



MCRA OVERLOOKING THE HILL

December 15, 2008

US healthcare finance reform received significant focus in 2008. Politicians espoused their desire for universal health care coverage and use of tax credits to encourage enrollment with health insurance plans. President-elect Obama's plan called for greater information technology investment and the use of the electronic medical record, require the use of disease management programs for chronic conditions, provide physician incentives through use of pay-for-performance programs, and establish an independent institute that would conduct comparative effectiveness research. For health plans, Obama campaigned on a promise to require health insurance plan disclosure on the value of premium monies used for program administration. While addressing pharmaceutical companies specifically, all medical technology companies should take note of the Democratic platform that will allow patients to purchase pharmaceuticals outside of the United States, and expand the power of the Secretary to negotiate rates with certain companies.

In this newsletter, MCRA Reimbursement experts review some of the legislation pending from 2008. While bills must be re-introduced in the 111th congress, they echo the President-elect's platform and are likely to receive a great deal of attention next year. Topics included within this bi-monthly newsletter include a review of comparative effectiveness legislation (S.3408), repeal of the Supreme Court decision in Riegel (H.R. 6381) as well as a review of the Sunshine Act (H.R. 5605) that prohibits certain payments to physicians. 2009 Medicare inpatient and outpatient rules are discussed, MCRA Director of Reimbursement Tim Hunter provides an analysis describing the broader implications associated with value-based purchasing. Given Medicare's recent announcement regarding the adoption of the ICD-10-PCS coding system, this newsletter will provide a brief introduction and raise questions of interest to medical technology companies.

**CHARLES E. SCHNEIDER, Vice President of Reimbursement
Musculoskeletal Clinical Regulatory Advisers, LLC**

Articles within this newsletter are provided by MCRA for informational purposes only. Information should not be relied upon, but rather stimulate further review and research. For questions or comments, please contact MCRA Vice President of Reimbursement Charles Schneider at CSchneider@MCRA.com or by calling (202) 552-5800.

INSIDE THIS ISSUE

Product Positioning & Reimbursement: An Update On Comparative Effectivenessp. 2

CMS to Encourage Further Care Coordination and Quality Reporting in 2009 and Beyondp. 3

Medical Device Safety Act of 2008: Implications for Industryp. 5

The Physician Payments Sunshine Act Of 2008 (H.r. 5605)p. 7

ICD-10 and Its Effects on New Technologyp. 8

MCRA was founded in 2003 and provides 1st in class regulatory, clinical, reimbursement, intellectual property, and quality assurance services to its clients through its superior knowledge base, global surgeon relationships, and deeply experienced management team. MCRA places particular emphasis on working with companies at all stages of development, whether they are single-product companies or companies with several thousand technologies.

Washington, DC

1331 H Street, NW 12th floor
Washington, DC 20005
Phone: 202.552.5800
Fax: 202.552.5798

info@mcra.com

New York, NY

505 Park Avenue, 14th floor
New York, NY 10022
Phone: 212.583.0250
Fax: 212.750.2112

www.mcra.com



MCRA

OVERLOOKING THE HILL

December 15, 2008

Product Positioning & Reimbursement: An Update On Comparative Effectiveness

CHARLES E. SCHNEIDER, Vice President of Reimbursement¹
Musculoskeletal Clinical Regulatory Advisers, LLC

Comparative effectiveness research examines clinical outcomes, or the “clinical effectiveness” of alternative therapies for the same condition. For purposes of medical technology development, such studies could dramatically affect the way in which future treatment options receive coverage, coding and payment within the United States. Industry stakeholders are keenly interested in the outcome of federal legislation, and would do well to consider comparison studies which best position their product for long-term success.

AHRQs Leadership in Comparative Effectiveness Research

In December 2007, the Agency for Healthcare Research and Quality (AHRQ) issued its draft guide describing comparative effectiveness research. *Methods Reference Guide for Effectiveness and Comparative Effectiveness Reviews*² provides researchers a recommended framework for completing such studies. In summary, the guide challenges researchers to consider the reasons for such research, how information may be used to better inform decision-makers and weighing the strength of available evidence. AHRQ counsels researchers to consider heterogeneity, with subgroup analysis or the use of meta-regression techniques to account for variances between groups and studies. Within orthopedics, AHRQ has completed comparative effectiveness reviews of drug treatments for arthritis, prevention of fractures in men and women who have low bone density tests or osteoporosis, as well as completed an assessment for the use of analgesics for osteoarthritis. AHRQ is currently examining the comparative effectiveness of operative versus non-operative treatments for rotator cuff tears.

A Federal Reaction to Health Care Cost

In March 2008, Senator Max Baucus (D-MT) and Kent Conrad (D-ND) introduced The Comparative Effectiveness Research Act

of 2008 (S.3408). The stated purpose of this pending legislation is to “...improve health care delivered to individuals in the United States by advancing the quality and thoroughness of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, and managed clinically through research and evidence synthesis, and the dissemination of research findings with respect to the relative outcomes, effectiveness, and appropriateness of the medical treatments, services, and [other] items...” S.3408 would amend Section 1181 of the Social Security Act to provide funding for such studies. As well, the legislation authorizes the establishment of a separate, not-for-profit, research organization to be called the Health Care Comparative Effectiveness Research Institute and to create a comparative effectiveness research fund. While the bill was introduced, no activity has yet to occur as of this date.

The Institute can contract with federal agencies, AHRQ and appropriate private entities to conduct the research, which will include systematic reviews, observational studies, clinical trials, and randomized controlled trials. Research findings will be peer-reviewed and publicly disseminated in ways patients and healthcare providers can easily understand. The Institute will be governed by a multi-stakeholder Board of Governors, including the Secretary of Health and Human Services (HHS), the Directors of AHRQ and the National Institutes of Health (NIH), and 18 additional members representing diverse public and private sector expertise and interests. These members will be appointed by the Comptroller General of the United States.

- Comparative Effectiveness Outcomes Growing In Popularity
- Federal Legislation Enables Research Through Appropriations
- Use of Outcomes by Payors Remains a Key Concern by Industry
- Quality & Cost Outcomes May be Used as Reimbursement Barriers to Entry

¹Mr. Schneider serves as MCRA's Vice President of Reimbursement. A 20 year veteran of health care finance and administration, Mr. Schneider has served in key positions within the payor, provider and medical technology companies. If you have any additional questions or comments on this article or a related matter, you may contact him at cschneider@mcra.com or (202) 552-5800.

²Agency for Healthcare Research and Quality. *Methods Reference Guide for Effectiveness and Comparative Effectiveness Reviews*, Version 1.0 [Draft posted Oct. 2007]. Rockville, MD. Available at: http://effectivehealthcare.ahrq.gov/repFiles/2007_10DraftMethodsGuide.pdf



MCRA

OVERLOOKING THE HILL

December 15, 2008

Comparative effectiveness research will likely be used by payors in the future to establish more specific coverage decisions, or perhaps to base future benefit levels on the selection of certain technologies or treatment options. Such activities are consistent with recent trends in physician incentives introduced through Medicare's pay-for-performance program under §501b of the Medicare Modernization Act (MMA; Pub. L. 108-173), state legislative mandates for hospital reporting, and NCQA outcomes reporting by health plans as a condition of accreditation clearly signal the need for medical technology innovators to ensure quality training programs are administered, and outcomes reporting that show technologies are as good as, or better than, alternative treatment options.

Creating Reimbursement Barriers to Entry

While provider payment is of major concern, manufacturers may also use such studies to create reimbursement barriers to entry. Product positioning through comparative effectiveness research will become an effective tool for use with public and private payors, and likewise will become a significant talking point with hospital administrators, value analysis committee members, health care providers and regulators searching for objective outcomes which support product pricing for these technologies.

Industry Considerations

At least four opportunities exist for manufacturers to consider comparative effectiveness research and outcomes reporting in product design and commercialization: (1) integration within pivotal clinical trials, (2) parallel studies which evaluate technologies against alternative treatment options, (3) use of registries that evaluate the long-term effectiveness of technologies against treatment alternatives, as well as (4) integration of quality through customer training and continuing education programs. Although the last chapter of this story has yet to be written, medical technology companies should consider comparisons to alternative treatment options and technologies within their clinical study strategy. Doing so will create more favorable reimbursement pathways for the technology. ■

CMS to Encourage Further Care Coordination and Quality Reporting in 2009 and Beyond

by *Tim Hunter, Director of Reimbursement³*
Musculoskeletal Clinical Regulatory Advisers, LLC

The Centers for Medicare and Medicaid Services (CMS) recently released hospital inpatient, hospital outpatient, and physician final rules outlining payment for services in 2009. While each rule contains important programmatic information, an intra-rule analysis provides a broader description of CMS's intentions with respect to value-based purchasing and developing incentives for coordination of patient care among providers and hospitals. This article examines programmatic changes implemented across settings of care by CMS to advance quality improvement and performance-based payment initiatives and identifies actions manufacturers can take to improve brand loyalty.

2009 Medicare Hospital Inpatient Final Rule

In the proposed rule, CMS described the next step(s) in the following programs related to value-based purchasing and coordinating financial incentives:

Never Events – CMS has identified a set of events that should never happen during the course of care in a hospital. CMS has initiated a National Coverage Analysis for “never events” to identify methods to ensure that patients receive all necessary care associated with treatment without paying the surgeon and hospital for an erroneous surgery and related care⁴. Examples of never events identified by CMS include⁵:

- Surgery on the wrong body part
- Surgery on the wrong patient
- Wrong surgery performed on a patient

Quality Reporting Measures⁶ – Hospitals are subject to a 2 percentage point decrease in payments if they do not submit qualifying quality data related to specific measures. For FY 2008, only

³ Mr. Hunter serves as the Director of Reimbursement for MCRA. Mr. Hunter previously worked within the US Department of Health & Human Services, Bio and represented multi-national medical technology companies. If you have any additional questions or comments on this article or a related matter, you may contact Mr. Hunter at thunter@mcra.com or at (202) 552-5800.

⁴ National coverage analyses for never events can be found at: <http://www.cms.hhs.gov/mcd/overview.asp>

⁵ CMS Medicare Fact Sheet: Medicare Takes New Steps to Help Make Your Hospital Stay Safer, August 4, 2008.

⁶ More information on the RHQDAPU can be found in the 2009 Medicare inpatient final rule, available at: <http://edocket.access.gpo.gov/2008/pdf/E8-17914.pdf>



MCRA

OVERLOOKING THE HILL

December 15, 2008

186 out of 3,538 eligible hospitals failed to submit qualifying data. CMS increased the number of reportable measures in 2009 to 42.

Hospital Acquired Conditions (HAC) – CMS has identified several conditions that it considers to be reasonably preventable, costly, and/or common. Of particular interest to orthopedic device manufacturers are the following conditions following certain orthopedic procedures:

- Surgical site infection
- Deep vein thrombosis and pulmonary embolism

Beginning October 1, 2008, CMS no longer will pay hospitals at a higher rate specifically for the increased costs associated with listed HACs. CMS estimates that this policy will result in annual savings of \$21 million in Medicare payments to hospitals and also that it will lead hospitals and surgeons to more properly document conditions present upon admission.

2009 Medicare Hospital Outpatient Final Rule

The 2009 final rule for Medicare outpatient programs includes a number of initiatives aimed at reporting of quality data, coordination of incentives across settings of care, and value-based purchasing. Finalized and future initiatives include the following:

Quality Reporting Measures – After successfully requiring hospitals to report quality data for specified measures, CMS has expanded the mandatory reporting to the hospital outpatient setting. Hospitals failing to report on these measures for 2009 also will be subject to a 2 percentage point reduction in the 2010 payment update, effectively linking quality data reporting across both settings.

Episode of Care and Composite Payments – CMS is actively considering and implementing efforts to consolidate outpatient payments into larger, more comprehensive, payments. For 2009, CMS has created new composite codes for multiple imaging procedures performed during the same during the same outpatient episode.

Hospital Acquired Conditions – CMS is actively considering when and how to incorporate the HAC concept in the hospital outpatient setting as well as in other settings such as Ambulatory Surgical Centers and physician offices.

Ongoing CMS Demonstration Programs and Other Initiatives

Several demonstration programs and programmatic changes can be viewed as at least tangible to the CMS goal of maximizing value-based healthcare and coordinating provider incentives.⁷

Coordination of Care Demonstrations – A patient is likely to receive medical care from a number of physicians as well as from hospital staff when a surgical procedure is performed. CMS often notes that physicians (or surgeons) and facilities do not always have financial incentives that align in treating the patient. For example, a surgeon is paid independently by Medicare regardless of where the surgery is performed (setting), how long the patient is hospitalized, or whether the patient suffers a hospital-acquired condition (outcome). Coordination of care demonstration programs seek to align financial incentives among providers and facilities, often by pooling payments for all treating providers under an episode of care designation.

For example, CMS currently is developing the Medicare Acute Care Episode (ACE) demonstration that bundles services (both hospital and physician) into a single episode of care with a negotiated payment amount. The demonstration allows select hospitals and providers in four states to share cost savings achieved through integrated care delivery for hip and knee replacement surgeries.

Implications for the Future

These initiatives and demonstrations are a subset of those designed by CMS to drive value-based payments, align incentives among providers and settings of care, and improve quality of care. Additionally, these initiatives are part of a constantly shift-

• 2009 Rules Promote Value Based Purchasing

• Non-Payment for “Never Events” Affirmed

• Product Training & Continuing Education May be Keys to Commercial Success

⁷ A complete description of the ACE demonstration can be found at: <http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/ACESolicitation.pdf>



MCRA

OVERLOOKING THE HILL

December 15, 2008

ing puzzle. The introduction of a new program requirement, such as reporting quality data remains a fluid process. For example, in 2009 CMS is expanding the quality reporting initiative in at least three ways:

- **New setting of care** – CMS has expanded the program to the hospital outpatient setting.
- **More reportable measures** – CMS has increased the number of hospital inpatient measures to 42 for 2009.
- **New uses of the data** – CMS has created Hospital Compare, which provides information to the public regarding the quality of care provided by hospitals and includes data from the quality reporting initiative.

In the future, CMS may also consider a fourth use:

- **Integrate physician quality data** – It is possible that CMS can link physician and hospital quality reporting initiatives to more closely analyze continuum of care for selected procedures.

Information from the demonstrations aimed at aligning incentives to physicians and hospitals could be used to drastically change, or even, link future payments for services. In addition, these initiatives, as well as the implementation of a streamlined claims processing system under Medicare Administrative Contractors (MACs), could be used to restrict payments to surgeons that are associated with never events and/or hospital-acquired conditions. Finally, it is likely that the number of quality data measures required for full payment in all settings will increase, allowing CMS to become a more prudent and selective payor of Medicare services.

Manufacturers' Role

Orthopedic device manufacturers can implement any number of initiatives to assist surgeon and hospital customers in adapting to these ongoing changes. Interactive product training, certification programs, educational outreach, and development of clinical standards can help hospitals and physicians succeed in a system

predicated on quality and value of care. Manufacturers also can sponsor the development of pre- and post-approval clinical data through clinical studies, registries, and meta-analyses to educate customers about the benefits of using a particular product. Finally, when appropriate, manufacturers should identify opportunities to participate with hospital/physician groups to develop protocols for participation in future coordination of care demonstrations that involve orthopedic procedures. These and other efforts can allow manufacturers to develop true partnerships aimed at improving patient care. ■

Medical Device Safety Act of 2008: Implications for Industry

by Jeffrey D. Zigler, JD, Associate⁸
Musculoskeletal Clinical Regulatory Advisers, LLC

Both the Food and Drug Administration (FDA) and the medical device industry continue to battle the would-be champions of healthcare consumer protectionism in Congress. House Resolution 6381, dubbed the "Medical Device Safety Act of 2008,"⁹ represents the most current, as well as one of the most sweeping, legislative changes to the regulatory environment for the industry today. As consultants to leading innovators of the medical device industry, acting as catalysts for their regulatory activity, and advocating before regulatory bodies tasked with enforcing Congress' will, firms like Musculoskeletal Clinical Regulatory Advisers (MCRA) in Washington, DC view this ongoing fight as one which industry professionals, manufacturers, and regulatory attorneys alike should all take notice.

Legislative History and Recent Supreme Court Decisions

Congressmen Frank Pallone, Jr. [D-NJ] and Henry Waxman [D-CA] are sponsoring the bill, which may gain traction in the House as it enters the House Committee on Energy and Commerce, of which both are members. According to a June 26, 2008 press release, the bill "protects patients from dangerous and defective devices by correcting the [Supreme] Court's flawed interpretation of the [Medical Device Amendments]"¹⁰. Rep. Pallone said in a statement

⁸ Mr. Zigler has been an orthopedic medical device consultant with MCRA since September 2007, advising clients on reimbursement and regulatory matters. If you have any additional questions or comments on this article or a related matter, you may contact him at zigler@mcra.com or (202) 552-5800.

⁹ <http://thomas.loc.gov/cgi-bin/query/C?c110:./temp/~c1101Avswd>.



MCRA OVERLOOKING THE HILL

December 15, 2008

that the Medical Device Safety Act of 2008 would reverse “an unfortunate Supreme Court decision that denied victims any legal recourse.”¹¹ The case referenced in Congressman Pallone’s statements is *Riegel v. Medtronic*¹², an 8-1 decision that denied plaintiffs the ability to successfully argue state common law tort claims because they were pre-empted under federal law.¹³

Following this decision, states cannot maintain requirements that are more stringent than federal standards. But the Medical Device Safety Act, if passed, would directly negate the Riegel decision, allowing product liability lawsuits to be pursued at the state level by individuals seeking damages for injuries alleged to have resulted from inadequate warnings as to medical devices provided by device manufacturers, even though such products had been reviewed by the FDA and met the agency’s approval standards. Indeed, the bill’s provision that the federal Food, Drug, and Cosmetic Act would have “No Effect on Liability Under State Law” leaves little ambiguity or room for interpretation; the bill, if passed, would effectively overturn the Supreme Court’s decision against this same attack on the FDA’s authority in Riegel.

In Riegel, decided in February 2008, the Court determined “whether the pre-emption clause enacted in the Medical Device Amendments of 1976, 21 U.S.C. § 360(k), bars common-law claims challenging the safety and effectiveness of a medical device given premarket approval by the . . . [FDA].”¹⁴ The device manufacturer’s arguments in Riegel were based on the particular language in the Medical Device Amendments’ built-in pre-emption clause, which was created to dispense with such arguments in the first place.¹⁵ In other words, the Riegel Court was unwilling to undo what it believed to be Congress’ original intent in construing this clause in favor of the federal Amendments. The Court held that the federal law creating the FDA’s review-and-approval mechanisms under the

Medical Device Amendments of 1976 “pre-empted,” or overrode, all state law claims.¹⁶ This was due largely to the fact that the FDA’s formal Premarket Approval (PMA) processes were found to already be stringent enough, and sufficiently protected consumers across the nation.¹⁷

Riegel was not the first time the Court has visited this issue. In 1996, twelve years before Riegel was decided, the Court heard arguments in *Medtronic v. Lohr* that a Florida state statute similarly pre-empted federal law establishing the § 510(k) process.¹⁸ The Lohr Court determined that since the § 510(k) process “is focused on equivalence, not safety, substantial equivalence determinations provide little protection to the public.”

Whereas the Riegel Court based its decision on the PMA process, the Lohr decision was based on the FDA’s review of a medical device for substantial equivalency under the § 510(k) process. In clarifying the Lohr decision, the Riegel Court noted that PMA approval 1) was specific to individual devices, 2) was focused on safety, and 3) could only be achieved if the applicant sufficiently demonstrated to the FDA that the device in question offered “a reasonable assurance of safety and effectiveness.”¹⁹

Framing the Issue for the Industry

The Medical Device Safety Act of 2008, if passed, could create flurries of legislative and litigious activity at the state level, as tort

- Legislation Attempts to Overturn Riegel Decision
- PMA v 510(k) Approval Routes Distinguishes
- Product Liability Lawsuits May Flourish if Enacted
- Concerns Raised Regarding Future Technology Development

¹⁰ http://www.house.gov/list/press/nj06_pallone/pr_june26_medicaldevice.html.

¹¹ <http://www.newsinferno.com/archives/3357>.

¹² 552 U.S. ____ (2008).

¹³ <http://www.newsinferno.com/archives/3357>.

¹⁴ 552 U.S. ____ (2008).

¹⁵ *Id.*; AdvaMed, a medical device industry trade association, recently commented on the Amendments’ express preemption clause, stating that “The Congress provided express preemption authority relative to FDA device approvals in 1976 because lawmakers recognized that a central, expert authority at the federal level would best serve the interests of public health and safety for all Americans...” http://medicaldesign.com/engineering-prototyping/regulatory/medical_device_safety_act_0207.

¹⁶ 21 U.S.C. § 360k(a).

¹⁷ Although affecting all devices approved under FDA’s PMA process, it should be noted that this decision remained silent on the issue of preemption of state laws for devices cleared under “510(k)” premarket notifications to the FDA.

¹⁸ 518 U.S. 470 (1996); the “510(k)” process allows for an FDA application to be made, whereby clearance is obtained by applicants who can demonstrate their products’ substantial equivalence to a predicate device(s).

¹⁹ 552 U.S. ____ (2008).



MCRA OVERLOOKING THE HILL

December 15, 2008

claims would immediately be filed seeking “jackpot jury awards,” and state laws unfavorable to the industry would be crafted in emergency legislative cram-sessions.²⁰

To this point, The Wall Street Journal raised an interesting argument in a recent op-ed article, the notion that subjecting medical device manufacturers to both federal and state law claims amounts to a sort of “double-jeopardy,” wherein manufacturers would ostensibly have to answer for their designs, claims, and warnings at both the federal and the state level. The author opined that this would have a chilling, and no doubt a crippling, effect on industry.²¹

The issue of states’ rights and federalism is one that has been debated for many years, and today strikes at the very heart of the medical device industry: its members’ freedom to innovate. If the Medical Device Safety Act of 2008 exits committee, and if its exposure in the House continues to increase, Senators Edward Kennedy (D-MA) and Patrick Leahy (D-VT) plan to introduce companion legislation in the Senate. If the bill does not die in committee, key members of the medical device industry need not only take notice, but perhaps active measures to re-frame the issue as one of federalism trumping states’ rights, emphasizing the industry’s (not to mention the economy’s) need for uninhibited growth of small-to-midsize manufacturers’ technological innovation. ■

The Physician Payments Sunshine Act Of 2008 (H.r. 5605)

by **Robert J. Hoehn, Senior Associate**²²
Musculoskeletal Clinical Regulatory Advisers, LLC

The Physician Payments Sunshine Act of 2008 (H.R. 5605) was introduced by Rep. Peter DeFazio (D-OR.) on March 13th, 2008. The intended purpose of this bill is to provide for transparency in the relationship between physicians and manufacturers of drugs, devices, or medical supplies for which payment is made under

Medicare, Medicaid, or other federal healthcare programs. The bill has garnered support from both government and industry. In fact, many manufacturers have taken it upon themselves to voluntarily implement programs disclosing their financial relationships with doctors. Most agree that a move toward transparency is one in the right direction; however the passage of this legislation may leave many members of industry unprepared for its impact.

H.R. 5605 would require quarterly and annual reporting to the Secretary of Health and Human Services (HHS) of any payment or transfer of value made to physicians over \$25. These payments or items of value include compensation, food, entertainment, gifts, travel, product rebates, consulting fees, stock and option grants, anything provided for less than fair market value, as well as a laundry list of other items and services valued above \$25 provided by drug, device and medical supply companies to physicians.²³ Companies must report the name and address of the physician, as well as other details such as the value and purpose of the payment. The Secretary of HHS would then make this information publicly available through an Internet website.²⁴ Knowingly failing to submit this information would result in civil monetary penalties of no less than \$10,000, but no more than \$100,000 for each occurrence.²⁵ Any company found to be non-compliant would also forfeit all tax deductions otherwise available for expenditures relating to advertising, promoting, or marketing of any covered drug, device, or medical supply.²⁶

This House bill applies to all companies with annual revenues over

- Bill Promotes Payment Transparency Between Manufacturers and Investigators
- Companion Bills Generally Supported by Industry
- Quarterly Reporting May be Mandated
- If Enacted Companies Should Prepare for Implementation & Reporting Requirements

²⁰ <http://www.medicalnewstoday.com/articles/118256.php>.

²¹ Op Ed, “Device for Lawyers,” Wall Street Journal, Aug. 13 2008, p. A16, <http://online.wsj.com/article/SB121858631283235063.html>.

²² Mr. Hoehn serves as a Senior Associate within MCRA. Mr. Hoehn has worked within the fields of Regulatory Affairs and Reimbursement. He is currently working with MCRA clients in their development and management of corporate compliance and physician ethics programs, as well as working with medical device and biologic companies in their execution of reimbursement programs. If you have any additional questions or comments on this article or a related matter, you may contact Mr. Hoehn at rhoehn@mcra.com or at (202) 552-5800.

²³ H.R. 5606 SEC. 1128G(a)(6)

²⁴ H.R. 5606 SEC. 1128G(e)

²⁵ H.R. 5606 SEC. 1128G(d)

²⁶ H.R. 5605 SEC. 2801(a)



MCRA OVERLOOKING THE HILL

December 15, 2008

\$1 million. A similar bill proposed by Sen. Charles Grassley (R-IA) would apply only to those companies whose annual revenues exceed \$100 million.²⁷ The House bill has been referred to the Subcommittee on Health and still requires approval by the House, Senate, and presentment to the President before having the effect of law.

In an effort to establish uniform rules and regulations that preempt state sunshine laws, several pharmaceutical and medical device manufacturers have endorsed these bills including Medtronic, Zimmer Holdings, Eli Lilly and Co., Merck, Astra Zeneca, and Johnson & Johnson. Several trade associations have also endorsed the Senate bill including PhRMA and AdvaMed.²⁸ The Consumers Union, the American Medical Student Association and the Medicare Rights Center have endorsed the House bill.

While many larger companies have the resources and expertise to quickly comply with this legislation, many smaller companies may not. Regardless of the outcome of this particular legislation, there seems to be a well supported move toward transparency. In order to prepare for such a move, it is critical that manufacturers and doctors are well educated with regard to what will be required of them. Proactively implementing a healthcare compliance program may be the best possible way to ensure manufacturers are conforming to all governmental regulations, and are conducting business with unquestionable ethics. Many companies may find this undertaking quite costly and burdensome. Depending on a given company's scale of operations and financial resources available to rely on consultants with expertise in healthcare, present compliance may be a fiscally sound alternative. ■

ICD-10 and Its Effects on New Technology

*by Mabelle Morningstar, CPC, CPC-H, CPC-E/M, PCS
Musculoskeletal Clinical Regulatory Advisers, LLC²⁹*

Along with the Department of Health and Human Services' recent announcement on August 22, 2008, signaling proposed imple-

mentation of ICD-10-CM and ICD-10-PCS coding systems on October 1, 2011, comes grave concern as to how such a transition will affect both physicians and hospitals alike.³⁰ Concerns range from the cost of training for coders, to the cost of implementation due to required software and hardware upgrades, as well as the possibility of experiencing sub-par healthcare services as providers and facilities work through the learning curve.

However, the fear and uncertainty surrounding this announcement may not necessarily be justified. Implementation of the ICD-10 system may not represent as big a hurdle as some believe, as the mere fact that coders will now have a greater number of codes does not necessarily mean that the system will be any more complex. After all, noted problems with the outgoing ICD-9 system have included inconsistency, a lack of clear definitions, not enough specificity, and ambiguity. Codes have found themselves in the wrong chapter. Also, under the ICD-9 system, coders have a varying level of detail and an overuse of "not elsewhere classified" (NEC) and "not otherwise specified" (NOS), which do not always give a clear picture of the actual procedure performed, along with nonstandard code elements. And above all else, there is a general (but quite serious) capacity issue—simply put, ICD-9 may run out of space by 2009.

A New Code Structure

Beginning with ICD-10-PCS, there will be a set code structure in each of 16 sections. For all sections, there are seven characters. Each character will have standard measures with clear definitions of each measure, in each section. An example in the medical/surgical section is that the 5th character is now "approach," which now has eight different choices. When coding a procedure for

- CMS Now Embracing Implementation of ICD-10
- Industry Must Work with CMS During Transition for New Code Development
- ICD-10-PCS Implementation Scheduled to Begin in 2011
- Manufacturers Should Consider Coding Impacts & Opportunities

²⁷ S. 2029

²⁸ <http://aging.senate.gov/record.cfm?id=298258>

²⁹ Ms. Morningstar is a certified professional coder with over 27 years experience with coding, along with practice and facility revenue cycle management. She has been a Coding Manager with MCRA since August 2007, advising clients on reimbursement matters. If you have any additional questions or comments on this article or a related matter, you may contact her at mmorningstar@mcra.com or (202) 552-5800.

³⁰ Federal Register, Vol. 73, No. 164, Proposed Rule



MCRA

OVERLOOKING THE HILL

December 15, 2008

medical/surgical, the coder will choose one of eight approaches the provider used. This will allow for greater consistency, clearer definitions, and will also be flexible, expandable and endlessly agreeable.

Medical/Surgical Section ³¹						
1st Character	2nd Character	3rd Character	4th Character	5th Character	6th Character	7th Character
Section (1)	Body System (31)	Root Operation (30)	Body Part (852)	Approach (8)	Device (53)	Qualifier (266)

Utilizing the above algorithm, an example of an ICD-10 code would be:

027004Z *Dilation of coronary artery, one site with drug-eluting intra-luminal device, open approach*

Impact on Reimbursement

CMS has contracted with 3M to effect immediate reimbursement during the transition. There is already in place a system for “general equivalence mapping” (GEM) from ICD-9 to both ICD-10-CM and ICD-10-PCS. Using a “find and replace” system, GEM will “find” an ICD-9 code’s new equivalent(s) based on certain verbiage descriptions, and “replace” it with the ICD-10 code(s) that are applicable. This process may combine several ICD-9 codes and create one ICD-10 code. Another process currently in place to help smooth the transition is one that allows for the addition of new codes to the ICD-10 draft documents. In 2008, approximately 300 new codes were added, which helps to narrow the gap in implementing the new system, as new codes are added through the current (and familiar) processes.

An example of GEM is:

ICD-10-PCS:

02733D6 *Dilation of coronary artery, four or more sites, bifurcation, with intra-luminal device, percutaneous approach*

Which comes from an ICD-9 cluster (more than one ICD-9 code) of:

- 00.66 (PTCA) or coronary atherectomy
- 00.43 Procedure on four or more vessels
- 00.48 Insertion of four or more vascular stents
- 36.06 Insertion of non-drug eluting coronary stent(s)
- 00.44 Procedure on vessel bifurcation

Based on the above illustration, one ICD-10 code can be the equivalent of several ICD-9 codes, exacting greater specificity.

In light of changes from the DRG system to the MS-DRG system, 3M is also implementing processes for GEMs of ICD-10 codes to the MS-DRG codes. Presently, Major Diagnostic Category (MDC) 6—gastrointestinal diseases—is completed, and the rest of the MDCs will be converted to GEM by late 2009. Initially, ICD-10 will not create any major increases (or decreases) in the MS-DRG values. According to CMS, the first year or two following its implementation will not see any major monetary changes. After that time period, CMS will begin evaluating the effect of ICD-10 on MS-DRGs and may make adjustments at such time.

New Technology and the New Code Creation Process

Device manufacturers and others lobbying for new coding of a particular device or procedure may not be able to obtain such codes during the transition period. At the recent Coordination and Maintenance meeting held at CMS in September 2008, many opinions speaking to this issue were expressed during the comment period. The overwhelming consensus of those who spoke was that the process of obtaining new codes was too much to handle in addition to the major changes from ICD-9 to ICD-10, and would only add confusion and slow this entire process even more. This could lead to delays in getting new and appropriate codes for new technology and procedures for possibly a year or more.

Conclusion

ICD-10 will most likely cause some initial confusion and frustration, but in the long-term will become a much more accurate coding system, and will prove more standardized, allowing for more

³¹ ICD-10-PCS Draft, 2008.



MCRA

OVERLOOKING THE HILL

December 15, 2008

consistency and detail, and for more accurate coding once implemented. Coding certification organizations are already in the process of designing coding training for ICD-10, and coders will most likely be required to pass an equivalency exam for the ICD-10 process during a specified window of time before and after its implementation. This training is another example of how the transition is being smoothed-over, and will ultimately increase efficiency (and proficiency) with the ICD-10 system immediately.

Technology-driven companies must consider available coding options now. If a new code is warranted, or an adjustment is needed for a current code, there is still time to get this implemented, prior to ICD-10. Also, there is still a possibility that ICD-10's implementation will be delayed until 2014.

While there may not be the much-feared disruption during the ICD-10 transition process, it is nevertheless critical that manufacturers and industry stakeholders have a comprehensive plan and strategies in place to successfully maneuver new coding environments. Providers and facilities must also begin the preparation process by evaluating their respective needs as they relate to coder training, software and hardware upgrades, as well as how they will handle any down-time caused by the transfer, so as to avoid unnecessary cash flow interruptions. ■

Links of Interest

Office of the President	www.WhiteHouse.gov
Government Accounting Office	www.GAO.gov
Department of Health & Human Services	www.HHS.gov
Centers for Medicare & Medicaid	www.CMS.gov
US Congress	www.House.gov
US Senate	www.Senate.gov
Congressional Legislation Tracking	www.GovTrack.us
Federal Register	www.GPOAccess.gov/fr/
Federal Regulations	www.Regulations.gov
Agency for Healthcare Research & Quality	www.AHRQ.gov
MCRA	www.MCRA.com