



January 3, 2011

Donald Berwick, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1503-FC
Mail Stop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medicare Program; Payment Policies Under the Physicians Fee Schedule and Other Revisions to Part B for CY 2011; Final Rule

Dear Dr. Berwick:

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 severe negative impact of changes to diagnostic cardiac catheterization and endovascular revascularization RVUs described in the **“Comprehensive Codes for a Bundle of Existing Component Services”** section of the above referenced Final Rule.

COCA is a national non-profit education and advocacy organization representing the majority of cardiology practices and organizations that own and operate non-hospital outpatient cardiac catheterization laboratories (OPCLs). We join the Cardiology Advocacy Alliance (CAA), the American College of Cardiology (ACC), and other cardiovascular organizations in expressing our alarm with CMS' continuing severe Medicare RVU cuts for cardiovascular procedure codes. The draconian RVU changes based on flawed surveys, skewed data, and an inherent lack of professional objectivity that began in 2006 have reduced Medicare reimbursement so significantly as to impair the ability of private practice cardiologists to provide the critical ambulatory services in their offices that have dramatically reduced the mortality rate for Medicare patients over the last few decades. In fact, it should be noted that private cardiology practices have been on the front line in reducing heart disease, *America's Number One Killer*, from a fatal disease to a chronic disease on the road to preventing cardiovascular disease in our country. These unrelenting cuts have caused a significant percentage of cardiology practices in the country to either integrate with hospital systems or enter into serious discussions to do so

by the end of 2011...with the resulting increase in overall costs to both Medicare beneficiaries and the Medicare program through payments under the Hospital Outpatient Prospective Payment System (HOPPS). It is not an exaggeration to express our concern that if this unilateral action by CMS is allowed to continue it will reduce Medicare patient access and increase patient/program costs to the point that the trend of reducing the severity of this disease will likely be reversed.

Background

In the case of OPCLs, the accumulation of severe arbitrary and unsupported cuts to OPCL procedures have driven most of our members' to either close their facilities or sell them to hospital systems where the same procedures are often performed by the same physicians and staff at the much higher HOPPS cost within a matter of days.

The following thoroughly documented description demonstrates the arbitrary nature of CMS' treatment of OPCL reimbursement since 2006 that is being continued in the 2011 bundling of cardiac catheterization and endovascular revascularization codes.

As we have stated in numerous meetings, written communications, and formal comments to CMS the impact of the flawed 2008-2010 PFS RVU changes for outpatient cath procedures that were first implemented by CMS on January 1, 2007 have been devastating to OPCLs and forced several centers to exit the market as early as 2008. As a direct result, Medicare beneficiaries in the locations where these OPCLs closed or sold to local hospitals were redirected to outpatient hospital facilities at much higher costs to both the Medicare beneficiaries and the Medicare program.

COCA made several efforts from 2006-2009 to submit accurate and thoroughly vetted direct and indirect cost data to the CMS Center for Medicare Management (CMM) to correct inaccurate data used and conclusions drawn from the AMA RUC process. Our most time and labor intensive attempt involved working with CMM from November 2007 through March 2008 in response to a specific request from the CMM Acting Director following a face-to-face meeting on November 30, 2007. COCA committed extensive resources to thoroughly reexamine and validate all of the pre-PERC/RUC meeting data and prepare the additional documents requested by CMM. The documents were submitted for analysis on December 17, 2007 along with an overview letter explaining COCA's position on the major discussion points. After several encouraging calls and emails from CMM staff, COCA was caught by surprise when CMM senior staff arbitrarily chose not only to continue to support the severe PE RVU reductions for procedures performed in OPCLs at the same time they increased APC reimbursement for hospital-based outpatient cath procedures, but also refused to share the results of their analysis with COCA and the Congressional offices that requested this information.

COCA subsequently met with CMM on April 30, 2008 after corresponding with the new Acting Director concerning the lack of a reasonable CMM response to COCA's extensive effort to provide the data they requested for their analysis independent of the AMA PERC/RUC process. The meeting concluded without an explanation of the results of the CMM data analysis, the next steps, or COCA's future involvement in the AMA PERC/RUC process. One enlightening moment occurred during the meeting 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 agreed and suggested that a workable solution would be for OPCL procedures to be reimbursed at a reasonable percentage of hospital outpatient diagnostic cardiac catheterization APC rates for the same procedures.

Needless to say this solution and others suggested by COCA were not pursued...in fact CMS chose not to respond to COCA's 2008 formal PFS Proposed Rule and Final Rule comments, additional informal communications concerning the OPCL cost data we provided at their request, or their analysis without any explanation for this silence.

We were particularly disheartened that CMS not only ignored COCA's complete direct and indirect cost data for the 2009 Medicare PFS Final Rule 2010 PE RVUs, but added insult to injury by implementing PE and malpractice RVU cuts for OPCL procedures that defied any logic whatsoever. These senseless reductions were supposedly based on data from the AMA Physician Practice Information Survey (PPIS) that included only 55 responses that were used for the cardiology survey recommendations...representing less than ¼ of 1% of the total number of cardiologists in the United States. In addition to CMS' indefensible position of utilizing a ridiculously small and statistically invalid sampling, we are skeptical that any of the responses actually included data about OPCLs given that the results show a decrease in costs while COCA data demonstrates that OPCLs have experienced significant cost increases over the past several years.

The negative results of the 2010 Proposed Rule PE RVUs and malpractice RVUs exacerbated a process that had already severely undervalued the direct and indirect costs associated with providing these procedures to our Medicare patients.

Current 2011 PFS Final Rule

As described in the 2011 Final Rule section "*Comprehensive Codes for a Bundle of Existing Component Services*", CMS decided to bundle both diagnostic cardiac catheterization and several endovascular revascularization procedures with the purpose of reducing PFS payments because of "potentially misvalued codes" and charged the AMA RUC with this task. In the case of diagnostic catheterization codes, the RUC did not find evidence that the physician work RVUs should be reduced. CMS took exception to this and arbitrarily reduced these RVUs by 10% because its staff believes that these "codes would be overvalued under the AMA RUC recommendations for CY 2011". They reason that "the physician survey appears to have overstated the work for these well-established procedures". On the other hand, CMS was more than happy to accept the RUC recommendations for cuts of over 51.63% and 55.73% for the physician work components of two common endovascular revascularization procedures...something we find difficult to believe was based on the survey results (and have been unable to ascertain from any source). It should also be noted that the 10% cut only reflects the work component of cardiac catheterizations...the total cuts for this procedure's professional fees is actually 36.53%.

This is just one more glaring example of why the severely negative reimbursement actions taken by CMS since 2006 against cardiovascular procedures in general and OPCL-related procedures specifically are unjustifiable. How can CMS possibly take the position that the 2010 survey data is flawed when as outlined above it readily accepted the flawed data of the 2009 PPIS based on 55 responses out of a universe of over 20,000 while the 2010

survey had a significantly larger response? Did CMS ever consider the possibility that instead of being overvalued the results of the past several years of reimbursement cuts have actually caused these procedures to be undervalued as COCA has demonstrated on several occasions with vetted data drawn from a large national base of OPCLs?

The fact remains that CMS has gutted OPCL Medicare reimbursement since 2006 based on flawed data and without considering any valid data that conflicted with its predetermined decisions...despite requesting this data directly from COCA on two separate occasions and promising independent, unbiased reviews. COCA has demonstrated to CMS that the cost structure for facility and OPCLs is comparable, yet CMS has chosen to cut PFS payments for left heart catheterizations by a total of 63.35% from 2007 to 2011 at the same time that outpatient hospital APC payments for the exact same procedure have increased by 19.41%. Since the APC reimbursement was already higher than the PFS rates in 2007, this means that **as of January 1, 2011 the reimbursement for this procedure in an OPCL will have dropped from 93.65% of the APC rate to just 28.74%.** If implemented for 2011, the Medicare PFS reimbursement rate will be several hundred dollars less than the cost of performing this procedure and will result in Medicare diagnostic catheterizations being sent to higher cost, less efficient outpatient hospital settings...and will more than likely force many remaining OPCLs to close or sell to hospitals.

We simply cannot understand any logical reason that CMS would choose to drive OPCLs out of business and force Medicare patients into outpatient hospital settings. As stated previously, these severe and misguided reductions have already resulted in the closing or sale of many OPCLs and if not reversed will result in the closure of the vast majority of OPCLs in the country. This result will 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 out of pocket than the same procedure in an OPCL.

Conclusion

Despite the results published in the 2011 Final Rule, COCA believes that the new CMS leadership has no interest in supporting the demonstrably flawed processes that have severely curtailed the ability of cardiology practices to provide critical ambulatory services or eliminating high quality, cost efficient facilities such as OPCLs from providing care for Medicare patients. We base this belief not only on statements made by you and other CMS senior staff, 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). This statement is even more relevant now as CMS struggles with containing Medicare expenditures in the face of rising healthcare costs and demands. COCA contends that this expressed concern about increased Medicare program and beneficiary costs must also apply to other services being driven toward more expensive hospital outpatient settings ...including cardiology practice and OPCL services being reimbursed in a fair and reasonable manner in order to provide lower cost options to Medicare beneficiaries.

COCA joins the Cardiology Advocacy Alliance in calling for CMS to reevaluate the severe impact of the bundling of diagnostic cardiac catheterization and endovascular revascularization procedure codes and implement a more balanced and fair valuation for these procedures in CY 2011 and future years.

We thank you for the opportunity to describe our concerns with the 2011 Physician Fee Schedule Final Rule and we hope you will honor our request for a reconsideration of reimbursement for cardiac catheterization and endovascular revascularization procedure codes. If you have any questions or need any additional information, please do not hesitate to contact me any time at (615) 776-1810.

Sincerely yours,

Steve Blades
President