

Proposed Changes to New Technology APC Assignment Applications

On July 25th the Centers for Medicare and Medicaid (CMS) published the proposed changes to the hospital outpatient prospective payment system for 2006.¹ Reimbursement for the outpatient prospective payment system is based upon Ambulatory Payment Classifications (APCs). The intention of APC groups is to organize services into categories that are similar in terms of clinical likeness and resource use. Services such as operating and recovery room, anesthesia, medical/surgical supplies, pharmaceuticals, and incidental services are “packaged” within an APC. The facility receives one predetermined payment based upon the APC to which the service was assigned.

For many new technologies, data does not exist as to what APC it should be assigned. For this reason, CMS established “New Technology APCs” in 2002. Assignment to a New Technology APC is temporary and lasts only until enough data is collected to move the service to an established APC. In the past, a new code was not required to be assigned to a New Technology APC. However, this may change in 2006.

CMS proposes that starting in 2006 all applications for a New Technology APC assignment be accompanied by a copy of the submitted application for a new CPT code with a letter acknowledging the coding application. CPT codes are issued by the American Medical Association.

This would have huge implications for companies with new technologies targeted to the outpatient setting. Although CMS states that it will accept either a CPT I or CPT III code, it is highly unlikely that any new technology will meet the criteria for a CPT I code, which includes evidence of wide diffusion and well-established clinical efficacy documented in U.S. peer review literature.

A new code and new APC assignment does not imply coverage. For technologies that are noncovered, a unique CPT code can easily identify noncovered services within an insurer’s billing system. On the positive side, for those new technologies that are covered, the CPT III code allows a mechanism in which additional data can be gathered via claims data bases, and thus document sufficient diffusion for potential “graduation” to a CPT I code.

Because of these new rules, it is now more important than ever that companies integrate reimbursement strategy within the regulatory and clinical strategy. This means including clinical endpoints that can serve as convincing evidence for positive coverage decisions.

Please contact Monica Schultz, RCRI Director of Reimbursement at 952-746-8721 for more information.

¹ Federal Register, Vol. 70, No. 141, July 25, 2005.

CMS Develops Draft Guidance Documents

While the regulatory approval process for medical products may seem like a mystery, the Food and Drug Administration (FDA) does have a library of guidance documents and process requirements that provide companies with requirements and general expectations. In contrast, the process for obtaining adequate reimbursement for a new medical device remains more of a puzzle. However, the Centers for Medicare and Medicaid (CMS) are attempting to change that.

CMS appears to be following in FDA’s footsteps by developing their own guidance documents. Thus far, CMS has issued preliminary drafts for four guidance documents on the following topics:

- **Opening a National Coverage Determination (NCD)**
- **Referring Topics to the Medicare Coverage Advisory Committee (MCAC)**
- **Commissioning an External Health Technology Assessment**
- **Making a Determination of Coverage with Evidence Development**

The process is in its early stages and the documents have inspired comments from companies and professional associations to offer ideas as to appropriate processes and procedures. The best way to begin to educate yourself regarding the draft guidance documents and the potential implications of their implementation is to explore the CMS website: www.cms.hhs.gov/coverage/guidance.asp.

RCRI Customer Satisfaction Surveys Help us Improve

RCRI sends customer satisfaction surveys to all clients who have reached a significant milestone in their project. RCRI reviews every response to learn about our clients' needs, likes, dislikes, and suggestions. This type of feedback is essential to our ability to assess and improve our customer service. Here are a few recent examples:

- A European regulatory client stated that "the work done by the person assigned to the project was excellent, and in some (categories) rated even higher. The weakness was the delay at the front end of the project." Based on this comment, we are now clarifying consultants' time restrictions and availability in preliminary work orders.
- One clinical study client stated "I am always impressed at how professionally run the CEC meetings are and that the minutes are received in such a timely fashion." At the next staff meeting, we reviewed our clinical department's standards for such meetings and now apply a similar level of customer service to all departments.
- A biostatistics client shared "Continued kudos on your statistical expertise. In addition, your guidance in assisting us with developing an Interim Analysis Review Board has been superb." RCRI now offers to assist with developing review boards as a standard service.

- One client shared that he wished his RCRI consultant would have more adamantly and persistently communicated a potential red flag that the consultant suspected early in the project. RCRI staff were immediately empowered with the right and responsibility to communicate and document suspicion of potential project problems with the client and with RCRI managers. Suspected project issues are now shared on many levels and documented to ensure consistency.

We thank you for your comments and suggestions. We are proud to share the cumulative results of all surveys (53) we have received through July of this year.

How satisfied are you with...	Satisfied
RCRI's understanding of the project requirements?	100%
The knowledge of RCRI personnel on the project?	98%
The resources RCRI provided for the project?	98%
RCRI's ability to complete tasks on time?	92%
How project problems/difficulties were handled?	96%
The quality of work performed by RCRI?	94%

When asked "would you give RCRI a favorable recommendation to others in/outside of your organization?"
"100% said "YES"

European Union Publishes Two Directives on Electrical and Electronic Equipment

As member states of the European Union embrace information technologies and the electrical and electronic equipment (EEE) industry expands to fill these needs, so, too, is the waste generated from new, obsolete or replacement components. Thus, on February 13th, 2003, the European Parliament published, in the official journal, two complementary directives designed to address this problem:

- 2002/95/EC Directive on the *Restriction of the use of Hazardous Substances in Electrical and Electronic Equipment* (the RoHS Directive)
- 2002/96/EC Directive on *Waste Electrical and Electronic Equipment* (the WEEE Directive)

The RoHS Directive (also known as the "Lead Free Directive") is intended to curb the flow of certain hazardous substances into the marketplace and, thus, the

environment, by banning the use of certain restricted substances in EEE end products. The directive requires that all new electrical equipment placed on the market in Europe after July 2006 contain less than certain maximum allowable levels of these substances. The substances include:

- heavy metals (lead, cadmium, mercury, hexavalent chromium); and
- brominated flame retardants (polybrominated biphenyl (PBB) or polybrominated diphenyl ethers (PBDE)).

While the maximum levels or maximum concentration values (MCV) of these substances are still being debated, the EC has proposed 0.1% by weight for all but cadmium which is suggested to be 0.01% by weight. It is widely expected that these values will ultimately be adopted throughout Europe.

Clearly, these MCV's are encouraging the EEE industry to develop and test new materials as substitutes to carry out the functions previously served by these banned substances. For example, tin-based or electrically conductive adhesives are being developed as substitutes for lead-based solders used in the electronics industry.

At the current time, the RoHS directive is not applicable to medical devices. However, it is anticipated that this is only a temporary exemption and that medical devices could be added to the scope of the directive as soon as 2008. There is also an exemption from the requirements if substitution is not possible from a scientific or technical view or if the negative environmental or health impacts caused by the substitution are likely to outweigh the human and environmental benefits of the substitution.

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We urge medical device manufacturers to review their raw materials with their component suppliers and begin looking for alternative and substitute materials. Because the majority of the EEE industry were to be compliant by July 1, 2006, it is likely that there will be alternatives available to the medical device manufacturers – but, the suitability of any substitution must be thoroughly examined in view of the application. This examination should include a thorough review of the impact of the substitution on the intended use(s), the design specifications, the risk analysis (new or modified risks or hazards), the compliance to the Essential Requirements, the existing safety testing (such as biocompatibility, electrical safety, EMC testing), and existing performance characteristics or effectiveness testing (animal or human testing). All changes must be verified and/or validated, and the Technical Documentation must be updated to reflect the new information prior to implementation of the substitute materials.

While the goal of the RoHS directive is to eliminate hazardous substances in new EEE entering the marketplace; the WEEE Directive is aimed at reducing the amount of EEE waste going for final disposal. Because many programs are already in place, it is generally agreed that member states will exercise wide discretion in transposing the WEEE Directive into their national law. Therefore, companies need to be aware of the specific legislation of the member states where they intend to sell.

The WEEE Directive addresses the waste management of EEE and requires that new equipment placed on the market within Europe after August 13, 2005 must comply with the collection, treatment, recycling and recovery requirements of the directive and is applicable to medical devices as well. Medical

device companies using EEE must be labeled with a symbol to discourage direct disposal:



This symbol should be placed visibly, legibly, and indelibly on the piece of equipment. Exceptions to the labeling on the device (due to size or function) are allowed in which case the symbol must be placed on the packaging, IFU, and warranty. After August 13, 2005, medical device manufacturers of EEE should have in place either a mechanism for return of the used product to their facility or plans to provide the financing of the costs for collection, treatment, recovery and environmentally sound disposal of their product.

The WEEE Directive is not applicable to "disposable/single use" devices that are likely to come into contact with body fluids. Such devices or accessories should be discarded in biohazard waste and handled (decontaminated and disposed of) according to local or regional regulations

As of March 2005, only about 1/2 of the EU member states had transposed the directive into their national law. Based on this, it is not likely that all member states will start enforcing this on August 13, 2005, although it would be prudent to be prepared to be in compliance.

We recommend that medical device companies who use EEE in their products revise their labeling to include the WEEE symbol, above, and start planning for methods to recover, recycle and dispose of their devices in accordance with the national laws of the member states of the EU.

New RCRI Employees

RCRI is pleased to announce the appointments of Jill Wass and Shantel Quinn as Assistant Clinical Research Associates. Jill and Shantel will be responsible for assisting clients with clinical study data management as well as database and data quality assurance activities.



Jill Wass is a graduate of the University of North Dakota, Grand Forks, ND. She has a background in Community Education and Life Sciences.



Shantel Quinn is a graduate of The Ohio State University. She has a background in healthcare with experience in both the Long Term Care and Pharmaceuticals.

FDA Fiscal Year 2006 Device User Fees

The following table denotes FDA Fiscal Year 2006 Device User Fee Rates. Fees are effective October 1, 2005 – September 30, 2006. Firms with annual gross sales of \$100 million or less, including those of all affiliates, partners & parent firms, may qualify for a reduced fee.

	2006		2005	
	Standard Fee	Small Business Fee	Standard Fee	Small Business Fee
510(k)	\$3,833*	\$3,066	\$3,502	\$2,802
Premarket Application (PMA, PDP, BLA, PMR)	\$259,600 (fee is waived if first application for firm with gross sales/receipts less than/equal to \$30 million)**	\$98,648**	\$239,237	\$90,910
Panel-track Supplement	\$259,600	\$98,648	\$239,237	\$90,910
180-day Supplement	\$55,814	\$21,209	\$51,436	\$19,546
Real-time Supplement	\$18,691	\$7,103	\$17,225	\$6,546
Efficacy Supplement (BLA)	\$259,600	\$98,648	\$239,237	\$90,910

*Standard fee applies to all 510(k) notifications including Traditional, Abbreviated and Special.

**Note change in definition of a small business for 2006: Firms with annual gross sales/receipts of \$30million or less may qualify for waiver for their FIRST PMA. Firms with annual gross sales/receipts of \$100 million or less may qualify for a reduced fee for all applications that are subject to a fee.

For more information, the following FDA website contains helpful information: www.fda.gov/cdrh/mdufma/index.html, or please contact RCRI. We would be happy to assist you.



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