FACT SHEET FOR THE CY 2016 FINAL RULE FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM (OPPS) AND AMBULATORY SURGICAL CENTER (ASC) PAYMENT SYSTEM

On October 30, 2015, the Centers for Medicare and Medicaid Services (CMS) issued a final rule that will update policies and payment rates under the OPPS and ASC payment systems for calendar year (CY) 2016. The following fact sheet highlights key payment and policy changes described in the final rule. A more in-depth analysis of payment and policy changes can be found in the attached detailed summary.

For questions regarding the CY 2016 OPPS and ASC Final Rule policies, analysis of claims from the OPPS dataset used by CMS to set payment rates, or regarding the formulating and submitting of a public comment, contact Quorum by sending an email to info@quorumconsulting.com.

Comment Period: CMS will accept comments on the final rule from the public until 5 p.m. EST on December 29, 2015. CMS encourages comments to be submitted electronically at http://www.regulations.gov (follow the instructions under the “submit a comment” tab).

OPPS and ASC Conversion Factor Updates
- For OPPS payments, CMS has finalized a conversion factor (CF) of $75.582 for CY 2016. This is a 1.9% increase from the CY 2015 CF of $74.173.
- For ASC payments, CMS has finalized a CF of $44.177 for CY 2016. This is a 0.8% increase from the CY 2015 CF of $44.058.

Outpatient Payment for Pass-Through Drugs and Biologicals
- For CY 2016, CMS will continue paying for pass-through drugs and biologicals at Average Sales Price (ASP) + 6%.

Outpatient Payment for Non-Pass-Through Drugs and Biologicals
- For CY 2016, non-pass-through drugs and biologicals whose per-day costs exceed a drug packaging threshold of $100 will receive separate payment under individual APCs. This packaging threshold is $5 more than the CY 2015 final packaging threshold of $95. Such items will be reimbursed at ASP + 6%, which is the same as the 2015 payment calculation.

Updates to Pass-Through Device Process and Requirements
- Beginning in CY 2016, CMS is adopting a policy that all device pass-through applications submitted through the quarterly subregulatory process will be subject to notice and comment rulemaking in the next OPPS annual rulemaking cycle. Applications not approved during the quarterly review due to evidence will be subject to comment in the next rulemaking cycle, to allow presentation on any additional evidence.
- CMS is also implementing a “newness” criterion for device-pass through applications starting in CY 2016. A device meets the newness criterion if it has an FDA approval or clearance date no more than 3 years old from the date of application for pass-through.
Changes to the Two-Midnight Rule

For CY 2016, CMS has finalized their proposal to allow exceptions to the two-midnight rule for inpatient admissions of fewer than two midnights may be acceptable depending on the judgment of the physician and the documentation justifying the short-stay inpatient admission. Exceptions to the two-midnight rule will be accepted on a case-by-case basis.

Items and Services to be “Packaged” or Included in Payment for a Primary Service

- CMS has finalized their proposal to conditionally package all ancillary services assigned to Ambulatory Payment Classifications (APCs). Specifically, CMS will package certain minor procedures and pathology services.
- CMS has finalized their proposal to packaged drugs that were separately paid in CY 2015 which function as supplies in a surgical procedure.
- CMS has finalized their proposal to create new conditional packaging status indicators for laboratory tests that will allow hospitals to receive separate payment for laboratory tests which are provided without other related OPPS services.

Restructuring of APC Families

- For CY 2016, CMS has restructured existing APCs for the following nine APC clinical families:
  - Airway Endoscopy Procedures
  - Diagnostic Tests and Related Services
  - Excision/Biopsy and Incision and Drainage Procedures
  - Gastrointestinal Procedures
  - Imaging Services
  - Orthopedic Procedures
  - Skin Procedures
  - Urology and Related Services
  - Vascular Procedures (excluding endovascular procedures)

Comprehensive APCs

- For CY 2016, CMS is not making any changes to the already established methodology of their Comprehensive APC (C-APC) policy.
- CMS has created ten new C-APCs for CY 2016:
  - Level 5 ENT Procedures
  - Level 2 Intraocular Procedures
  - Level 6 Gynecologic Procedures
  - Level 1 Laparoscopy
  - Level 2 Laparoscopy
  - Level 3 Musculoskeletal Procedure
  - Level 5 Musculoskeletal Procedures
  - Level 5 Urology and Related Services
  - Ancillary Outpatient Services When a Patient Expires
  - Comprehensive Observation Services

New P Codes for Pathogen-Reduced Blood Products

- For CY 2016, the Healthcare Common Procedure Coding System (HCPCS) Workgroup created three new codes for pathogen-reduced blood products.
  - P9070, Plasma, pooled multiple donor, pathogen reduced, frozen, each unit
  - P9071, Plasma (single donor), pathogen reduced, frozen, each unit
  - P9072, Platelets, pheresis pathogen reduced
- CMS has created interim payment amounts for these three codes via crosswalks to existing blood products while claims data accumulates.
Quality Program Changes: OQR

- Effective January 1, 2016, CMS will remove one measure (Use of Brain Computed Tomography (CT) in the Emergency Department for Atraumatic Headache) from the Hospital Outpatient Quality Reporting (OQR) Program because the measure does not align with the most updated clinical guidelines or practice.
- For CY 2016, CMS is adding one new measure to the OQR Program: External Beam Radiotherapy for Bone Metastases
- The OQR Program has also implemented several administrative policies in order to align with the Ambulatory Surgical Center Quality Reporting Program (ASCQRP).

Quality Program Changes: ASCQR

- CMS did not finalize any new ASCQRP measures. They are requesting comment on two outcome measures for future consideration:
  - Normothermia Outcome
  - Unplanned Anterior Vitrectomy
- CMS has finalized their policy to exclude Indian Health Service hospital outpatient departments from the ASCQRP as these entities are required to meet the conditions of participation for hospitals – not the conditions of coverage for ASCs – and therefore should not be included in the ASCQRP Program.
DETAILED SUMMARY OF THE CY 2016 FINAL RULE FOR HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM (OPPS) AND AMBULATORY SURGICAL CENTER (ASC) PAYMENT SYSTEM

On October 30, 2015, the Centers for Medicare and Medicaid Services (CMS) issued the final rule that will update payment policies and rates under the Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgery Center (ASC) Payment System for calendar year (CY) 2016. A full publication of the final rule is published by the Federal Register, and can be found here: [https://www.federalregister.gov/articles/2014/11/10/2014-26146/medicare-and-medicaid-programs-hospital-outpatient-prospective-payment-and-ambulatory-surgical](https://www.federalregister.gov/articles/2014/11/10/2014-26146/medicare-and-medicaid-programs-hospital-outpatient-prospective-payment-and-ambulatory-surgical)

For questions regarding the CY 2016 OPPS and ASC Final Rule policies, analysis of claims from the OPPS dataset used by CMS to set payment rates, or regarding the formulating and submitting of a public comment, contact Quorum by sending an email to info@quorumconsulting.com.

OPPS TECHNICAL PAYMENT CALCULATION/METHODOLOGY CHANGES

I. OPPS Payment Methodology and Conversion Factor

OPPS payments in a given year are calculated by multiplying the relative weight for each Ambulatory Payment Classification (APC), which is based on the geometric mean costs, by the annual conversion factor (except in the case of separately payable drugs and biologicals, the payments of which are calculated at Average Sales Price (ASP) plus some percentage determined by CMS).

- For OPPS payments, CMS has finalized a conversion factor (CF) of $75.582 for CY 2016. This is a 1.9% increase from the CY 2015 CF of $74.173.
- Hospitals failing to meet the reporting requirements of the Hospital Outpatient Quality Reporting (OQR) Program are subject to a reduction of 2.0% from the market basket update, resulting in a lowered conversion factor of $72.478.

II. OPPS Outlier Payments

For CY 2016, CMS will make outlier payments when the cost of furnishing a service by a hospital:

1. Exceeds 1.75 times the APC payment amount; AND
2. Exceeds the APC payment rate by at least $3,250.

CY 2016 outlier criteria are similar to the current criteria for 2015, except that the fixed-dollar threshold for 2015 is $475 higher than it is in 2015 ($2,775). Consistent with current policy, the outlier payment for a particular service would then equal 50% of the amount by which the cost to the hospital exceeds 1.75 times the APC payment rate.

III. Outpatient Payment for Drugs and Biologicals

*With Pass-Through Status*

For CY 2016, CMS will continue paying for pass-through drugs and biologicals at ASP + 6%, equivalent to the rate at which they would be paid in the physician office setting. This payment is the same as the payment for 2015.
Without Pass-Through Status
Drugs and biologicals without pass-through status are paid under OPPS in one of two ways:
1. Packaged into the associated procedural APCs (i.e., not separately payable); OR
2. Assigned to individual APCs (i.e., separately payable)

For CY 2016, drugs and biologicals whose per-day costs exceed the final drug packaging threshold of $100 would receive separate payment under individual APCs. This is a $5 increase over the CY 2015 threshold of $95. Such items will be reimbursed at ASP + 6%, which is the same as the 2015 payment calculation.

IV. Outpatient Payment for Therapeutic Radiopharmaceuticals

With Pass-Through Status
For pass-through payment purposes, CMS considers therapeutic radiopharmaceuticals to be drugs. Therefore, similar to the payment policy for drugs and biologicals with pass-through status, CMS will pay for pass-through therapeutic radiopharmaceuticals at ASP + 6% in CY 2016. This payment calculation is the same as the payment for 2015.

In the absence of ASP data for a therapeutic radiopharmaceutical, CMS will provide pass-through payment at Wholesale Acquisition Cost (WAC) + 6%. If WAC data are also not available, CMS will provide payment at 95% of the most recent Average Wholesale Price (AWP).

Without Pass-Through Status
For CY 2016, CMS will pay for non-pass-through separately payable therapeutic radiopharmaceuticals at the rate of ASP + 6%, consistent with the payment rate for non-pass-through separately payable drugs and biologicals. In the event that ASP data are unavailable, CMS will make payments based on 2014 mean unit cost data derived from hospital claims.

V. Outpatient Payment for Skin Substitutes

Without Pass-Through Status
CMS currently unconditionally packages skin substitute products into their associated surgical procedures. Skin substitutes are divided into high cost and low cost groups, in order to ensure resource homogeneity among APC assignments for skin substitute application procedures.

For CY 2016, CMS will determine high cost status for each skin substitute product that meets the following criteria:
- Mean unit cost (MUC) threshold of $25 per cm²; OR
- Per day cost (PDC) exceeding the PDC threshold of $1,050

Any skin substitute product that does not meet these criteria would be assigned to the low cost category.

For any new skin substitutes without pricing information, CMS is proposing assignment to the low cost category until pricing information is available.
With Pass-Through Status
For CY 2016, CMS will continue assigning skin substitute products with pass-through payment status to the high cost category. For skin-substitute products with pricing information but without claims, CMS will continue to calculate an MUC are either assigned to high or low cost category based on the product’s ASP + 6%. If ASP is not available, CMS will provide payment at WAC +6%. If WAC data are also not available, CMS will provide payment at 95% of the most recent AWP.

OPPS POLICY CHANGES

I. Changes to the Two-Midnight Rule

In the CY 2016 OPPS/ASC Final Rule, CMS has finalized their proposal to allow for exceptions to the two-midnight rule for stays expected to last fewer than two midnights. Under this proposal, CMS is allowing exceptions for services. Exceptions will be determined on a case-by-case basis by the administering physician, and would be subject to medical review. The following documentation would be needed to support the medical necessity of such an inpatient admission:

- The severity of the signs and symptoms exhibited by the patient
- The medical predictability of something adverse happening to the patient
- The need for diagnostic studies that are more appropriately outpatient services (that is, their performance does not ordinarily require the patient to remain at the hospital for 24 hours or more)

Responsibility for enforcement and education of the two-midnight rule will fall to quality improvement organizations (QIO) instead of recovery auditors.

II. Final Packaging Policies for CY 2016

Background
As part of a larger initiative by CMS to move the OPPS away from a fee-for-service payment methodology to a more complete prospective payment system, CMS packages payment under OPPS for numerous items and services. In this way, CMS is incentivizing hospitals to focus on the efficiency of patient care as well as the utilization of hospital resources. Items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service have been packaged since OPPS’ implementation in 2000.

Packaging Policies
1. Ancillary Services

In CY 2015, CMS implemented a policy to package payment for all ancillary services assigned to APCs with a geometric mean cost (GMC) of $100 or less. For CY 2016, CMS is expanding packaging of ancillary services, regardless of whether services have a GMC of $100 or less.
2. **Drugs and Biologicals Used as Supplies in a Surgical Procedures**

In CY 2014, CMS implemented a policy to package payment for all drugs and biologicals that are used as supplies during a surgical procedure, regardless of whether their cost per day exceeds the drug packaging threshold. For CY 2016, CMS conducted a comprehensive review of the CY 2015 separately payable OPPS drugs to determine whether each drug was indicated for use in a surgical procedure. Effective January 1, 2016, CMS will package payment for the following drugs and biologicals:

- J0583, *Injection, bivalirudin, 1 mg*
- J7315, *Mitomycin, ophthalmic, 0.2 mg*
- J0130, *Injection, abciximab, 10 mg*

3. **Clinical Diagnostic Laboratory Tests**

In CY 2014, CMS implemented a policy to package certain diagnostic laboratory tests that were listed on the Clinical Laboratory Fee Schedule (CLFS) and met the following criteria:

1. Provided on the same date of service as the primary service; AND
2. Ordered by the same practitioner who ordered the primary service

Under this packaging policy, molecular pathology laboratory tests (CPT codes 81200-81383, and 81400-81408, 81479) are exempt.

For CY 2016, CMS has finalized the following revisions to the current laboratory packaging policy:

- Molecular pathology tests will continue to be excluded from packaging; payment will be made separately under CLFS.
- Laboratory tests that are classified as preventative services will be excluded from packaging; payment will be made separately under CLFS.
- Expand packaged policy to include laboratory tests that are reported on the same claim with a primary service, regardless of the date of service.

### III. Revisions to Application Process for Device Pass-Through Payments

For CY 2016, CMS is implementing a rulemaking component to the current device pass-through payment application process. Under this policy, CMS will supplement the quarterly submission process by including a description of applications received, as well as CMS’ rationale for approving or denying the application in the next applicable OPPS proposed rule. CMS believes that allowing for public comment will make the device-pass through payment and review process more transparent and realize the benefit of public input. They also believe it will align OPPS pass-through with the IPPS process for new medical services and New Technology Add-on Payments (NTAPs).
Under this system, information related to the establishment of the new device category (i.e., cost thresholds, substantial clinical improvement criterion) will be published in the proposed rulemaking for public comment. Additionally, instead of denying applications based on quarterly review, for applications that CMS does not approve based on evidence available during the quarterly review process, they will seek public comment on the application in the next applicable annual rulemaking cycle. Applications that are approved upon quarterly review will be automatically included in the next applicable OPPS annual rulemaking cycle. Submitters of applications which were not approved upon quarterly review will have the option of withdrawing their application from consideration entirely.

For CY 2016, CMS has also added a “newness” requirement for devices seeking pass-through payment. Beginning with applications received on or after January 1, 2016, a device will only be eligible for transitional pass-through payment under OPPS if, in cases in which the device requires FDA approval, the date of the original FDA approval is within 3 years from the date of the application for transitional pass-through.

IV. Restructuring of APC Groups

For CY 2016, CMS has restructured nine APC clinical families based on the following principals: improved clinical homogeneity, improved resource homogeneity, reduced resource overlap in APCs with clinical family, and greater simplicity and improved understanding of the structure of APCs. Listed below are the following APC clinical families which have been restructured:

- Airway Endoscopy Procedures
- Diagnostic Tests and Related Services
- Excision/Biopsy and Incision and Drainage Procedures
- Gastrointestinal (GI) Procedures
- Imaging Services
- Orthopedic Procedures
- Skin Procedures
- Urology and Related Services Procedures
- Vascular Procedures

V. Comprehensive APCs

**Background**

In CY 2015, CMS implemented a comprehensive APC (C-APC) policy, which is designed to make the OPPS more consistent with a prospective payment system by packaging items and services into a single payment for a comprehensive primary service. A C-APC is defined as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of a primary service. In CY 2015, CMS established 25 C-APCs.
New Comprehensive APCs
For CY 2016, CMS has established the following ten additional C-APCs:

- C-APC 5165, Level 5 ENT Procedures
- C-APC 5492, Level 2 Intraocular Procedures
- C-APC 5416, Level 6 Gynecologic Procedures
- C-APC 5361, Level 1 Laparoscopy
- C-APC 5362, Level 2 Laparoscopy
- C-APC 5123, Level 3 Musculoskeletal Procedures
- C-APC 5125, Level 5 Musculoskeletal Procedures
- C-APC 5375, Level 5 Urology and Related Services
- C-APC 5881, Ancillary Outpatient Services When Patient Expires
- C-APC 8011, Comprehensive Observation Studies

C-APC for Observation Services
For CY 2016, CMS has established a C-APC to pay for observation services, which were previously paid as a single payment for non-surgical encounters with a high-level visit and 8 or more hours of observation and then separate payment for most other services reported on the claim. With the finalization of the C-APC for observation services, CMS will now bundle all non-surgical procedures performed, regardless of date of service. Surgical procedures will be excluded from this bundling.

VI. New P-Codes for Pathogen-Reduced Blood Products
For CY 2016, the HCPCS Workgroup has created three new HCPCS codes for pathogen-reduced blood products. CMS calculates payment rates for blood and blood products using their blood-specific cost-to-charge ratio (CCR) methodology, which utilizes actual or simulated CCRs from the most recent available hospital cost reports to convert hospital charges for blood and blood products to costs. Given the newness of the three P-codes, there are currently no claims data on the charges and costs for these blood products. Therefore, CMS has established interim payment rates based on the following crosswalks to existing blood products:

<table>
<thead>
<tr>
<th>New HCPCS P-Code</th>
<th>Descriptor</th>
<th>Crosswalked HCPCS P-Code</th>
<th>Descriptor</th>
<th>Final CY 2016 Payment Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>P9070</td>
<td>Plasma, pooled multiple donor, pathogen reduced, frozen, each unit</td>
<td>P9059</td>
<td>Fresh frozen plasma between 8-24 hours of collection, each unit</td>
<td>$73.08</td>
</tr>
<tr>
<td>P9071</td>
<td>Plasma (single donor), pathogen reduced, frozen, each unit</td>
<td>P9017</td>
<td>Fresh frozen plasma (single donor), frozen within 8 hours of collection, each unit</td>
<td>$72.56</td>
</tr>
<tr>
<td>P9072</td>
<td>Platelets, pheresis, pathogen reduced, each unit</td>
<td>P9037</td>
<td>Platelets, pheresis, leukocytes reduced, irradiated, each unit</td>
<td>$641.85</td>
</tr>
</tbody>
</table>

CMS will begin calculating payment rates for these products once claims data is available, beginning in CY 2018.
VII. Revisions to the Hospital Outpatient Quality Reporting (OQR) Program

Background
Under the Hospital OQR program, hospitals are required to report on a set of 27 quality measures determined by CMS; hospitals that fail to comply are penalized with a 2.0% reduction in the conversion factor used to calculate APC payments under OPPS.

A list of the 27 quality measures can be found at the following link:
http://www.qualitynet.org/dcs/ContentServer?c=Page&pagemName=QnetPublic%2FPage%2FQnetTier3&cid=1192804531207

CMS’ Removal and Addition of OQR Program Measures
CMS has added the following measure to the current set of quality measures that would affect hospital payments in CY 2019:

- External Beam Radiotherapy (EBRT) for Bone Metastases (NQF #1822)

CMS has finalized their proposal to remove the following data quality measure beginning with the CY 2017 payment determination and subsequent years, as it does not align with current clinical guidelines or practice:

- Use of Brain Computer Tomography (CT) in the Emergency Department for Atraumatic Headache.

OQR Program Policy Changes
In order to align the OQR Program with the Ambulatory Surgical Center Quality Reporting Program (ASCQR), CMS will implement the following administrative policy changes for CY 2016:

- Change the deadline for withdrawing from the program from November 1 to August 31.
- Shift the quarters on which payment determinations are based and make conforming changes to the validation process to reflect proposed changes in the payment determination timeframes, requiring a one-time change in the payment determination timeframe to cover three quarters instead of four quarters.
- Make conforming changes to the OQR Program’s validation scoring process to reflect changes in the APU determination timeframe.
- Change the data submission timeframe for measures submitted via QualityNet from July 1 – November 1, to January 1 - May 15.
- Fix a typographical error to correct the name of the OQR Program’s extension and exception policy to exemption and exemption policy.
- Change the deadline for submitting a reconsideration request from the first business day of the month of February of the affected payment year to the first business day on or after March 17 of the affected payment year.
- Amend 42 CFR 419.46(f)(1) and 42 CFR 419.46(e)(2) to replace the term “fiscal year” with the term “calendar year.”
ASC TECHNICAL PAYMENT CALCULATION/METHODOLOGY CHANGES

I. ASC Payment Methodology and Conversion Factor

Since 2011, payment rates for ASC covered surgical procedures have been set based on the APC relative weights used in OPPS, then converted into payment amounts by the ASC conversion factor.

- The CY 2016 final rule ASC conversion factor is $44.177. This is a 0.8% increase from the CY 2015 conversion factor of $44.058.
- ASCs that do not meet the quality reporting requirements defined by the ASC Quality Measure Reporting (ASQR) Program are subject to a reduced conversion factor of $43.296.

ASC POLICY CHANGES

I. Additions to ASC Quality Measure Reporting (ASCQR) Program

In the 2014 OPPS final rule, CMS finalized their decision to implement a quality reporting program for ASCs. This program began in 2012 and is aligned with other existing quality reporting programs for inpatient and outpatient hospitals.

For CY 2016, CMS did not propose any new program measures but is requesting comment on future consideration of the following two measures:

- Normothermia Outcome, which assesses the percentage of patients having surgical procedures under general or neuroaxial anesthesia of 60 minutes or more in duration who are normothermic within 15 minutes of arrival in post-anesthesia care unit.
- Unplanned Anterior Vitrectomy, which assesses the percentage of cataract surgery patients who have an unplanned anterior vitrectomy (removal of the vitreous present in the anterior chamber of the eye).

Additionally, CMS has finalized their proposal to exclude Indian Health Service hospital outpatient departments from the ASCQR, as they are required to meet the conditions of participation for hospitals – not the conditions of coverage for ASCs – and therefore should not be included in the ASCQR program.

Quorum Consulting, Inc. is a medical consulting firm located in San Francisco, California. The mission of Quorum is to help medical innovators improve people’s lives by enabling payment for their products and services. Quorum staff consists of experts who approach reimbursement by aligning clinical, regulatory, and commercial strategies throughout the product life cycle.

For more information about Quorum, or for questions regarding the CY 2016 OPPS and ASC Final Rules or a more in-depth look at finalized policies, please feel free to visit our website at www.quorumconsulting.com, or send an email to info@quorumconsulting.com.