On July 13, 2017, CMS issued the Calendar Year (CY) 2018 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center Payment System (ASCPS) proposed rule (Proposed Rule). CMS proposes to update OPPS rates by 1.75 percent for CY 2018 and to increase payment rates under the ASCPS by 1.9 percent. Additionally, as detailed below, CMS proposes several potential policy changes, including significant reductions to Medicare payments for drugs that are acquired under the 340B Drug Pricing Program.

CMS is accepting comments on the Proposed Rule until September 11, 2017 and indicated it anticipates issuing a final rule on or about November 1, 2017. King & Spalding’s Healthcare and FDA & Life Sciences Practice Groups welcome the opportunity to assist providers, product manufacturers, and other interested parties with analyzing the provisions of the Proposed Rule, submitting comments and preparing for compliance with anticipated changes to OPPS and ASC reimbursement policy.

I. OPPS Proposed Payment Policy Changes

a. Proposed OPPS Payment Update

As noted, CMS proposes to update OPPS rates by 1.75 percent for 2018. This change is based on the projected hospital market basket increase of 2.9 percent minus a 0.4 percentage point adjustment for multi-factor productivity and a 0.75 percentage point adjustment required by the Affordable Care Act.

Based on the proposed updates, CMS estimates total payments to OPPS providers in CY 2018 would be approximately $70 billion, an increase of approximately $5.7 billion compared to estimated CY 2017 OPPS payments.

b. Drugs Purchased Under the 340B Program

CMS is proposing to reduce the payment rate under Medicare Part B beginning in CY 2018 for separately payable drugs and biologicals (other than drugs on pass-through and vaccines) acquired under the 340B Drug Pricing Program.
Pricing Program. Hospitals participating in the 340B program would see Medicare Part B reimbursement for these 340B drugs cut from a current rate of average sales price (ASP) plus 6 percent to ASP minus 22.5 percent. CMS supports this change by pointing to recent studies and reports by the Office of Inspector General, the Medicare Payment Advisory Commission (MedPAC), and the Government Accountability Office alleging that 340B hospitals appear to prescribe more drugs or more expensive drugs to beneficiaries and that the OPPS payment received for 340B drugs significantly exceeds the drug acquisition cost. CMS based the proposed payment reduction on MedPAC’s conclusion that, on average, hospitals in the 340B program receive a minimum discount of 22.5 percent of ASP for drugs paid under the OPPS. CMS believes that its new payment methodology would allow Medicare beneficiaries to share in 340B savings through lower coinsurance payments. (Part B coinsurance is generally 20 percent of the Medicare allowable amount.) To facilitate the new payment rate, CMS is also proposing to establish a modifier to identify drugs billed under the OPPS that are not purchased under the 340B program.

CMS is requesting comments regarding whether CMS should (i) adopt a different payment rate for 340B drugs, (ii) phase in the payment rate reduction over time, (iii) require 340B hospitals to report their acquisition costs for each drug on the Medicare claim, (iv) grant exceptions from the new payment rate to certain groups of hospitals, and/or (v) exclude other types of drugs, such as blood clotting factors, from the reduced payment.

CMS previously raised the possibility of reducing the payment rate for 340B drugs in the CY 2009 OPPS/ASC final rule, in which CMS asked, among other things, whether CMS should consider adjusting the OPPS payment rate for 340B drugs to reflect lower acquisition costs. In response to CMS’s questions, several commenters representing 340B covered entities submitted comments arguing that a reduction in the OPPS payment rate for 340B drugs would contravene the Congressional intent behind the 340B program: to enable safety-net providers to stretch limited resources, reaching more eligible patients and providing more comprehensive services. Commenters asserted that the entities that acquire drugs at 340B prices rely on the savings to remain solvent and to expand healthcare services to vulnerable populations, including by reducing or waiving patient co-pays for Part D drugs.

c. Supervision of Hospital Outpatient Therapeutic Services

In the Proposed Rule, CMS proposes to reinstate the non-enforcement of direct supervision enforcement instructions for outpatient therapeutic services for Critical Access Hospitals (CAHs) and small rural hospitals having 100 or fewer beds for calendar years 2018 and 2019.

By way of background, in the CY 2009 and CY 2010 OPPS/ASC proposed rule and final rule with comment period, CMS clarified that direct physician supervision is generally required for hospital outpatient therapeutic services that are furnished in hospitals, critical access hospitals and in provider-based departments of hospitals. However, for several years there has been a moratorium on the enforcement of the direct supervision requirement for CAHs and small rural hospitals, with the latest moratorium on enforcement expiring on December 31, 2017. CMS is proposing to reinstate the enforcement moratorium for an additional two years in an effort to alleviate some burdens that rural hospitals experience in recruiting physicians.

d. Payment Packaging Proposals

Since 2014 CMS has embarked on a number of “package payment” proposals, including several “policy package payment” requirements that package payment for drugs used in hospital outpatient departments or ambulatory surgical centers into the procedure payments if CMS deems those drugs to be “supplies” used in either a surgical or diagnostic procedure. Since the initiation of the policy, CMS has packaged approximately nine different drugs into the procedure payments. At the same time, and effective in 2015, CMS also adopted a number of “Comprehensive”
Ambulatory Payment Classifications (APCs), which have a similar effect of packaging drug payments, along with blood and durable medical equipment payments appearing on the same claim into the procedure payment.

Unfortunately the packaged payments have had a negative effect upon patient access, and several therapeutic areas, including bladder cancer treatment, have been affected. In the Proposed Rule, CMS acknowledges that the packaging proposals have impacted patient care, and for the first time proposes to address these issues by adding a new HCPCS code for certain procedures that utilize a drug which would otherwise be packaged, and adding a “complexity adjustment” to the pairs of codes (the procedure code and the new packaged drug code) to increase reimbursement and account for the dilution of the drug reimbursement in the procedure payment. The CMS proposal is the first instance in which the Agency has proposed a complexity adjustment for procedures using a drug, and it will be important to follow how the Agency implements the proposal and how it in the future will evaluate other packaged drugs for inclusion in the complexity adjustment process.

e. Inpatient-Only List

For CY 2018, CMS is proposing to remove total knee arthroplasty from the Inpatient-Only List based on feedback it received from various stakeholders including the Advisory Panel on Hospital Outpatient Payment. CMS is also seeking comments on whether partial and total hip arthroplasty should be removed from the Inpatient-Only List and added to the ASC Covered Surgical Procedures List.

f. 14-Day Rule for Billing Clinical Laboratory Tests

CMS is seeking comments on its “14-day rule” policy regarding the date of service billed on claims for clinical diagnostic laboratory tests, codified at 42 C.F.R. § 414.510. The 14-day rule determines whether the performing laboratory or the hospital can bill Medicare for the test, depending on when the test is ordered by the patient’s physician. When applying the 14-day rule, if the date of service falls during an inpatient or outpatient hospital stay, based on Medicare “under arrangements” regulations, payment for the laboratory test is bundled or packaged with the hospital service so the hospital bills Medicare for the test, and the laboratory performing the test must bill the hospital for the test rather than billing Medicare directly.

CMS is evaluating the 14-day rule because laboratory stakeholders identified certain operational issues with the policy, including beneficiary access problems caused by delays in physician ordering of tests in order to avoid application of the 14-day rule, inconsistent billing for tests performed by specialty laboratories located in a different Medicare jurisdiction from hospitals where specimens are obtained, and the disproportionate impact on smaller laboratories performing innovative diagnostic tests. For this reason, CMS is considering potential modifications to the date of service or under arrangements regulations that would allow laboratories to bill Medicare directly for certain laboratory tests excluded from the OPPS packaging policy, including molecular pathology tests and tests designated by CMS as “advanced diagnostic laboratory tests.”

g. Off-Campus Department Reimbursement

For CY 2017, CMS proposed (but did not finalize) limitations on service line expansion and volume at off-campus provider-based departments excepted from OPPS reimbursement; CMS is not making similar proposals for CY 2018.
h. Proposed High Cost/Low Cost Threshold for Packaged Skin Substitutes

CMS indicated that it is analyzing its current skin substitute payment methodology in order to determine whether refinements to the existing methodologies may be warranted. In the interim, to maintain similar levels of payment for skin substitute products in CY 2018, CMS proposes certain policy revisions.

Skin substitutes are products used to aid in wound healing and, under the OPPS, payment for skin substitutes is packaged into the payment for the associated primary procedure. Products are assigned to either a “high cost” or a “low cost group,” depending on how costly they are relative to certain cost thresholds.

For CY 2018, CMS is proposing to assign skin substitutes with a geometric mean unit cost (MUC) or a per day cost (PDC) that exceeds either the MUC threshold (a weighted average of all skin substitutes’ MUCs) or the PDC threshold (a weighted average of all skin substitutes’ PDCs) to the high cost group. However, a skin substitute that does not exceed either the CY 2018 MUC or PDC threshold for CY 2018, but was assigned to the high cost group for CY 2017, will continue to be assigned to the high cost group for CY 2018.

II. Ambulatory Surgical Center Payment System (ASCPS) Changes

a. Coding

CMS is seeking public comment on finalizeg timeframes for new or revised HCPCS Codes, summarized below.

<table>
<thead>
<tr>
<th>ASC Quarterly Update CR</th>
<th>Type of Code</th>
<th>Effective Date</th>
<th>Comments Sought</th>
<th>When Finalized</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 1, 2017</td>
<td>Level II HCPCS Codes</td>
<td>April 1, 2017</td>
<td>CY 2018 OPPS/ASC proposed rule</td>
<td>CY 2018 OPPS/ASC final rule with comment period</td>
</tr>
<tr>
<td>July 1, 2017</td>
<td>Level II HCPCS Codes</td>
<td>July 1, 2017</td>
<td>CY 2018 OPPS/ASC proposed rule</td>
<td>CY 2018 OPPS/ASC final rule with comment period</td>
</tr>
<tr>
<td></td>
<td>Category I (certain vaccine</td>
<td>July 1, 2017</td>
<td>CY 2018 OPPS/ASC proposed rule</td>
<td>CY 2018 OPPS/ASC final rule with comment period</td>
</tr>
<tr>
<td></td>
<td>codes) and III CPT codes</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>October 1, 2017</td>
<td>Level II HCPCS Codes</td>
<td>October 1, 2017</td>
<td>CY 2018 OPPS/ASC final rule with</td>
<td>CY 2019 OPPS/ASC final rule with comment period</td>
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<td></td>
<td></td>
<td></td>
<td>comment period</td>
<td></td>
</tr>
<tr>
<td>January 1, 2018</td>
<td>Level II HCPCS Codes</td>
<td>January 1, 2018</td>
<td>CY 2018 OPPS/ASC final rule with</td>
<td>CY 2019 OPPS/ASC final rule with comment period</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>comment period</td>
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</tbody>
</table>
CMS is also seeking public comments on the proposed payment indicators summarized below.

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>C9484</td>
<td>Injection, eteplirsen, 10 mg</td>
<td>K2</td>
</tr>
<tr>
<td>C9485</td>
<td>Injection, olaratumab, 10 mg</td>
<td>K2</td>
</tr>
<tr>
<td>C9486</td>
<td>Injection, granisetron extended release, 0.1 mg</td>
<td>K2</td>
</tr>
<tr>
<td>C9487*</td>
<td>Ustekinumab, for intravenous injection, 1 mg</td>
<td>K2</td>
</tr>
<tr>
<td>C9488</td>
<td>Injection, conivaptan hydrochloride, 1 mg</td>
<td>K2</td>
</tr>
<tr>
<td>J7328</td>
<td>Hyaluronan or derivative, gel-syn, for intra-articular injection, 0.1 mg</td>
<td>K2</td>
</tr>
<tr>
<td>C9489</td>
<td>Injection, nusinersen, 0.1 mg</td>
<td>K2</td>
</tr>
<tr>
<td>C9490</td>
<td>Injection, bezlotoxumab, 10 mg</td>
<td>K2</td>
</tr>
<tr>
<td>C9745</td>
<td>Nasal endoscopy, surgical; balloon dilation of eustachian tube</td>
<td>J8</td>
</tr>
<tr>
<td>C9746</td>
<td>Transperineal implantation of permanent adjustable balloon continence device, with cystourethroscopy, when performed</td>
<td>J8</td>
</tr>
<tr>
<td>C9747</td>
<td>Ablation of prostate, transrectal, high intensity focused ultrasound (HIFU), including imaging guidance</td>
<td>G2</td>
</tr>
<tr>
<td>Q9986</td>
<td>Injection, hydroxyprogesterone caproate (Makena), 10 mg</td>
<td>K2</td>
</tr>
<tr>
<td>Q9989*</td>
<td>Ustekinumab, for Intravenous Injection, 1 mg</td>
<td>K2</td>
</tr>
<tr>
<td>0474T</td>
<td>Insertion of anterior segment aqueous drainage device, with creation of intraocular reservoir, internal approach, into the supraciliary space</td>
<td>J8</td>
</tr>
</tbody>
</table>

In addition, CMS is proposing to have all Level II HCPCS codes effective October 1, 2017 and January 1, 2018 flagged with an interim status indicator “NI” with the payment rates finalized in the CY 2019. The list of these codes is available in Addendum B to the Proposed Rule.
Finally, CMS is soliciting comments on the CY 2018 payment indicators for new and revised Category I and III CPT codes that will be effective January 1, 2019, which are available in Addendum AA and Addendum BB to the Proposed Rule.

b. Covered Surgical and Ancillary Procedures Rates

i. Covered Surgical and Ancillary Procedure Updates

CMS annually reviews and updates the list of covered surgical procedures eligible for payment in ASCs and identifies covered surgical procedures either as temporarily office-based, permanently office-based, or non-office based taking into account updated volume and utilization data. For CY 2018, CMS proposes the following:

- Designate CPT Code 37241 (Vascular embolize/occlude venous) and CPT Code 67227 (Destruction extensive retinopathy) as office-based;

- Maintain temporary office-based designation for: CPT code 0402T (Collagen cross-linking of cornea); CPT code 10030 (Image-guided fluid collection drainage by catheter); CPT code 36473 (Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanothermal; first vein treated); CPT code 36901 (Introduction of needle(s) and/or catheter(s), dialysis circuit, with diagnostic angiography of the dialysis circuit, including all direct puncture(s) and catheter placement(s), injection(s) of contrast, all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava, fluoroscopic guidance, radiological supervision and interpretation and image documentation and report ); CPT code 64461 (Paravertebral block (PVB) (paraspinal block), thoracic; single injection site (includes imaging guidance, when performed); CPT code 64463 (Paravertebral block (PVB) (paraspinal block), thoracic; continuous infusion by catheter (includes imaging guidance, when performed)); CPT code 6578 (Implantation of intrastromal corneal ring segments); and CPT code 67229 (Treatment of extensive or progressive retinopathy, one or more sessions; preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age;

- Designate HCPCS code G0429 (Dermal injection procedures for facial lipodystrophy syndrome and provision of Fadiesse or Sculptra dermal filler) as office-based;

- Remove HCPCS code 0299T (Extracorporeal shock wave for integumentary wound healing) because it will be deleted by the AMA effective December 31, 2017; and

- Add CPT code 382X3 (Diagnostic bone marrow; biopsy and aspiration) as a temporary office based ASC covered surgical procedure.

In addition, CMS is soliciting comments on whether CPT code 27447 (Total knee arthroplasty), CPT code 27125 (Hemiarthroplasty, hip, partial), and CPT code 27130 (Arthroplasty, acetabular and proximal femoral prosthetic replacement) should be added to the list of surgical procedures covered in an ASC, and whether CPT code 55866 (Laparoscopy, surgical prostatectomy, retro-pubic radical, including nerve sparing, includes robotic assistance, when performed) should continue to be excluded from the list.
Finally, CMS proposes to update the list of covered ancillary services to reflect the payment status for the services under the CY 2018 OPPS. Specifically, if a covered ancillary service was separately paid under the ASC payment system in CY 2017, but is proposed for packaged status under CY 2018 OPPS, it would also be packaged under the ASC payment system.

**ii. Device-Intensive Procedure Updates**

Device-intensive procedures (defined as those with a device offset greater than 40 percent) are reimbursed using the device-intensive procedure payment methodology under 42 C.F.R. § 416.171. For CY 2018, CMS proposes to update the list of procedures that are eligible for device intensive procedure payments, which will be listed in Addendum AA of the Proposed Rule with a J8 indicator code.

**iii. Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices**

Under the ASC payment system, CMS reduces ASC payments by 100 percent or 50 percent of the device offset amount when an ASC furnishes a device without cost or with full or partial credit. For CY 2018, CMS proposes to update the list of device-intensive procedures subject to the no cost/full credit and partial credit device adjustment policy to include CPT codes 22856 (total disc arthroplasty, anterior approach, single interspace, cervical); 22858 (total disc arthroplasty, anterior approach, second level cervical); and 58572 (laparoscopy, surgical, with total hysterectomy, for uterus greater than 250g).

For partial credit device adjustments, CMS is proposing to reduce the payment for implantation procedures that are subject to the no cost/full credit or partial credit device adjustment policy by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of a new device. To report that the ASC received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a new device, ASCs would have the option of either: (1) submitting the claim for the device replacement procedure to their Medicare contractor after the procedure’s performance but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment once the credit determination is made; or (2) holding the claim for the device implantation procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the “FC” modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the replacement device.

**c. Surgical Procedure Payments**

CMS proposes updating ASC payment rates for CY 2018 and subsequent years using the established rate calculation methodologies under 42 C.F.R. § 416.171, using the definition of device-intensive procedures. For this reason, the ASC system would use geometric means to determine proposed relative payment rates under the ASC standard methodology. CMS proposes to continue to use the amount calculated under the ASC standard rate setting methodology for procedures subject to transitional payments (indicator A2) and non-office based surgical procedures (indicator G2).

CMS is proposing to update the payment amount for the service portion of device-intensive procedures using the ASC standard rate setting methodology and the payment amount for the device portion based on the proposed CY 2018 OPPS device offset percentages that have been calculated using the standard OPPS APC rate setting methodology. Payment for office based procedures would be the lesser of the proposed CY 2018 MPFS non-facility PE RVU-based amount or the proposed CY 2018 ASC payment amount calculated according to the ASC standard rate setting methodology.
CMS proposes to continue its policy for device removal procedures calculated according to the ASC standard rate setting methodology to the MPFS non-facility PE RVU based amount to determine which was lower and would be the CY 2017 payment rate for the procedure under the final ASC payment system.

Finally, CMS is proposing to continue its policy that device removal procedures that are conditionally packaged in the OPPS be assigned the current ASC payment indicators associated with these procedures and would continue to be paid separately under the ASC payment system.

d. Ancillary Services Payments

CMS policy provides separate ASC payments for certain ancillary items and services integrally related to the provision of ASC covered surgical procedures that are paid separately under the OPPS and provides packaged ASC payment for the other ancillary items and services that are packaged or conditionally packaged. 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 regarding the packaged or separately payable status of services and the proposed CY 2018 OPPS and ASC payment rates. CMS is also proposing to set the rates for brachytherapy sources and separately payable drugs and biologicals equal to the OPPS payment rates starting CY 2018. For those ancillary services where the payment rate is lower of the proposed rates, the proposed payment indicators and rates are set based on a comparison using the proposed MPFS rates. Covered ancillary services and their proposed indicators for CY 2018 are listed on Addendum BB of the Proposed Rule.

e. Relative Payment Weights

CMS updates the ASC relative payment rates each year using the national OPPS relative payment weights, and MPFS non-facility PE RVU-based amounts (as applicable). For CY 2018, CMS proposes to scale the payment weights for ASCs by comparing the total payment using the CY 2017 relative payment weights with the total payment using the CY 2018 ASC relative payment weights, in order to take into account the changes in the OPPS relative payment weights before CY 2017 and CY 2018. CMS proposes to use the ratio of CY 2017 and 2018 total payments (weight scalar) to scale the ASC relative payment weights for CY 2018. The proposed weight scalar for CY 2018 is 0.8995, which would apply to the ASC relative payment weights of covered surgical procedures, covered ancillary radiology services, and certain diagnostic tests within the medicine range of CPT codes which are covered ancillary services where the ASC payment rates are based on OPPS relative payment weights.

f. ASC Conversion Factor

For ASC payments, CMS applies a budget neutrality adjustment to the ASC conversion factor for supplier level changes in wage index for the upcoming year. The annual update to the ASC payment system is the CPI-U, which may not be a negative percentage. Under the Affordable Care Act, any annual update must be reduced by the productivity adjustment, which is equal to the ten-year moving average of changes in annual economy wide private nonfarm business multifactor productivity (MFP), which will be reduced for failure to report on quality measures.

For CY 2018, CMS is proposing to reduce the CPI-U update of 2.3 percent by the MFP adjustment of 0.4 percent, resulting in an MFP adjusted CPI-U update factor of 1.9 percent for ASCs meeting the quality reporting requirements. CMS is proposing to apply a 1.9 percent MFP adjusted CPI-U update factor to the CY 2017 ASC conversion factor for ASCs meeting the quality reporting requirements. Further, CMS proposes to reduce the CPI-U 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 MFP adjustment. CMS proposes to adjust the conversion factor by the proposed wage index budget neutrality factor of 1.0004 in addition to the MPF adjusted CPI-U update factor of 1.9 percent, which results
in a proposed CY 2018 ASC conversion factor of $45.876 for ASCs meeting the quality reporting requirements, for those not meeting the quality requirements the proposed conversion factor is $44.976.

g. ASC Payment Reform

CMS is broadly seeking recommendations and ideas for ASC payment system reform, and from stakeholders regarding potential reforms including but not limited to:

- Rate update factor applied to ASC payments;
- Whether and how ASCs should submit costs;
- Whether ASCs should bill on the institutional claim form rather than professional claim form; and
- Other ideas to improve payment accuracy for ASCs.

In addition, CMS is seeking public comment on whether the Secretary should collect cost data from ASCs to use in determining ASC payment rates.

III. Quality Reporting

CMS has implemented quality reporting programs for multiple care settings, including hospital outpatient and ambulatory surgical centers. In connection with the Hospital Outpatient Quality Reporting and Ambulatory Surgical Center Quality Reporting Programs, CMS is seeking public comment on whether social risk factors (e.g. low income, race, ethnicity, and geographic area) should be accounted for, and if so what method or methods would be most appropriate for accounting for social risk factors.

a. Hospital Outpatient Quality Reporting Program (HOQR)

Hospital outpatient facilities must submit data on quality measures and meet certain data collection requirements in order to avoid a reduction of 2.0 percentage points to their annual payment update under the HOQR.

CMS proposes to remove the following quality measures described below:

- Median Time to Pain Management for Long Bone Fracture (assessing median time from ED arrival to pain management);
- Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures (assessing total count of certain surgical procedures performed on outpatient basis);
- Median Time to Fibrinolysis (assessing median time from ED arrival to administration of fibrinolytic therapy);
- Aspirin at Arrival (assessing the rate of patients with chest pain or possible heart attack who received aspirin within 24 hours of arrival);
Door to Diagnostic Evaluation by a Qualified Medical Professional (assessing time from ED arrival to provider contact for emergency department patients); and

Safe Surgery Checklist Use (assessing whether a hospital employed a safe surgery checklist).

CMS is also seeking public comment on future outcome measures, specifically any outcome measure that would be useful to add and any that should be eliminated. Specifically, CMS seeks comment on the possible future adoption of OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival as an electronic clinical quality measure (eCQM) and proposing the eCQM in future rulemaking.

CMS is also proposing to update the OP-18 measure; specifically, CMS is proposing to publicly report OP-18c as early as July 2018 using data from patient encounters during the third quarter of 2017.

Additionally, CMS is proposing to delay OP-37a-e, the mandatory implementation of the Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery Survey (OAS CAHPS) under the Hospital OQR Program for CY 2018 data collection. Hospitals choosing to continue to administer the survey under the voluntary national implementation may do so in CY 2018.

Additional proposals by CMS include:

- Changing the Notice of Participation (NOP) deadline (e.g. any time prior to submitting data on the QualityNet website and the submission deadline of August 1, 2019); and

- Alignment of the naming of the Extraordinary Circumstances Exceptions (ECE) policy with other quality reporting programs and corresponding regulatory updates to reflect these proposals.

b. **Ambulatory Surgical Center Quality Reporting Program (ASCQR)**

Ambulatory surgical centers must meet administrative, data collection, and reporting requirements, or receive a reduction of 2.0 percentage points in their annual payment update under the ASCQR.

CMS proposes to add three measures to the ASCQR program measure set for the CY 2021 and CY 2022 payment determinations and subsequent years. The proposed new measure set includes procedure-type specific measures that, according to CMS, will provide patients with more valuable ASC performance data and address the clinical areas that are critical to providers. The three proposed measures are:

- Toxic Anterior Segment Syndrome (TASS) measure, which is based on aggregate measure data and assesses the number of ophthalmic anterior segment surgery patients diagnosed with TASS within two days of surgery, beginning with the CY 2021 payment determination (ASC-16);

- Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures, which assesses all-cause, unplanned hospital visits within seven days of an orthopedic procedure performed at an ASC, beginning with the CY 2022 payment determination (ASC-17); and
Hospital Visits after Urology Ambulatory Surgical Center Procedures, which assesses all-cause, unplanned hospital visits occurring within seven days of the urology procedure performed at an ASC, beginning with the CY 2022 payment determination (ASC-18).

CMS also proposes to remove a total of three measures for the CY 2019 payment determination and subsequent years. CMS estimates removal of these measures would result in a burden reduction of 1,314 hours and $48,066 for the CY 2019 payment determination. The three measures proposed for removal are:

- Prophylactic Intravenous (IV) Antibiotic Timing, which assesses whether intravenous antibiotics given for prevention of surgical site infection were administered on time (ASC-5);
- Safe Surgery Checklist Use, which is a structural measure of facility process that assesses whether an ASC employed a safe surgery checklist that covered each of the three critical perioperative periods; and
- ASC Facility Volume Data on Selected Procedures, which is a structural measure of facility capacity that collects surgical procedure volume data on six categories of procedures frequently performed in the ASC setting (ASC-7).

CMS is also seeking public comment on the following proposals:

- For the CY 2020 payment determination (CY 2018 data collection) and subsequent years, delay the mandatory implementation of ASC-15a-e, the Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery Survey (OAS CAHPS) under the ASCQR Program for CY 2018 data collection. Under this proposal, ASCs that would like to continue to administer the survey under the voluntary national implementation, may do so in CY 2018;
- Future inclusion of Ambulatory Breast Procedure Surgical Site Infection Outcome measure (NQF #3025) in the ASCQR Program in the future. This measure would assess the risk-adjusted Standardized Infection Ratio for all surgical site infections following breast procedures conducted at ASCs among adult patients and reported to the CDC’s National Healthcare Safety Network; and
- Expansion of the CMS online data submission tool, QualityNet, to also allow for batch submission of ASCQR Program measure data beginning with data submitted during CY 2018. Batch submission allows submission of data for multiple facilities simultaneously using a single, electronic file containing data from multiple facilities submitted via one agent QualityNet account.