Cardiovascular Market Impacts

Introduction
On August 2, 2013, the Centers for Medicare and Medicaid Services (CMS) released the final policy changes and payment rates for the Hospital Inpatient Prospective Payment System (IPPS) for Fiscal Year 2014. The final rule will apply to approximately 3,400 acute care hospitals, beginning with discharges occurring on or after October 1, 2013.

The cardiovascular device market is expected to receive favorable increases in payment relative to FY 2013 payments. See the list below for a summary of the final weighted average of payment estimates for FY 2014 as compared to final FY 2013.

- ICD and CRT-D system implants increase 6%
- ICD and CRT-D generator and ICD lead replacements increase 9%
- Pacemaker and CRT-P implants increase 4%
- Pacemaker and CRT-P generator replacements increase 5%
- Transcatheter ablations increase 4%
- Stand-alone surgical ablations decrease -2%

1. General Updates

The final FY 2014 Hospital Inpatient Prospective Payment System (IPPS) rule increases overall hospital payments (capital and operating) by $1.2 billion. The final rule would increase IPPS operating rates by 0.7 percent after accounting for inflation and other adjustments required by the law. This increase reflects a temporary reduction of 0.8 percent to implement the American Taxpayer Relief Act’s requirement to recoup overpayments from prior years as a result of a new patient classification system that better recognizes patient severity of illness. CMS is also making an additional 0.2 percent reduction to offset projected spending increases associated with changes to admission and medical review criteria for inpatient services.

Cardiac hospitals (15 total) are expected to experience a payment increase of 1.5 percent in FY 2014 relative to FY 2013 primarily due to the final changes in the relative weights and the application of

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the frontier State wage index (Section 10324 of Pub. L. 111-148 requires that hospitals in frontier States cannot be assigned a wage index of less than 1.0000.)

**Documentation and Coding Adjustment.** Section 631 of the American Taxpayer Relief Act of 2012 requires CMS to recover $11 billion over the next four years to fully recoup documentation and coding overpayments for prior years. The basis of this adjustment is the Medicare adoption of the new patient classification system (MS-DRGs) in FY 2008 that better recognized severity of illness but also led to increases in Medicare spending as a result of changes in documentation and coding. For FY 2014, CMS is implementing a negative 0.8 percent recoupment adjustment as the first step in this recovery process. CMS expects to make similar adjustments in FYs 2015, 2016, and 2017 in order to recover the full $11 billion. Once the recovery is complete, a positive adjustment will be made to remove the effects of these one-time recoupment adjustments.

**Market Basket.** CMS finalizes the revising and rebasing of the hospital market basket for FY 2014. The final FY 2014 market basket will use FY 2010 data for the base-year cost weights in place of FY 2006 data.

Effective for cost reporting periods beginning on or after July 1, 1979, CMS developed and adopted a hospital input price index (that is, the hospital market basket for operating costs). Although “market basket” technically describes the mix of goods and services used in providing hospital care, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies combined) derived from that market basket. Accordingly, the term “market basket” refers to the hospital input price index. Since the inception of the IPPS, the projected change in the hospital market basket has been the integral component of the update factor by which the prospective payment rates are updated every year.

The terms “rebasing” and “revising,” while often used interchangeably, actually denote different activities. “Rebasing” means moving the base year for the structure of costs of an input price index (for example, in this final rule, CMS is shifting the base year cost structure for the IPPS hospital index from FY 2006 to FY 2010). “Revising” means changing data sources, or price proxies, used in the input price index.

As published in the FY 2006 IPPS final rule (70 FR 47387), in accordance with section 404 of Pub. L. 108-173, CMS determined a new frequency for rebasing the hospital market basket. CMS established a rebasing frequency of every 4 years and, therefore, for the FY 2014 IPPS update, it will rebase and revise the IPPS market basket.

**MS-DRG Relative Weight Refinement.** In the FY 2009 and the FY 2011 final rules, CMS created new cost centers for Implantable Devices Charged to Patients, MRIs, CT scans, and cardiac catheterization. In those rules, CMS stated that it would consider creating separate cost to charge ratios (CCRs) for the new cost centers to calculate the relative weights. For FY 2014
CMS will implement the new cost centers for Implantable Devices, MRIs, CT scans, and cardiac catheterization for FY 2014, which would increase the total number of CCRs used to calculate the FY 2014 relative weights from 15 to 19.

Beginning in FY 2007, CMS implemented relative weights for DRGs based on cost report data instead of charge information. To address the issue of charge compression (the hospital practice of applying higher charges to lower cost items and applying lesser charges to higher cost items) when using cost report data to set the MS-DRG relative weights, in FYs 2009 and 2010, CMS created additional cost centers on the Medicare cost report to distinguish implantable devices from other medical supplies, MRIs and CT scans, respectively, from other radiology services, and cardiac catheterization from other cardiology services. As compared to previous years, CMS currently reports a significant volume of hospitals completing all, or some, of these new cost centers on the Medicare cost report. Therefore, beginning in FY 2014, CMS will calculate the MS-DRG relative weights using 19 CCRs, creating distinct CCRs from cost report data for implantable devices, MRIs, CT scans, and cardiac catheterization.

**Critical Access Hospitals (CAH) Conditions of Participation.** To ensure continued access to inpatient services, critical access hospital Conditions of Participation requires that CAHs have the capacity to provide inpatient care on-site. In the final rule, CMS notes it has received a number of questions from stakeholders in the CAH provider community relating to whether CAHs are required to furnish acute care inpatient services under the CAH CoPs. CMS’s interpretation is that CAHs must provide acute care inpatient services, and therefore finalizes revisions to clarify and restate this requirement.

**Medicare-Dependent Small-Rural Hospital (MDH) Program.** Section 1885(d)(5)(G) of the Act provides special payment protections, under the IPPS, to a Medicare-dependent, small rural hospital (MDH). Section 3124 of the Affordable Care Act extended the expiration of the MDH program from the end of FY 2011 (that is, for discharges occurring before October 1, 2011) to the end of FY 2012 (that is, for discharges occurring before October 1, 2012). The American Taxpayer Relief Act extended the MDH program for one additional year, through FY 2013. The final rule includes the expiration of the MDH payment designation for discharges occurring on or after October 1, 2013.

**Low-Volume Hospitals.** The temporary changes to low-volume hospital definition and payment adjustment methodology provided for by the Affordable Care Act and the American Tax Relief Act for FY 2011 through FY 2013 are expiring. Consistent with statute, CMS finalizes in FY 2014 to return the low-volume hospital definition and payment adjustment methodology that was in place prior to FY 2011, before the temporary provisions took effect.

Beginning with FY 2014, the preexisting low-volume hospital qualifying criteria and payment adjustment, as implemented in FY 2005, will resume. Therefore, consistent with section
(12) of the Act, as amended, under the conforming changes to § 412.101(b)(2), effective for FY 2014 and subsequent years, in order to qualify as a low-volume hospital, a subsection (d) hospital must be more than 25 road miles from another subsection (d) hospital and have less than 200 discharges (that is, less than 200 discharges total, including both Medicare and non-Medicare discharges) during the fiscal year. Under the existing policy, effective for FY 2014 and subsequent years, qualifying hospitals would receive the low-volume hospital payment adjustment of an additional 25 percent for discharges occurring during the fiscal year.

**Admission and Medical Review Criteria for Inpatient Services.** In the final rule, CMS clarifies its longstanding policy on how Medicare contractors review inpatient admissions for payment purposes. This final policy is intended to address longstanding concerns from hospitals that they need more guidance on when a patient is appropriately treated and paid by Medicare as an inpatient. At the same time, the change would help beneficiaries who in recent years have been staying in the hospital longer as outpatients because of the hospital’s uncertainty about Medicare payment if they admit the patient to the hospital.

In recent years, the number of cases of Medicare beneficiaries receiving observation services for more than 48 hours, while still small, has increased from approximately 3 percent in 2006 to approximately 8 percent in 2011. This trend concerns CMS because of the potential financial impact on Medicare beneficiaries, and CMS has published educational materials for beneficiaries to inform them of their respective liabilities as a hospital outpatient or inpatient. Beneficiaries who are treated for extended periods of time as hospital outpatients receiving observation services may incur greater financial liability than they would if they were admitted as hospital inpatients.

For FY 2014 CMS is implementing a time-based presumption of medical necessity for hospital inpatient services based on the beneficiary’s length of stay, as part of the medical review criteria for payment of hospital inpatient services under Part A. Specifically, a hospital inpatient admissions spanning at least two midnights (that is, at least more than one Medicare utilization day), will presumptively qualify as appropriate for payment under Medicare Part A. Conversely, hospital inpatient admissions spanning less than two midnights (that is, less than one Medicare utilization day) will presumptively be inappropriate for payment under Medicare Part A. This presumption may be overcome by documentation in the medical record supporting the admitting physician’s expectation that the beneficiary would need care spanning at least two midnights and an unforeseen circumstance results in a shorter beneficiary stay than the physician’s expectation. Physicians must support their expectation, and accordingly their order for admission, through clear and complete medical documentation.

In this final rule, CMS provides inpatient hospital admission guidance under which a physician or other practitioner should order admission if he or she expects that the beneficiary’s length of stay will exceed a 2-midnight threshold or if the beneficiary requires a procedure specified as inpatient-only. CMS finalizes that the starting point for this time-based instruction would be when the
beneficiary is moved from any outpatient area to a bed in the hospital in which the additional hospital services will be provided.

Under the final policy, the judgment of the physician and the physician’s order for inpatient admission should be based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event.

CMS notes its actuaries estimate that the rule would increase IPPS expenditures by approximately $220 million due to an expected net increase in inpatient encounters. CMS will use its exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to make a reduction of 0.2 percent to the standardized amount, the Puerto Rico standardized amount, and the hospital-specific payment rate to offset this estimated $220 million in additional IPPS expenditures. CMS also will apply that 0.2 percent reduction to the capital Federal rates using its authority under section 1886(g) of the Act.

**Direct Graduate Medical Education (DGME).** CMS will revise the GME policy addressing inpatient labor and delivery days in the inpatient Medicare utilization calculation. CMS also finalizes, for portions of cost reporting periods beginning on or after October 1, 2013, that a hospital may not claim full-time equivalent residents training at a Critical Access Hospital (CAH) for Indirect Medical Education (IME) and/or direct GME purposes. However, if a CAH itself incurs the costs of training the full-time equivalent residents when these residents rotate to the CAH, the CAH may receive payment based on 101 percent of those Medicare reasonable costs under the regulations.

Finally, in accordance with section 5506 of the Affordable Care Act, which redistributes residency slots from closed hospitals, CMS is notifying the public of the closure of a hospital and initiating another application and selection process to redistribute the closed hospital’s GME full-time equivalent caps.

**Medicare Disproportionate Share Hospitals (DSH).** Medicare pays an additional amount to hospitals that serve a disproportionate share of low-income patients. Section 3133 of the Affordable Care Act, as amended, requires that instead of the amount that would otherwise be paid, hospitals will receive 25 percent of their current Medicare DSH payments beginning in FY 2014. The remaining 75 percent will be adjusted for decreases in the rate of uninsured individuals nationally and distributed as additional payments to hospitals that receive DSH payments based on each hospital’s share of uncompensated care relative to all hospitals that are estimated to receive DSH payments. In the FY 2014 final rule, CMS is estimating the three factors required to determine the amount of these new uncompensated care payments.
2. Quality Data Reporting

**CHANGES TO THE HOSPITAL IQR PROGRAM AND THE EHR INCENTIVE PROGRAM**

The Hospital IQR Program grew out of the Hospital Quality Initiative developed by CMS in consultation with hospital groups. By statute, hospitals that do not participate successfully in the Hospital IQR program have their annual payment updates reduced by 2.0 percentage points. Since the implementation of this financial penalty, hospital participation has increased to well over 99 percent of Medicare-participating hospitals that are reimbursed under the IPPS.

Measures reported under the IQR Program are published on the Hospital Compare Web site ([http://www.hospitalcompare.hhs.gov/](http://www.hospitalcompare.hhs.gov/)), and may later be adopted for use in the Hospital VBP Program, mandated by the Affordable Care Act, which affects payment rates to hospitals beginning in FY 2013.

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 listed in this final rule. These measures include chart-abstracted measures, such as heart attack, heart failure, pneumonia, and surgical care improvement measures; claims-based measures such as mortality and readmissions; healthcare-associated infections measures; a surgical complications measure; survey-based measures, such as patient experience of care; immunization measures, and structural measures that assess features of hospitals—such as hospital volume, how the hospital deploys staff, or provider qualifications—to assess their capacity to improve quality of care.

For the FY 2016 payment determination and subsequent years, CMS will remove four chart abstracted measures and one structural measure as well as adopt five new claims based measures.

CMS will validate two new chart abstracted HAI measures: hospital-onset methicillin-resistant *staphylococcus aureas* (MRSA) bacteremia, and *clostridium difficile*. Also the reduction in the number of records used for HAI validation from 48 to 36 patient charts for individual hospitals annually for the FY 2015 payment determination and subsequent years. CMS also will provide hospitals with the option to securely transmit electronic versions of medical information to meet validation requirements.

CMS also will reduce providers’ reporting burden by expanding several Medicare Electronic Health Record (EHR) Incentive Program policies with the Hospital IQR Program policies. This would include expanding the submission period for electronic clinical quality measures to begin January 2, 2014; allowing eligible hospitals and critical access hospitals that would like to submit aggregate data for Meaningful Use the option of attesting, and streamlining the
submission of aggregate population data in order to invoke the case number threshold exemption for an electronic clinical quality measure.

CMS is implementing that hospitals participating in the IQR program have the option to electronically submit one quarter’s data for 16 quality measures from four measure sets. Hospitals that do not submit electronically would have to submit a full year’s worth of data via chart-abstraction. CMS also will collect and report this measure data through Certified Electronic Health Record Technologies (CEHRTs).

CMS believes the use of CEHRTs will greatly simplify and streamline reporting for many hospital quality-reporting programs. CMS also anticipates that through electronic reporting, hospitals will be able to leverage electronic health records for Hospital IQR Program quality data that is now manually abstracted from charts. The intent is to harmonize measures across hospital quality reporting programs, improve care, and minimize the reporting burden on hospitals. If hospitals choose to electronically report these four measure sets, this will satisfy the reporting requirement for both the CQM component of the Medicare EHR Incentive program and the requirement to report these measures under the Hospital IQR program.

**CHANGES IN THE HOSPITAL VBP PROGRAM:**

**Program Requirements for FY 2014.** The final rule outlines operational details for FY 2014, including an increase in the applicable percent reduction to base operating DRG payment amounts (1.25 percent) and the total estimated amount available for value-based incentive payments (approximately $1.1 billion).

**Program Requirements for FY 2016.** The final rule would readopt all finalized FY 2015 Clinical Process of Care measures for the FY 2016 measure set, except primary percutaneous coronary intervention received within 90 minutes of hospital arrival; blood cultures performed in the emergency department prior to initial antibiotic received in hospital, and discharge instructions for heart failure patients.

CMS also will adopt new measures for FY 2016, including one new clinical process measure, influenza immunization, and two new healthcare-associated infection measures, Catheter-Associated Urinary Tract Infection (CAUTI) and Surgical Site Infection (SSI), the latter of which is stratified into two separate surgery sites.

The final rule outlines the performance and baseline periods for the FY 2016 program, and will re-classification of the Hospital VBP program domains to more closely align with the National Quality Strategy in FY 2017.
The final rule implements performance standards, including achievement thresholds and benchmarks for the FY 2016 program, including the “floors” for all eight Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) dimensions.

The final rule will use the same scoring methodology and performance standards previously adopted for the three 30-day mortality and Agency for Healthcare Research and Quality (AHRQ) patient safety composite measures for FYs 2017-2019. CMS will implement performance and baseline periods, as well as performance standards, for the three 30-day mortality and Agency for Healthcare Research and Quality (AHRQ) patient safety composite measures for FYs 2017-2019.

HOSPITAL READMISSIONS REDUCTION PROGRAM

The Hospital Readmissions Reduction program began on October 1, 2012. The maximum reduction under this program, which was one percent of payment amounts in FY 2013, will increase to two percent of payment amounts in FY 2014, as specified under the Affordable Care Act. CMS defines a readmission as when a patient is discharged from the applicable hospital to a non-acute setting (for example, home health, skilled nursing, rehabilitation or home) and then is admitted to the same or another acute care hospital within a 30 day period from the time of discharge from the index hospitalization, however, the measures also “have exclusions for readmissions that are unrelated to the prior discharge.”

CMS currently assesses hospitals’ readmission penalties using three readmissions measures endorsed by the National Quality Forum (NQF): heart attack, heart failure, and pneumonia. For FY 2014, CMS will revise methodology to take into account planned readmissions for these three existing readmissions measures. CMS also will add two new readmission measures, which would be used to calculate readmission penalties beginning for FY 2015: readmissions for hip/knee arthroplasty and chronic obstructive pulmonary disease.

The law allows CMS to expand the applicable conditions beyond the three conditions for which measures have been endorsed above. . . to an additional 4 conditions that have been identified by the Medicare Payment Commission in its report to Congress in June 2007, and to other conditions and procedures as determined appropriate. The four conditions and procedures recommended by MedPAC are: (1) coronary artery bypass graft (CABG) surgery; (2) chronic obstructive pulmonary disease (COPD); (3) percutaneous coronary intervention (PCI); and (4) other vascular conditions. The law stipulates in selecting an “applicable condition,” to choose from among conditions and procedures “that represent conditions or procedures that are high volume or high expenditures under this title (or other criteria specified by the Secretary).” In accordance with this law, effective for the calculation of the readmissions payment adjustment factors in FY 2015, CMS will expand the applicable conditions and procedures to include: (1)
patients admitted for an acute exacerbation of COPD; and (2) patients admitted for elective total hip arthroplasty (THA) and total knee arthroplasty (TKA).

At this point, it is not feasible for CMS to add readmission measures for the three remaining conditions CABG, PCI, and other vascular conditions. CMS notes that inpatient admissions for PCI and other vascular conditions seem to be decreasing, and these procedures are being performed more in hospital outpatient departments. This shift in setting for these procedures may make their future inclusion in the Hospital Readmission Reduction Program more difficult and impracticable.

NEW HOSPITAL-ACQUIRED CONDITION REDUCTION PROGRAM

Section 3008 of the Affordable Care Act required CMS to establish a financial incentive for IPPS hospitals to improve patient safety by imposing financial penalties on hospitals that perform poorly with regard to hospital-acquired conditions (HACs). HACs are conditions that patients did not have when they were admitted to the hospital, but that developed during the hospital stay. The provisions for CMS evaluation of a condition for HAC classification include: (a) the condition is high cost, high volume, or both; (b) the ICD-9-CM diagnosis code is assigned to a higher paying MS-DRG when present as a secondary diagnosis (that is, conditions that are CCs or MCCs); (c) the condition could reasonably have been prevented through the application of evidence-based guidelines. This rule outlines a general framework for the HAC Reduction Program for the FY 2015 implementation.

Under this program, hospitals that rank in the lowest-performing quartile of hospital acquired conditions would be paid 99 percent of what they would otherwise be paid under the IPPS beginning in FY 2015. To determine this quartile, CMS is implementing quality measures and a scoring methodology as well as a process for hospitals to review and correct their data.

For FY 2015, the first year of the program, CMS will measure HACs using measures that are either calculated using claims or are part of the Inpatient Quality Reporting program and would consist of two domains of measure sets.

The Domain 1 measures would include six patient safety indicator (PSI) measures developed by the Agency for Health Care Research and Quality (AHRQ). These measures are: pressure ulcer rate; volume of foreign object left in the body; iatrogenic pneumothorax rate; postoperative physiologic and metabolic derangement rate; postoperative pulmonary embolism or deep vein thrombosis rate, and accidental puncture and laceration rate. An alternative to Domain 1 is also being implemented, which would consist of a composite PSI measure set.
The Domain 2 measures would include two healthcare-associated infection measures developed by the Centers for Disease Control and Prevention’s (CDC) National Health Safety Network: Central Line-Associated Blood Stream Infection and Catheter-Associated Urinary Tract Infection.

Under the scoring methodology, hospitals would be given a score for each measure within the two domains. A domain score would be calculated and the two domains would be weighted equally to determine a total score under the program. Risk factors such as the patient’s age, gender, and comorbidities would be considered in the calculation of the measure rates so that hospitals serving a large proportion of sicker patients would not be unfairly penalized. In accordance with the statute, CMS will implement a process for hospitals to review and correct their information.

3. MS-DRG Updates

For FY 2014 CMS will not implement any cardiovascular related MS-DRG changes. CMS does however finalize revisions to discharge status codes within the MS-DRG system for a few cardiovascular MS-DRGs.

**Discharge/Transfer to Designated Disaster Alternative Care Site.** CMS will add new patient discharge status code 69 (Discharged/ transferred to a designated disaster alternative care site) to the MS-DRG GROUPER logic for MS-DRGs 280 (Acute Myocardial Infarction Discharged Alive with MCC), 281 (Acute Myocardial Infarction Discharged Alive with CC), and 282 (Acute Myocardial Infarction Discharged Alive without CC/MCC) to identify patients who are discharged or transferred to an alternative site that will provide basic patient care during a disaster response. This new discharge status code is also being added to the Medicare Code Editor (MCE) software.

**Discharges/Transfers With a Planned Acute Care Hospital Inpatient Readmission.** CMS also will add 15 new discharge status codes to the MS-DRG GROUPER logic for MS-DRGs 280, 281, and 282 that will identify patients who are discharged with a planned acute care hospital inpatient readmission. Shown in the table below are the current discharge status codes that are assigned to the GROUPER logic for MS-DRGs 280, 281, and 282, along with the new discharge status codes and their titles.

<table>
<thead>
<tr>
<th>Current Code</th>
<th>New Code</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>81</td>
<td>Discharged to home or self care with a planned acute care hospital inpatient readmission</td>
</tr>
<tr>
<td>02</td>
<td>82</td>
<td>Discharged/ transferred to a short term general hospital for inpatient care with a planned acute care hospital inpatient readmission</td>
</tr>
<tr>
<td>03</td>
<td>83</td>
<td>Discharged/ transferred to a skilled nursing facility (SNF) with Medicare certification with a</td>
</tr>
</tbody>
</table>
planned acute care hospital inpatient readmission

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>04</td>
<td>Discharged/transferred to a facility that provides custodial or supportive care with a planned acute care hospital inpatient readmission</td>
</tr>
<tr>
<td>05</td>
<td>Discharged/transferred to a designated cancer center or children’s hospital with a planned acute care hospital inpatient readmission</td>
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<tr>
<td>06</td>
<td>Discharged/transferred to home under care of organized home health service organization with a planned acute care hospital inpatient readmission</td>
</tr>
<tr>
<td>21</td>
<td>Discharged/transferred to court/law enforcement with a planned acute care hospital inpatient readmission</td>
</tr>
<tr>
<td>43</td>
<td>Discharged/transferred to a federal health care facility with a planned acute care hospital inpatient readmission</td>
</tr>
<tr>
<td>61</td>
<td>Discharged/transferred to a hospital-based Medicare approved swing bed with a planned acute care hospital inpatient readmission</td>
</tr>
<tr>
<td>62</td>
<td>Discharged/transferred to an inpatient rehabilitation facility (IRF) including rehabilitation distinct part units of a hospital with a planned acute care hospital inpatient readmission</td>
</tr>
<tr>
<td>63</td>
<td>Discharged/transferred to a Medicare certified long term care hospital (LTCH) with a planned acute care hospital inpatient readmission</td>
</tr>
<tr>
<td>64</td>
<td>Discharged/transferred to a nursing facility certified under Medicaid but not certified under Medicare with a planned acute care hospital inpatient readmission</td>
</tr>
<tr>
<td>65</td>
<td>Discharged/transferred to a psychiatric distinct part unit of a hospital with a planned acute care hospital inpatient readmission</td>
</tr>
<tr>
<td>66</td>
<td>Discharged/transferred to a critical access hospital (CAH) with a planned acute care hospital inpatient readmission</td>
</tr>
<tr>
<td>70</td>
<td>Discharged/transferred to another type of health care institution not defined elsewhere in this code list with a planned acute care hospital inpatient readmission</td>
</tr>
</tbody>
</table>

4. **New Technology Add-On Payments**

**Status of FY 2013 Add-On Payments**

Cook® Medical submitted an application for new technology add-on payments for the Zenith® Fenestrated Abdominal Aortic Aneurysm (AAA) Endovascular Graft (Zenith® F. Graft) for FY 2013. The applicant stated that the current treatment for patients who have had an AAA is an endovascular graft. The applicant explained that the Zenith® F. Graft is an implantable device designed to treat patients who have an AAA and who are anatomically unsuitable for treatment with currently approved AAA endovascular grafts because of the length of the infrarenal aortic neck. The applicant noted that, currently, an AAA is treated through an open surgical repair or medical management for those patients not eligible for currently approved AAA endovascular grafts. After evaluation of the newness, costs, and substantial clinical improvement criteria for new technology add-on payments for the Zenith® F. Graft and consideration of the public comments received in response to the FY 2013 IPPS final rule, CMS approved the Zenith® F. Graft for new technology add-
on payments for FY 2013. Cases involving the Zenith® F. Graft that are eligible for new technology add-on payments are identified by ICD-9-CM procedure code 39.78 (Endovascular implantation of branching or fenestrated graft(s) in aorta).

The new technology add-on payment regulations provide that “a medical service or technology may be considered new within 2 or 3 years after the point at which data begin to become available reflecting the ICD-9-CM code assigned to the new service or technology”. With regard to the newness criterion for the Zenith® F. Graft, CMS considers the beginning of the newness period to commence when the Zenith® F. Graft was approved by the FDA on April 4, 2012. Because the Zenith® F. Graft is still within the 3-year newness period, CMS will continue new technology add-on payments for this technology for FY 2014.

New FY 2014 Add-On Applications

CMS received five applications for new technology add-on payments for FY 2014. The following two applications relate to cardiovascular procedures.

MitraClip® System
Abbott Vascular submitted an application for new technology add-on payments for the MitraClip® System for FY 2014. The MitraClip® System is a transcatheter mitral valve 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 surgery. With regard to the newness criterion, the manufacturer submitted a Premarket Approval (PMA) application in support of obtaining FDA approval for the MitraClip® System. Effective October 1, 2010, ICD-9-CM procedure code 35.97 (Percutaneous mitral valve repair with implant) was created to identify and describe the MitraClip® technology.

The Abbott Vascular MitraClip® System, did not receive FDA approval by the July 1 deadline. Therefore, this application is not eligible for consideration for new technology add-on payments for FY 2014.

Zilver® PTX® Drug Eluting Stent
Cook® Medical submitted an application for new technology add-on payments for the Zilver® PTX® Drug Eluting Stent (Zilver® PTX®) for FY 2013. Because the Zilver® PTX® had not yet received FDA approval, and therefore, did not meet the newness criterion, it was not eligible for IPPS new technology add-on payments for FY 2013.

Cook® Medical re-submitted an application for new technology add-on payments for the Zilver® PTX® Drug Eluting Peripheral Stent (Zilver® PTX®) for FY 2014. The Zilver® PTX® is intended for use in the treatment of peripheral artery disease (PAD) of the above-the-knee femoropopliteal arteries (superficial femoral arteries). According to the applicant, the stent is percutaneously inserted into
the artery(s), usually by accessing the common femoral artery in the groin. The applicant stated that an introducer catheter is inserted over the wire guide and into the target vessel where the lesion will first be treated with an angioplasty balloon to prepare the vessel for stenting. The applicant indicated that the stent is self-expanding, made of nitinol (nickel titanium), and is coated with the drug Paclitaxel. Paclitaxel is a drug approved for use as an anticancer agent and for use with coronary stents to reduce the risk of renarrowing of the coronary arteries after stenting procedures. The applicant received FDA approval on November 15, 2012, for the Zilver® PTX®. The applicant maintains that the Zilver® PTX® is the first drug-eluting stent used for superficial femoral arteries. The technology is currently described by ICD-9-CM procedure code 00.60 (Insertion of drug-eluting stent(s) of the superficial femoral artery).

In an effort to demonstrate that the technology meets the substantial clinical improvement criterion, the applicant shared several findings from the clinical trial data. The applicant stated that current treatment options for patients who have been diagnosed with PAD includes angioplasty, bare metal stenting, bypass graft, and endarterectomy. The applicant asserted that the Zilver® PTX® meets the substantial clinical improvement criterion because it decreases the recurrence of symptoms arising from restenotic SFA lesions, the rate of subsequent diagnostic or therapeutic interventions required to address restenotic lesions, and the number of future hospitalizations.

CMS expressed concerned that on April 24, 2013, the FDA announced that, based on its investigation into a small number of complaints that the delivery system of the device had separated at the tip of the inner catheter, Cook Medical has initiated a nationwide/global voluntary recall of its Zilver® PTX® Drug Eluting Peripheral Stent.

After consideration of the public comments received in response to CMS concerns and proposals presented in the proposed rule, it agrees that the Zilver® PTX® represents a substantial clinical improvement over existing technologies because it decreases the recurrence of symptoms arising from restenotic SFA lesions, the rate of subsequent diagnostic or therapeutic interventions required to address restenotic lesions, and the number of future hospitalizations. However, CMS will continue to monitor the long-term clinical trial data concerning the primary and secondary endpoints as it becomes available.

The Zilver® PTX® meets all of the new technology add-on payment policy criteria. Therefore, CMS is approving the Zilver® PTX® for new technology add-on payments in FY 2014. Cases involving the Zilver® PTX® that are eligible for new technology add-on payments will be identified by ICD-9-CM procedure code 00.60. To determine the amount of Zilver® PTX® stents per case, instead of using the amount of stents used per case based on the ICD-9-CM codes, the applicant used an average of 1.9 stents per case based on the Zilver® PTX® Global Registry Clinical Study. The applicant stated in its application that the anticipated cost per stent is approximately $1,795. Therefore, cases of the Zilver® PTX® would incur an average cost per case of $3,410.50 ($1,795 x 1.9). Under § 412.88(a)(2), new technology add-on payments are limited to the lesser of 50 percent of the average cost of the
device or 50 percent of the costs in excess of the MS-DRG payment for the case. As a result, the maximum add-on payment for a case of the Zilver PTX® is $1,705.25.

5. FY 2014 ICD-9-CM Diagnosis & Procedure Code Changes

For FY 2014, there are no changes to the ICD-9-CM coding system due to the partial code freeze or for new technology. There are no new, revised or deleted diagnosis or procedure codes for FY 2014. There were no requests approved for an expedited April 1, 2013 new technology implementation of an ICD-9-CM code at the September 19, 2012 Committee meeting. Therefore, there were no new ICD-9-CM codes to be implemented on April 1, 2013.

6. CC/MCC Updates

Coronary Atherosclerosis Due to Calcified Coronary Lesion
CMS received a request to consider changing the severity levels for the ICD-9-CM diagnosis code 414.4 (Coronary atherosclerosis due to calcified coronary lesion). The requestor suggested that CMS change the severity level for diagnosis code 414.4 from a non-CC to an MCC. CMS’s clinical advisors reviewed the data and evaluated this condition. They recommended that CMS not change the severity level of diagnosis code 414.4 from a non-CC to an MCC or a CC. They do not believe that this diagnosis would increase the severity level of patients. They pointed out that a similar code, diagnosis code 414.2 (Chronic total occlusion of coronary artery), is a non-CC. CMS’s clinical advisors believe that diagnosis code 414.4 represents patients who are less severe than diagnosis code 414.2. Considering the C1 and C2 ratings and the input from the clinical advisors, CMS will not reclassify diagnosis code 414.4 to an MCC; the diagnosis code would continue to be considered a non-CC. Therefore, based on the data and clinical analysis, CMS will maintain diagnosis code 414.4 as a non-CC.

Chronic Total Occlusion (CTO) of Artery of the Extremities Diagnosis Code
CMS received a request to consider removing atherosclerosis and aneurysm codes from the CC Exclusion List for diagnosis code 440.4 (Chronic total occlusion of artery of the extremities). For FY 2013, CMS changed the designation of diagnosis code 440.4 from a non-CC level to a CC level. According to the commenter, aneurysm diagnoses are not closely related clinically to peripheral CTOs. Aneurysms result from the weakening of an artery wall and manifest in an out-pouched pocket of the lumen. Conversely, patients with CTOs present with extended segments of diseased and narrowed vessels and in most cases, complex lesions containing fibro-calcified plaques. The commenter stated that CTOs represent a high severity complication, which is not closely related to basic atherosclerosis. CMS’s clinical advisors agree with the commenter that the aneurysm and most of the atherosclerosis codes should be removed from the CC Exclusion List for diagnosis code 440.4. A case with a principal diagnosis of aneurysm with CTO adds substantial complexity and does not necessarily have the same immediate cause. A case with a principal diagnosis of atherosclerosis
with CTO reported represents a more severe form of the disease and, therefore, is more complex. CMS’s clinical advisors do not agree with the commenter that diagnosis codes 443.81 through 443.9 (Other and unspecified peripheral vascular diseases) should be removed from the CC Exclusion List. These cases are more likely related to CTO and meet one of the principles for exclusion that were previously outlined above. Therefore, for FY 2014, CMS will remove the following diagnosis codes from the CC Exclusion List for diagnosis code 440.4: atherosclerosis codes 440.20 through 440.32, 443.22, and 443.29, and aneurysm codes 441.00 through 441.03, 441.1 through 441.7, 441.9, 442.0, 442.2, 442.3, and 442.9. Diagnosis codes 443.81 through 443.9 would remain on the CC Exclusion List for diagnosis code 440.4.

7. **ICD-10 Coding and MS-DRG Status**

At the September 15-16, 2010 ICD-9-CM Coordination and Maintenance Committee meeting an announcement was made that the Committee will implement a partial freeze of the ICD-9-CM and ICD-10 (ICD-10-CM and ICD-10-PCS) codes prior to the implementation of ICD-10 on October 1, 2013.

The last regular, annual updates to both ICD-9-CM and ICD-10 code sets were made on October 1, 2011. On October 1, 2012, there will be only limited code updates to both the ICD-9-CM and ICD-10 code sets to capture new technologies and diseases as required by section 503(a) of Pub. L. 108-173.

The Secretary of Health and Human Services issued a final rule that delays, from October 1, 2013, to October 1, 2014, the compliance date for the International Classification of Diseases, 10th Edition diagnosis and procedure codes (ICD-10). On October 1, 2014, there were to be only limited code updates to ICD-10 code sets to capture new technology and diagnoses as required by section 503(a) of Pub. L. 108-173. There were to be no updates to ICD-9-CM on October 1, 2014, as the system would no longer be a HIPAA standard and, therefore, no longer be used for reporting.

On October 1, 2015, one year after the implementation of ICD-10, regular updates to ICD-10 will begin. CMS will continue to work with the public to explain it is approaching the conversion of MS-DRGs to ICD-10 and will post drafts of updates as they are developed for public review. The final version of the ICD-10 MS-DRGs will be implemented at the same time as ICD-10 and will be subject to notice and comment rulemaking. In the meantime, CMS will provide extensive and detailed information on this activity through the ICD-9-CM Coordination and Maintenance Committee.