June 30, 2014

Marilyn Tavenner, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1607–P
P.O. Box 8011
Baltimore, MD 21244–1850

**Submitted electronically via http://www.regulations.gov**

http://www.regulations.gov/#!documentDetail;D=CMS-2014-0051-0002

RE: “Medicare Programs: Hospital Inpatient Prospective Payment Systems; Quality Reporting Requirements, Reasonable Compensation, etc. [CMS-1607-P]”

Dear Ms. Tavenner:

The Society for Cardiovascular Angiography and Interventions (SCAI) is a non-profit professional association with over 4,000 members representing the majority of practicing interventional cardiologists in the United States including the majority of structural heart disease specialists. SCAI promotes excellence in invasive and interventional cardiovascular medicine through physician education and representation, and the advancement of quality standards to enhance patient care. SCAI having reviewed the “Medicare Programs: Hospital Inpatient Prospective Payment Systems; Quality Reporting Requirements, Reasonable Compensation, etc. [CMS-1607-P]” offers the following comments:

**Summary**

Many of the issues of high interest to SCAI and the interventional cardiology community contained in this proposed rule have to do with DRG reclassification and proposed new technology add-on payments for structural heart disease (SHD) procedures.

“Over the last decade, structural heart disease (SHD) interventions have emerged as a new field in interventional cardiology. With an expanding adult congenital heart disease (ACHD) population and recent advances in structural interventions especially the advent of transcatheter aortic valve replacement (TAVR), pulmonic valve implantation (TPVI), mitral valve repair (MitraClip), and shunt closure procedures.”
SCAI, the primary voice for the experts performing SHD procedures, is uniquely posed to provide CMS with clinical guidance regarding the appropriate classification of these procedures.

We commend CMS for proposing the creation of a new DRG for Transcatheter/Endovascular Cardiac Valve procedures and urge CMS to include the entire related, family of valve procedures currently being performed including Transcatheter Mitral Valve Repair. We also urge CMS to grant new technology add-on payment for these technologies to facilitate Medicare beneficiary access to these procedures.

**SCAI supports the creation of an Endovascular/Transcatheter Cardiac Valve DRG, urging CMS to include the entire related, family of valve procedures currently being performed including Transcatheter Mitral Valve Repair.**

**SCAI urges CMS to consider creating a new DRG for Structural Heart Disease procedures not captured by the newly proposed Endovascular/Transcatheter Cardiac Valve DRG.**

**SCAI urges CMS to grant new technology add-on payments for the SHD Watchman™ and MitraClip® devices.**

**Specific Comments**

**APPROPRIATE DRG CLASSIFICATION OF STRUCTURAL HEART PROCEDURES**

Endovascular Cardiac Valve Replacement Procedures (FR pages 28009-28011)

SCAI commends CMS for proposing the creation of a new DRG for Endovascular/Transcatheter Valve procedures. However, the established, accepted nomenclature for these procedures is “Transcatheter” and not, “Endovascular”. SCAI urges CMS to align the terminology for this new proposed DRG with the established nomenclature universally being used, naming the newly proposed DRG “Transcatheter Cardiac Valve Procedures”. Also, SCAI strongly disagrees with CMS assessment that Transcatheter mitral valve repair (TMVR) is somehow, significantly different from Transcatheter aortic valve replacement (TAVR) warranting separate DRG classification for “repair” procedures as compared to “replacement” procedures. Unlike alternative open repair and replacement procedures, a heart valve prosthesis is being manipulated/modified from a Transcatheter approach; whether the prosthesis serves to “replace” or “repair” an existing valve is irrelevant in regards to resource consumption. Transcatheter aortic and mitral valve replacement and repair...
procedures are both currently limited to the treatment of patients that are found to be ineligible or at high risk for the open alternative procedures. As a matter of fact, leading structural heart disease (SHD) specialists performing both procedures find TMVR cases to typically be MORE intensive than TAVR.

We strongly urge CMS to treat all Transcatheter valve procedures equally and fairly in regards DRG assignment. We urge CMS staff responsible for DRG classification to review the numerous comments submitted by the public during the 5/15/2014-6/14/2014 comment period in response to CMS draft National Coverage Determination (NCD) for TMVR that speak to the current inadequacy in the payment rate for these procedures. These comments can be found on the CMS Website at [http://www.cms.gov/medicare-coverage-database/details/nca-view-public-comments.aspx?NCAId=273&NcaName=Transcatheter+Mitral+Valve+(TMV)+Procedures&ExpandComments=n&bc=AAAAAAAAAAEAAAA%3d%3d#Results](http://www.cms.gov/medicare-coverage-database/details/nca-view-public-comments.aspx?NCAId=273&NcaName=Transcatheter+Mitral+Valve+(TMV)+Procedures&ExpandComments=n&bc=AAAAAAAAAAEAAAA%3d%3d#Results)

SCAI recommends CMS use established nomenclature for the newly proposed DRG for Transcatheter valve procedures, aptly naming it “Transcatheter Cardiac Valve Procedures”. Additionally, SCAI urges CMS to support patient access to all of these new procedures, by placing them all into the same proposed DRG grouping, rather than unfairly singling out one valve procedure- TMVR for underpayment, potentially thwarting patient access to this beneficial, life-altering service.

Exclusion of Left Atrial Appendage (FR pages 28007-28008)

Per the proposed rule, CMS received a request to reclassify *Exclusion of Left Atrial Appendage*, ICD-9-CM procedure code 37.36 (Excision, destruction or exclusion of left atrial appendage (LAA)) from MS–DRGs 250 (Percutaneous Cardiovascular without Coronary Artery Stent with MCC) and 251 (Percutaneous Cardiovascular without Coronary Artery Stent without MCC) to MS–DRGs 237 (Major Cardiovascular Procedures with MCC) and 238 (Major Cardiovascular Procedures without MCC). Per CMS data, the average cost of the atrial appendage exclusion procedures is $29,637. The average costs for the proposed DRG are $24,511 for DRG 238 and $35,642 for DRG 237. The cost data alone would seem to support reassignment as requested, so we are dismayed at CMS decision to keep 37.36 under the current DRG groupings, which clearly result in under payment for these SHD procedures.

In the spectrum of SHD procedures, “Exclusion of Left Atrial Appendage” using a suture technique is considered one of the more intensive SHD procedures involving transseptal puncture. SCAI’s leading SHD experts find the current performance of *Exclusion of left atrial appendage* to be most comparable with a cardiovascular embolization procedure, ICD-9-CM code 39.79. ICD-9-CM code 39.79 is currently classified under MS–DRGs 237 (Major Cardiovascular Procedures with MCC) and 238 (Major Cardiovascular Procedures without MCC). Most certainly, *Exclusion of left atrial appendage* is much more closely aligned with the procedures included in the proposed MS-DRGs 237 and 238 than its current DRG assignment. SCAI urges CMS to consider the creation of a new DRG for Structural Heart Disease.
procedures (other than valve), similar to the proposed creation of a new DRG for Endovascular/Transcatheter Cardiac Valve procedures.

**SCAI urges CMS to consider the creation of a new DRG for Structural Heart Disease procedures (other than valve), similar to the proposed creation of a new DRG for Endovascular/Transcatheter Cardiac Valve procedures.**

**Transcatheter Mitral Valve Repair: MitraClip® (FR pages 28008-28009)**

The proposed rule details the history of repeated public requests to have the Transcatheter Mitral Valve Repair (TMVR) ICD-9-CM code, 35.97 reassigned to a more appropriate DRG class. SCAI has submitted comments on every given occasion recommending reassignment of ICD-9-CM procedure code 35.97 to a more appropriate DRG classification. We are dismayed why CMS has repeatedly ignored the recommendations of the leading experts performing these procedures in regards to the appropriate assignment of this procedure to align it with procedures that are more clinical homogeneous than its current DRG assignment. Additionally, CMS cost data appears to support the need for reassignment.

CMS clinical advisors assert “the operating room resource utilizations of percutaneous procedures, such as those found in MS–DRGs 250 and 251, tend to group together, and are generally less costly than open procedures”. Perhaps CMS clinical advisors are unfamiliar with the unique imaging equipment needed in support of the performance of structural heart disease (SHD) procedures as compared to traditional interventional cardiology procedures. SHD procedures are most commonly performed in specialized hybrid suites which require the use of specialized imaging equipment that allows for the imaging of the structures of the heart not just the vessels. Visualization of the hearts structures is not typically a requirement for most percutaneous coronary intervention (PCI) cases which are focused on the treatment of coronary vessels. SCAI finds CMS’s assertion in regards to operating room resource utilization to be inaccurate. As with previous comments, SCAI urges CMS to treat TMVR in the same manner as other Transcatheter valve procedures in regards to DRG assignment and urges CMS to assign ICD-9-CM code, 35.97 to the same DRG as other Transcatheter valve procedures, which for 2015 would mean assigning 35.97 to the newly proposed Endovascular/Transcatheter Cardiac Valve Procedure DRG.

**SCAI, again, recommends ICD-9-CM code, 35.97 used to report TMVR be assigned to the same DRG class as all other Transcatheter Cardiac Valve procedures.**

**FY 2015 Applications for New Technology Add-On Payments**

SCAI supports the request for new technology add-on payments for the following new Structural Heart Disease procedure devices,

- Watchman® Left Atrial Appendage Closure Technology (F.R. pages 28043-28045)
- MitraClip® System (F.R. pages 28048-28051)
SCAI finds these devices all meet the criteria for new technology add-on payment. These procedures are currently inadequately paid under the existing DRG system. They all meet the CMS definition of “new” in regards to new technology. Finally, they all represent an advancement in medical technology that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

**SCAI recommends CMS provide new technology add-on payments for Watchman® Left atrial Appendage Closure Technology and the MitraClip® System.**

**Conclusion**

SCAI appreciates the opportunity to provide comment to CMS on issues of high interest to the interventional cardiology community contained in the “Medicare Programs: Hospital Inpatient Prospective Payment Systems; Quality Reporting Requirements, Reasonable Compensation, etc. [CMS-1607-P]”. If SCAI can be of any assistance as CMS continues to consider and review these issues, please do not hesitate to contact Ms. Dawn R. Gray (Hopkins), Director of Reimbursement & Regulatory Affairs at (800) 253-4636, ext. 510 or dgray@scai.org.

Sincerely,

Charles E. Chambers, MD, FSCAI
SCAI President, 2014-2015

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