



August 28, 2008

Kerry N. Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1403-P
Mail Stop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Revisions to Payment Policies Under the Physicians Fee Schedule and Other Revisions to Part B for CY 2009; Proposed Rule

Dear Mr. Weems:

On behalf of the members of the Cardiovascular Outpatient Center Alliance (COCA), we appreciate the opportunity to submit these comments to the Centers for Medicare & Medicaid Services (CMS) regarding the **“Resource-Based PE RVU’s”** section of the above referenced Proposed Rule as published in the July 7, 2008 *Federal Register*. We are specifically concerned with the proposed 2009-2010 PE RVU’s established for non-facility outpatient cardiac catheterization procedure codes and the significant negative impact on the physician practices and Medicare patients of our members that would result if these PE RVU changes are implemented.

COCA is a national non-profit organization representing over 60 medical cardiology practices and organizations and more than 1,000 cardiologists that own and operate non-hospital outpatient cardiac catheterization laboratories (OPCLs). As will be described below, the impact of the CMS PE RVU changes would be devastating to cardiovascular OPCLs with the potential to force these facilities to exit the market. As a result, Medicare beneficiaries would be denied access to high quality, convenient cardiovascular services at a reasonable cost. In addition, the overall cost to the Medicare program and the copayment obligation for Medicare beneficiaries for these services would increase dramatically if OPCLs are forced to close. COCA has been informed by at least five of its members with large Medicare patient populations that their OPCLs have either closed or sold to local hospitals in the first half of 2008, resulting in Medicare patient cardiac catheterizations being performed in hospital outpatient settings with a dramatic increase in costs to the Medicare program and individual beneficiaries that we will outline below.

Summary of PE RVU Methodology Change on OPCLs from 2006-2008

The history of COCA's participation in this process with CMS is critical to understanding our request for fair and reasonable reimbursement of non-facility outpatient cardiac cath procedure codes and the need to address this issue prior to the release of the 2009 Physician Fee Schedule (PFS) Final Rule. We are utilizing a bullet-point format to simplify the summary of this complex history:

- **In 2007 CMS introduced the “bottom up” PE RVU methodology**
 - Each CMS RVU determination is dependent on recommendations from what has become a highly-politicized AMA *Relative Scale Value Update Committee* (RUC) process and *Practice Expense Review Committee* (PERC)
 - The RUC/PERC process results in determinations based more on the specific interests and influence of some medical specialty societies than the logical analysis of the actual direct and indirect costs of services
 - Lack of significant OPCL data (the RUC/PERC relied mostly on hospital-based data and only gathered partial OPCL data from one source with 3 labs for their 2006 recommendations) produced severely flawed data that undervalued OPCL costs

- **Proposed 2007 CMS PE RVU changes would have cut OPCL technical reimbursement by 64% over 4 years (16% per year), resulting in reimbursement several hundred dollars below the cost of performing these services**
 - At the same time, corresponding 2007 hospital APC outpatient cath reimbursement was already 6.35% higher (APC left heart cath code 0080 mirrors PFS technical components for 93510, 93555, and 93556)
 - 2008 APC cath reimbursement rates were increased by an additional 8.56%
 - Proposed 2009 APC cath rates are to be increased by another 4.84%

- **COCA challenged the 2007 proposed Medicare PFS PE RVU changes**
 - CMS agreed in the November 2006 *Federal Register* 2007 PFS Final Rule that the RUC/PERC baseline data was limited and lacked credibility
 - 2007 PFS reimbursement was delegated to Medicare carriers for carrier-pricing
 - COCA members proactively engaged their Medicare carriers to present their direct and indirect cost data resulting in 2007 reimbursement for OPCLs equal to 2006

- **At CMS's request, COCA fully participated in the 2008 RUC/PERC process**
 - COCA readily agreed to participate after commissioning a detailed study of OPCL direct costs (conducted by Epstein Becker & Green). The preliminary results of this study were presented to CMS in COCA's formal comments to the August 22, 2006 Proposed Rule for the 2007 Physician Fee Schedule. The final report was presented to CMS Deputy Administrator Herb Kuhn by COCA leadership on May 3, 2007 at a meeting organized by Representatives from the Florida Congressional delegation.
 - COCA members and physicians committed extensive time and resources over several months in a good faith effort to provide accurate direct and indirect cost data through the American College of Cardiology to the RUC/PERC
 - COCA's input was altered significantly by the RUC/PERC process
 - RUC/PERC defines a “typical” case as one where staffing/supplies/etc. must be used at least 51% or they are not included as direct costs
 - This definition does not allow for essential supplies and equipment such as crash carts, closure devices, etc. to be included

- COCA was not allowed to present all of our documented direct cost data related to specialized staffing time and compensation
 - The process does not address indirect cost data that are unique to OPCLs
- **COCA's post-RUC CMS input was severely limited**
 - COCA representatives were told on several occasions by CMS/CMM that they would meet with them to address PE RVU issues unique to OPCLs if the RUC/PERC process did not adequately deal with these issues before the 2008 Proposed PFS was released. These meetings did not materialize.
 - After several letters and calls to CMS from COCA Congressional supporters, COCA was finally granted a conference call with CMS/CMM senior management on October 30, 2007; two days before the release of the 2008 Medicare PFS Final Rule
 - COCA explained the flaws in the RUC/PERC process and that we were not allowed to present all of our data to the RUC
 - CMS/CMM requested and received COCA's direct cost study for review
- **The 2008 PFS Final Rule accepted the RUC PE RVU recommendations without considering COCA's additional data, resulting in draconian cuts for 2008-2010**
 - 23.33% cut in cath technical codes (93510, 93555, 93556) in 2008
 - 46.36% cut when fully implemented in 2010
 - CMS acknowledged COCA's concerns in their published Final Rule comments and suggested that COCA work through the same RUC/PERC process for 2009
 - COCA believed that the same flawed process would produce the same flawed results
 - ACC went on record opposing another RUC/PERC review of outpatient cath procedures for the 2009 PFS
- **CMS/CMM meeting with COCA to discuss the PFS Final Rule on November 30, 2007**
 - Discussion focused on complete COCA data gathered through the EBG commissioned report and the need to convert the data to the RUC/PERC format
 - COCA presented the following points:
 - OPCLs are fundamentally different from physician offices and are therefore a true anomaly within the RUC process resulting in severely understated direct costs and PE RVU values
 - OPCL staffing models are more intensive than physician offices and hospital outpatient cath lab settings because of necessary staff cross-training
 - OPCL specialized staffing compensation is more expensive than the general nursing and technician compensation modeled by CMS
 - Overutilization is not an issue for OPCLs as national cath volumes have actually declined as a percentage of new patient consultations for the past several years (documented by an extensive MedAxiom national database)
 - CMS agreed to review COCA's complete data and staffing compensation models for 2009-2010 PFS changes and possible 2008 PFS reconsideration. COCA was asked to submit the following: the original data set prepared for the RUC/PERC prior to pre-meeting negotiations, a separate document thoroughly explaining the differences, and a realistic OPCL specialized staffing model and compensation structure
 - COCA offered to commission (and fund) a new direct and indirect cost study by an independent third-party acceptable to CMS, such as The Moran Company or The Lewin Group, if CMS thought the results would be more objective than the EBG study. CMS/CMM senior staff stated that this would not be necessary.

- **Post-CMS/CMM Meeting Actions**
 - COCA submitted the requested direct cost documents on December 17, 2007
 - COCA thoroughly reexamined and vetted all of the pre-PERC/RUC meeting data and prepared the additional documents requested by CMS/CMM
 - The documents were submitted to Whitney May as directed by CMM Acting Director Liz Richter along with an overview letter explaining COCA's position on the major discussion points
 - COCA raised two issues concerning cardiac cath procedure injection codes
 - CPT cath injection codes 93543 and 93545 should have professional and technical components assigned to them because the increase in the PE RVUs for these codes in a non-hospital setting means by definition that the procedures were performed in an OPCL and the practice expenses are directly related to the staff, supplies, and equipment in those centers
 - The -51 modifier exemption was incorrectly removed from 93543 (and only 93543) even though this code is consistently part of the five codes routinely billed for left heart cath

- **COCA submitted formal comments to CMS in response to the 2008 PFS Final Rule on December 28, 2008**

- **Interim and formal responses from CMS/CMM regarding the COCA data**
 - COCA received the two interim email responses and a formal letter response of March 27, 2008
 - These responses reversed the November 30, 2007 agreement for a direct CMS review of COCA data for 2008 and 2009-2010 and recommended sending the COCA data back through the RUC/PERC process
 - There was a clear misunderstanding of COCA's position on the injection codes (we support the PE RVU increases especially since we provided the data to develop the increases that were RUC-approved) as well as a lack of understanding of the practice expenses related to these codes
 - There was also a clear lack of understanding of the -51 modifier exemption revocation for injection code 93543
 - COCA met with CMS/CMM on April 30, 2008 after corresponding with Dr. Jeffrey Rich concerning the lack of CMM response to COCA's extensive effort to provide CMM with the data they requested for their analysis independent of the PERC/RUC process. The meeting concluded without an explanation of the results of the CMM data analysis, the next steps, or future involvement in the PERC/RUC process. One enlightening moment occurred when a member of the CMM senior staff commented that OPCLs had much more in common with hospital outpatient cath labs than physician offices. We obviously agreed and requested that OPCL procedures be reimbursed at a reasonable percentage of the APC rates.

Current 2009 PFS Proposed Rule

In the November 27, 2007 published 2008 PFS Final Rule CMS specifically addressed COCA's comments concerning the PE RVU changes that were detailed in the July 2, 2007 Proposed Rule. Unfortunately, CMS did not address the specific issues that COCA raised concerning the flaws in the AMA RUC process when dealing with certain procedures that do not conform to the RUC's arbitrarily-defined "standards". The ultimate evidence of the failure of this process in the case of cardiac catheterization procedures is the

unreasonable and capricious PE RVU reductions that resulted in severe reimbursement cuts; which when fully implemented will cause Medicare reimbursement to fall below the cost of providing these services. As COCA clearly demonstrated in our previous comments, these cuts are being implemented at the same time that the same procedures performed on the same patients by the same physicians in outpatient hospital settings are receiving significant regular annual increases in APC reimbursement.

While COCA appreciates the need for CMS to rely on the AMA RUC process for their input in setting RVUs for the significant majority of procedure codes, we remain resolute in our position that the PERC/RUC did not consider all of the data that COCA made available through the process. The RUC's unwavering adherence to a set of "standards" that does not allow for unique procedural settings (i.e. anomalies such as non-hospital cardiac catheterization procedures) combined with the natural politicization of the process caused by the "specialty-developed PE recommendations" and "multi-specialty scrutiny" (as described on page 66235 of the November 27, 2007 *Federal Register*) continues to produce an unreasonable outcome.

As we mentioned above in our summary of events, CMS/CMM senior staff chose not to share the results of their analysis with COCA or the Congressional offices that requested this information in May-June 2008 and instead returned the issue to the AMA PERC/RUC for reconsideration. The AMA PERC/RUC declined to reconsider their 2007 recommendations without contacting COCA for any additional information or comments. As a result, CMS states in the July 7, 2008 *Federal Register*, page 38512: "*We are in agreement with RUC recommendations, (including the recommendation that no change be made to the direct inputs for CPT 93510, a cardiac cath code)*".

We are disheartened that CMS chose not to use or even share its February 2008 analysis of COCA's complete cost data; once again resulting in PE RVU recommendations that severely undervalue the direct and indirect costs associated with providing these procedures to our Medicare patients. The PE RVU values published in the July 7, 2008 Proposed Rule would result in additional severe cuts in reimbursement for cardiac catheterizations performed in OPCLs. For example, the 2008 reimbursement for the technical components of the primary three CPT codes for a left heart cath (93510TC, 93555TC, and 93556TC) that were cut by 23.33% in 2008 would be cut by an additional 14.38% in 2009 and cut an additional 18.29% in 2010 for a total reduction of 46.36% from 2007 levels. At the same time, the outpatient hospital APC payment for the exact same procedure was increased by 8.56% in 2008 and is proposed to increase by another 4.84% in 2009. Since the APC reimbursement for a left heart cath was already 6.35% higher than the PFS rates in 2007, this means that as of January 1, 2009 the reimbursement for this procedure in an OPCL will have dropped from 93.65% of the APC rate to 54.02%.

These severe and misguided reductions have already resulted in the closing (or sale to hospitals) of several OPCLs and if not reversed will more than likely result in the closure of the majority of OPCLs in the country. This result would force thousands of Medicare patients who now benefit from improved access and lower costs into more acute hospital settings where their individual copayments will cost each Medicare beneficiary several hundred dollars more than the same procedure in an OPCL. Even comparing the original 2007 PFS payment with the proposed 2009 APC rate, the increased cost to the Medicare

Trust Fund and Medicare beneficiaries from this shift would conservatively add up to \$28.5 million. If the current 2008 PFS payment is compared to the 2009 APC rate, the additional cost to the Medicare program increases to \$59.5 million.

COCA's Request for Reconsideration

COCA is on record in their April 30, 2008 meeting with Dr. Jeffery Rich requesting that CMS reconsider the complete cost data provided to them by COCA in December 2007 and establish PE RVU's for non-facility outpatient cardiac catheterization procedures that more reasonably reflect the direct and indirect costs of providing these procedures. In addition, the American College of Cardiology (ACC) is on record in their June 11, 2008 letter to Dr. Rich requesting that CMS at least freeze the 2009 reimbursement at 2008 levels until an additional review of OPCL indirect costs can be conducted. Both organizations have requested that CMS correctly apply the 2007 RUC recommendations for 2008-2010 PE RVUs added to cardiac injection procedure codes and establish professional and technical component allocations for these services.

COCA requests that CMS reconsider the 2009 Physician Fee Schedule PE RVUs for cardiac catheterization procedures and increase them based on the additional data that COCA submitted to CMS outside of the RUC process. We base this request on the following unique and compelling reasons:

1) OPCLs are Fundamentally Different than Physician Offices

COCA believes that OPCLs are a true anomaly within the RUC process. This became painfully clear when CMS changed the PE RVU formula to a "bottom up" calculation for 2007. The PERC/RUC definitions and templates are designed to develop PE RVUs for services and procedures performed in physician offices, while OPCLs require much more intensive infrastructure, equipment, staffing, and supplies. The RUC templates and definitions are based on office-based medical practice assumptions that automatically eliminate much of the direct and indirect resources (and costs) required to perform invasive cardiac procedures. After spending several months and countless hours working through the 2008 RUC process, COCA experienced this bias first-hand. In the case of OPCLs, there is simply no possibility of the current RUC process being capable of meeting the PE RVU requirements stated by CMS in the published 2008 Physician Fee Schedule Final Rule: "Section 4505(d) of the BBA required that, in developing the resource-based PE RVU's, the Secretary must: Use, to the maximum extent possible, generally-accepted cost accounting principles that recognize all staff, equipment, supplies, and expenses, not solely those that can be linked to specific procedures and actual data on equipment utilization."

2) OPCL Staffing Mix

The RUC templates define OPCL staff as a mix of Radiology Technicians (RTs), Registered Nurses (RNs), Cardiovascular Technicians (CV Techs), Licensed Practical Nurses (LPNs), and Medical Assistants (MAs). This staffing model is not practical for an efficient OPCL. The RUC template is based on a hospital staffing model where a variety of staff can be utilized in the cath lab for short periods of time and then rotated elsewhere within the hospital (e.g. MAs as transporters, LPNs in recovery, etc.).

In an OPCL, the staff is dedicated to that facility and cannot be shifted to other areas because the OPCL is a self-contained unit unlike a hospital or physician office setting. In order to maximize the use of existing staff, OPCLs cross train clinical staff to be able to handle all clinical functions in the cath lab and recovery areas. Naturally, this requires that all clinical staff are able to function at the same level. The most effective and cost-efficient staffing model for an OPCL is an RT/RN mix, as it would not be possible to cross train LPNs or MAs for the majority of these functions and CV Techs are unavailable in most parts of the country (their functions are limited by state regulations in many states). In addition, most state regulations require an RT's direct involvement in procedures exposing a patient to ionizing radiation.

3) OPCL Staffing Compensation Differential

One thing that OPCLs and hospital outpatient cath labs have in common is the necessity to provide higher compensation for qualified RTs and RNs. Cath lab personnel are required to have a specific clinical skill set that commands a compensation premium in the medical personnel marketplace. In addition, the need for OPCLs to use RTs and RNs exclusively because of cross training and efficiency significantly changes the personnel mix from that defined by the RUC templates.

Cardiac Catheterization Injection Codes

As mentioned above, both COCA and ACC have pointed out that the RUC PE RVU recommendations for cardiac injection code procedures were incorrectly applied by CMS in 2008. We will specifically address the inconsistencies contained in the 2009 PFS Proposed Rule below:

1) Injection Code PE RVU Changes

The usual injection codes (93543 and 93545) associated with a left heart cath were included in the RUC template tied to the procedures discussed above and we believe that it is important to address them in these comments.

In the past these injection codes have been billed by physicians and did not contain TC or -26 modifiers, primarily because they did not include significant PE RVU values. COCA provided data for the 2008 PERC/RUC process through ACC that resulted in PE RVU values being added to these injection codes; however for some reason CMS did not include TC and -26 modifiers in the 2008 Physician Fee Schedule, even though the PE RVU work is performed by OPCL personnel rather than physician office personnel. The need for this to be revised in the 2009-2010 PFS is self-evident if CMS will evaluate the difference between the PE RVUs listed for these codes performed in a facility (hospital) and non-facility (OPCL). The facility PE RVUs reflect the amount of PE costs represented by the physician office staff while the non-facility PE RVUs represent the costs represented by the OPCL staff.

2) -51 modifier: The 2008 Physician Fee Schedule Final Rule produced an unusual change that removed the -51 modifier exemption from CPT 93543. We are mystified as to why this would occur since this code is almost always performed (>90%) when a left heart cath is performed (as is 93545 which is still exempt). We assume that this was a mistake by CMS staff, but despite this issue having been raised by COCA and other cardiology

organizations this obvious error has neither been addressed nor corrected. We request that this issue be corrected or a reasonable and logical explanation be provided as to why this change was deemed appropriate.

Conclusion

COCA believes that CMS has no interest in supporting a flawed process that would drive non-facility cardiac catheterization centers out of business. We base this belief not only on statements made by CMS senior staff at our previous meetings, but also on the written statement CMS made in the July 2, 2007 Proposed Rule when expressing concern with services furnished under arrangement with a hospital because it “not only costs the Medicare program more, but also costs Medicare beneficiaries more in the form of higher deductibles and coinsurance” (CMS-1385-P, pages 349-50). CMS’ expressed concern about increased Medicare program and beneficiary costs must also apply to other services, which is the very point that COCA has consistently expressed about providing lower cost services in non-facility outpatient cardiac catheterization centers for the past two and a half years. Unfortunately, CMS has not shown an interest in actually supporting this stated position as it continues to ignore the increasingly likely outcome of closing OPCLs and driving Medicare patients into significantly higher cost hospital settings resulting directly from the flawed PE RVU application to OPCLs.

We thank you for the opportunity to describe our concerns with the proposed 2009 Physician Fee Schedule; specifically as it relates to the development of fair and reasonable reimbursement for cardiac catheterization procedures performed in a non-hospital setting.

We sincerely hope that CMS will respond favorably to our requests. If you have any question or need any additional information, please do not hesitate to contact me any time at (615) 776-1810.

Sincerely yours,

Steve Blades
President