method for controlling overutilization of services?
- For what reasons might it ever be appropriate to pay a higher OPPS rate for services that can be performed in lower cost settings?
- How might Medicare use the authority at section 1833(t)(2)(F) of the Act to implement an evidence-based, clinical support process to assist physicians in evaluating the use of medical services based on medical necessity, appropriateness and efficiency? Could utilization management help reduce the overuse of inappropriate or unnecessary services?
- Should there be exceptions to this policy for rural providers, such as those at risk of hospital closure or that are sole community hospitals?
- What impact would such a method to control for unnecessary increases in the volume of covered OPD services have on beneficiaries and the health care market?
- What exceptions, if any, should be made in future proposals to control for unnecessary increases in the volume of outpatient services?

Expansion of Site-Neutral Payment Policies to Clinical Families of Services at Excepted Off-Campus PBDs

As noted earlier, Section 603 of the BBA excludes from the definition of covered OPD services "applicable items and services" furnished on or after January 1, 2017, by certain off-campus outpatient departments of a provider (generally, those that did not furnish covered OPD services before November 2, 2015) and provides for payment for those services furnished by off-campus PBDs under the applicable payment system (e.g., PFS) for the majority of nonexcepted items and services furnished by nonexcepted off-campus PBDs.

In implementing Section 603, CMS previously proposed to limit the items and services for which payment would be made under the OPPS in an excepted off-campus PBD to items and services furnished before November 2, 2015; items and services not included in that group would be paid under the applicable payment system. CMS did not propose to limit the volume of excepted items and services within a clinical family of services that an excepted off-campus PBD could furnish. Stakeholders expressed concerns about the proposal, including that CMS lacked the authority to implement the policy, that limiting service expansion would stifle innovative care delivery and new technologies, and that the proposal was not workable. The agency did not finalize this proposal but indicated it would continue to monitor service line expansion and consider how potential limitations on expansion might work; it sought comments on the issue.

Citing its previous concerns about expansion of services in excepted off-campus PBDs, CMS proposes to revise the definition of "excepted items and services" under §419.48 to include only those from certain clinical families of services furnished during certain baseline periods (generally from November 1, 2014, through November 1, 2015). The clinical families are listed in Table 32 of the proposed rule, reproduced below.

Thus, beginning January 1, 2019, excepted items and services include only those furnished and billed by an excepted off-campus PBD from the clinical families of services for which the excepted off-campus PBD furnished (and subsequently billed the OPPS) at least one item or service during the baseline period. CMS also proposes that, if an excepted off-campus PBD furnishes a new item or service from a clinical family of services from which it furnished a service during the baseline period, it would not be treated as a service expansion and would be paid under the OPPS. However, if an excepted off-campus PBD furnishes items or services from any clinical family of services from which it did not furnish an item or service during the baseline period (and subsequently bill the OPPS), these items and services would be paid under the PFS because they would be from a new clinical family of services and would no longer be considered excepted items or services.

CMS believes a full 12-month period would adequately reflect the types of service lines furnished and billed by excepted off-campus PBDs, and proposes a baseline period of November 1, 2014, through November 1, 2015, because it is the most recent 12-month period that precedes the enactment of Section 603. For excepted off-campus PBDs that did not furnish OPPS services until after November 1, 2014, CMS proposes that the 12-month baseline period begin on the first date the PBDs furnished covered OPD services before November 2, 2015. For providers that met the mid-build requirements, the baseline period would begin on the first date the excepted off-campus PBD furnished a service billed under the OPPS. CMS seeks comments on whether it should shorten the baseline period (e.g., to three or six months) for facilities that first began billing after November 1, 2014, or met the mid-build requirement.

To comply with this proposed policy, excepted off-campus PBDs must ascertain the clinical families of services from which they furnished services during the baseline period. CMS also notes that items and services not identified in Table 32 that are furnished by excepted off-campus PBDs must be reported with modifier "PN."

CMS acknowledges stakeholder concerns with limiting service line expansion using the 19 clinical families listed in Table 32. CMS believes that these families recognize all clinically distinct service lines for which a PBD may bill under the OPPS and that the ability to furnish new services within a clinical family affords providers the ability to furnish services, including those using new or innovative technologies. CMS seeks comments on the proposed clinical families.

TABLE 32. PROPOSED CLINICAL FAMILIES OF SERVICES FOR PURPOSES OF SECTION 603 IMPLEMENTATION

Clinical Families	APCs
Airway Endoscopy	5151-5155
Blood Product Exchange	5241-5244
Cardiac/Pulmonary Rehabilitation	5771; 5791
Diagnostic/Screening Test and Related Procedures	5721-5724, 5731-5735, 5741-5743
Drug Administration and Clinical Oncology	5691-5694
Ear, Nose, Throat (ENT)	5161-5166
General Surgery and Related Procedures	5051-5055; 5061; 5071-5073; 5091-5094; 5361-5362
Gastrointestinal (GI)	5301-5303; 5311-5313; 5331; 5341
Gynecology	5411-16
Major Imaging	5523-5525; 5571-5573; 5593-5594
Minor Imaging	5521-5522; 5591-5592
Musculoskeletal Surgery	5111-16; 5101-02
Nervous System Procedures	5431-5432; 5441-5443; 5461-5464; 5471
Ophthalmology	5481; 5491-5495; 5501-5504
Pathology	5671-5674
Radiation Oncology	5611-5613; 5621-5627; 5661
Urology	5371-5377
Vascular/Endovascular/Cardiovascular	5181-5184; 5191-5194; 5200; 5211-5213, 5221-5224; 5231-
Visits and Related Services	5012; 5021-5025; 5031-5035; 5041; 5045, 5821-5823

CMS seeks comments on the proposed clinical families and whether specific groups of hospitals (such as rural hospitals) should be excluded from its proposal. CMS also seeks comments on alternative methodologies to limit the expansion of excepted services.

The agency is particularly interested in comments on the adoption and implementation of MedPAC's proposal to cap the amount of OPPS payments made to an excepted off-campus PBDs in a year, based on payment for OPPS services furnished by the PBD during the 12-month baseline period that preceded the enactment of Section 603. CMS notes that, under this methodology, hospitals would have to report service volume for each excepted off-campus PBD for the applicable baseline period.

Applying the 340B Drug Payment Policy to Non-Excepted Off-Campus PBDs

Under Section 603 of the BBA, CMS is precluded from paying off-campus PBDs that opened after November 2, 2015 (with limited exceptions) under the OPPS. CMS pays for services in these "non-excepted off-campus PBDs" under a special PFS rate that pays 40 percent of the OPPS rate. However, Part B drugs furnished in non-excepted off-campus PBDs are paid at ASP plus 6 percent and are not subject to any reduction in payment. CMS' 340B policy — which pays for drugs acquired under the 340B drug discount program at ASP minus 22.5 percent in hospital outpatient departments — does not apply

to non-excepted off-campus PBDs. However, CMS did indicate that it might consider applying its 340B payment policy in non-excepted off-campus PBDs through future notice and comment rulemaking.

Prior to CMS adopting its 340B drug policy, separately payable drugs and biologicals were paid at ASP plus 6 percent in both excepted and non-excepted off-campus PBDs. Effective January 1, 2018, CMS pays at ASP minus 22.5 percent for drugs and biologicals acquired under the 340B program and paid under the OPPS in excepted off-campus PBDs and on-campus departments of a hospital. However, services furnished by non-excepted off-campus PBDs are not payable under the OPPS, so the 340B payment changes do not apply. Drugs and biologicals furnished in non-excepted off-campus PBDs are currently paid in the same way as Medicare Part B drugs in the physician office and other nonhospital settings — typically ASP plus 6 percent — regardless of whether they are acquired under the 340B program.

In the CY 2018 OPPS final rule, CMS discussed concerns that not applying the 340B drug payment policy to non-excepted off-campus PBDs incentivizes hospitals to move drug administration services for 340B-acquired drugs to non-excepted off-campus PBDs to receive a higher payment. CMS expressed concern that this payment difference could undermine CMS' goal of reducing beneficiary cost-sharing for these drugs and biologicals and moving toward site neutrality for services paid in non-excepted off-campus PBDs.

To address this concern, **CMS proposes to pay the adjusted amount of ASP minus 22.5 percent for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B program when they are furnished by non-excepted off-campus PBDs of a hospital, effective January 1, 2019. CMS proposes to exempt rural sole community hospitals, children's hospitals and PPS-exempt cancer hospitals from this payment adjustment, consistent with the policy it applies for on-campus PBDs and excepted off-campus PBDs.** CMS believes the proposed policy would better reflect the resources and acquisition costs that non-excepted off-campus PBDs incur for drugs and biologicals acquired under the 340B program.

CMS notes that its payment at ASP minus 22.5 percent for separately payable drugs and biologicals acquired under the 340B program in non-excepted off-campus departments will differ from the ASP plus 6 percent payment for drugs and biologicals made in physicians' offices and other non-hospital settings. The proposed rule further indicates that there are also circumstances in which low-cost drugs are paid separately in physician offices but packaged into the special PFS payment made to non-excepted off-campus PBDs. In those circumstances, Medicare's payment reflects the 40 percent relativity adjuster that would not apply to drugs and biologicals that are separately paid in physician offices and other non-hospital settings. CMS provides this information as part of a legal justification for why it believes it has the authority to apply the 340B policy in non-excepted off-campus PBDs, despite these sites not being paid under the OPPS.

In summary, CMS cites section 1833(t)(21)(C) of the Social Security Act as its authority for applying the 340B policy to non-excepted off-campus PBDs and designating PFS as the applicable payment system. This section of the law authorizes the Health and Human Services Secretary to identify the "applicable payment system" (other than OPPS) to pay for services provided in non-excepted off-campus PBDs. Further, these statutory provisions require CMS to pay ASP plus 6 percent for drugs and biologicals furnished in non-hospital settings. CMS believes this section also authorizes it to pay for 340B-acquired drugs and biologicals that are furnished by non-excepted off-campus PBDs under a special PFS rate — ASP minus 22.5 percent — instead of the rate outlined in section 1847A/1842(o) of the Act. CMS believes the proposed change in policy would eliminate the significant incongruity between the payment amounts for these drugs, which CMS believes is unnecessary.

OPPS Payment Methodology for 340B-Purchased Drugs, Including Biosimilar Biological Products

In the 2018 OPPS/ASC final rule, CMS adopted a policy to pay for separately payable drugs acquired through the 340B program at ASP minus 22.5 percent instead of ASP plus 6 percent. CMS has received questions about whether the 340B payment adjustment applies to drugs that are priced using either WAC or average wholesale price (AWP). The proposed rule indicates that it has been CMS' policy to subject 340B-acquired drugs that use these pricing methodologies to the 340B payment adjustment by paying WAC minus 22.5 percent and 69.46 percent of AWP, for AWP-priced drugs.

The 69.46 percent of AWP is calculated by first reducing the original 95 percent of AWP price by 6 percent to generate a value that is similar to ASP or WAC with no percentage markup and then applying a 22.5 percent reduction. The number of separately payable drugs receiving WAC or AWP pricing that are affected by the 340B payment adjustment is small — less than 10 percent of all separately payable Medicare Part B drugs in April 2018.

In addition, CMS pays for biosimilar biological products using policies parallel to those for other drugs and biologicals, with one important distinction — the 6 percent add-on to ASP and the 22.5 percent subtraction from ASP is based on the ASP of the reference product, not the ASP of the biosimilar. The 6 percent add-on is consistent with the statutory requirement in section 1847A of the Social Security Act that applies to drugs and biologicals furnished in physicians' offices. CMS' policy to subtract 22.5 percent of the reference product's ASP from the ASP of the biosimilar for biosimilars acquired under the 340B program was adopted in the 2018 OPPS final rule when CMS established its 340B drug payment policy.

CMS received concerns about this policy, specifically that 22.5 percent of a biosimilar's reference product ASP is higher than the 22.5 percent of the biosimilar's own ASP because the reference product will generally have a higher price than a biosimilar. Commenters believe it is unfair to subtract a larger amount from the biosimilar's ASP than 22.5 percent of its own ASP. CMS agrees and proposes that — when a biosimilar is acquired under the 340B program — Medicare will pay the hospital based on ASP minus 22.5 percent of the biosimilar's ASP and not the reference product's ASP, except where a

biosimilar is paid on pass-through. In those circumstances, the biosimilar will continue to receive ASP plus 6 percent of the reference product's ASP.

In summary, for 2019, CMS proposes to continue the 340B program policies that were implemented in 2018, with the exception of calculating payment for 340B-acquired biosimilars at ASP minus 22.5 percent of the biosimilar's ASP rather than minus 22.5 percent of the reference product's ASP.

CHA DataSuite estimates the impact of this policy for California below. Estimates are based on Medicare claims data from the CY 2016 Medicare 100 percent standard analytic file. Hospitals flagged as 340B entities are based on the list maintained by the Health Resources & Services Administration as of August 6, 2018. Currently, the impact of this policy is isolated to HCPCS code Q5101 since the pass-through status for this biosimilar biologic will expire on December 31, 2018.

Estimated Impact of CMS' Proposal to Change Payment Rate for Biosimilars Purchased Through the 340B Drug Pricing Program (Currently only HCPCS Q5101)	*CY 2016 OPPS Revenue for Biosimilar Biological Products*	*Estimated Current Payment for Biosimilars Affected by CMS' 340B Payment Reduction*	*Estimated Proposed Payment for Biosimilars Affected by CMS' 340B Payment Reduction*
	$513,800	*$398,200*	*$615,200*
Estimated Impact/Change to CY 2019 OPPS Revenue	*$217,000*		*54.5%*

Collecting Data on Services Furnished in Off-Campus PBDs

CMS expresses concerns similar to those expressed by MedPAC and other entities that higher payment rates for services furnished in off-campus provider-based emergency departments may be a significant factor in the their growth. Higher payment in these settings is due in part to the Section 603 exemption from payment under the applicable payment system (i.e., the PFS) for all services (emergency and nonemergency) furnished an off-campus provider based hospital emergency department. CMS believes it must collect data to assess the extent to which OPPS services are shifting to off-campus provider-based emergency departments.

Effective January 1, 2019, CMS will implement a new modifier ("ER" - Items and services furnished by a provider-based off-campus emergency department) for this purpose through the subregulatory Healthcare Common Procedure Coding System (HCPCS) modifier process. The modifier must be reported with every claim line for outpatient hospital services furnished in off-campus provider-based emergency departments.

The modifier would be reported on the UB-04 form (CMS Form 1450) for hospital outpatient services. Critical access hospitals would not have to report this modifier. **Most importantly, the ER modifier will not be applicable in California, as state law prohibits the licensure of provider-based and freestanding emergency departments.**

Recalibration of APC Relative Payment Weights

CMS is largely continuing past policies unchanged. The only changes CMS proposes are to exclude procedures assigned to new technology APCs from being packaged with C-APCs and to create three new C-APCs for ENT and vascular procedures.

Blood and Blood Products

For 2019, CMS is continuing, 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

CMS recounts the history and coding, since 2016, of pathogen-reduced platelets and rapid bacterial testing of platelets. For 2019, CMS believes that the billing data are accurate for the temporary predecessor codes to P9073 and will use its normal methodology to develop pricing.

Brachytherapy Sources

CMS proposes no changes to its brachytherapy policy for 2019. The proposed payment rates appear in Addendum B to the proposed rule and are identified with status indicator "U."

C-APCs for 2019

A 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 are integral, ancillary, supportive, dependent and adjunctive to the primary service.

CMS also assigns a C-APC to specific services performed in combination with each other. 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.

CMS proposes to add three C-APCs under the existing C-APC payment policy beginning in CY 2019: C-APC 5163 (Level 3 ENT Procedures), C-APC 5183 (Level 3 Vascular Procedures) and C-APC 5184 (Level 4 Vascular Procedures). Table 3 of the proposed rule lists all C-APCs for 2019.

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

CMS proposes to exclude 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. The proposed rule indicates that packaging in this circumstance is contrary to the objective of the New Technology APC payment policy, which is to gather sufficient claims data to enable CMS to assign the service to an appropriate clinical APC.

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 is continuing, without changes, composite policies for mental health services and multiple imaging services for 2019.

Changes to Packaged Items and Services

Drugs that function as a supply, regardless of cost, are packaged under the OPPS and the ASC payment system. These costs are included in the rate-setting methodology for the surgical procedures with which they are billed. The payment rate for the associated procedure reflects the costs of the packaged drugs and other packaged items and services, to the extent they are billed with the procedure.

CMS examined this packaging policy for 2019 in response to a report from the President's Commission on Combating Drug Addiction and the Opioid Crisis. The commission recommended that CMS "…review and modify rate setting policies that discourage the use of non-opioid treatments for pain, such as certain bundled payments that make alternative treatment options cost prohibitive for hospitals and doctors, particularly those options for treating immediate postsurgical pain." The commission's concern is that the policy incentivizes prescription of opioid — rather than non-opioid — medications to patients for post-surgical pain.

CMS evaluated utilization patterns associated with specific drugs that function as a supply from 2013 to 2017 to determine whether the packaging policy has reduced their use. CMS did not observe significant declines in the total number of units used in the HOPD for a majority of the drugs included in its analysis, and, in fact, observed the opposite effect for several drugs that function as a supply.

The proposed rule provided a detailed analysis of Exparel (HCPCS code C9290) — a liposome injection of bupivacaine, an amide local anesthetic — indicated for single-dose infiltration into the surgical site to produce post-surgical analgesia. According to CMS, utilization of this drug in the HOPD continued to increase beyond the period of pass-through payment, even though payment for the drug was packaged with its associated surgical procedure.

CMS' findings in the ASC setting differed. From 2013 through 2017, CMS found a decrease in claims and utilization of Exparel after pass-through payments ended. CMS indicates that several variables may contribute to this difference, including lower payments to ASCs than hospitals; this may make ASCs more sensitive to the costs of packaged products. Alternatively, ASCs do not typically report packaged items and services. The proposed rule suggests that CMS' analysis may not have fully counted the number of Exparel units utilized in the ASC setting.

As a result of declining utilization of Exparel in the ASC setting once the drug stopped receiving pass-through payment, CMS proposes to unpackage and separately pay for non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting for 2019. While this proposal is a departure from CMS' current ASC packaging policy for drugs that function as a supply, CMS believes the proposed change will provide incentives to use non-opioid pain management drugs with surgical procedures in the ASC setting and is responsive to the commission's recommendation.

CMS also seeks public comments and peer-reviewed literature on whether separate payment would provide incentives to use Exparel or other non-opioid drugs or devices during an outpatient visit or procedure and lead to a decrease in opioid use and addiction among Medicare beneficiaries. CMS would determine whether separate payment is warranted in the HOPD for 2019 based on factors that would reduce opioid prescription.

Examples of evidence that may be relevant could include an indication on the product's Food and Drug Administration (FDA) label or studies published in peer-reviewed literature that suggest the product is a non-opioid alternative that aids in the management of acute or chronic pain. CMS would also be interested in evidence that such products have shown clinical improvement over other alternatives, such as a device that has been shown to provide a substantial clinical benefit over the standard of care for pain management. Spinal cord stimulators used to treat chronic pain were provided as examples.

CMS is also interested in comments on whether to provide an equitable adjustment using its authority at section 1833(t)(2)(E) of the Social Security Act to provide an add-on payment for non-opioid treatment alternatives. To the extent that commenters provide evidence to support this approach, CMS would consider a final rule policy that provides an exception to the packaging of certain non-pass-through devices that represent non-opioid alternatives for acute or chronic pain that have evidence to demonstrate that their use leads to a decrease in opioid prescriptions or addictions.

Alternatively, CMS is interested in comments on reorganizing or establishing more granular APC groupings to provide incentives for increased use of non-opioid alternatives. For example, CMS would consider finalizing a policy to establish new APCs for procedures involving non-opioid pain management packaged items or services if such APCs would better recognize the resources involved in furnishing such items and services, and decrease or eliminate the need for prescription opioids. Because patients may receive opioid prescriptions following receipt of a non-opioid drug or implantation of a device, CMS is interested in identifying any cost implications for the patient and the Medicare program caused by this potential change in policy.

Area Wage Index

As in past years, for CY 2019 OPPS payments, CMS proposes to use the federal fiscal year (FFY) 2019 inpatient PPS (IPPS) wage indexes, including all reclassifications, add-ons, rural floors and budget neutrality adjustments. CMS is using this proposed rule to inform the public that the Census Bureau has created a core-based statistical area (CBSA) for the metropolitan statistical area of Twin Falls, Idaho (CBSA 46300), which is comprised of the principal city of Twin Falls in Jerome County, Idaho and Twin Falls County, Idaho. CMS proposes that the imputed rural floor policy will expire after December 31, 2018, with regard to the OPPS. Notably, CMS finalized this policy in the FFY 2019 IPPS final rule issued in early August. The wage index is applied to the portion of the OPPS conversion factor that CMS considers to be labor-related. For CY 2019, CMS proposes to continue to use a labor-related share of 60 percent.

Payment Increase for Rural Sole Community, Essential Access Community Hospitals

CMS proposes to continue a 7.1 percent 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.

Cancer Hospital Payment Adjustment and Budget Neutrality Effect

CMS will continue its policy to provide payment increases to the 11 hospitals identified as exempt cancer hospitals. Previously, CMS did this by providing a payment adjustment such that the cancer hospital's target payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals; thus, the adjustment was budget neutral.

To determine a budget neutrality factor for the cancer hospital payment adjustment, CMS calculated a proposed PCR of 0.89, which, after applying the one percentage point reduction mandated by the 21st Century Cures Act, results in the proposed target PCR being equal to 0.88 for each cancer hospital, which is equivalent to the target PCR for CY 2018. Therefore, CMS has proposed a 0 percent adjustment to the CY 2019 conversion factor to account for this policy.

Outlier Payments

To maintain total outlier payments at 1 percent of total OPPS payments, CMS proposes a CY 2019 outlier fixed-dollar threshold of $4,600 — an increase over the current threshold of $4,150. Outlier payments will continue to be paid at 50 percent 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 proposed rule, CMS applied the hospital-specific overall ancillary CCRs available in the April 2018 update to the Outpatient Provider-Specific File after adjustment (using a CCR inflation adjustment factor of 0.987842 to approximate 2019 CCRs) and to charges on 2017 claims. CMS is using the one-year average annualized rate-of-change in charges per case (1.04205) for two years, for a total increase factor of 1.085868, to approximate 2019 charges. The inflation adjustment factors for CCRs and charges are the same used in the FY 2019 IPPS proposed 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 community mental health center (CMHC). PHP providers are paid on a per diem basis with payment rates calculated using CMHC- or hospital-specific data.

The table below compares the final CY 2018 and proposed CY 2019 PHP payment rates.

	Final Payment Rate 2018	Proposed Payment Rate 2019	% Change
APC 5853: Partial Hospitalization (3+ services) for CMHCs	$143.30	$117.35	-18.1%
APC 5863: Partial Hospitalization (3+ services) for Hospital-based PHPs	$208.21	$216.55	+4.0%

For CMHCs, CMS proposes to continue to make outlier payments at 50 percent of the amount by which the cost for the PHP service exceeds 3.4 times the highest CMHC PHP APC payment rate implemented for that calendar year.

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 2019, CMS proposes to make the following changes to the services included on the inpatient-only list:

Remove:

- CPT code 31241— Nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery [proposed assignment to APC 5153]

- CPT code 01402 — Anesthesia for open or surgical arthroscopic procedures on knee joint; total knee arthroplasty

Add:

- HCPCS code C9606 — Percutaneous transluminal revascularization of acute total/subtotal occlusion during acute myocardial infarction, coronary artery or coronary artery bypass graft, and combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including aspiration thrombectomy when performed, single vessel

In addition, CMS seeks public comment on whether CPT code 0266T — "Implantation or replacement of carotid sinus baroreflex activation device; total system (includes generator placement, unilateral or bilateral lead placement, intra-operative interrogation, programming, and repositioning, when performed)" — should also be removed from the inpatient-only list.

Payment for Medical Devices With Pass-Through Status

There are currently no device categories eligible for pass-through payment. CMS has not yet approved any new device pass-through payment applications for CY 2019.

Proposed Changes to the Device-Intensive Procedure Policy for 2019

In the 2017 OPPS final rule, CMS finalized a change in its methodology to assign device-intensive status. CMS assigns device-intensive status to all procedures that require the implantation of a device and have an individual HCPCS code-level device offset of greater than 40 percent, regardless of the APC assignment. All procedures that meet these requirements are identified as device-intensive, and are subject to the device edit and no cost/full credit and partial credit device policies.

In the 2018 OPPS final rule, CMS clarified that — to be identified as device-intensive procedures and subject to all applicable policies — procedures must require the implantation of a device and meet the following 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, at least temporarily, after the procedure's conclusion.
- The device offset amount must be "significant," which is defined as exceeding 40 percent of the procedure's mean cost.

In response to stakeholders' comments, and as part of an effort to better capture costs for procedures with significant device costs, for 2019 CMS proposes to modify the criteria for device-intensive procedures. CMS no longer believes that whether a device remains in the patient's body should affect its designation as a device-intensive procedure. In addition, to allow a greater number of procedures to qualify as device-intensive, CMS proposes to lower the device offset percentage threshold from 40 to 30

percent. CMS believes this will help ensure these procedures receive more appropriate payment in the ASC setting. CMS also states this change will help to ensure more procedures containing relatively high-cost devices are subject to device edits, which leads to correct coding and greater accuracy in the claims data.

Specifically, for 2019 and subsequent years, CMS proposes that device-intensive procedures would be subject to the following criteria:

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

To align the device-intensive policy with the criteria used for device pass-through status, CMS proposes that, for 2019 and subsequent years, a device-intensive procedure must involve a device that:

- Has received FDA marketing authorization, has received an FDA IDE and has been classified as a Category B device by the FDA in accordance with 42 CFR 405.203 – 405.207 and 405.211 – 405.215, or meets another appropriate FDA exemption from premarket review
- Is an integral part of the service furnished
- Is used for one patient only
- Comes in contact with human tissue
- Is surgically implanted or inserted, either permanently or temporarily
- Is not:
    a. Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1)
    b. A material or supply furnished incident to a service (e.g., a suture, customized surgical kit, or a clip, other than a radiological site marker)

CMS seeks comments on these proposed criteria, including whether there are any devices not included in capital equipment that should be deemed part of device-intensive procedures but would not meet the proposed definition of single-use device.

CMS also seeks comments on the full list of proposed 2019 device-intensive procedures provided in Addendum P. CMS requests comments identifying any procedure proposed to receive device-intensive status that should not receive this status according to the proposed criteria, or any procedure it did not assign device-intensive status that should receive such status.

For new HCPCS codes describing procedures requiring the implantation of medical devices that do not yet have associated claims data, in the 2017 OPPS final rule, CMS finalized a policy to apply a device-intensive status with a default device offset set at 41 percent until claims data are available to establish the HCPCS code-level device offset. CMS also finalized that in certain rare instances, such as in the case

of a very expensive implantable device, CMS may temporarily assign a higher offset percentage if warranted by additional information, such as pricing data from a device manufacturer.

In accordance with the proposal to lower the device offset percentage threshold from 40 to 30 percent, CMS proposes to apply a 31 percent HCPCS code-level offset to new HCPCS codes that describe procedures requiring the implantation of medical devices that do not yet have associated claims data, until such data are available. CMS proposes to continue its current policy of temporarily assigning a higher offset percentage if warranted by additional information, such as pricing data from a device manufacturer.

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

CMS reduces OPPS payments by the full or partial credit a provider receives for a replaced device for the applicable device-dependent APCs. Hospitals report the amount of the credit in the amount portion for value code "FD" (credit received from the manufacturer for a replaced medical device) when the hospital receives a credit for a replaced device that is 50 percent or greater than the device's cost.

For 2019 and subsequent years, CMS proposes to apply the no cost/full credit and partial credit device policies to all procedures that qualify as device-intensive under the proposed modified criteria discussed above.

Proposed Payment Policy for Low-Volume Device-Intensive Procedures

For 2019, CMS proposes to continue its policy of establishing the payment rate for any device-intensive procedure that is assigned to a clinical APC with fewer than 100 claims for all procedures in the APC based on calculations using the median cost instead of the geometric mean cost. For 2019, there are no procedures to which this policy would apply. CMS refers readers to section III.D.4 of the proposed rule for the discussion on the proposed APC assignment change for CPT code 0308T to APC 5493, which has more than 100 total claims.

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 newly approved since CY 2017 to grant a pass-through period as close to three full years as possible and to eliminate the variability of the pass-through payment eligibility period without exceeding the statutory three-year limit.

For CY 2019, CMS proposes a packaging threshold of $125. Drugs, biologicals and radiopharmaceuticals that are above the $125 threshold are paid separately using individual APCs; the baseline payment rate for CY 2018 is the ASP plus 6 percent.

For separately payable drugs and biological products that do not have pass-through status and are not acquired under the 340B program, CMS proposes to reduce wholesale acquisition cost (WAC)-based drug payments from WAC plus 6 percent to WAC plus 3 percent for CY 2019 and future years, a proposal advanced by MedPAC in its June 2017 *Report to Congress: Medicare and the Health Care Delivery System*.

Finally, CMS proposes to allow the pass-through status to expire on December 31, 2018, for 23 drugs and biologicals listed in Table 19 of the proposed rule, and continue pass-through status in CY 2019 for 49 others, shown in Table 20.

High Cost/Low Cost Threshold for Packaged Skin Substitutes

CMS divides skin substitutes into high-cost and low-cost groups 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 is proposing to continue to assign those skin substitutes that did not exceed the thresholds but were assigned to the high-cost group in CY 2018 to the high-cost group in CY 2019 as well. CMS will also assign those with pass-through payment status to the high-cost category. However, there are no skin substitutes with pass-through payment for CY 2018. The list of packaged skin substitutes and their group assignments may be found in Table 23 of the proposed rule.

In the CY 2018 OPPS final rule, CMS requested public comment about refinements that could be made to the existing payment methodology for packaged skin substitutes to stabilize payments for these products. The four potential methodologies CMS is reviewing are:

- *Establish a lump-sum "episode-based" payment for a wound care episode*. Under this option, a hospital would receive a lump sum payment for an "episode" (such as 12 weeks) for all wound care services involving procedures using skin substitutes. Quality metrics could be established to ensure the beneficiary receives appropriate care while limiting excessive additional applications of skin substitute products.
- *Eliminate the high-cost/low-cost categories.* Under this option, CMS would establish a single payment category that has a payment rate between the current rates paid for high-cost and low-cost skin substitute procedures.
- *Pay add-ons based on the size of the skin graft*. Under this option, payment for skin substitutes would be made based on the size of the skin substitute product being applied.
- *Change the threshold used to assign skin substitutes in the high-cost or low-cost groups*. Under this option, CMS would consider fixing the MUC or PDC threshold at an amount from a prior year or setting global payment targets for high-cost and low-cost skin substitutes and establishing a threshold that meets the payment targets.

CMS proposes to continue the current skin substitute payment policy for CY 2019, but is considering implementing one of these methodologies — or any new ones received in the current comment period — in CY 2020.

Hospital Outpatient Quality Reporting Program

In support of its Meaningful Measures Initiative, CMS proposes to remove 10 measures from the Outpatient Quality Reporting (OQR) Program. The total number of mandatory measures would be reduced from 21 previously adopted for the 2020 and 2021 payment determinations to 20 measures for 2020 and 12 measures for 2021 payment.

CMS also proposes to modify the factors it considers when removing measures from the OQR program, remove the requirement that hospitals submit a notice of participation form, update the measure specifications manual less frequently and lengthen the reporting period for one claims-based measure.

Policies for Removal of Quality Measures From the OQR Program

Currently, CMS uses a set of seven factors to determine whether to remove a measure from the OQR program. Removal of measures meeting any of the criteria is not automatic and is made on a case-by-case basis. In this rule, CMS proposes to modify the wording of one of the current seven factors to better align it with the ASC quality reporting program, clarify CMS' calculations for determining topped-out measures and adopt an eighth factor.

The proposed "Factor 8" would be that the costs associated with a measure outweigh the benefit of its continued use in the program. CMS reviews a number of different costs associated with measures, including provider and clinician information collection and reporting burden, as well as the costs to CMS associated with program implementation and oversight. CMS also notes that beneficiaries may find it confusing to see public reporting on the same measure in different programs.

Removal of Measures Beginning With 2020 and 2021 Payment Determinations

CMS proposes to remove the following 10 measures from the OQR program. One measure would be removed beginning with the 2020 payment year and the others beginning with the 2021 payment year. CMS notes that measures proposed for removal based on proposed Factor 8 would not be finalized for removal should that factor not be adopted in the final rule; however, in the FFY 2019 Medicare payment rules, CMS finalized Factor 8 for its other quality reporting programs.

- **OP-27: Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431):** CMS proposes to remove the measure beginning with the 2020 payment determination based on the proposed Factor 8. CMS notes that some hospital outpatient departments are required to participate in the Centers for Disease Control and Prevention National Healthcare Safety Network reporting system only for the purpose of reporting this measure. However, the vast majority of facilities participating in the OQR program report this measure for these other

programs, and the inpatient version of the measure captures the vast majority of hospital personnel.

- **OP-5: Median Time to Electrocardiogram (ECG) (NQF #0289)**: CMS proposes to remove the measure beginning with the 2021 payment determination based on Factor 8. CMS has determined that the measure shows minimal performance variation, despite not meeting the definition of "topped out." The median time to ECG differs from the 75th and 90th percentile times by less than two minutes, and the difference between the 25th and 75th percentiles is only five-and-a-half minutes. CMS does not consider these differences meaningful in helping beneficiaries make informed care decisions.
- **OP 31: Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (NQF #1536)**: The measure would be removed beginning with the 2021 payment determination based on proposed Factor 8. CMS believes that the high technical and administrative costs and burden outweigh the measure's limited benefit. CMS says that it can be operationally difficult for facilities to collect and report on the measure, as they might not have access to the pre-operative and post-operative patient surveys of visual function from clinicians. In addition, CMS is concerned that different surveys may be used, making data validation difficult. After initially adopting OP-31 as a mandatory OQR program measure for the 2016 payment determination, CMS subsequently delayed data collection and made the measure voluntary. It reports that only 59 facilities (1.2 percent) reported this voluntary measure.
- **OP-29: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients (NQF #0658) and OP-30: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use (NQF #0659):** CMS proposes to remove these measures beginning with the 2021 payment determination under proposed Factor 8. CMS bases its proposal on the combination of the cost of chart-abstraction, availability of both these measures for reporting in the Merit-based Incentive Payment System, and preference for outcome measures in the OQR program. CMS notes that the claims-based outcome measure — OP-32: Facility 7-Day Risk Standardized Hospital Visit Rate After Outpatient Colonoscopy (NQF #2539) — would continue to be included in the OQR program.
- **OP-9: Mammography Follow-up Rates**: CMS proposes to remove this measure beginning with the 2021 payment determination because the measure does not align with current clinical guidelines or practice. Specifically, the measure does not take into account more recent guidelines and literature on the clinical benefits of diagnostic digital breast tomosynthesis (DBT), for which CMS cites various studies and the American College of Radiology breast cancer screening appropriateness criteria. CMS will investigate re-specification of this measure to capture a broader spectrum of mammography services, including DBT.
- **OP-11: Thorax Computed Tomography (CT) – Use of Contrast Material (NQF #0513) and OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT:** CMS proposes to remove the measures beginning with the 2021 payment determination because measure performance is topped out.

- **OP-12: The Ability for Providers with HIT (Health Information Technology) to Receive Laboratory Data Electronically Directly into Their Qualified/Certified EHR System as Discrete Searchable Data and OP-17: Tracking Clinical Results between Visits**: CMS proposes to remove the measures beginning with the 2021 payment because performance or improvement does not result in better patient outcomes. CMS notes that these measures assess functionality of health information technology and do not address patient outcomes, and as a result, are not consistent with the goals of its Meaningful Measures Initiative.

A table showing the OQR proposed measure set through 2021, including previously adopted and measures proposed for removal, is included in the appendix to this summary. Specifications for OQR Program measures are available on the QualityNet website.

OQR Measures and Topics for Future Consideration

CMS requests public comment on future measure topics for the OQR program, noting that across all the Medicare quality reporting and value-based purchasing programs, the agency is moving toward greater use of outcome measures and away from use of clinical process measures. CMS specifically seeks comments on any outcome measures that should be added to and process measures that should be removed from the program.

Notice of Participation Form

CMS proposes to remove the requirement that hospitals submit a notice of participation form for participation in the OQR program, as submission of any OQR program data would indicate a hospital's status as a program participant. Under the proposal, a hospital would still need to register on the QualityNet website before beginning to report data, identify and register a QualityNet security administrator and submit data.

Frequency of OQR Program Specifications Manual Release

CMS proposes that, beginning with 2019, it would update the OQR program measure specifications manual every six to 12 months, depending on need, rather than maintaining its semi-annual update schedule. CMS believes that unnecessarily maintaining this schedule may be confusing to program participants. The schedule would consider CMS' policy of providing at least six months' notice for substantive changes in measure specifications. The proposed rule does not mention how the proposal might affect the policy of providing three months' notice for subregulatory nonsubstantive changes, such as changes to ICD-10, CPT, NUBC and HCPCS codes.

Extension of Reporting Period for OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy

CMS proposes to change the reporting period for the claims-based measure OP-32 from one year of data to three years of data because it believes that better information would be provided to beneficiaries. While its analysis of data from the 2015 dry run of this measure has supported the finding

that using one year of data provides sufficient reliability for measure calculation, CMS also found that using a three-year reporting period increases the measure's reliability and precision. In addition, the longer period is estimated to increase the number of HOPDs with eligible cases for this measure by 5 percent, adding 235 facilities to the measure calculation.

Under the proposal, the reporting period for OP-32 would be changed beginning with the 2020 payment determination and would use claims from calendar years 2016, 2017 and 2018 instead of 2018 alone. A similar pattern would be used for later payment determinations. Because CMS proposes to add prior years, it says payment determinations and public display of the measure would not be disrupted. For example, public display for the 2020 payment determination would occur in January 2020.

Payment Reduction for Hospitals That Fail to Meet the OQR Program Requirements for 2019 Payment

CMS continues to apply existing policies with respect to computing and applying the payment reduction for hospitals that fail to meet the Hospital OQR Program requirements for 2019. The reduction ratio for hospitals that fail to meet OQR Program requirements, called the "reporting ratio," is 0.98.

The reporting ratio would continue to be applied to the national unadjusted payment rates and minimum unadjusted and national unadjusted copayment rates of all applicable services. All other applicable standard adjustments to the OPPS national unadjusted payment rates would apply, and OPPS outlier eligibility and outlier payment would be based on the reduced payment rates. Beneficiaries and secondary payers share in the reduced payment to hospitals that are subject to the payment reduction. CMS reports that for 2018 payment, 36 hospitals out of about 3,300 failed to meet the OQR Program requirements for a full update factor; half of these hospitals chose not to participate in the program.

Inpatient Quality Reporting Program Policies

CMS proposes a change to the Inpatient Quality Reporting Program in addition to those that were proposed as part of the FFY 2019 IPPS proposed rule issued in April 2018. Specifically, in this rule, CMS proposes to remove the three "communication about pain" questions from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) measure beginning with 2022 discharges (for FY 2024 payment).

The history of the HCAHPS pain questions is reviewed, including the replacement of the original pain management questions with the communication about pain questions now proposed for removal. The communication about pain questions were finalized for addition to the survey beginning with 2018 discharges (FFY 2020 payment). The first public reporting of these new questions is scheduled for October 2020 (data for 2019 discharges). Confidential preview reports on 2018 data are expected to be provided to hospitals as early as July 2019. The three communication about pain questions are:

HP1: "During this hospital stay, did you have any pain?"

☐ Yes

☐ No

HP2: "During this hospital stay, how often did hospital staff talk with you about how much pain you had?"

- ☐ Never
- ☐ Sometimes
- ☐ Usually
- ☐ Always

HP3: "During this hospital stay, how often did hospital staff talk with you about how to treat your pain?"

- ☐ Never
- ☐ Sometimes
- ☐ Usually
- ☐ Always

CMS proposes to remove these questions from the survey because it says that some stakeholders remain concerned that the revised questions could potentially impose pressure on hospital staff to prescribe more opioids in order to achieve higher scores on the HCAHPS survey. In addition, the President's Commission on Combating Drug Addiction and the Opioid Crisis recommended in its final report that CMS remove pain survey questions entirely on patient satisfaction surveys, so that providers are never incentivized for offering opioids to raise their survey score. In addition, the report recommended that the Department of Health and Human Services establish a policy to prevent hospital administrators from improperly using patient ratings from CMS surveys.

Although it is not aware of any scientific studies that support an association between scores on the communication about pain questions and opioid prescribing practices, CMS believes that is appropriate to remove the communication on pain questions out of an abundance of caution. **Under the proposal, the questions would be removed, effective with January 2022 discharges, for the FFY 2024 payment determination and subsequent years. The final public reporting of performance on these questions would be made in October 2022 for 2021 discharges. CMS would not change the scoring of the remaining 29 HCAHPS questions because of this proposal.**

CMS notes that it considered proposing earlier removal of the questions, but proposes January 2022 to allow sufficient time to make needed updates to the data collection tools — including the CMS data submission warehouse and related reporting tools — and to update the survey instrument itself. In addition, CMS believes the later data would allow time to assess the impact of using the questions while monitoring unintended consequences and empirical testing of how removal of these questions might affect responses on other survey items.

In addition to comments on the proposal to remove the questions, CMS seeks feedback on whether the communication about pain questions should be retained but with a further delay in public reporting. For example, public reporting could be delayed one year until October 2021. This would allow further time

for CMS to engage a broad range of stakeholders and to assess the impact of the new communication about pain questions.

Promoting Electronic Interoperability Request for Information

CMS discusses the status of adoption of health information technology among Medicare and Medicaid participating providers. It says that as of 2015, 96 percent of hospitals had adopted certified electronic health records (EHRs) with the capability to electronically export a summary of clinical care, yet significant obstacles to electronic exchange of health information remain. It reviews CMS and Office of National Coordinator (ONC) initiatives and regulatory activities aimed at advancing health information exchange. The January 2018 ONC draft Trusted Exchange Framework and Common Agreement (TEFCA) is highlighted.

CMS continues to solicit input from stakeholders on how it could use the Conditions of Participation (CoPs), Conditions for Coverage (CfCs) and Requirements for Participation (RfPs) for Long-Term Care Facilities to advance electronic exchange of health information in support of care transitions between hospitals and community providers. As an example, CMS says it might consider revising the hospital CoPs to require that hospitals electronically transfer medically necessary patient information to the other facility when a patient is transferred. Similarly, it might require that hospitals electronically send discharge information to a patient's community provider when possible, and to provide discharge instructions electronically to patients or a third-party application, if requested. The proposed rule request for information is nearly identical to that included in the fiscal year proposed rules.

Improving Beneficiary Access to Provider and Supplier Charge Information Request for Information

CMS repeats the comment solicitation that it included in the FFY 2019 IPPS/long-term care hospital PPS proposed rule (83 FR 20548 and 20549). In general, CMS encourages all providers and suppliers of health care services to undertake efforts to engage in consumer-friendly communication of their charges to help patients understand what their potential financial liability might be for services they obtain, and to enable patients to compare charges for similar services.

CMS is concerned that challenges continue to exist for patients due to insufficient price transparency, including patients being surprised by out-of-network bills that the beneficiary might consider to be a part of an episode of care involving a hospitalization but that are not services furnished by the hospital. CMS is further concerned that standard charges are not helpful to patients for determining what they are likely to pay for a particular service or facility encounter. To promote greater price transparency for patients, CMS is considering ways to improve the accessibility and usability of current charge information.

Competitive Acquisition Program for Part B Drugs Innovation Center Model Request for Information

CMS is seeking additional public feedback on a potential model design that would accelerate the move to a value-based health care system building on the Competitive Acquisition Program (CAP). Topics for comments include:

- Design features, such as the potential model's scope
- Which providers and suppliers should be included or excluded from the model
- Types of Medicare Part B drugs and biologicals that should be included or excluded
- The role of private-sector vendors in the model
- A defined population of beneficiaries to be addressed by the model
- Appropriate beneficiary protections
- Possible inclusion of other payers
- Options for model payments

CMS is also interested in how to best handle Medicare payment for the new high-cost therapies, and if a CAP-like model could be appropriate for these drugs and biologicals. Finally, CMS solicits comments on how a model could be structured to advance the goals of the President's *Blueprint to Lower Drug Prices* to increase competition, strengthen negotiation, and create incentives for lower list prices and lower out-of-pocket costs.

Appendix

Summary Table—OQR Measures for Payment Determination Years 2018-2021
(X= Adopted; *Proposals in Italics)*

NQF	Measure Title	2018	2019	2020	2021
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
0290	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention	X	X	X	X
0286*	OP-4: Aspirin at Arrival	X	X	Removed	
0289*	OP-5: Median Time to ECG	X	X	X	*Remove*
0514	OP-8: MRI Lumbar Spine for Low Back Pain	X	X	X	X
	OP-9: Mammography Follow-up Rates	X	X	X	*Remove*
	OP-10: Abdomen CT – Use of Contrast Material	X	X	X	X
0513	OP-11: Thorax CT – Use of Contrast Material	X	X	X	*Remove*
	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	*Remove*
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low-Risk Surgery	X	X	X	X
	OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)	X	X	X	*Remove*
0491*	OP-17: Tracking Clinical Results between Visits	X	X	X	*Remove*
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients	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
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
	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	*Remove*	
0658	OP-29: Appropriate Follow- up Interval for Normal Colonoscopy in Average Risk Patients	X	X	X	*Remove*
0659	OP-30: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use	X	X	X	*Remove*

1536	OP-31: Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	Voluntary			*Remove*
2539	Op-32: Facility Seven Day Risk Standardized Hospital Visit Rate After Outpatient Colonoscopy	X	X	X	X
1822	OP-33: External Beam Radiotherapy for Bone Metastases	X	X	X	X
	OP-35 Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy			X	X
2687	OP-36 Hospital Visits After Hospital Outpatient Surgery				Voluntary
	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