



# AMERICAN SOCIETY OF EXTRACORPOREAL TECHNOLOGY

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## Medicare Developments – Its Not Just Dust In The Wind

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The AmSECT Government Relations Program is more than just proactively monitoring and reporting to the membership on state legislative and regulatory matters impacting the clinical practices of the profession. It also involves helping perfusionists gain state legal credentialing. The other side of the professional representational coin includes federal Congressional and regulatory agency issues. The two federal agencies with the most influences are the Food and Drug Administration (FDA) and its regulation of medical devices and the Medicare program and the Centers for Medicare and Medicaid Services (CMS).

At the time of this writing, there are four Medicare matters in the works that could and will influence the future practices of the profession – one is pending in Congress and three with the CMS. All are related to the federal payments for covered Medicare hospital and physician services, the dollars attached thereto, and the policy translation back to the clinical practice setting.

### **National Coverage Decision for Blood-Derived Products (PRP)**

In 2003, CMS first issued a national non-coverage determination for use of autologous PRP for the treatment of chronic non-healing cutaneous wounds except for routine costs when used in accordance with clinical trials. In 2005, CMS issued a non-covered determination for local Medicare carriers/regional contractors for the same. In 2007, the FDA granted 510(k) approval and clearance for the Cytomedix Autologel System. The system is used at point-of-care for the safe and rapid preparation of platelet-rich-plasma (PRP) from a patient's own blood to be used to heal chronic wounds and in the management of mechanically or surgically debrided wounds.

In 2007 and 2008, Cytomedix petitioned CMS to reconsider its non-coverage position and issue a National Coverage Decision (NCD) that would classify PRP products and the point-of-care services of a healthcare professional, i.e. a perfusionist, as being eligible for Medicare reimbursement by the regional Medicare insurance contractors. Both of these requests were denied as non-covered items under the Medicare program. In November of 2011, Cytomedix in conjunction with seven leading wound-healing organizations and leaders in the field, petitioned CMS for reconsideration of their earlier decisions, and CMS granted the request.

Throughout the history of the covered vs. non-covered by Medicare decisions has been the issue of proving to the CMS Coverage and Analysis Group, a group of medically trained bureaucrats, that there is sufficient scientific evidence demonstrating that autologous platelet-rich plasma (PRP) is reasonable and necessary for the treatment of chronic non-healing wounds. Previously, the CMS decided that the evidence was not adequate to conclude that autologous PRP is reasonable and necessary for the treatment of chronic non-healing wounds nor for acute surgical wounds.

The reconsideration request letter includes twenty-five references to peer-reviewed and published studies to rebut the previous reasons for a non-coverage determination. As part of the review process, public comments were also solicited, as is the regulatory requirement under the federal Administrative Procedures Act. The notice for comments limited the scope of public comments that would be accepted to only those pertaining to “clinical studies” either supporting or not supporting the position that autologous PRP is reasonable and necessary for the treatment of chronic non-healing wounds and surgical wounds. In other words, publically filed comments with anecdotal evidence would be excluded from consideration by the CMS.

This is an important Medicare coverage issue for perfusionists, surgeons in general and wound care specialists, as well as to hospitals and for the quality of patient care. The fact that the scope of public comments was limited is not, in and of itself, surprising. Regulatory process/payment process wise, if the CMS reverses its position and covers PRP devices and services, initially it will be left to the regional Medicare insurance contractors to decide what the reimbursement amount will be for their region. Eventually, a national fee schedule payment amount will be established. It is important to keep in mind that private insurance companies are likely to follow the CMS decision and also adopt the value of the reimbursement amount, if they do not cover it now.

### **Medicare Physician Payment Reductions**

As of early December 2011, the Congress had yet to resolve several big issues on the federal spending plate. Among these is the annual fight over the rate at which doctors are to be paid for treating Medicare patients in 2012. Since the mid 1990’s and the imposition of fixed annual reductions in the Medicare Physician Fee Schedule, Congress has delayed the actual imposition of across-the-board reductions in payments. The 2011 “doc fix” patch added \$19 billion to the federal deficit. Absent another paper-over, payment rates are expected to be cut by 27 percent starting in January of 2012. This will not impact perfusionists employed by hospitals or employed by perfusion contract companies who contract with hospitals since dollars for salaries come from the Part A side of Medicare, which applies, to hospitals. On the other hand, perfusionists employed by surgical groups, if an extension is not enacted, are very likely to feel the impact as the Medicare patient portion of a surgical group’s revenues will decline, on average, by 27 percent, in 2012. However, it is possible that a delayed “fix” will be made in 2012. It has happened before.

## **Medicare Crack Down On Unnecessary Stents**

In early December 2011, CMS announced a new "Recovery Audit Contractor Prepayment Review Demonstration Program" targeted on ICDs for pacemakers, stent implantations, percutaneous coronary intervention procedures without stents, and other vascular and circulatory system procedures. The new program goes into effect January 2012. To be implemented first in 11 states for a three-year period, the program will allow Medicare recovery auditors to review medical records and gauge the appropriateness of procedures performed, the devices used, and claims for procedures or hospital stays prior to paying those submitted bills. Seven states that are targeted in the new CMS program were singled out because they have had the highest rates of fraudulent claims and/or providers - California, Florida, Illinois, Louisiana, New York, Michigan and Texas. Four states were identified as having high claims volumes for short inpatient hospital stays - Missouri, North Carolina, Ohio, and Pennsylvania. The unstated public policy agenda is to put cardiothoracic surgeons on notice that Medicare is watching for the unnecessary implantation of stents in people who do not meet professional guidelines.

## **Acute Care Hospital Medicare Payments for 2012**

The hospital DRG payment rates in 2012 will be increased by 1.1%. This means that the DRG payments for cardiovascular and related medical procedures will go up by this amount from their respective 2011 reimbursement rate to a hospital. Despite the potential net negative fiscal impact for perfusionists employed by surgical group practices, the increase in hospital DRGs is good news for 2012 for hospital employed and contract company employed perfusionists. It is a bit of good news from the heretofore-yearly decreases in the hospital Inpatient Prospective Payment System (IPPS) rates. To be fair, while reductions have at least been spared for one year, it is unclear how this will or will not translate down a surgical department's operating budget for an individual hospital and its perfusion staff.