September 2, 2014

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

Marilyn Tavenner  
Administrator  
Centers for Medicare and Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015; Proposed Rule (CMS-1612-P)

Dear Administrator Tavenner:

The CardioVascular Coalition (CVC) is pleased to offer its comments to the Centers for Medicare and Medicaid Services (CMS) on the Proposed Rule: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015; Proposed Rule (CMS-1612-P). The CVC was established to provide policymakers and the public with a greater understanding of the value that non-facility providers of cardio/vascular interventions (“Freestanding Cardio/Vascular Centers”, or “FCVCs”) bring to their patients and of the importance of logical, predictable payments to align incentives and ensure patient access to quality vascular care. CVC members include providers (National Cardiovascular Partners and the Outpatient Endovascular and Interventional Society) and manufacturers (Cardiovascular Systems, Inc. and Covidien).

This letter will comment on the following issues:

- Overview of Freestanding Cardio/Vascular Centers
- Overview of the CY 2015 Physician Fee Schedule Proposed Rule
- CMS Concerns with Current PFS Data
- CMS Should Increase Equipment Cost Maintenance Factor Where Appropriate
- CMS Should Establish Non-facility PERVUs for Intravascular Ultrasound

Overview of Freestanding Cardio/Vascular Centers

In 2012, there were an estimated 362 FCVCs in 218 separate markets in the United States. Approximately 737 physicians, primarily trained in vascular surgery or cardiology, treated nearly 113,000 Medicare fee-for-service patients at these FCVCs. Florida has the most FCVCs, with 54

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1 Federal Register, 79 FR 40318 (July 11, 2014)
centers in 28 different markets. Texas has 51 FCVCs in 18 markets, while California has 38 FCVCs in 29 different markets. Altogether, FCVCs operate in markets where over 6 million Medicare beneficiaries lived in 2012, and treat an average of 2 patients per 1,000 Medicare beneficiaries per market.

FCVCs focus on providing endovascular revascularization of the femoral or popliteal arteries, often with angioplasty. While hospital outpatient departments often offer the same set of services as FCVCs, in markets where an FCVC is available, more Medicare beneficiaries used the FCVC than a hospital outpatient department for their revascularization procedure. This preference for FCVCs persisted despite a greater number of physicians who offer endovascular revascularization procedures at hospital outpatient departments compared to FCVCs.

**FCVCs Treat a Vulnerable Patient Population**

One of the key Medicare patient populations treated in FCVCs are those patients with peripheral artery disease (PAD). PAD is a significant clinical concern to Medicare beneficiaries suffering from the disease. For example, PAD has been shown to be a leading cause of amputation. A May 2013 study in the American Heart Journal also found that Medicare beneficiaries over the age of 65 with PAD face very high mortality rates noting “unacceptably high rates of mortality in patients with PAD with and without major LE amputation.” In addition to the clinical concerns relating to PAD, acute and postacute medical care costs associated with caring for beneficiaries with dysvascular amputation are significant. A March 2005 study in the Archives of Physical Medicine and Rehabilitation found, using 1996 data, that such costs exceed $4.3 billion annually. A 2011 study published by the American Heart Association notes that “treatment of lower extremity PAD and its consequences are among the most costly and morbid challenges faced by elderly Medicare patients” and “efforts to limit major amputation secondary to PAD are a priority recognized by several societies and leaders in vascular care.” A comprehensive review of all of the economic literature on lower extremity arterial revascularization procedures for patients with PAD found that endovascular therapy was the least costly therapy in the short-term, although long-term outcome data was not available. Finally, amplifying these patient care and costs concerns is the fact that significant variation in care exists today with almost 5 times higher amputation rates for African Americans and those of lower socioeconomic status.

Key CPT codes used by FCVCs to treat patients with PAD are included in the following table.

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2 Ibid; page 813
3 Tentoeouris et al., Diabetes Care; Jul 2004; 27, 7:1603
4 Jones et al., Am Heart J 2013;165:813
5 Dillingham et al., Arch Phys Med Rehabil 2005;86:480
8 Goodney; pages 94-95
Key CPT Codes for PAD

<table>
<thead>
<tr>
<th>Key Code</th>
<th>Description</th>
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<tr>
<td>37220</td>
<td>(Iliac revasc)</td>
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<tr>
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</tr>
<tr>
<td>37222</td>
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<td>(Tib/per revasc stnt &amp; ather)</td>
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Overview of the CY 2015 Physician Fee Schedule Proposed Rule

CMS indicates that the overall impact of the CY 2015 PFS Proposed Rule for most specialties is roughly flat. This is true for those specialties chiefly involved in the treatment of peripheral artery disease such as cardiology, interventional radiology and vascular surgery.

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Percent Change</th>
</tr>
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<tbody>
<tr>
<td>Cardiology</td>
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</tr>
<tr>
<td>Interventional Radiology</td>
<td>– 1%</td>
</tr>
<tr>
<td>Vascular Surgery</td>
<td>+ 1%</td>
</tr>
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</table>

CMS Concerns with Current PFS Data

In the CY 2015 PFS Proposed Rule, CMS did not propose to cap physician payments based on the hospital outpatient department (OPD) rates stating it was “persuaded that the comparison of OPPS (or ASC) payment amounts to PFS payment amounts for particular procedures is not the most appropriate or effective approach to ensuring that that PFS payment rates are based on accurate cost assumptions.” In the CY 2014 PFS Final Rule, CMS included many of these objections raised by commenters, including the following:

- Facilities’ costs for providing all services are not necessarily higher than the costs of physicians or other practitioners.
- Resources required to furnish services in non-facility physician settings cannot be accurately measured using the OPPS methodology;
• The proposal would result in rank order anomalies;
• It is inappropriate to base PFS payment on OPPS payment since a single APC contains multiple services that can involve a wide a range of costs that are averaged under the OPPS methodology.
• Hospitals typically provide a broad range of services and therefore have the ability to make up for losses on one service with profits on another.

However, the agency notes it is still “seeking comment on the possible uses of the Medicare hospital outpatient cost data (not the APC payment amount) in potential revisions of the PFS PE methodology.”9 CMS appears to seek such comments under the continued rationale that OPPS data is inherently better than data through the Physician Fee Schedule. CMS states it continues to believe “there are various possibilities for leveraging the use of available hospital cost data in the PE RVU methodology to ensure that the relative costs for PFS services are developed using data that is auditable and comprehensively and regularly updated.”10 In the CY 2014 PFS Proposed Rule, CMS also noted “PFS PE RVUs rely heavily on the voluntary submission of information by individuals furnishing the service and who are paid at least in part based on the data provided.”11

There are several fundamental flaws with the above rationale. First, like physician fee schedule payment rates, hospital outpatient payment rates also are based on submission of data by entities who are paid based on the data provided. Second, hospital charge data itself has come under intense scrutiny as outlined in a 2013 Times magazine article. The Times investigative report found, “No hospital’s chargemaster prices are consistent with those of any other hospital, nor do they seem to be based on anything objective – like cost ….”.12 This finding is not new. A 2005 study requested by MedPAC found, “[T]he fact that charges are often not closely tied to costs implies that the current Medicare payment systems may not be closely tied to resource utilization.”13 Indeed, although chargemasters are the basis for Medicare cost reports, CMS itself seems to recognize issues with hospital outpatient charge data. CMS’s own website acknowledges, “As part of the Obama administration’s work to make our health care system more affordable and accountable, [hospital outpatient] data are being released that show significant variation across the country and within communities in what providers charge for common services.”14 Finally, hospital data is no more “auditable” than data provided under the processes to set rates under the PFS. The former utilizes hospital cost reports, while the latter utilizes paid invoices and physician surveys. All of this data in both settings is “auditable,” and audits could be done in either setting on an annual basis.

The CVC does acknowledge CMS interests in collecting the most up-to-date and reliable direct cost practice expense data with which to set proper reimbursement in the Physician Fee Schedule.

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9 Ibid.
10 79 FR 40333
11 78 FR 43296
12 Brill, Steven, Bitter Pill: Why Medical Bills are Killing Us, Time, 4 March 2013
13 Dobson, Alllen et al, A Study of Hospital Charge Setting Practices: A Study Conducted by the Lewin Group for the Medicare Payment Advisory Commission, December 2005
We look forward to working with the agency towards that end. Moreover, we acknowledge CMS’ statement in the CY 2015 PFS Proposed Rule relating to the collection of appropriate indirect practice expense data. CMS noted in addition to concerns regarding direct cost inputs, “the allocation of indirect PE is based on information collected several years ago … and will likely need to be updated in the coming years” and “many in the community expressed serious concerns over the accuracy of this (the PPIS) or other PE surveys as a way of gathering data on PE inputs from the diversity of providers paid under the PFS.” The CVC also supports CMS efforts in this regard and would be in favor of a new indirect practice expense survey as soon as practicable.

**CMS Should Increase Equipment Cost Maintenance Factor Where Appropriate**

In the Proposed Rule, CMS explains that the equipment cost per minute, used to calculate PE RVUs for services under the PFS, is calculated using a formula that includes a factor for equipment maintenance, which was established at 0.05 (5 percent of purchase price) in the PFS rulemaking for CY 1998. CMS acknowledges suggestions from stakeholders that the maintenance factor should be variable and seeks comment on maintenance costs that vary for particular items.

The CVC agrees that the maintenance factor used to calculate equipment cost should vary based on the type of equipment used in a given procedure, and we believe in some cases a higher equipment maintenance factor would more accurately reflect the costs that providers incur in maintaining equipment used under the PFS. Providers who perform PAD services may incur considerable costs as a result of the unusual complexity of the equipment used in those services and the special requirements imposed on maintenance of that equipment. We recommend that CMS consider using different maintenance adjustments for different types of medical equipment, which will account for substantial maintenance costs incurred with highly specialized equipment. We encourage CMS to work with stakeholders to define service contracts and maintenance contracts, collect data on their associated costs, and update the equipment maintenance adjustment factor as necessary.

**CMS Should Establish Non-facility PERVUs for Intravascular Ultrasound**

In the Proposed Rule, CMS notes that a stakeholder requested that the agency establish non-facility PE RVUs for CPT code 37250 (Intravascular ultrasound (non-coronary vessel) during diagnostic evaluation and/or therapeutic intervention; each additional vessel (List separately in addition to code for primary procedure)) and 37251 (Intravascular ultrasound (non-coronary vessel) during diagnostic evaluation and/or therapeutic intervention; each additional vessel (List separately in addition to code for primary procedure)). CMS is seeking comment regarding whether it is appropriate to have non-facility PE RVUs for this code and if so what inputs should assigned to this code.

Intravascular ultrasound (IVUS) has long been the gold standard for treating coronary lesions. IVUS also has emerged as a useful and often necessary adjunct in a rising number of

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15 79 FR 40333
catheter-based peripheral interventions. IVUS enables luminal and trans-mural cross-sectional imaging of peripheral vessels with high dimensional accuracy and provides detailed information about lesion morphology. IVUS is able to assist in guiding the optimal choice of appropriate angioplasty technique and guide a superior delivery of endovascular stents. IVUS plays a major role in the assessment of the immediate outcome of an intervention, thus improving long term patency rates and decreased complication rates by providing information concerning wall apposition of the stented vessel area.

Although the Medicare Physician Fee Schedule reimburses for the uses of angioplasty, stenting, and/or atherectomy to treat peripheral arterial/venous disease, it does not reimburse for the use of IVUS to appropriately diagnose and guide treatment. The lack of an office practice expense valuation for non-coronary IVUS creates a significant reimbursement barrier to IVUS use in the freestanding setting. As such, the CVC supports the establishment of non-facility PERVUs for IVUS in the freestanding setting. Practice expenses for IVUS in the office include, among other things, (1) the catheter, (2) the IVUS console, and (3) nursing and technician time.

**Conclusion**

CVC’s comments on the Physician Fee Schedule regulations seek to ensure ongoing access to high-quality, state-of-the-art freestanding centers. FCVCs provide an integral service in the overall healthcare continuum. These places of service are an important part of patient access to care and their survival depends on a balanced approach to reimbursement for their services. We hope that our comments highlight our sincere interest in continuing to provide cost-avoiding FCVC services that are fairly reimbursed and readily accessible to Medicare patients. We look forward to continuing to work with CMS to guarantee quality cardiovascular services are provided by our centers to every Medicare patient. If you have additional questions regarding these matters and the views of the CVC, please contact Jason McKitrick at (202) 442-3710.