RCRI

More than a CRO

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New Services from RCRI

RCRI is pleased to announce the appointment of Charmaine Munt as Director of Reimbursement Services and Marilyn Waxberg as Principal Advisor for Regulatory Affairs and Biosciences. Charmaine brings over 17 years of diversified reimbursement services management experience to RCRI and has held significant roles in a number of medical technology companies and third party payor/providers in the Twin Cities such as Medtronic, Urologix and United HealthCare. Marilyn brings over 20 years of diversified health industry management experience to RCRI and has held significant roles in a number of bioscience companies including Veracel Biotechnologies, Dade-Behring, Abbott Laboratories and Surgitek. Prior to joining RCRI, she was Director of Regulatory Affairs/Quality at GeneWorks, Inc., in Michigan.

"These appointments will have a major impact on RCRI's business" said David Meyer, Chief Operating Officer. "With the ever changing dynamics in today's global healthcare marketplace, it is vital that we extend our services and recognize the growing importance of biosciences and reimbursement to the device and IVD industries. Reimbursement strategy and planning are a critical aspect of new product development and planning. The need for an integrated process between the 'Regulatory', 'Reimbursement' and 'Outcomes Research' functions during the product development cycle of any medical device is vital."

RCRI is also launching new services in global strategic market planning and venture capital due diligence preparation.

For further information, contact John Lambert, Director of Marketing at 952-746-8080 x 250 or email jlambert@rcri-inc.com or info@rcri-inc.com.

FDA Issues IVD Symbol Draft Guidance

The Food and Drug Administration (FDA) has issued draft guidance for the professional use of in vitro diagnostic devices (IVDs).

These recommendations do not apply for over-the-counter or prescription home-use IVDs.

The European Union (EU) member countries have attempted to harmonize their national legislation governing IVDs through the European Union's ***Directive on In Vitro Diagnostic Medical Devices***. As of December 8, 2003, IVD products marketed in the EU must comply with the IVD Directive and bear the CE mark (mark showing that the product is certified for sale in the European community) to indicate compliance.

Similarly, the use of symbols helps IVD manufacturers to create uniform labels and labeling for the United States and European Union, instead of needing designated labels for each marketplace.

Because symbols take up less space than the text for which they may substitute, the use of symbols promotes less crowded and more legible IVD labels, says the FDA. An additional advantage is that there are likely to be fewer labeling errors when using a single label, rather than having one set of labels for use in the United States and another set for use in the European Union.

For further information or to view symbols, visit www.fda.gov/cdrh/ocd/guidance/4444.html or contact RCRI at 952-746-8080 or info@rcri-inc.com

Inside this issue:

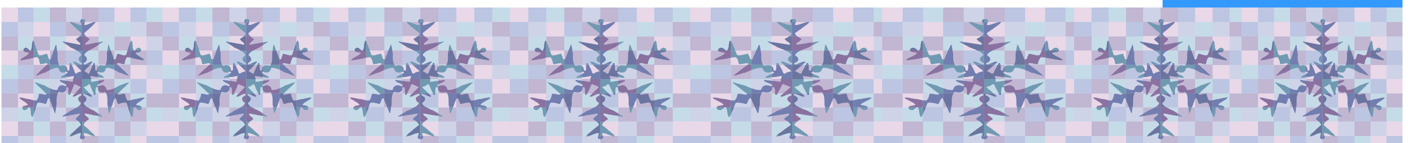
New services from RCRI — 1

IVD Symbols — 1

ISO 14155 — 2

Medical coding systems — 2

Reprocessed single use devices — 3



ISO 14155 - Clinical Trials in EU

In an attempt to standardize the requirements for clinical trials of medical devices in the EU and to meet the requirements of EU Directives 90/385/EEC and 93/42/EEC, ISO (International Organization for Standardization) and CEN (European Committee for Standardization) agreed to harmonize the corresponding European standard EN 540 with ISO 14155. The result, ***ISO 14155: Clinical investigation of medical devices for human subjects***, was published in two parts in 2003, and essentially replaces EN 540.

The purpose of ISO 14155 is to provide guidelines to protect human subjects, to ensure the scientific conduct of clinical investigations and to assist sponsors, monitors, investigators and ethics committees. The standard does not apply to in-vitro diagnostic medical devices. It is hoped that by standardizing the requirements at the international level, the results achieved in one country will be accepted in others, cutting the costs of medical device development.

Part 1: General requirements was published in February of 2003. Part 1 re-emphasizes the importance of ethical considerations in a clinical investigation. The report includes general requirements, detailed information on the elements of informed consent as well as direction for ethics committees.

Part 2: Clinical investigation plans was published in May of 2003. This part is intended to assist manufacturers, sponsors, monitors and clinical investigators in the design and conduct of clinical investigations. It is also intended to assist regulatory bodies and ethics committees in their roles of reviewing Clinical Investigation Plans. Part 2 specifically addresses the preparation and content of the clinical investigation plan, or protocol. It provides guidance in justification of the study, study design, study population and statistical considerations. ***For further information, contact RCRI at 952-746-8080 or info@rcri-inc.com***

Medical Coding Systems - Important Dates

As the first and third quarters of each calendar year roll around, once again it is time to educate your sales force regarding changes in the medical coding systems and payment methodologies relative to your organization's products and provider reimbursement. Updates should include code revisions, additions and deletions. Additionally, reassignment of procedures to DRG's, APC's and the ASC Payment Groups should be addressed.

New Code-Payment Group	Effective Date	Grace Period
CPT-4 Codes	January 1 annually	April 1 annually
Level II HCPCS Codes	Typically January 1 but because these codes can be issued quarterly they may have different effective dates	April 1 annually
ICD-9-CM Diagnosis Codes and Procedure codes	October 1 annually	Typically January 1 annually, but can be at the Medicare payer discretion
Diagnostic Related Groups (DRG's) - Inpatient Hospital	October 1 annually	Payment effective October 1 annually
Ambulatory Payment Classifications (APC's)–Outpatient Hospital	January 1 annually	Payment effective January 1 annually
ASC Groups-Ambulatory Surgery Center	July 1, 2003	Payment frozen to 2009

Remember to use caution when providing coding and payment information to providers. Be sure your materials represent only suggested coding guidelines or options. Give clear instruction that the providers are responsible for coding for the actual services rendered. This is an effort to prevent any unnecessary fraud upon a retrospective audit. The National Center for Health Statistics (NCHS) has announced three new ICD-9-CM diagnosis codes to be effective October 1, 2003. The Centers for Medicare & Medicaid Services (CMS) web site ***www.cms.hhs.gov/medlearn/icd9code.asp*** contains the new, revised and deleted International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes that are effective for dates of service on or after October 1, 2003. ***For further information, contact Charmaine Munt, Director of Reimbursement Services at 952-746-8080 x 124 or cmunt@rcri-inc.com.***

Reprocessed Single-Use Devices

Before enactment of MDUFMA, the regulatory requirements for manufacturers of reprocessed single-use devices (the persons who are reprocessing the device) basically depended upon the class of the device. Manufacturers of reprocessed class I and II single-use devices were required to have a 510(k), unless the device was exempt from 510(k). Reprocessors of class III devices were required to obtain premarket approval. Under the new law, reprocessors of some previously-exempt devices will no longer be exempt from the 510(k) submission requirements and will need to submit 510(k)s that include validation data.

Validation data will also be required for many reprocessors of single-use devices that are currently the subject of cleared 510(k)s. Finally, reprocessors of class III devices will need to submit a premarket report (a new type of premarket application). FDA reviewed the types of reprocessed single-use devices that were previously exempt from 510(k), and determined which of these exemptions should be terminated. On April 30, 2003, FDA published a *Federal Register* notice that included a list of *critical* reprocessed single-use devices whose exemption from 510(k) is being terminated and for which validation data is now required in 510(k)s.

For a previously-exempt critical reprocessed single-use device to remain on the market after July 30, 2004, a 510(k) must be submitted, including "validation data . . . regarding cleaning and sterilization, and functional performance" to show that the reprocessed device "will remain substantially equivalent . . . after the maximum number of times the device is reprocessed as intended" and FDA clearance must be obtained. If a 510(k) is not submitted, or if FDA finds the device to be "not substantially equivalent," marketing of the device must cease. A reprocessed single-use device *not* included on this list may continue to be marketed without submission of a 510(k).

If my reprocessed single-use device was 510(k) exempt before the new law, is it still exempt?

Not necessarily.

By April 26, 2004, FDA is to review the types of *semi-critical* reprocessed single-use devices that are currently exempt from 510(k), and determine which of these exemptions is to be terminated. FDA must publish a Federal Register notice listing these devices. 510(k)s submitted for these devices must include validation data, and must be submitted within 15 months of publication of the list.

The April 30, 2003, *Federal Register* notice also included a list of *critical* reprocessed single-use devices that are already subject to 510(k), but for which the manufacturer must now submit "validation data . . . regarding cleaning and sterilization, and functional performance" to show that the reprocessed device "will remain substantially equivalent . . . after the maximum number of times the device is reprocessed as intended" by the person who submits the 510(k).

For a reprocessed single-use device that obtained 510(k) clearance prior to April 30, 2003, the manufacturer must submit validation data to FDA by January 30, 2004 if the device is to remain on the market. Any new 510(k) (any 510(k) submitted after April 30, 2003) for a device on this list must include validation data. The requirement for submission of premarket reports for class III reprocessed single-use devices went into effect on the act's effective date, October 26, 2002. Previously, PMAs were required for these devices.

Any reprocessed single-use device (i.e., devices exempt from 510(k) requirements, subject to 510(k) requirements, or subject to a premarket report) introduced into interstate commerce after January 25, 2004 must "prominently and conspicuously" bear the statement: ***Reprocessed device for single use. Reprocessed by [name of manufacturer that reprocessed the device] .***

The listing of critical reprocessed single use devices whose exemption from 510(k) is terminated and for which validation data is now required is available at ***http://www.fda.gov/OHRMS/DOCKETS/98fr/03-10413.pdf.***

For further information, contact Jennifer Marrone at 952-746-8080 x 223, or email jmarroe@rcri-inc.com or info@rcri-inc.com.

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Contact Information

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