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Regulatory Update: CMS Proposed Rule – 2018 Policy and Rate Changes for Medicare Hospital Outpatient, Ambulatory Surgical Center Payment Systems

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Background & Summary

On Thursday, July 13, the Centers for Medicare & Medicaid Services (CMS) issued the annual proposed rule to update the 2018 Medicare payment and policies for the Hospital Outpatient Prospective Payment System (OPPS) and the Ambulatory Surgical Center (ASC) Payment System. The OPPS and ASC payment system are updated annually to include changes to payment policies, payment rates, and quality provisions for those Medicare patients who receive care at hospital outpatient departments or receive care at ambulatory surgical centers. Additionally, the proposed rule updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program and the ASC Quality Reporting (ASCQR) Program. This year's proposed rule also implements certain provisions under the 21st Century Cures Act.

CMS notes that this proposed rule is one of several for 2018 that reflect a broader strategy to relieve regulatory burdens for providers. As they did earlier this year in the inpatient prospective payment system (IPPS) proposed rule, the agency included a Request for Information (RFI) for continued feedback on "flexibilities and efficiencies in the Medicare program to support the patient-doctor relationship in health care and promote transparency, flexibility and innovation in the delivery of care."

Comments on the proposed rule and the RFI are due September 11.

OPPS Payment Update

After accounting for inflation and other adjustments required by law, the proposed rule would increase outpatient operating payment rates by 1.75 percent in calendar year (CY) 2018. The chart below details factors CMS includes in their estimate.

Proposed OPPS Payment Rate Update for CY 2018

Proposed Policy	Average Impact on Payments (Rate)
Estimated market-basket update for IPPS	2.9%
ACA productivity adjustment	- 0.4%
ACA market-basket cut	- 0.75%
Estimated payment rate update compared to CY 2017	**1.75%**

For CY 2018, CMS is proposing to increase the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 1.75 percent. This proposed increase factor is based on the proposed hospital inpatient market basket percentage increase of 2.9 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS – and recently finalized to 2.7 percent), minus the proposed multifactor productivity (MFP) adjustment of 0.4 percentage point, and minus a 0.75 percentage point adjustment required by the Affordable Care Act (ACA). Based on this proposed update, CMS estimates that "proposed total payments to OPPS providers (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix), for CY 2018 would be approximately $70 billion, an increase of approximately $5.7 billion compared to estimated CY 2017 OPPS payments." The combined policy changes proposed under the OPPS, including estimated spending for pass-through payments – and

not including the 340B drug payment proposal – will result in an estimated 2.0 percent payment increase for hospitals paid under the OPPS in CY 2018.

Hospitals that fail to meet the Hospital OQR Program reporting requirements are subject to an additional reduction of 2.0 percentage points. This statutorily required 2.0 percentage point reduction will be implemented by applying a proposed reporting factor of 0.980 to the OPPS payments and copayments for all applicable services.

Complexity Adjustment Proposals

CMS uses complexity adjustments to administer an increased payment for particular comprehensive services. The agency packages payment for add-on codes into the comprehensive Ambulatory Payment Classification (C-APC) payment rate. CMS lists the complexity adjustments proposed for "J1" and add-on code combinations for CY 2018, along with all of the other proposed complexity adjustments, in Addendum J to this proposed rule (available on the CMS website). CMS notes that providing the information contained in Addendum J allows stakeholders "the opportunity to better assess the impact associated with the proposed reassignment of claims with each of the paired code combinations eligible for a complexity adjustment."

Analysis of Comprehensive APC (C-APC) Packaging under the OPPS

In reviewing the cost statistics for the Healthcare Common Procedure Coding System (HCPCS) codes for procedures with status indicator "S", "T", or "V" in CY 2014 that were assigned to a C-APC in either CY 2015 or CY 2016, CMS saw an overall increase in claim line frequency, units billed, and Medicare payment. CMS states that this suggests that the C-APC payment policy did not adversely affect access or reduce payments to hospitals.

CMS notes that if they had found decreases in these cost statistics, it would suggest that the agency's comprehensive packaging logic is not working as intended, and/or the C-APC payment rates were inadequate – resulting in lower volume due to services moving to other settings or providers no longer offering these services. CMS found that the cost statistics of major separately payable codes (i.e., HCPCS codes with status indicator "S", "T", or "V") that were packaged into a C-APC prospectively were consistent with the cost statistics of the codes packaged on the claim in actuality – indicating that costs were appropriately redistributed. Thus, CMS concludes that the C-APC payment methodology is working as the agency anticipated.

Proposed Calculation of Composite APC Criteria-Based Costs

CMS developed composite APCs in CY 2008 to provide a "single payment for groups of services that are usually performed together during a single clinical encounter and result in the provision of a complete service." CMS asserts that combining payment for multiple, independent services into a single OPPS payment in this way "enables hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves." Under the OPPS, CMS currently has composite policies for low dose rate (LDR) prostate brachytherapy, mental health services, and multiple imaging services.

For CY 2018 and subsequent years, CMS is proposing to continue the composite APC payment policies for mental health services and multiple imaging services. CMS is proposing to assign Current Procedural Terminology (CPT) code 55875 (Transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy) a status indicator of "J1" and assign it to a C-APC. In conjunction with this proposal, CMS is also proposing to delete the low dose rate (LDR) prostate brachytherapy composite APC for CY 2018 and subsequent years. **CMS has an ongoing request for hospitals and other parties to submit recommendations for new codes to describe new brachytherapy sources**. Recommendations should be directed to the Division of Outpatient Care, Mail Stop C4-01-26, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244. CMS will add new brachytherapy source codes and descriptors to the agency's systems for payment on a quarterly basis.

Mental Health Services Composite APC Proposals

Last year, CMS finalized a policy to combine the existing Level 1 and Level 2 hospital-based Partial Hospitalization Program (PHP) APCs into a single hospital-based PHP APC. The agency discontinued APCs

5861 (Level 1 Partial Hospitalization (3 services) for Hospital-Based PHPs) and 5862 (Level 2 Partial Hospitalization (4 or more services) for Hospital-Based PHPs), and replaced them with new APC 5863 (Partial Hospitalization (3 or more services per day)).

CMS is proposing for CY 2018 and subsequent years that "when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services would be paid through composite APC 8010 (Mental Health Services Composite)." CMS is further proposing to set the payment rate for composite APC 8010 for CY 2018 at the same payment rate that the agency is proposing for APC 5863, and that hospitals continue to be paid the payment rate for composite APC 8010.

CMS considers the most resource-intensive of all outpatient mental health services to be partial hospitalization. The agency continues to maintain their longstanding policy that they should not pay more for mental health services under the OPPS than the highest partial hospitalization per diem payment rate for hospitals.

Packaging Policies and Proposals

The OPPS – like other prospective payment systems – is based on the "concept of averaging" to formulate a payment rate for services. The OPPS packages many related items and services into one payment to both encourage efficiency and provide flexibility.

CMS states: "Packaging also encourages hospitals to effectively negotiate with manufacturers and suppliers to reduce the purchase price of items and services or to explore alternative group purchasing arrangements, thereby encouraging the most economical health care delivery. Similarly, packaging encourages hospitals to establish protocols that ensure that necessary services are furnished, while scrutinizing the services ordered by practitioners to maximize the efficient use of hospital resources."

CMS has expanded OPPS packaging policies as the agency continues to develop larger payment groups that are more broad reflections of services provided in an encounter or episode of care. A major part of their efforts has been an ongoing examination of the payment for items and services provided under the OPPS to determine which services that can be packaged together. In this proposed rule, for CY 2018 CMS is proposing to conditionally package the costs of "selected newly identified ancillary services (detailed further below) into payment with a primary service where the proposed packaged item or service is integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by the primary service HCPCS code."

CY 2018 Drug Administration Packaging Proposal

In CY 2015 rulemaking, CMS implemented a conditional policy packaging payment for low-cost ancillary services (such as minor diagnostic tests and procedures associated with another, primary service) assigned to APCs with a mean cost of less than or equal to $100. However, hospitals do provide these services alone and without another primary service during an encounter. CMS assigns status indicator "Q1" to indicate that the "service is separately payable when not billed on the same claim as a HCPCS code assigned status indicator 'S', 'T', or 'V'". This packaging policy has some exclusions – including preventive services and low-cost drug administration services.

CMS observed drug administration billing patterns and payments under the OPPS in CY 2016, and found that APC 5691 (Level 1 Drug Administration) and APC 5692 (Level 2 Drug Administration) had geometric costs of less than or equal to $100 – and were often reported on the same claim with other separately payable services (e.g., ED or clinic visits). CMS indicates that excluding these low-cost drug administration services from packaging under the ancillary services policy is no longer necessary and, for CY 2018, proposes to conditionally package payment for low-cost drug administration services. Table 7 of the proposed rule contains the drug administration services included in APCs 5691 and 5692, as well as their proposed status indicators.

For CY 2018, CMS is not proposing to package any drug administration services in APC 5693 (Level 3 Drug Administration) or APC 5694 (Level 4 Drug Administration), but is seeking comments "pertaining to whether services in these APCs may be appropriate for packaging."

Comment Solicitation Regarding Unconditionally Packaging Drug Administration Add-on Codes

In the CY 2014 OPPS/ASC proposed rule, CMS finalized a policy to unconditionally package all drug administration services described by add-on codes. Many commenters, including providers, objected to packaging drug administration add-on codes – which typically describe each additional hour of infusion or each additional intravenous push, among others – in addition to the initial drug administration service. Stakeholders commented that this policy could "disadvantage providers of longer drug administration services, which are often protocol-driven and are not necessarily dictated by the hospital, but by the characteristics of the specific drug or biological being administered to the patient." In response, CMS did not finalize this policy – and said that additional study of the payment methodology was warranted for future consideration.

While CMS is not proposing to package drug administration add-on codes for CY 2018, they are requesting feedback on a payment methodology that "supports the principles of a prospective payment system, while insuring patient access to prolonged infusion services." CMS is seeking comment on whether conditionally or unconditionally packaging such codes would create access to care issues, or have other unintended consequences. **The agency is specifically requesting public comments on the following:**

1) Whether CMS should conditionally or unconditionally package drug administration services add-on codes;
2) How CMS should consider or incorporate the varied clinical drug protocols that result in different infusion times into a drug administration service add-on code payment proposal; and
3) Other recommendations on an encounter-based payment approach for drug administration services that are described by add-on codes when furnished in the hospital outpatient setting.

Analysis of Packaging of Pathology Services in the OPPS

At the August 2016 Advisory Panel on Hospital Outpatient Payment (HOP Panel) meeting, the Panel recommended that CMS develop a composite APC for pathology services when multiple pathology services are provided on a claim with no other payable services. For this proposed rule, CMS used CY 2016 claims data available and the agency's standard packaging methodology to model four hypothetical pathology composite APCs based on clinical scenarios – as specifically requested by a stakeholder at the August 2017 HOP Panel meeting. Additionally, the agency evaluated the volume of services and costs for each hypothetical composite. CMS states that the results from modeling the four composite scenarios show low claim volume, which indicates that the suggested pathology code combinations are not frequently billed by hospital outpatient departments – and therefore are not likely clinical scenarios.

Given the "infrequent occurrence of multiple pathology services on the same claim without a separately payable service, CMS does not believe a composite APC is necessary or warranted." Therefore, they are not proposing to create a pathology composite APC or additional composite APCs for stakeholder-requested services, such as X-ray services, respiratory services, cardiology services, or allergy testing services. CMS cites that as they move toward larger payment bundles under the OPPS, the necessity of composite APCs diminishes – and contends that composite APCs were a precursor to comprehensive APCs (C-APCs).

Comment Solicitation – Packaging of Items and Services under the OPPS

CMS asserts that packaging is an inherent principle of a prospective payment system. As the OPPS advances in the shift from separate fee schedule-like payments, CMS continues to hear concerns from stakeholders that their packaging policies may be limiting patient access to care or resulting in other "undesirable consequences."

Within the framework of existing packaging categories (e.g., drugs that function as supplies in a surgical procedure or diagnostic test or procedure**), CMS is seeking comment on "common clinical scenarios involving currently packaged HCPCS codes for which stakeholders believe packaged payment is not appropriate under the OPPS." CMS is also seeking comment on common clinical scenarios – outside the framework of existing packaging categories – involving separately payable HCPCS codes for which payment would be most appropriately packaged under OPPS.**

Proposed Care Management Coding Changes Effective January 1, 2018 (APCs 5821 and 5822)

As noted in the CY 2018 MPFS proposed rule, CMS is still interested in the "ongoing work of the medical community to refine the set of codes used to describe care management services, including chronic care management." For CY 2018, CMS is proposing to adopt CPT replacement codes for several of the care management services finalized last year. CMS refers readers to Addendum B for the proposed CY 2018 payment rates for the replacement codes. **The agency is also seeking comments on how they may further reduce burdens on providers, within the requirements of both CMS and CPT guidance.**

Variations Within APCs – Proposed OPPS Changes

Proposed New Technology APCs

There are currently 51 levels of New Technology APCs. For CY 2018, CMS is proposing to improve their ability to make payments for services more than $100,000 more closely matched to the actual cost of the service. Table 17 "Proposed CY 2018 Additional New Technology APC Groups" includes the complete list of the proposed modified and additional New Technology APC groups for CY 2018.

Proposed OPPS Payment Changes for Drugs, Biologicals, and Radiopharmaceuticals

For CY 2018, CMS is proposing to continue their payment policy that has been in effect since CY 2013, and pay for separately payable drugs and biologicals at Average Sales Price (ASP) ASP+6 percent (the statutory default). CMS believes that this payment rate does not need to be modified as it appropriately represents the acquisition and pharmacy overhead costs for drugs and biologics.

Alternative Payment Methodology for Drugs Purchased under the 340B Drug Discount Program

The Public Health Service Act by the Veterans Health Care Act of 1992 established the 340B Drug Discount Program. The 340B Drug Discount Program allows participating hospitals and other health care providers to purchase certain "covered outpatient drugs" at discounted prices from drug manufacturers, and is administered by the Health Resources and Services Administration (HRSA) within HHS. Per the statute, the intent of the program is to "maximize scarce Federal resources as much as possible, reaching more eligible patients, and providing care that is more comprehensive."

The ceiling price represents the maximum price a drug manufacturer can charge a covered entity for the drug. Covered entities have the option to participate in HRSA's Prime Vendor Program (PVP), under which the prime vendor (in some circumstances) can negotiate additional discounts (known as "subceiling prices") on certain covered outpatient drugs. According to CMS: "By the end of FY 2014, the PVP had nearly 7,000 products available to participating entities below the 340B ceiling price, including 3,557 covered outpatient drugs with an estimated average savings of 10 percent below the 340B ceiling price."

CMS cites a May 2015 MedPAC report[1] as "just one example of drug spending increases that is correlated with participation in the 340B program and calls into question whether Medicare's current payment policy for separately payable drugs at ASP+ 6 percent is appropriate in light of the discounted rates at which 340B hospitals acquire such drugs, especially because beneficiary cost-sharing for these drugs is based on the Medicare payment rate." CMS contends that it is timely to reexamine the "appropriateness" of the 340B program, due to the growth of the program in terms of provider participation as well as the increasing prices of several drugs that are reimbursed by Medicare Part B.

Additionally, CMS notes that MedPAC's March 2016 Report to Congress[2] recommended a (theoretical) legislative proposal, where Congress should direct the Secretary of HHS "to reduce Medicare payment rates for 340B hospitals' separately payable 340B drugs by 10 percent of the average sales price (ASP), and direct the program savings from reducing Part B drug payment rates to the Medicare-funded uncompensated care pool[3]."

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[1] The Medicare Payment Advisory Commission (MedPAC). *Report to the Congress – Overview of the 340B Drug Pricing Program*. May 2015.
[2] The Medicare Payment Advisory Commission (MedPAC). March 2016 Report to Congress.
[3] The Medicare Payment Advisory Commission (MedPAC). March 2016 Report to the Congress – Fact Sheet.

Proposed OPPS Payment Rate for 340B Purchased Drugs

CMS is proposing significant changes to their current Medicare Part B drug payment methodology for 340B hospitals so that, according to the agency, the payment rates will more closely match the actual resources and costs that hospitals incur. Because beneficiary cost-sharing is based on Part B payment rates, CMS believes that these changes will result in lower cost-sharing for 340B drugs. As such, CMS proposes to reduce payment for separately payable drugs (excluding drugs on pass-through status and vaccines that were acquired under the 340B program), "by 22.5 percent of ASP for all drugs for which a hospital does not append on the claim the modifier proposed."

CMS maintains that their proposal will allow eligible hospitals to "stretch scare resources while continuing to provide access to care." Any payment changes the agency finalizes would be limited to separately payable drugs under the OPPS, with the following exceptions: 1) drugs on pass-through status, which are required to be paid based on the ASP methodology and 2) vaccines, which are excluded from the 340B program.

CMS states that researchers and the agency have a limited ability to "precisely analyze differences in acquisition cost of 340B and non-340B-acquired drugs" due to claims data limitations. For that reason, they propose establishing a modifier – effective January 1, 2018 – for hospitals to report with separately payable drugs that were not acquired under the 340B program. The agency asserts that "because a significant portion of hospitals paid under the OPPS participate in the 340B program, [they] believe it is appropriate to presume that a separately payable drug reported on an OPPS claim was purchased under the 340B program, unless the hospital identifies that the drug was not purchased under the 340B program." CMS will provide further details regarding the proposed modifier in the CY 2018 OPPS/ASC final rule with comment period, and/or through subregulatory guidance – including guidance related to billing for dual-eligibles.

Additionally, CMS claims the agency has limited ability to "precisely calculate the price paid by 340B hospitals for a particular covered outpatient drug" due to the confidentiality of ceiling and subceiling prices. Thus, CMS is proposing to apply an "average discount of 22.5 percent of the average sales price for nonpass-through separately payable drugs purchased under the 340B program, as estimated by MedPAC[4]". CMS states that "in the near-term", the estimated average minimum discount calculated by MedPAC (22.5 percent of the ASP) is an adequate representation of the discount 340B participating hospitals receive for separately payable drugs under the OPPS. CMS suggests that the average discount is likely higher – and potentially significantly higher – than the average 22.5 percent found by MedPAC's analysis.

In summary, CMS is proposing to continue to pay for 340B drugs at ASP, and then to adjust that amount by applying a reduction of 22.5 percent to all separately payable drugs and biologicals, including Specified Covered Outpatient Drugs (SCODs) acquired under the 340B program (versus ASP + 6 percent, as is current law). This reduction would not apply to drugs on pass-through and vaccines.

In regard to using MedPAC's analysis, CMS is requesting comment on whether they should adopt a different payment rate to account for the average minimum discount of OPPS drugs purchased under the 340B drug discount program. Additionally, CMS is seeking comment on whether the proposal to pay ASP minus 22.5 percent for 340B purchased drugs should be phased in over time – "such as over a period of 2 to 3 years."

CMS is requesting comment on whether other types of drugs, such as blood clotting factors, should also be excluded from the reduced payment.

CMS is proposing to increase the overall 2018 OPPS conversion factor to account for the reduction of spending on 340B drugs – which would result in an estimated 1.4 percent increase to non-drug OPPS payment rates for CY 2018. **CMS is seeking comment on whether they should apply all or part of the savings resulting from the payment reduction to boost payments for specific services paid under the OPPS – or under Part B in general – in CY 2018, instead of just increasing the conversion factor. The agency is seeking specific feedback on "whether and how the offsetting increase could be targeted to hospitals that treat a large share of indigent patients, especially those patients who are uninsured." Additionally, CMS is seeking comment on whether the redistribution of savings**

[4] The Medicare Payment Advisory Commission (MedPAC). May 2015 Report to Congress.

associated with this proposal would result in "unnecessary growth in the volume of services paid for under the OPPS."

In this proposal, CMS is already considering longer-term refinements to the proposed 340B pricing policy. In addition to the comment areas discussed above, the agency is seeking specific feedback on the following:

- Ways to identify actual acquisition costs that each hospital incurs, instead of using an average minimum discounted rate that applies uniformly across all 340B hospitals (e.g., size, patient volume, labor market area and case-mix);
- Whether Medicare should require 340B hospitals to report their acquisition costs in addition to charges for each drug on the Medicare claim – noting that "having the acquisition cost on a drug-specific basis would enable [CMS] to pay a rate under the OPPS that is directly tied to the acquisition costs for each separately payable drug";
- How to address challenges with keeping the ceiling price confidential as required by statute, as acquisition costs for some drugs may equal the ceiling price;
- Whether exceptions should be granted to certain groups of hospitals due to access to care issues, such as those with special adjustments under the OPPS (e.g., rural sole-community hospitals or PPS-exempt cancer hospitals) – if a policy were adopted to adjust OPPS payments to 340B participating hospitals; and
- Whether hospital-owned or affiliated ASCs should have access to 340B discounted drugs.

Proposed Changes to the Inpatient Only (IPO) List

The complete proposed list of codes that would be paid by Medicare in CY 2018 as inpatient only procedures (the proposed IPO list) is included as Addendum E to the proposed rule. Procedures proposed to be removed from the IPO list for CY 2018 and subsequent years – including the HCPCS code, long descriptors, and the proposed CY 2018 payment indicators – are displayed in the table below.

Proposed Procedures to be Removed from the IPO List for CY 2018

CY 2018 CPT Code	CY 2018 Long Descriptor	Proposed CY 2018 OPPS APC Assignment	Proposed CY 2018 OPPS Status Indicator
27447	Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty)	5115	J1
55866	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed	5362	J1

CMS has established and utilizes five criteria as part of their methodology when reviewing procedures to determine whether or not they should be removed from the IPO list (note: a procedure is not required to meet all of the established criteria to be removed):

1) Most outpatient departments are equipped to provide the services to the Medicare population.
2) The simplest procedure described by the code may be performed in most outpatient departments.
3) The procedure is related to codes that [they] have already removed from the IPO list.
4) A determination is made that the procedure is being performed in numerous hospitals on an outpatient basis.
5) A determination is made that the procedure can be appropriately and safely performed in an ASC, and is on the list of approved ASC procedures or has been proposed by [CMS] for addition to the ASC list.

Total Knee Arthroplasty

CMS is proposing to remove total knee arthroplasty (TKA) from the inpatient-only list for CY 2018. The agency notes that they have taken into account both industry input as well as the recommendation from the summer 2016 Advisory Panel on Hospital Outpatient Payment (HOP Panel) meeting to remove the TKA procedure from the IPO list.

CMS asserts that the TKA procedure meets criteria for removal from the list – including criteria 1, 2, and 4. **The agency is seeking comment on general agreement (or disagreement) that these criteria are met, and/or whether the TKA procedure meets any of the other criteria. CMS is also seeking comment on whether the TKA procedure meets the criteria to be added to the list of ASC covered surgical procedures.** CMS continues to maintain that because these procedures usually "require more than 24 hours of active medical care following the procedure", they should continue to be excluded from the list of ASC covered surgical procedures.

If CMS finalizes their proposal to remove the TKA procedure from the IPO list, they would concurrently prohibit Recovery Audit Contractor (RAC) review for patient status for procedures performed in the inpatient setting for a period of two years (i.e., RAC denial of a hospital claim for patient status would be prohibited). CMS notes that contractor reviews for issues other than patient status as an inpatient or outpatient would continue to be permitted – including those for underlying medical necessity.

Level 2 Laparoscopy & Related Services

For CY 2018, CMS is also proposing to remove the procedure described by CPT code 55866 from the IPO list. After consulting with stakeholders and the agency's clinical advisors, the agency asserts that this procedure meets criteria 1 and 2 for removal from the list. **CMS is seeking comment on general agreement (or disagreement) that these criteria are met, and/or whether the procedure meets any of the other criteria.**

Comment Solicitation – Possible Removal of Partial Hip Arthroplasty (PHA) & Total Hip Arthroplasty (THA) Procedures from the IPO List

Partial hip arthroplasty (PHA), CPT code 27125 (Hemiarthroplasty, hip, partial (eg, femoral stem prosthesis, bipolar arthroplasty)), and total hip arthroplasty (THA) or total hip replacement, CPT code 27130 (Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft), have traditionally been considered inpatient surgical procedures.

CMS cites recent innovations have enabled surgeons to perform the PHA and THA procedures on an outpatient basis on non-Medicare patients (both in the HOPD and in the ASC). These innovations in PHA and THA care – based on feedback the agency has received – include "minimally invasive techniques, improved perioperative anesthesia, alternative postoperative pain management and expedited rehabilitation protocols." CMS notes however, that not all patients are candidates for minimally invasive PHA or THA.

CMS is seeking comments on whether they should remove the procedures described by CPT codes 27125 and 27130 from the IPO list from "all interested parties, including the following groups or individuals: Medicare beneficiaries and advocate associations for Medicare beneficiaries; orthopedic surgeons and physician specialty societies that represent orthopedic surgeons who perform PHA and/or THA procedures; hospitals and hospital trade associations; and any other interested stakeholders."

CMS is also specifically seeking comments on the following questions:

- Are most outpatient departments equipped to provide PHA and/or THA to some Medicare beneficiaries?
- Can the simplest procedure described by CPT codes 27125 and 27130 be performed in most outpatient departments?
- Are the procedures described by CPT codes 27125 and 27130 sufficiently related to or similar to other procedures [they] have already removed from the IPO list?
- How often is the procedure described by CPT codes 27125 and 27130 being performed on an outpatient basis (either in an HOPD or ASC) on non-Medicare patients?

- Would it be clinically appropriate for some Medicare beneficiaries in consultation with his or her surgeon and other members of the medical team to have the option of either a PHA or THA procedure as a hospital outpatient, which may or may not include a 24-hour period of recovery in the hospital after the operation?

Additionally, CMS is seeking comments on whether the PHA and THA procedures meet the criteria to be added to the ASC Covered Procedures List. CMS continues to maintain that because these procedures usually "require more than 24 hours of active medical care following the procedure, they should continue to be excluded from the list of ASC covered surgical procedures."

Potential Revisions to the Laboratory Date of Service (DOS) Policy

The date of service (DOS) is a required data field on all Medicare claims for laboratory services. However, a laboratory service may take place over a period of time. For example – the date the physician orders the laboratory test, the date the specimen is collected from the patient, the date the laboratory accesses the specimen, the date the laboratory performs the test, and the date results are produced – each might take place on different dates.

The current DOS requirements are used to determine whether a hospital bills Medicare for a clinical diagnostic laboratory test (CDLT) or whether the laboratory performing the test bills Medicare directly. This is because separate regulations dictate when the hospital, as opposed to the laboratory, are responsible for billing Medicare. These regulations, which are called 'under arrangements' provisions, require that if the DOS occurs during an inpatient or outpatient stay, payment for the laboratory test is bundled with the hospital service.

Under current policy, "certain clinical diagnostic laboratory tests (CDLTs) that are listed on the Clinical Laboratory Fee Schedule (CLFS) are packaged as integral, ancillary, supportive, dependent, or adjunctive to the primary service or services provided in the hospital outpatient setting during the same outpatient encounter and billed on the same claim." CMS conditionally packages most CDLTs and only pays separately for a laboratory test when it is 1) the only service provided to a beneficiary on a claim; 2) considered a preventive service; 3) a molecular pathology test; or 4) an advanced diagnostic laboratory test (ADLT). CMS notes that the current laboratory DOS rule "may impose administrative difficulties for hospitals and laboratories that furnish laboratory tests that are excluded from OPPS packaging and therefore paid separately at CLFS payment rates."

CMS states that they have recently heard about operational issues the current laboratory DOS policy creates for hospitals and laboratories specifically with regard to molecular pathology tests and laboratory tests they expect will be designated by CMS as advanced diagnostic laboratory tests (ADLTs). These "certain laboratory stakeholders" have communicated that although these particular tests are not packaged under the OPPS, under current DOS policy, "if the tests are ordered within 14 days of a patient's discharge from the hospital, Medicare still treats the tests as though they were ordered and furnished by the hospital itself. Under those circumstances, laboratories cannot directly seek Medicare payment for the molecular pathology test or ADLT; the hospital must bill Medicare for the test, and the laboratory must seek payment from the hospital." The proposed rule outlines some of the specific concerns raised by stakeholders representing laboratories. In light of the concerns raised by stakeholders, CMS is considering modifying the DOS policy to allow laboratories to bill Medicare directly for some tests that have been excluded from the OPPS packaging policy.

In this proposed rule, CMS outlines one approach they are considering – creating a new exception to the DOS policy for molecular pathology tests and ADLTs that have been granted ADLT status by CMS. As CMS stated in the CY 2017 OPPS/ASC rulemaking, these tests may have a different pattern of clinical use than more conventional laboratory tests – which may make them less tied to a primary service in the hospital outpatient setting than more common and routine laboratory tests that are packaged. **CMS is seeking comment on whether these tests can be appropriately separated from a hospital stay and thus have a DOS that is a date of performance, versus a date of collection.**

Furthermore, CMS is also seeking comment on alternative approaches to addressing stakeholders' concerns regarding the DOS policy, such as potentially modifying the "under arrangements" provisions and/or whether exceptions should be added – and if so, how they should be framed. CMS specifically states that feedback

on these topics will help inform the agency regarding potential refinements to their DOS policy. **CMS states that they are "especially interested in comments regarding how the current DOS policy and 'under arrangements' provisions may affect access to care for Medicare beneficiaries" –** and the agency will consider finalizing the modifications described based on comments and feedback provided.

Proposed OPPS Payment for Hospital Outpatient Visits and Critical Care Services

For CY 2018, CMS is proposing to continue with and not make any changes to current clinic and emergency department (ED) hospital outpatient visits payment policies. Likewise, CMS is proposing to continue with and not make any changes to current payment policy for critical care services.

Proposed Payment for Partial Hospitalization Services – Proposed PHP APC Update for CY 2018

A partial hospitalization program (PHP) is an intensive outpatient program of psychiatric services, provided as an alternative to inpatient psychiatric care for "individuals who have an acute mental illness, which includes, but is not limited to, conditions such as depression, schizophrenia, and substance use disorders." For CY 2018, CMS is proposing to continue to apply previously established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims and cost data for each provider type.

CY 2018 Proposed PHP APC Geometric Mean Per Diem Costs

CY 2018 APC	Group Title	Proposed PHP APC Geometric Mean Per Diem Costs
5853	Partial Hospitalization (3 or more services per day) for CMHCs	$128.81
5863	Partial Hospitalization (3 or more services per day) for hospital-based PHPs	$213.60

With the CY 2017 implementation of APC 5853 and APC 5863 for providing 3 or more PHP services per day, CMS is continuing to monitor utilization of days with only 3 PHP services. CMS notes that the agency is aware the "single-tier payment policy may influence a change in service provision because providers are able to obtain payment that is heavily weighted to the cost of providing 4 or more services when they provide only 3 services."

Additionally, CMS is seeking comment on "the advisability of applying a payment requirement conditioned on a beneficiary's receipt of a minimum of 20 hours of therapeutic services per week", as well as comments addressing the need for exceptions to such a policy. CMS specifically wants to "know and understand the type of occurrences or circumstances that would cause a PHP patient to not receive at least 20 hours of PHP services per week, particularly where payment would still be appropriate."

Rural Adjustment Proposals

For CY 2018, CMS is proposing to maintain the current rural adjustment policy; thus, the proposed budget neutrality factor for the rural adjustment would be 1.0000. CMS is proposing to continue the adjustment of 7.1 percent to the OPPS payments to certain rural sole community hospitals (SCHs), including essential access community hospitals (EACHs). This proposed adjustment would apply to "all services paid under the OPPS, excluding separately payable drugs and biologicals, devices paid under the pass-through payment policy, and items paid at charges reduced to cost."

Cancer Hospital Payment Adjustment Proposals

Since the inception of the OPPS, Medicare has paid the 11 hospitals that meet the criteria for cancer hospitals an enhanced rate under the OPPS for covered outpatient hospital services. For CY 2018, CMS is proposing to continue to provide additional payments to cancer hospitals so that the cancer hospital's

payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals using the most recently submitted or settled cost report data.

CMS is proposing to continue to provide additional payments to the 11 specified cancer hospitals so that each cancer hospital's final PCR is equal to the weighted average PCR (or "target PCR") for the other OPPS hospitals. The agency is using the most recent submitted or settled cost report data that is available at the time of the development of the proposed rule, reduced by 1.0 percentage point to comply with section 16002(b) of the 21st Century Cures Act. Section 16002(b) requires this weighted average PCR be reduced by 1.0 percentage point. Based on the data and the required 1.0 percentage point reduction, a proposed target PCR of 0.89 would be used to determine the CY 2018 cancer hospital payment adjustment to be paid at cost report settlement.

The actual amount of the CY 2018 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement, and will depend on each hospital's CY 2018 payments and costs. Table 11 (on page 158 of the proposed rule) indicates the proposed estimated percentage increase in OPPS payments to each cancer hospital for CY 2018 due to the 21st Century Cures Act's cancer hospital payment adjustment policy.

Supervision of Outpatient Therapeutic Services in CAHs & Small Rural Hospitals

In prior rulemaking, CMS clarified that hospital outpatient therapeutic services paid by Medicare and furnished in hospitals, critical access hospitals (CAHs), and provider-based departments (PBDs) of hospitals required direct supervision. However, Congress has taken multiple legislative actions to extend nonenforcement (moratoriums) of the direct supervision of hospital outpatient therapeutic services in CAHs and small rural hospitals having 100 or fewer beds since December 31, 2013. The latest legislative action extended nonenforcement until December 31, 2016. CMS is proposing to reinstate the nonenforcement of direct supervision enforcement instruction for outpatient therapeutic services for CAHs and small rural hospitals having 100 or fewer beds for CY 2018 and 2019. CMS notes that this will "give CAHs and small rural hospitals having 100 or fewer beds more time to comply with the supervision requirements for outpatient therapeutic services, and to give all parties time to submit specific services to be evaluated by the Advisory Panel on Hospital Outpatient Payment for a recommended change in the supervision level." **The agency welcomes comments on this proposal.**

Hospital Outpatient Quality Reporting (OQR) Program Proposals

CMS has implemented quality reporting programs for multiple care settings – including for hospital outpatient care – the Hospital Outpatient Quality Reporting (OQR) Program. CMS notes that the Hospital OQR Program is aligned with that of hospital inpatient services, the Hospital Inpatient Quality Reporting Program, or IQR Program.

As previously mentioned, hospitals that fail to meet the reporting requirements of the Hospital Outpatient Quality Reporting (OQR) Program would continue to be subject to a further reduction of 2.0 percentage points to the OPD fee schedule increase factor. CMS is proposing to continue their established policy of "applying the reduction of the OPD fee schedule increase factor through the use of a reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for the full CY 2018 annual payment update factor." For the CY 2018 OPPS, the proposed reporting ratio is 0.980, calculated by dividing the proposed reduced conversion factor of 74.953 by the proposed full conversion factor of 76.483. CMS is proposing to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor.

For the Hospital OQR Program, CMS is proposing to remove and delay certain measures for the CY 2020 and CY 2021 (and subsequent years) payment determination. CMS is not proposing any new measures for the Hospital OQR Program in this rulemaking. Additionally, CMS "does not expect the proposed CY 2018 policies to significantly affect the number of hospitals that do not receive a full annual payment update."

Hospital OQR Program Quality Measures – Accounting for Social Risk Factors

CMS notes that "social risk factors such as income, education, race and ethnicity, employment, disability, community resources, and social support (certain factors of which are also sometimes referred to as socioeconomic status (SES) factors or socio-demographic status (SDS) factors) play a major role in health."

The agency continues to consider the analyses and recommendations from multiple reports and is awaiting the results of the National Quality Forum's (NQF) trial on risk adjustment for quality measures; when NQF issues its recommendations, CMS will analyze the findings closely. Simultaneously, the agency is considering options on how to address the issue of measuring and accounting for social risk factors in CMS' value-based purchasing and quality reporting programs. In the FY 2018 IPPS Proposed Rule, CMS requested stakeholder feedback on how best to factor SES/SDS adjustment into the Value-Based Purchasing (VBP), Hospital-Acquired Condition (HAC), and Inpatient Quality Reporting (IQR) programs – and all quality programs.

Likewise, in this proposed rule, CMS is seeking comment on whether they should account for social risk factors in the Hospital OQR Program, and if so, what method or combination of methods would be most appropriate. The agency cites some examples of methods, including:

- Confidential reporting to providers of measure rates stratified by social risk factors;
- Public reporting of stratified measure rates; and
- Potential risk adjustment of a particular measure as appropriate based on data and evidence.

CMS is seeking comment on which social risk factors might be most appropriate for reporting stratified measure scores and/or potential risk adjustment of a particular measure. Additionally, they are seeking comments on which social risk factors – including the data sources where information may be available – could be used alone or with others, and whether additional/different data should be collected to better determine the effects of social risk.

The agency states that they look forward to continued work with stakeholders as they consider the issue of accounting for social risk factors and reducing health disparities in CMS programs. Of note, implementing any method or methods would be taken into consideration in the context of how it and other CMS programs operate (for example, data submission methods, availability of data, statistical considerations relating to reliability of data calculations, among others); thus, **CMS is seeking comment on operational considerations.** It is likely that we will continue to see SES/SDS adjustments develop in Medicare's pay-for-performance and quality reporting programs in the future.

Quality Measures Proposed for Removal from the Hospital OQR Program

CMS is proposing to remove a total of six quality measures from the Hospital OQR Program, with the intent of alleviating costs and burden on hospitals. **CMS invites comment on each of the proposals to remove these measures.**

For the CY 2020 payment determination (CY 2018 reporting) and subsequent years, CMS is proposing to remove:

- OP-21: Median Time to Pain Management for Long Bone Fracture; and
- OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures.

For the CY 2021 payment determination (CY 2019 reporting) and subsequent years, CMS is proposing to remove:

- OP-1: Median Time to Fibrinolysis;
- OP-4: Aspirin at Arrival;
- OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional; and,
- OP-25: Safe Surgery Checklist Use.

Proposal to Delay OAS CAHPS Survey-Based Measures

Beginning with the CY 2020 payment determination (CY 2018 reporting), CMS is proposing to delay the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems Survey (OAS CAHPS) Survey measures (OP-37-a-e). In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79771 - 79784), CMS adopted OP-37a-e and finalized data collection and data submission timelines. Since adoption of these measures, the agency has recognized that they lack important operational and implementation data.

National implementation of the survey began in January 2016 and will conclude in December 2017 – which CMS maintains will provide valuable information moving forward. The agency will conduct analyses of the national implementation data to "undertake any necessary modifications to the survey tool and/or CMS systems." The agency states that it is important to allow time for any modifications before requiring the survey under the Hospital OQR Program – therefore, the OAS CAHPS Survey-based measures are delayed until future rulemaking.

Additionally, CMS will continue to evaluate the utility of individual questions as they collect new data from the survey's voluntary national implementation, and will consider different options for shortening the OAS CAHPS Survey without the loss of important data in the future. Specifically, the agency continues to consider the removal of two demographic questions—the ''gender'' and ''age'' questions—from the OAS CAHPS Survey in a future update.

Hospital OQR Program Measures and Topics for Future Consideration

In this proposed rule, CMS is seeking comment on: 1) future measure topics; and 2) future development of OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival as an electronic clinical quality measure (eCQM). Through future rulemaking, CMS intends to propose new measures for the Hospital OQR Program while aligning quality measures across Medicare.

CMS is seeking comments on possible measure topics for future consideration in the Hospital OQR Program – and is specifically seeking comment on any outcome measures that would be useful to add to the Hospital OQR Program as well as any clinical process measures that should be eliminated from the Hospital OQR Program.

Additionally, CMS is considering developing OP-2: Fibrinolytic Therapy Received Within 30 Minutes of Emergency Department Arrival[5] as an eCQM, and proposing the eCQM in future rulemaking. CMS notes that since OP-2 is not yet developed as an eCQM, electronic measure specifications are not available at this time. CMS is considering OP-2 in particular because the agency "believes it is the most feasible out of all the existing Hospital OQR Program measures." **Thus, CMS is seeking comment on the possible future development and future adoption of an eCQM version of OP-2.**

Public Reporting of OP-18c: Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients - Psychiatric/Mental Health Patients

In the CY 2011 OPPS/ASC final rule with comment period, OP-18 was finalized for reporting for the CY 2013 payment determination and subsequent years. This measure "addresses ED efficiency in the form of the median time from ED arrival to time of departure from the ED for patients discharged from the ED (also known as ED throughput)." OP-18 measure data is stratified into four separate calculations: 1) OP-18a is defined as the overall rate; 2) OP-18b is defined as the reporting measure; 3) OP-18c is defined as assessing Psychiatric/Mental Health Patients; and 4) OP-18d is defined as assessing Transfer Patients.

Currently, and as detailed in the OP-18 Measure Information Form (MIF)[6], the OP-18 measure publicly reports data only for the calculations designated as OP-18b: Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients - Reporting Measure, which excludes psychiatric/mental health patients and transfer patients.

The ICD-10 diagnostic codes for OP-18c include numerous substance abuse codes for inclusion in this subset, along with numerous non-substance abuse codes. CMS asserts that "it is important to publicly report data for OP-18c (Median Time from Emergency Department Arrival to Emergency Department Departure for

[5] eCQI Resource Center: https://ecqi.healthit.gov/eh/ecqms-2016-reporting-period/fibrinolytic-therapyreceived-within-30-minutes-hospital-arrival.

[6] Hospital OQR Program ED Throughput Measures Information Form: http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FSpecsManualTemplate&cid=1228775748170.

Discharged Emergency Department Patients- Psychiatric/Mental Health Patients) to address a behavioral health gap in the publicly reported Hospital OQR Program measure set."

Thus, CMS is proposing to also publicly report OP-18c – and begin public reporting as early as July of 2018 using data from patient encounters during the third quarter of 2017. Additionally, CMS would make corresponding updates to the MIF to reflect these proposals. The agency notes that administrative changes made to the MIF would not affect hospital reporting requirements or create additional burden; the data required for public reporting are already collected and submitted by participating outpatient hospital departments. In accordance with previously established 30-day preview period procedures, hospitals would be able to preview this data.

In developing this proposal, CMS also considered an alternative date to begin publicly reporting – around July 2019 (not 2018 as proposed) using data from patient encounters occurring during the first quarter of 2018. CMS decided against this timeline because the agency would not be able to publicly report behavioral health data until as early as July of 2019 – creating a further delay in efforts to address the behavioral health data gap. **The agency is seeking comment on their proposal to publicly report OP-18c beginning with third quarter 2017 data.**

Proposed Changes to the Notice of Participation (NOP) Submission Deadline

CMS is proposing to change the Hospital OQR Notice of Participation (NOP) submission deadlines such that hospitals are required to submit the NOP Form any time prior to registering on the QualityNet website – rather than by the previously codified deadlines. Registration with the QualityNet website is necessary to submit data, and CMS maintains that "extending the NOP submission deadline will better enable hospitals to meet the Hospital OQR Program participation requirements." **CMS is seeking comment on this proposal.**

Form, Manner, and Timing of Data Submitted for the Hospital OQR Program

The previously finalized deadlines for the CY 2020 payment determination and subsequent years are illustrated in the following table. CMS is not proposing changes to these data submission deadlines for each quarter.

CY 2020 Payment Determination and Subsequent Years

Patient Encounter Quarter	Clinical Data Submission Deadline
Q2 2018 (April 1 – June 30)	November 1, 2018
Q3 2018 (July 1 – September 30)	February 1, 2019
Q4 2018 (October 1 – December 31)	May 1, 2019
Q1 2019 (January 1 – March 31)	August 1, 2019

For the CY 2020 payment determination and subsequent years, CMS is proposing to revise the data submission requirements for hospitals that did not participate in the previous year's Hospital OQR Program. The agency is proposing to revise the first quarter for which newly participating hospitals are required to submit data.

Specifically, the agency is proposing that any hospital that did not participate in the previous year's Hospital OQR Program "must submit data beginning with encounters occurring during the first calendar quarter of the year prior to the affected annual payment update." **CMS is seeking comment on their proposals to align the initial data submission timeline for all hospitals that did not participate in the previous year's Hospital OQR Program.**

Requirements for Chart-Abstracted Measures Where Patient-Level Data Are Submitted Directly to CMS for the CY 2021 Payment Determination & Subsequent Years

In this proposed rule, the agency is not proposing any changes to policies regarding the submission of chart abstracted measure data where patient-level data are submitted directly to CMS. However, if their proposals to remove six quality measures from the Hospital OQR Program are finalized, the following previously

finalized Hospital OQR Program chart-abstracted measures will require patient-level data to be submitted for the CY 2021 payment determination and subsequent years:

- OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival (NQF #0288);
- OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention (NQF #0290);
- OP-5: Median Time to ECG (NQF #0289);
- OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF #0496);and
- OP-23: Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke Patients who Received Head CT Scan Interpretation Within 45 Minutes of ED Arrival (NQF #0661).

Claims-Based Measure Data Requirements for the CY 2020 Payment Determination & Subsequent Years

In this proposed rule, the agency is not proposing any changes to claims-based measures submission policies for the CY 2020 payment determination and subsequent years. There are a total of nine claims-based measures for the CY 2020 payment determination and subsequent years:

- OP-8: MRI Lumbar Spine for Low Back Pain (NQF #0514);
- OP-9: Mammography Follow-Up Rates;
- OP-10: Abdomen CT – Use of Contrast Material;
- OP-11: Thorax CT – Use of Contrast Material (NQF #0513);
- OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low Risk Surgery (NQF #0669);
- OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT);
- OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (NQF #2539);
- OP-35: Admissions and Emergency Department Visits for Patients Receiving Outpatient Chemotherapy; and
- OP-36: Hospital Visits after Hospital Outpatient Surgery (NQF #2687).

Hospital OQR Program Validation Requirements for Chart-Abstracted Measure Data Submitted Directly to CMS for the CY 2020 Payment Determination & Subsequent Years

For the CY 2018 payment determination and subsequent years, validation is based on four quarters of data: validation quarter 1 (January 1 – March 31); validation quarter 2 (April 1 – June 30); validation quarter 3 (July 1 – September 30); and validation quarter 4 (October 1 – December 31).

CMS is proposing to clarify the hospital selection process for validation and codify the procedures for targeting hospitals. In the CY 2012 OPPS/ASC final rule with comment period (76 FR 74485), CMS finalized a validation selection process in which the agency selects a random sample of 450 hospitals for validation purposes, and selects an additional 50 hospitals based on the following specific criteria:

- Hospital fails the validation requirement that applies to the previous year's payment determination; or
- Hospital has an outlier value for a measure based on the data it submits. CMS defined an "outlier value" for purposes of this targeting as a measure value that appears to deviate markedly from the measure values for other hospitals. "CMS would select hospitals for validation if their measure value for a measure is greater than 5 standard deviations from the mean, placing the expected occurrence of such a value outside of this range at 1 in 1,744,278."

The criteria for targeting 50 outlier hospitals, described above, does not specify whether high or low performing hospitals will be targeted. In this proposed rule, CMS is clarifying that hospitals "with outlier values indicating specifically poor scores on a measure (for example, a long median time to fibrinolysis) will be targeted for validation" (i.e., an "outlier value" is a measure value that is greater than 5 standard deviations from the mean of the measure values for other hospitals, and indicates a poor score).

Proposed Formalization & Modifications to the Educational Review Process for Chart-Abstracted Measures Validation

CMS is proposing to formalize and update the agency's processes for educational review on the QualityNet website. In an effort to streamline this process, CMS is proposing to change it from informal to formal, and

specify that if the results of an educational review indicate that the agency "incorrectly scored a hospital's medical records selected for validation, the corrected quarterly validation score would be used to compute the hospital's final validation score at the end of the calendar year."

In order to determine whether a quarterly validation score was correct, CMS is proposing to use a similar process as one previously finalized for reconsideration requests. During an educational review request, evaluating a validation score would consist of and be limited to reviewing data elements that were labeled as mismatched in the original validation results. CMS would also take into consideration written justifications provided by hospitals in the Educational Review request.

For the CY 2020 payment determination and subsequent years, CMS is further proposing that "if an educational review requested for any of the first 3 quarters of validation yields incorrect CMS validation results for chart-abstracted measures, the agency would use the corrected quarterly score, as recalculated during the educational review process, to compute the final confidence interval (CI) at the end of the calendar year." CMS needs to calculate the confidence interval in a timely manner, and given the insufficient time available to conduct educational reviews prior to the annual payment update – the agency notes the validation score review and correction would not be available for the last quarter of validation. Instead, the existing reconsideration process would be used to dispute any unsatisfactory validation result.

The corrected scores would be applicable to the corresponding quarter, for the first 3 quarters of validation, for which a request was submitted. If results show that there was indeed an error in the originally calculated score, CMS would take steps to correct it. To prevent dissuading participation in the educational review process, corrected scores identified would only be used to recalculate the CI if they indicate that the hospital performed more favorably than previously determined. If the hospital performed less favorably, their score would not be updated to reflect the less favorable score.

CMS notes that the quarterly validation reports issued to hospitals would not be updated to reflect the corrected score due to the burden associated with reissuing corrected reports; however, the corrected score would be communicated to the hospital via secure file format. **CMS is seeking comment on their proposal to use corrected quarterly scores as recalculated during the educational review process described above, and to compute the final confidence interval for the first 3 quarters of validation.**

CMS is proposing to formalize this educational review process, for the CY 2020 payment determination and subsequent years – in other words, starting for validations of CY 2018 data affecting the CY 2020 payment determination and subsequent years.

ASC Payment Update

For CY 2018, CMS is proposing to increase payment rates under the ASC payment system by 1.9 percent for ASCs that meet the quality reporting requirements under the ASC Quality Reporting (ASCQR) Program. CMS is proposing to reduce the Consumer Price Index for All Urban Consumers (CPI-U) update of 2.3 percent by 2.0 percentage points for ASCs that do not meet the quality reporting requirements, and then apply the 0.4 percentage point multifactor productivity (MFP) adjustment. Thus, CMS would apply a -0.1 percent MFP-adjusted CPI-U update factor to the CY 2017 ASC conversion factor for ASCs not meeting the quality reporting requirements.

Proposed ASC Payment Rate Update for CY 2018

Proposed Policy	Average Impact on Payments (Rate)
Projected CPI-U Update	2.3%
Multifactor productivity adjustment	- 0.4%
Estimated payment rate update compared to CY 2017	**1.9%**

Based on this proposed update, CMS estimates that proposed total payments to ASCs (including beneficiary cost sharing and estimated changes in enrollment, utilization, and case-mix), for CY 2018 would be approximately $4.68 billion, approximately $155 million more than estimated CY 2017 Medicare payments.

Additionally, CMS is proposing that if more recent data are subsequently available (e.g., a more recent estimate of the CY 2018 CPI-U update and MFP adjustment), the agency would use such data, if appropriate, to determine the CY 2018 ASC update for the final rule with comment period.

For impact purposes, the surgical procedures on the ASC list of covered procedures are aggregated into surgical specialty groups using Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) code range definitions. "The proposed percentage change in estimated total payments by specialty groups under the proposed CY 2018 payment rates, compared to estimated CY 2017 payment rates ranges between 5 percent for integumentary system procedures and 1 percent for genitourinary system procedures."

Comment Solicitation on ASC Payment Reform

An annual review of the ASC payment system is conducted by the Medicare Payment Advisory Commission (MedPAC), and the Commission submits its findings and recommendations in a report to Congress. In this year's report[7], MedPAC recommended that Congress require ASCs to report cost data "to enable the Commission to examine the growth of ASCs' costs over time and analyze Medicare payments relative to the costs of efficient providers, which would help inform decisions about the ASC update". Additionally, while MedPAC is concerned that the Consumer Price Index for All Urban Consumers (CPI-U) may not reflect ASCs' cost structure, until cost information is available from ASCs – MedPAC cannot determine whether an alternative update factor would be more appropriate[6].

CMS is "broadly interested in feedback, including recommendations and ideas for ASC payment system reform." The agency acknowledges that ASCs are a critically important access point to patients who may be too ill or have the need for too complicated a procedure to be treated in the physician office setting, but for whom hospital care is "either not medically necessary or undesirable." The current ASC payment system was implemented in 2008 and no major revisions have been made since. Relative to OPPS payment rates, average ASC payment rates have declined over the past 10 years – from 65 to 56 percent of average OPPS rates in CY 2008 and 2018, respectively. However, without ASC-specific cost data, the agency cannot fully ascertain whether payment rates are truly in line with costs, and what, if any, impact on access to care these payment rates may have.

CMS is seeking comment on payment reform for ASCs, including an alternative method of collecting cost data – which may be more supportive CPI-U. CMS is also interested in data from ASCs that would help determine whether the ASC payment should be updated by an alternative update factor (e.g., the hospital market basket, the Medicare Economic Index, a blend of update factors, or other mechanism). The agency notes that the hospital market basket update is typically higher than the CPI-U, while the Medicare Economic Index is typically lower – because the rate update is not applied in a budget neutral manner, applying a higher update factor would be a cost to the Medicare program while applying a lower update factor would result in savings to the Medicare program.

CMS is also seeking comment – including qualitative and quantitative data from ASCs – regarding ASC costs for items such as supplies, drugs, employee compensation, rent and other inputs as compared to those of hospitals or physician offices.

Additionally, the agency is broadly interested in feedback regarding potential reforms to the current payment system, including, but not limited to:

1) The rate update factor applied to ASC payments;
2) Whether and how ASCs should submit data relating to costs;
3) Whether ASCs should bill on the institutional claim form rather than the professional claim form; and
4) Other ideas to improve payment accuracy for ASCs.

[7] MedPAC. March 2017 Report to Congress. Chapter 5 "Ambulatory Surgical Center Services". http://www.medpac.gov/docs/default-source/reports/mar17_medpac_ch5.pdf?sfvrsn=0

With respect to the ability to adopt payment policies that exist under the OPPS into the ASC payment system, due to differences in the systems used to process claims for hospitals and ASCs, CMS is not able to implement certain OPPS payment policies in the ASC payment system – such as comprehensive APCs, conditional packaging, and the "FD" value modifier for device credits (79 FR 66923). **CMS is seeking comment on "whether billing on an institutional claim form (as hospitals do) rather than a professional claim form would address some of the issues affecting ASC payment reform."**

Proposed Updates to the Ambulatory Surgical Center (ASC) Payment System

In CMS's annual updates to the ASC list of, and payment rates for, covered surgical procedures and covered ancillary services, the agency undertakes a review of excluded surgical procedures, new codes, and codes with revised descriptors. CMS identifies any that meet the criteria for designation as ASC covered surgical procedures or covered ancillary services and updates the lists and payment rates of ASC covered surgical procedures and covered ancillary services. The agency updates the ASC payment system in association with the annual OPPS rulemaking cycle because the OPPS relative payment weights and, in some cases, payment rates, are used as the basis for the payment of many covered surgical procedures and covered ancillary services under the revised ASC payment system.

Display of CY 2018 ASC Payment Rates

For CY 2018, CMS is proposing to update the ASC payment rates and to make changes to ASC payment indicators as necessary to maintain consistency between the OPPS and ASC payment system. Addenda AA and BB to this proposed rule (available on the CMS website) display the proposed updated ASC payment rates for CY 2018 for covered surgical procedures and covered ancillary services, respectively. Addendum EE provides the HCPCS codes and short descriptors for surgical procedures that are proposed to be excluded from payment in ASCs for CY 2018. **CMS is seeking comments on these proposals**.

Definition of ASC Covered Surgical Procedures – Proposals & Comment Solicitation

CMS has heard from stakeholders that certain procedures that are outside the CPT surgical range should be ASC covered surgical procedures. These procedures are similar to surgical procedures currently covered in an ASC setting. CMS continues to believe that using the CPT code range to define surgery "represents a logical, appropriate, and straightforward approach to defining a surgical procedure" and the agency notes that it may be appropriate to use the CPT surgical range as a guide rather than a requirement as to whether a procedure is surgical. This would give CMS more flexibility to include "surgery-like" procedures on the ASC Covered Procedures List (CPL).

CMS is seeking comments regarding services that are "described by Category I CPT codes outside of the surgical range, or Level II HCPCS codes or Category III CPT codes that do not directly crosswalk and are not clinically similar to procedures in the CPT surgical range, but that nonetheless may be appropriate to include as covered surgical procedures payable when furnished in the ASC setting."

CMS is particularly interested in commenters' views regarding additional criteria they might use to consider when a procedure that is surgery-like could be included on the ASC CPL. CMS requests that commenters on this issue take into consideration whether each individual procedure can be safely and appropriately performed in an ASC as required by statute. CMS is also interested in commenters' views on whether and how, if they were to include such services as ASC covered surgical procedures, they would need to revise the ASC covered surgical procedures definition.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program Proposals

As previously noted, CMS has implemented quality reporting programs for multiple care settings – to measure the quality of Ambulatory Surgical Center (ASC) services, the agency has implemented the ASC Quality Reporting (ASCQR) Program.

ASCQR Program Quality Measures – Accounting for Social Risk Factors

In addition to seeking feedback on whether to include social risk factors in the hospital OQR Program, **CMS is seeking comment on whether they should account for social risk factors in the ASCQR Program,**

and if so, what method or combination of methods would be most appropriate. Any changes to the ASCQR Program would be proposed through future notice and comment rulemaking.

Quality Measures Proposed for Removal from the ASCQR Program

CMS is proposing to remove a total of three measures for the CY 2019 payment determination and subsequent years; and invites comment on each of the proposals to remove these measures:

- ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing;
- ASC-6: Safe Surgery Checklist Use; and
- ASC-7: ASC Facility Volume Data on Selected Procedures.

Proposal to Delay OAS CAHPS Survey-Based Measures

Additionally, beginning with the CY 2020 payment determination (CY 2018 reporting), CMS is proposing to delay the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems Survey (OAS CAHPS) Survey measures (ASC-15a-e). In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79771 - 79784), CMS adopted ASC-15a-e and finalized data collection and data submission timelines.

Proposed New ASCQR Program Quality Measures for the CY 2021 and CY 2022 Payment Determinations & Subsequent Years

CMS is proposing to adopt a total of three new measures for the ASCQR Program. CMS is proposing one measure collected via a CMS web-based tool for the CY 2021 payment determination and subsequent years:

- ASC-16: Toxic Anterior Segment Syndrome.

CMS is proposing two measures collected via claims for the CY 2022 payment determination and subsequent years:

- ASC-17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures; and
- ASC-18: Hospital Visits after Urology Ambulatory Surgical Center Procedures.

ASCQR Program Measures and Topics for Future Consideration

CMS is seeking comment on one measure developed by the CDC for potential inclusion in the ASCQR Program in future rulemaking – the Ambulatory Breast Procedure Surgical Site Infection Outcome measure (NQF #3025). CMS believes this measure, if adopted in the future, "could serve as a quantitative guide for ASCs, enabling them to benchmark SSI [surgical site infection] rates in their facilities against nationally aggregated data and set targets for improvement."

Form, Manner, and Timing of Data Submitted for the ASCQR Program

Beginning with the CY 2019 payment determination, CMS is proposing to remove one claims-based measure using Quality Data Codes (QDCs) – ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing.

In this proposed rule, the agency is not proposing any changes to policies regarding data processing and collection periods for claims-based measures using Quality Data Codes (QDCs). However, if their proposal to remove one claims-based measure using QDCs is finalized, the following previously finalized claims-based measures using QDCs will be collected for the CY 2020 payment determination and subsequent years:

- ASC-1: Patient Burn;
- ASC-2: Patient Fall;
- ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and
- ASC-4: Hospital Transfer/Admission.

Proposals Regarding Requirements for Data Submitted via a CMS Online Data Submission Tool

CMS currently uses the QualityNet website as the agency's online data submission tool – and is making one proposal to the method of data submission via a CMS online data submission tool. CMS is not proposing any changes to policies regarding data submitted via a CMS online data submission tool when data is entered for individual facilities.

Currently, for individual facility data entry, users must have a QualityNet account and use one Hospital Quality Reporting (HQR) External File per facility that is uploaded into the QualityNet secure portal. Using one HQR External File only allows data entry for one facility – and can be burdensome for entities responsible for submitting data for multiple facilities (e.g., multi-facility ASCs). In an effort to streamline the process, the agency is proposing to expand the CMS online tool to also allow for batch submission beginning with data submitted during CY 2018 (for CY 2020 payment determination and subsequent years).

Under the proposed batch submission process, ASC agents would be assigned a vendor ID and an ASC's representative would submit the Security Administrator (SA) form with the assigned vendor ID for the agent to establish their own QualityNet account. Once approved, the agent may submit data for any ASC associated with that ID – individually or in a batch – and access data reports for the same ASCs. Agents would only have access to data reports for facilities that have authorized them to have access. "For batch submission, agents would be provided the HQR external file layout with which to upload their associated ASCs' data under the agents' QualityNet account." In order to submit batch data, agents would need to meet all QualityNet account requirements (i.e., establishing a QualityNet account and maintaining a QualityNet security administrator). CMS notes that additional details regarding logistics of batch data submission would be included in future guidance in the Specifications Manual.

Public Comments Received on the CY 2017 OPPS/ASC Final Rule with Comment Period

Medicare Site-of-Service Price Transparency (Sect. 4011 of the 21st Century Cures Act)

Section 4011 of the 21st Century Cures Act provides that, "in order to facilitate price transparency with respect to items and services for which payment may be made either to a hospital outpatient department or to an ambulatory surgical center under Title XVIII, the Secretary shall, for 2018 and each year thereafter, make available to the public via a searchable website, with respect to an appropriate number of items and services, the estimated payment amount for the item or service under the OPPS and ASC payment system and the estimated beneficiary liability applicable to the item or service."

In this proposed rule, CMS announces their plan to establish the searchable website required by the 21st Century Cures Act. The agency notes that details regarding the website will be issued through the subregulatory process, and anticipates that the website will be made available in early CY 2018.

Request for Information and Public Comments

CMS is seeking public comment on ideas that would reduce burdens on providers and patients, improve quality of care, decrease costs, and support the physician-patient relationship. This could include payment system redesign, streamlining or elimination of reporting, aligning Medicare with Medicaid and other payors, operational flexibility, among other options."

Eliminating Medicare Payment Differentials for Similar Services in the Inpatient & Outpatient Settings

CMS has previously sought and considered comments on potential payment policy options to address the issue of payment differentials between hospital services provided in the inpatient and outpatient settings. The agency's most recent solicitation for comments on these issues was in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70549). CMS notes that since that time, both hospitals and the agency have had "the opportunity to gain experience under the various policy changes that have occurred with respect to short inpatient hospital stays." **In this context, CMS "believe[s] it is an appropriate time to seek public comment again on transparent ways to identify and eliminate inappropriate payment differentials for similar services provided in the inpatient and outpatient settings."**

Request for Information Regarding Physician-Owned Hospitals

CMS is seeking comment on the appropriate role of physician-owned hospitals in the delivery system – and whether these specialty hospitals could play a more prominent role in the healthcare delivery system. Comments regarding the impact on Medicare beneficiaries are of particular interest to the agency.

What's Next?

CMS publishes the final OPPS/ASC regulation around November 1, and the changes are effective at the beginning of the calendar year (Jan. 1, 2018). The 60-day comment period is set to close on Sept. 11, 2017. Vizient's Office of Public Policy and Government Relations looks forward to hearing continued

member feedback on this proposed rule. Stakeholder input plays a major role in shaping future changes to policy. We encourage you to reach out to our office if you have any questions or regarding any aspects of this proposed regulation – both positive reactions and provisions that cause you concern.

As always, it is possible that we'll see substantial shifts between the proposed and final rule based on public comments and further analysis by CMS. Look for another detailed summary from our office when the final rule is released in November.

Additional Resources

Chelsea Arnone, Regulatory Affairs and Government Relations Director in Vizient's Washington, D.C. office, can be reached at (202) 354-2608, and is monitoring this rule and other regulatory developments. Please reach out to her if you have any questions or if Vizient can provide any assistance as you consider these issues.

The proposed rule's Addenda are published and available only on the CMS website. The Addenda relating to the OPPS are available here. The Addenda relating to the ASC payment system are available here. All OPPS Addenda to this proposed rule are contained in the zipped folder entitled "2018 OPPS 1678-P Addenda" at the bottom of the page. All ASC Addenda to this proposed rule are contained in the zipped folders entitled "Addendum AA, BB, DD1, DD2, and EE."