KEY FINAL CHANGES TO THE
MEDICARE HOSPITAL INPATIENT PROSPECTIVE PAYMENT SYSTEM (IPPS)
FOR FY 2015

This memo highlights the key payment policy changes described in the rule, which will take effect October 1, 2014. The final rule will appear in the Federal Register soon and can be downloaded from the Federal Register at http://ofr.gov/inspection.aspx.

CONTENTS AND EXECUTIVE SUMMARY

On August 4, 2014 the Centers for Medicare and Medicaid Services (CMS) issued a final rule that updates fiscal year (FY) 2015 Medicare payment policies and rates for inpatient stays at general acute care and long-term care hospitals (LTCHs), and continues to implement a number of Affordable Care Act (ACA) initiatives aimed at controlling health care costs and aligning Medicare payments with quality metrics.

How to Comment

CMS will accept comments from the public. The comment deadline has yet to be released by CMS; however, the deadline is typically 60 days from the date of public display at the Office of the Federal Register. Quorum Consulting provides expert services in drafting comments for submission to CMS.

I. TECHNICAL CHANGES

- Final Changes in the Inpatient Hospital Update for FY 2015 (§ 412.64(d))
  - Payment for hospitals will be directly impacted by whether they participate in submitting quality data and are meaningful Electronic Health Record (EHR) users.

II. POLICIES THAT ARE NOT TECHNOLOGY SPECIFIC

- ICD-10 Conversion
  - Implementation is still on-track for October 2015.

- Two-Midnight Rule
  - This final rule builds on previous rulemaking with regard to the Two Midnight Rule but does not alter the rule itself.

- Disproportionate Share Hospital (DSH) Payment
To protect hospitals from abrupt reductions in IPPS reimbursements, CMS plans to adopt new Office of Management and Budget (OMB) delineations for labor market areas over the course of a staggered three-year period.

DSH program payments are being reformed due to the expansion of health insurance coverage via the Affordable Care Act (ACA).

Proposals to Improve Quality of Care during Hospital Inpatient Stays

The final rule will update the measures and financial incentives in the Hospital Acquired Condition Reduction, Hospital Readmission Reductions program, the Hospital Inpatient Quality Reporting (IQR) Program and Electronic Health Records Incentive Program, and the Value-Based Purchasing Program. It would also revise measures for the Long-Term Care Hospital (LTCH) Quality Reporting Program and the PPS-Exempt Cancer Hospital Quality Reporting Program.

III. MEDICAL TECHNOLOGY RELATED ISSUES AND OTHER CMS RECOMMENDATIONS THAT HELP INFORM ON RATIONALE FOR PAYMENT POLICY

New Technology Add-On Payment (NTAP) Applications

Three applications submitted for NTAP were approved for FY2015:

- HF (Heart Failure) System (CardioMEMS, Inc.)
- MitraClip® System (Abbott Vascular)
- Responsive Neurostimulator (RNS®) System (NeuroPace, Inc.)

MS-DRG Classifications: Payment Updates

CMS approved the following:

- To reassign seven diagnoses to the “only secondary diagnosis list” under MS–DRG 794 (Neonate with her Significant Problems) so that the case would be assigned to MS–DRG 795 (Normal Newborn)
- To collapse MS-DRGs 483 and 484 into a single MS-DRG by deleting MS-DRG 484 and revising the title of MS-DRG 483 to read “Major Joint/Limb Reattachment Procedure of Upper Extremities.” CMS is also maintaining the current MS-DRG assignments for revisions of upper joint replacement procedures in MS-DRGs 515, 516, and 517.
- Creation of three new MS-DRGs for back and neck procedures and to delete MS-DRGs 490 and 491. These new MS-DRGs would be titled as follows and would be effective as of October 1, 2014:
  - MS-DRG 518 (Back & Neck Procedures Except Spinal Fusion with MCC or Disc Device/Neurostimulator);
  - MS-DRG 519 (Back & Neck Procedures Except Spinal Fusion with CC);
  - MS-DRG 520 (Back & Neck Procedures Except Spinal Fusion without CC/MCC).
I. TECHNICAL CHANGES

❖ **Final Changes in the Inpatient Hospital Update for FY 2015 (§ 412.64(d))**

This rule finalizes the adoption of provisions affecting hospital DRG base payments. Payment for hospitals will be directly impacted by whether they participate in submitting quality data and are meaningful Electronic Health Record (EHR) users. The public will not be able to determine exact hospital-specific payment rates until CMS releases the list of meaningful EHR users and qualified reporters of quality data.

Based on these changes, there are three possible scenarios for payment:

1. Hospitals that **do not** submit quality data and are not meaningful EHR users. These hospitals are eligible for a percentage increase that is 0.75% above the operating standardized payment.
2. Hospitals that **do submit** quality data but are not a meaningful EHR user or a hospital that does not submit quality data but is a meaningful EHR user are eligible for a percentage increase that is 1.425% to the operating standardized amount.
3. Hospitals that **submit quality data and are meaningful EHR users**. These hospitals are eligible for a percentage increase that is 2.2% to the operating standardized amount.

Did you know? Quorum has an MS-DRG Calculator that provides national base payment and hospital-specific MS-DRG payments for all 751 MS-DRGs. In addition, the tool also allows access to historical Medicare statistics and trends extracted from Medicare claims data, by DRG and provider (e.g., discharge volume, avg. length of stay, avg. charges). To sign up for a subscription or to request a free trial, please contact drg.calculator@quorumconsulting.com.

II. POLICIES THAT ARE NOT TECHNOLOGY SPECIFIC

❖ **ICD-10 Conversion**

ICD-10-CM/PCS implementation is planned for October 1, 2015. CMS has also updated its MS-DRG Grouper algorithm for the ICD-10 system, known as ICD-10 MS-DRGs Version 31.0-R. The latest update reflects public comment on an earlier version of the Grouper logic. CMS intends for the transition from an ICD-10 based MS-DRG system to mirror the MS-DRG assignments under ICD-9. Additional information on the ICD-10 MS-DRG conversion project can be found on the ICD-10 MS-DRG Conversion Project Web site at: [http://cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRGConversion-Project.html](http://cms.hhs.gov/Medicare/Coding/ICD10/ICD-10-MS-DRGConversion-Project.html)

❖ **Two-Midnight Rule**

Numerous comments were submitted to CMS from hospitals concerning the confusion surrounding the two midnight rule. Two Midnight Rule establishes criteria under which a patient admission would be considered valid for the purposes of inpatient reimbursement: 1) the physician expects the beneficiari
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to require a medically necessary hospital stay spanning at least two midnights; and 2) the physician admits the beneficiary to the hospital based on that expectation. Despite the comments and concerns received, the rule will continue in effect.

- **Disproportionate Share Hospital (DSH) Payment**

Disproportionate Share Hospitals (DSHs) serve a high number of low-income patients and, as such, qualify for additional Medicare payments.

- **Labor Market Designations**

In the FY2015 IPPS Final Rule, CMS plans to adopt new Office of Management and Budget (OMB) delineations for labor market areas. The new OMB delineations are meant to reflect the results of the latest decennial census (last completed in 2010), and will cause some urban hospitals to be reclassified as rural, and some rural hospitals to be reclassified as urban. Because rural and urban hospitals follow different payment methodologies under the DSH program, hospitals that lose their urban status with the adoption of the new OMB delineations would lose payment. This rule creates an arrangement such that hospitals losing urban status (and higher urban payments) see their payments reduced in a gradual way, over the course of three years. This is presumably being done to protect hospitals from abrupt reductions in IPPS reimbursements.

- **Payment Methodology Changes Due to Affordable Care Act**

DSH program payments are being reformed due to the expansion of health insurance coverage via the Affordable Care Act (ACA). Previously, the DSH payment formulae primarily considered two figures:

1. Proportion of a hospital’s inpatient Medicare utilization that can be attributed to beneficiaries who also receive Supplemental Security Income (SSI)
2. Proportion of a hospital’s total inpatient utilization attributable to patients eligible for Medicaid

Beginning in 2014, the ACA greatly increased the number of patients eligible for Medicaid, and CMS will rely on the above formula to a much smaller extent. As of FY2014, discharges at DSH-qualified hospitals will only receive 25% of the payment adjustment described in the old formula. The remaining 75% of the adjustment will be calculated under a separate formula and will instead be based on the amount of uncompensated care provided by each DSH-qualified hospital, specifically:

1. The change in uninsured rate in individuals under age 65 between 2013 (the most recent year before coverage expansion) and the current year in which DSH adjustments are being calculated

   a. For FYs 2014-2017, the 2013 baseline uninsured rate is an estimate calculated by the Congressional Budget Office (CBO); and the current year change is based on CBO estimates immediately prior to the passage of the ACA

   b. For FYs 2018 and beyond, the 2013 baseline and current year change can be based on more accurate sources, such as recent census data or other sources deemed appropriate by the Secretary of Health and Human Services

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1 The calculation is $1 - [(2013 uninsured rate) - (Current Year uninsured rate)]$ such that larger increases in coverage result in a smaller weight for this compensation factor
2. The amount of uncompensated care provided by the given hospital, expressed as a fraction of the aggregate amount of uncompensated care provided by all DSH hospitals

Proposals to Improve Quality of Care during Hospital Inpatient Stays

The proposed rule will update the measures and financial incentives in the Hospital Acquired Condition Reduction, Hospital Value-Based Purchasing and Hospital Readmissions Reduction programs, as well as the Hospital Inpatient Quality Reporting (IQR) Program and Electronic Health Records Incentive Program. It would also revise measures for the Long-Term Care Hospital (LTCH) Quality Reporting Program and the PPS-Exempt Cancer Hospital Quality Reporting Program. The information below summarizes the major quality-related provisions of the proposed rule.

- **Hospital-Acquired Condition (HAC) Reduction Program**

  The HAC Reduction Program was created by the ACA to establish a financial incentive for hospitals to improve patient safety and prevent patients from developing conditions that were not present upon admission, but which developed during the course of an inpatient stay. For participating hospitals, this program applies a 1% payment reduction to facilities in the worst-performing quartile.

  In the FY 2014 IPPS/LTCH PPS final rule, CMS finalized a scoring methodology to calculate a Total HAC Score for each hospital. Under the scoring methodology, hospitals are given a score for each measure within two domains. A score is calculated for each domain and the two domains are weighted to determine a Total HAC Score.

  For FY 2016 a third CDC NHSN-developed healthcare associated infection measure, Surgical Site Infections (SSI), will be added to the program in domain 2. In order to better assess hospital performance on these measures, CMS is proposing refinements of the scoring methodology finalized in the FY 2014 IPPS/LTCH PPS final rule.

- **Hospital Readmissions Reduction Program**

  The Hospital Readmissions Reduction program began on October 1, 2012 and adjusts payments based on each hospital’s ratio of actual versus expected readmissions.

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2 Domain 1 comprises the Patient Safety Indicator (PSI) 90 measure; an administrative claim based measure developed by the Agency for Healthcare Research and Quality (AHRQ). PSI-90 is a composite of 8 measures: 1) PSI-03 Pressure Ulcer; 2) PSI-06 Iatrogenic Pneumothorax; 3) PSI-07 Central Venous Catheter-related bloodstream infections; 4) PSI-08 Postoperative Hip fracture; 5) PSI-12 Postoperative Pulmonary Embolism or Deep Venous Thrombosis; 6) PSI-13 Postoperative Sepsis; 7) PSI-14 Postoperative Wound Dehiscence; and 8) PSI-15 Accidental Puncture or Laceration.

Domain 2 measures include two health care-associated infection measures developed by the Centers for Disease Control and Prevention’s (CDC) National Health Safety Network (CDC NHSN): Central Line-Associated Blood Stream Infection (CLABSI) and Catheter-Associated Urinary Tract Infection (CAUTI).

All measures are risk adjusted and endorsed by the National Quality Foundation. Risk factors such as the patient’s age, gender, and comorbidities are considered in the calculation of the measure rates so that hospitals serving a large proportion of sicker patients are not unfairly penalized. In accordance with the statute, a review and correction process allows hospitals to review their measure, domain and Total HAC scores.
CMS currently uses the CMS Planned Readmission Algorithm Version 2.1 to distinguish between planned and unplanned readmissions. For each of the measures under surveillance (acute myocardial infarction, heart failure, pneumonia, chronic obstructive pulmonary disease, and total hip/knee arthroplasty), the algorithm organizes procedures and diagnoses into several groupings:

- The first grouping identifies procedures that, if coded on readmission, cause the readmission to be classified as planned
- The second grouping identifies primary discharge diagnoses that cause the readmission to be classified as planned
- The third grouping identifies procedures that, if coded on readmission, may potentially cause the readmission to be classified as planned as long as an acute (i.e. unplanned) diagnosis is not present
- The fourth grouping identifies acute (i.e. unplanned) diagnoses that identify the readmission as unplanned; CMS believes that there are no clinical situations in which a patient with such acute conditions would be readmitted for a planned procedure

This rule finalizes the adoption of a new algorithm, CMS Planned Readmission Algorithm 3.0, which refines the logic of the previous version to more accurately identify unplanned admissions. The updated version will reflect CMS’s finding that two types of procedures listed in the third grouping, on potentially planned procedures, were almost always unplanned: therapeutic radiation, and cancer chemotherapy. Version 3.0 will remove these two procedures from that list. CMS also found that three types of diagnosis should be added to the fourth grouping, on acute diagnoses: hypertension with complications, acute pancreatitis, and acute biliary tract diseases. As mentioned above, CMS believes that any diagnoses included on this list are indicative of an acute – and therefore unplanned – readmission.

CMS is finalizing its proposal to refine the data capture around an existing readmission reduction measure. The total hip arthroplasty (THA) and total knee arthroplasty (TKA) measure is only intended to monitor readmissions of patients undergoing elective THA/TKAs. Because THAs were occasionally performed on patients who had a hip fracture, this rule proposes to exclude THAs with a principal or secondary diagnosis of hip fracture.

This rule does not adopt the monitoring of any new measures for FY2016. However, CMS plans to add coronary artery bypass graft (CABG) to the set of conditions under surveillance for excess readmissions for FY2017. CMS states that this is based on MedPAC recommendations, elaborating that CABG has one of the highest potentially preventable readmission rates among several conditions studied, based on analyses showing a strong variation on 30-day risk-standardized readmissions among hospitals. The proposed measure will be: Hospital-Level, 30-day, All-Caused, Unplanned Readmission Following CABG Surgery.

- **Hospital Inpatient Quality Reporting (IQR) Program and the EHR Incentive Program**

The Hospital IQR Program requires hospitals to submit quality and safety data to CMS in order to remain eligible for full DRG payments. Starting for the FY 2015 payment determination, a penalty will be applied to one quarter of the applicable IPPS market basket update.
Measures reported under the Hospital IQR Program are published on the Hospital Compare Web site (http://www.medicare.gov/hospitalcompare/search.html), and may later be adopted for use in the Hospital VBP Program.  

CMS is reducing the number of Hospital IQR Program measures to 47 measures in FY 2017, down from 57 measures in FY 2016. Specifically, for the FY 2017 payment determination, CMS initially proposed removing a total of twenty measures: sixteen “topped out” measures showing hospitals have generally achieved these measures with little remaining variation and four previously suspended clinical process-of-care measures. CMS is retaining 10 of the topped-out chart abstracted measures as voluntary electronic clinical quality measures. However, in this Final Rule, CMS opted not to finalize the removal of required chart-abstracted measure, SCIP-Inf-4, Cardiac Surgery Patients With Controlled 6AM Postoperative Blood Glucose.  

Outcome and cost measures are among the measures being proposed for the FY 2017 payment determination and for subsequent years. CMS is adding a total of eleven measures to the Hospital IQR measure set: nine new measures (episode of care payment measures for pneumonia and heart failure; a sepsis reduction bundle; breast feeding; hearing screening; readmissions for CABG and vascular access; home management plan of care document, and mortality for CABG), and two measures that were previously removed from the program (aspirin prescribed at discharge for AMI and statin prescribed at discharge – both electronically specified).  

Providers participating in the Hospital IQR Program have the option to voluntarily report a minimum of 16 electronically specified measures over three domains from 28 available measures. CMS is modifying its proposal for voluntary electronic measure submission and will only require one quarter of the data submission in CY 2015 for the FY 2017 payment determination. Because of this change, CMS is changing the submission deadline for CY 2015 to November 30, 2015.  

- **Value Based Purchasing Program (VBP)**  

The rule outlines an expansion of the Value Based Purchasing Program (VPB) program, which funds incentive payments to high performing hospitals through a coefficient reduction in base operating DRG payments for all hospital discharges.  

- In FY2014, the coefficient for the reduction was set at 1.25%  
- **In FY2015, the coefficient will be set at 1.5%;**  
- In FY2016, the coefficient will be 1.75%  
- In FY2017 and beyond, the coefficient will be 2%  

Under this program, all the base payment reductions will be reallocated within the IPPS system in order to fund an equivalent amount of value-based incentive payments, and the size of the reallocations will be...  

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3 The Hospital IQR Program measure set has grown from a starter set of 10 quality measures in 2004 to the set of 57 quality measures for the FY 2016 payment determination. These measures include chart-abstracted measures, such as heart attack and surgical care improvement measures; claims-based measures such as mortality and readmissions; healthcare-associated infections measures; survey-based measures, such as patient experience of care; and structural measures that assess features of hospitals to assess their capacity to improve quality of care.
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increase for the next several years before maxing out in FY2017. In FY2015, the amount of funding shifted through the VBP program is estimated at $1.4 billion.  

This Final Rule implements the removal of six “topped out” measures from the FY2017 performance measurement set. As with the IQR measures, CMS is shifting its emphasis away from clinical process measures. Below are the measures slated for removal:

1. PN-6 Initial antibiotic selection for CAP in immunocompetent patient
2. SCIP-CARD-2 Surgery patients on beta-blocker therapy prior to arrival who received a beta-blocker during the perioperative period
3. SCIP-INF-2 Prophylactic antibiotic selection for surgical patients
4. SCIP-INF-3 Prophylactic antibiotic discontinued within 24 hours after surgery end time
5. SCIP-INF-9 Urinary catheter removed on postoperative day 1 or postoperative day 2
6. SCIP-VTE-2 Surgery patients who received appropriate venous thromboembolism prophylaxis within 24 hours prior to surgery to 24 hours after surgery

CMS is adding three measures to the VBP program. CMS indicates that over 80% of the FY2017 measures will focus on health outcomes, patient experience, and cost; two of the new metrics will measure safety outcomes, while one will be a clinical care/process measure:

1. Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia (NQF #1716)
2. Clostridium difficile Infection (NQF #1717)
3. PC-01 Elective Delivery Prior to 39 Completed Week Gestation (NQF #0469)

CMS is also finalizing its earlier proposal to carry over one performance measure from FY2016 through FY2017, which was not previously proposed for automatic renewal:

1. Central Line-Associated Blood Stream Infection (CLABSI) (NQF #0139)

For the FY2019 program, the rule adopts two new measures:

1. Hospital-level Risk-Standardized Complication Rate (RSCR) following elective primary Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) (NQF #1550)
2. PSI-90 Complication/patient safety for selected indicators, composite

Finally, CMS would like to revise the weighting of the various performance domains, especially due to the removal of a large number of “topped out” measures in the clinical care/process domain. CMS proposes to reduce the weight of that domain to 5%, while increasing the weight of the safety domain to 20%.

• Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)

The ACA established the LTCHQR Program, which requires long-term care hospitals to report on quality measures or face a financial penalty. Beginning in FY 2014, the applicable annual increase factor for any LTCH that did not submit the required quality data to CMS was reduced by two percentage points. In the FY 2015 IPPS/LTCH PPS NPRM, CMS is proposing to include 3 additional quality measures, for a total of 12.

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4 CMS will continue to quantify hospital performance using a composite Total Performance Score (TPS). Depending on each hospital’s TPS, CMS will continue to apply adjustment factors to the base operating DRG payment amount for each discharge.

5 To date, CMS has finalized 9 measures for inclusion in the LTCH QRP.
Proposed Quality Measures: For the FY 2018 payment determination and subsequent years, CMS is proposing to add three additional quality measures: National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure; Functional Outcome Measure: Change in Mobility among LTCH Patients Requiring Ventilator Support; and Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function.

Proposed Policies: CMS is proposing a mandatory Reconsideration procedure for the LTCH QRP, which proposes to require that LTCH providers follow specific procedures when submitting a request for CMS’ reconsideration of an initial LTCH QRP provider compliance determination. This proposal would also expand the exception and extension process to allow LTCH providers to request exceptions or extensions for circumstances beyond their control, including those that are not classified as natural disasters. Finally, CMS is proposing to implement a new Data Validation process, which will require randomly selected LTCH providers to meet a proposed 90% data reliability score for required LTCH CARE Data Set items.

- New PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

CMS is not proposing to remove or replace any of the previously finalized measures from the PCHQR Program for the FY 2017 program and subsequent years. However, the proposed rule proposes to adopt a new measure beginning with the FY 2017 PCHQR Program. The addition of this measure, external beam radiotherapy for bone metastases, would increase the number of measures beginning with the FY 2017 program to a total of 19. Additionally, CMS is also proposing to adopt a number of other reporting updates.

III. MEDICAL TECHNOLOGY RELATED ISSUES AND OTHER CMS RECOMMENDATIONS THAT HELP INFORM ON RATIONALE FOR PAYMENT POLICY

❖ New Technology Add-On Payment (NTAP) Applications

CMS received seven New Technology Add-On Payment (NTAP) applications for FY 2015, three of which were applications resubmitted from FY 2014. One applicant withdrew its application prior to the publication of this proposed rule. In addition, the applicant for the Watchman® System withdrew its application prior to the publication of this final rule.

The five remaining applications reviewed by CMS are as follows:

a) Dalbavancin (Durata Therapeutics, Inc.)
b) Heli-FX™ EndoAnchor System (Aptus Endosystems, Inc.)
c) CardioMEMS™ HF (Heart Failure) System (CardioMEMS, Inc.)
d) MitraClip® System (Abbott Vascular)
e) Responsive Neurostimulator (RNS®) System (NeuroPace, Inc.)

In the Final Rule, CMS considered public comments and expressed favor or concern on whether the remaining applicants met the eligibility criteria for NTAP. The criteria for evaluating whether a new
technology is substantially similar to an existing technology is based on the following: (1) whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome (newness criterion); (2) whether a product is assigned to the same or a different MS-DRG (coding criterion); and (3) whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population (clinical improvement criterion).

If a technology meets all three of the criteria above, it would be considered substantially similar to an existing technology and would not be considered “new” for purposes of new technology add-on payments.

### Table I: FY2015 NTAP Applications and CMS’ Response

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<thead>
<tr>
<th>Technology (Manufacturer)</th>
<th>Description</th>
<th>CMS’ Response</th>
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<tbody>
<tr>
<td>Dalbavancin (Durata Therapeutics, Inc.)</td>
<td>Dalbavancin is an intravenous (IV) lipoglycopeptide antibiotic administered as a once-weekly 30-minute infusion via a peripheral line for the treatment of patients with acute bacterial skin and skin structure infections, or ABSSSI. Dalbavancin’s unique pharmacokinetic profile demonstrates rapid bactericidal activity that is potent and sustained against serious gram-positive bacteria, including methicillin-resistant Staphylococcus aureus (MRSA).</td>
<td>CMS does not believe that Dalbavancin meets the substantial clinical improvement criterion to qualify the technology for new technology add-on payments under the IPPS in FY 2015.</td>
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<tr>
<td>Heli-FX™ EndoAnchor System (Aptus Endosystems, Inc.)</td>
<td>The Heli-FX™ EndoAnchor System is indicated for use in the treatment of patients whose endovascular grafts during treatment of aortic aneurysms have exhibited migrations or endoleaks, or in the treatment of patients who are at risk of such complications, and in whom augmented radial fixation and/or sealing is required to regain or maintain adequate aneurysm exclusion.</td>
<td>CMS does not believe that the Heli-FX™ meets the newness criterion and the substantial clinical improvement criterion to qualify the technology for new technology add-on payments under the IPPS in FY 2015.</td>
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<tr>
<td>WATCHMAN® Left Atrial Appendage Closure Technology (Boston Scientific Corporation)</td>
<td>The WATCHMAN® Left Atrial Appendage (LAA) Closure Device is an implant that acts as a physical barrier, sealing the LAA to prevent thromboemboli from entering into the arterial circulation from the LAA, thereby reducing the risk of stroke and potentially eliminating the need for Warfarin therapy in those patients diagnosed with nonvalvular atrial fibrillation (AF) and who are eligible for Warfarin therapy.</td>
<td>Withdrawn.</td>
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<tr>
<td>CardioMEMS™ HF (Heart Failure) System (CardioMEMS, Inc.)</td>
<td>The CardioMEMS™ HF (Heart Failure) System is an implantable hemodynamic monitoring system comprised of an implantable sensor/monitor placed in the distal pulmonary artery. The CardioMEMS™ HF System measures multiple pulmonary artery pressure parameters for an ambulatory patient to measure and transmit data via a wireless sensor to a secure Web site. The system provides the physician with the patient’s PA pressure waveform (including systolic, diastolic, and mean pressures) as well as heart rate. Interpretation of trend data allows the clinician to make adjustments to therapy and can be used along with heart failure signs and symptoms to adjust medications.</td>
<td>CMS approved new technology add-on payments for the CardioMEMS™ HF Monitoring System for new technology add-on payments in FY 2015. Cases involving the CardioMEMS™ HF Monitoring System that are eligible for new technology add-on payments will be identified by ICD-9-CM procedure code 38.26 (Insertion of implantable wireless pressure sensor for intracardiac or great vessel hemodynamic monitoring), which was effective October 1, 2011. With the new technology add-on payment application, the applicant stated that the total operating cost of the CardioMEMS™ HF Monitoring System is $17,750. The maximum payment for a case involving the CardioMEMS™ HF Monitoring System is $8,875 for FY 2015.</td>
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MitraClip® System (Abbott Vascular)

The MitraClip® System is a transcatheter mitral valve repair system that includes a MitraClip® device implant, a Steerable Guide Catheter, and a Clip Delivery System. It is designed to perform reconstruction of the insufficient mitral valve for high-risk patients who are not candidates for conventional open mitral valve repair surgery.

CMS approved new technology add-on payments for the MitraClip® System for new technology add-on payments in FY 2015. Any payment made under the Medicare program for services provided to a beneficiary is contingent upon CMS' coverage of the item, and any restrictions on the coverage apply. This approval is on the basis of using the MitraClip® consistent with any coverage decision that will be issued by CMS after the publication of this final rule. Subject to any coverage determinations made by CMS regarding the MitraClip® System, cases involving the MitraClip® System that are eligible for the new technology add-on payments will be identified by ICD-9-CM procedure code 35.97. The average cost of the MitraClip® System is reported as $30,000. The maximum add-on payment for a case involving the MitraClip® System is $15,000 for FY 2015.

Responsive Neurostimulator (RNS®) System (NeuroPace, Inc.)

The RNS® System is an implantable medical device for treating persons diagnosed with epilepsy whose partial onset seizures have not been adequately controlled with antiepileptic medications. According to the applicant, the RNS® System is the first closed-loop, responsive system to treat partial onset seizures.

CMS approved new technology add-on payments for the RNS® System for FY 2015. Cases involving the RNS® System that are eligible for new technology add-on payments will be identified using the following ICD-9-CM procedure codes: 01.20 (Cranial implantation or replacement of neurostimulator pulse generator) in combination with 02.93 (Implantation or replacement of intracranial neurostimulator lead(s)). According to the applicant, cases using the RNS® System would incur an anticipated cost per case of $36,950. The maximum add on payment for cases involving the RNS® System is $18,475 for FY 2015.

MS-DRG Classifications: Final Changes

Table II: MS-DRG Classification Updates

<table>
<thead>
<tr>
<th>Request</th>
<th>CMS Response</th>
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<tr>
<td><strong>MDC 1 (Diseases and Disorders of the Nervous System)</strong></td>
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<tr>
<td>CMS received a request to create a new MS-DRG for intracerebral therapies, including implantation of chemotherapeutic agents. Specifically, the Gliadel® Wafer for the treatment of High-Grade Malignant Gliomas (HGGs) defined as aggressive tumors originating in the brain.</td>
<td>CMS determined they will maintain the current MS-DRG assignments for cases where ICD-9-CM procedure code 00.10 is reported.</td>
</tr>
<tr>
<td>CMS received a request to change the MS-DRG assignment for the following three ICD-9-CM procedure codes representing endovascular embolization or occlusion procedures of the head and neck: • 39.72 • 39.75 • 39.76</td>
<td>CMS determined they will maintain the current MS-DRG assignments for endovascular embolization or occlusion of head and neck procedures.</td>
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| **MDC 4 (Diseases and Disorders of the Ear, Nose, Mouth and Throat): Avery Breathing Pacemaker System** | |
| CMS received a request to create a new MS-DRG for the Avery Breathing Pacemaker System. | CMS is finalizing its proposal to maintain the current MS-DRG assignments and will not create a new MS-DRG for diaphragmatic pacemaker |
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**MDC 5 (Diseases and Disorders of the Circulatory System)**
- CMS received a request to move the exclusion of the left atrial appendage procedure, which is a non-O.R. procedure and captured by ICD-9-CM procedure code 37.36, from MS-DRGs 250 and 251 to MS-DRGs 237 and 238.
- CMS is not reassigning exclusion of atrial appendage procedure cases from MS-DRGs 250 and 251 to MS-DRGs 237 and 238 at this time.
- CMS received a request to reassign cases reporting a transcatheter mitral valve repair using the MitraClip® from MS-DRGs 250 and 251 to MS-DRGs 216, 217, 218, 219, 220, and 221.
- CMS is not planning to modify the current MS-DRG assignment for cases reporting procedure code 35.97. Therefore, for FY 2015, CMS is not proposing to create a new MS-DRG to group cases reporting the percutaneous mitral valve repair (MitraClip®) procedure with transcatheter/endovascular cardiac valve replacement procedures.
- CMS received a second request to examine the creation of a new base MS-DRG for transcatheter valve therapies.
- CMS is finalizing its proposal to create the following MS-DRGs for endovascular cardiac valve replacements:
  - Proposed new MS-DRG 266 (Endovascular Cardiac Valve Replacement with MCC); and
  - Proposed new MS-DRG 267 (Endovascular Cardiac Valve Replacement without MCC).
- CMS received a request to change the MS-DRG assignment for procedure code 39.71, which is assigned to MS-DRGs 237 and 238. The requester asked that CMS reassign procedure code 39.71 to MS-DRGs 228, 229, and 230.
- CMS is maintaining the current MS-DRG assignments for endovascular abdominal aorta graft implantation cases.

**MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)**
- CMS received a request to change the MS-DRG assignment for shoulder replacement procedures.
- CMS is finalizing its earlier proposal to collapse MS-DRGs 483 and 484 into a single MS-DRG by deleting MS-DRG 484 and revising the title of MS-DRG 483 to read “Major Joint/Limb Reattachment Procedure of Upper Extremities”. CMS is proposing to maintain the current MS-DRG assignments for revisions of upper joint replacement procedures in MS-DRGs 515, 516, and 517.
- CMS received a request to reassign cases identified with a complication or comorbidity (CC) in MS-DRG 490 to MS-DRG 491. The requester suggested that CMS create a new MS-DRG that would be subdivided based solely on the “with MCC or Disc device/Neurostimulator” and the “without MCC” (and no device) criteria.
- CMS determined they will create three new MS-DRGs and to delete MS-DRGs 490 and 491. These new MS-DRGs are as follows and will be effective as of October 1, 2014:
  - MS-DRG 518 (Back & Neck Procedures Except Spinal Fusion with MCC or Disc Device/Neurostimulator);
  - MS-DRG 519 (Back & Neck Procedures Except Spinal Fusion with CC); and
  - MS-DRG 520 (Back & Neck Procedures Except Spinal Fusion without CC/MCC).

**MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders): Disorders of Porphyria Metabolism**
- CMS received a request for the creation of a new MS-DRG to better identify cases where patients with disorders of porphyrin metabolism exist, to recognize the resource requirements in caring for these patients, to ensure appropriate payment for these cases, and to preserve patient cases at this time.
- CMS is not creating a new MS-DRG for porphyria cases.
Key Final Changes to the IPPS for FY2015

### MDC 15 (Newborns and Other Neonates with Conditions Originating in the Perinatal Period)

| CMS received a request to evaluate the MS–DRG assignment of seven ICD–9–CM diagnosis codes in MS-DRG 794 (Neonate with Other Significant Problems) under MDC 15. | For FY 2015, CMS is reassigning seven diagnoses to the “only secondary diagnosis list” under MS–DRG 795 so that the case would be assigned to MS–DRG 795. |

- **Proposed Medicare Code Editor (MCE) Changes**

For FY 2015, CMS is removing extracranial-intracranial (EC-IC) bypass surgery from the “Noncovered Procedure” edit code list for Version 32.0 of the MCE. This procedure is identified by ICD-9-CM procedure code 39.28 (Extracranial intracranial (EC-IC) vascular bypass).

- **Proposed Changes to Surgical Hierarchies**

CMS is revising the surgical hierarchy for MDC 5 (Diseases and Disorders of the Circulatory System) and MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) as follows:

  - In MDC 5, CMS is adopting the proposal to sequence new MS-DRG 266 (Endovascular Cardiac Valve Replacement with MCC) and new MS-DRG 267 (Endovascular Cardiac Valve Replacement without MCC) above MS-DRG 222 (Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock with MCC).

  - In MDC 8, CMS is deleting MS-DRGs 490 (Back & Neck Procedures Except Spinal Fusion with CC/MCC or Disc Device/Neurostimulator) and MS-DRG 491 (Back & Neck Procedures Except Spinal Fusion without CC/MCC or Disc Device/Neurostimulator) from the surgical hierarchy. CMS is sequencing new MS-DRG 518 (Back & Neck Procedure Except Spinal Fusion with MCC or Disc Device/Neurostimulator), new MS-DRG 519 (Back & Neck Procedure Except Spinal Fusion with CC), and new MS-DRG 520 (Back & Neck Procedure Except Spinal Fusion without CC/MCC) above MS-DRG 492 (Lower Extremity and Humerus Procedure Except Hip, Foot, Femur with MCC).

- **Proposed Changes to the MS-DRG Diagnosis Codes for FY 2015**

**Major Complications or Comorbidities (MCCs) and Complications or Comorbidities (CCs) Severity Levels for FY 2015**

A complete updated MCC, CC, and Non-CC Exclusion List is available via the Internet on the CMS Web site at: [http://cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html](http://cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html)

**Coronary Atherosclerosis Due to Calcified Coronary Lesion**

CMS received a request to change the severity level for ICD-9-CM diagnosis code 414.4 (Coronary atherosclerosis due to calcified coronary lesion) from a non-CC to an MCC. Based on the data and clinical analysis, CMS is maintaining diagnosis code 414.4 as a non-CC. CMS reviewed the MedPAR data to compare the number of patients with diagnosis ICD-9 Dx 414.4 who also presented with secondary diagnoses that are considered non-CCs, CCs, and MCCs, respectively. It found that ICD-9 Dx code 414.4 produced values that one would have expected of a non-CC. Finally, CMS consulted clinical advisors...
who pointed out that a similar code 414.2 (Chronic total occlusion of coronary artery) is also a non-CC and is likely more severe than 414.4.

- Complications or Comorbidity (CC) Exclusions List

Under the IPPS MS-DRG classification system, CMS has developed a standard list of diagnoses that are considered CCs. For FY 2015, CMS is not adopting any changes to the CC Exclusion List.

- Review of Procedure Codes in MS-DRGs 981 through 983, 984 through 986, and 987 through 989

For FY 2015, CMS is not making changes the procedures assigned among these MS-DRGs.