CCH Health Care Compliance LETTER

Volume 12, Issue 3 health.cch.com February 10, 2009

Obama orders review that may delay pending regulations

One of the first actions of the new Obama administration was to issue an order to undertake a legal and policy review of all regulations issued by federal agencies under the Bush administration that have not yet gone into effect. The review may push back the effective dates of several regulations issued by CMS and HHS, or lead to their repeal.

A memorandum signed by White House chief of staff Rahm Emanuel notes that "no proposed or final regulation should be sent to the Office of the Federal Register (OFR) for publication unless and until it has been reviewed and approved by a department or agency head appointed or designated by the President."

Any regulations that have been submitted to the OFR but not yet published will be withdrawn and reviewed by department or agency officials. The order also would possibly extend for 60 days the effective date of regulations that have been published in the *Federal Register* but have not yet taken effect. The delay would give administration officials time to review questions of law and policy raised by the regulations. If an extension is made, a new 30-day notice and comment period will be allowed.

Included in recently issued final rules that will be affected by this order are:

- *Final rule*, 74 FR 3328, January 16, 2009 (*Health Care Compliance Reporter* ¶700,108)—Modifies medical data Code set standards to adopt the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) and International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS); final rule effective March 17, 2009. (See story on page 3.)
- *Final rule*, 74 FR 3296, January 16, 2009 (¶700,107)—Adopts updated versions of standards for electronic transactions under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This final rule also adopts a transaction standard for Medicaid pharmacy subrogation. In addition, this final rule adopts two standards for billing retail pharmacy supplies and professional services. Effective date March 17, 2009, and January 1, 2010. (See story on page 8.)
- *Final rule*, 74 FR 2399, January 15, 2009 (¶700,106)—Requires institutional review boards (IRB) that review human subjects research conducted or supported by HHS and that are designated under an assurance of compliance for federal wide use by the Office for Human Research Protections to register their contact information, approximate numbers of all active protocols and active protocols involving research conducted or supported by HHS, and staffing for the IRB with HHS. Effective date July 14, 2009.
- *Final rule*, 74 FR 2873, January 16, 2009 (¶700,105)—Implements certain provisions of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) related to the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) Competitive Acquisition Program. Effective date February 17, 2009.

continued on page 2

Wolters Kluwer Law & Business

- *Final rule*, 74 FR 1494, January 12, 2009 (¶700,103)—Contains final regulations governing the Medicare Advantage (MA) program (Part C) and the prescription drug benefit program (Part D), and interim final regulations governing certain aspects of the Retiree Drug Subsidy (RDS) Program, and reflecting new statutory definitions relating to Special Needs Plans under Part C. Effective date March 13, 2009.
- *Final rule, correction*, 74 FR 166, January 2, 2009 (¶700,101)—Implements §1834(a)(16) of the Social Security Act by requiring certain Medicare suppliers of DMEPOS to furnish CMS with a surety bond. Effective date March 3, 2009.
- *Final rule*, 73 FR 73694, December 3, 2008 (¶700,095)—Implements provisions of the Deficit Reduction Act (DRA), which amends the Social Security Act by adding a new section related to the coverage of medical assistance under approved state plans. It also provides states increased flexibility under an approved state plan to define the scope of covered medical assistance by offering coverage of benchmark or benchmark-equivalent benefit packages to certain Medicaid recipients. Effective February 2, 2009.
- *Final rule*, 73 FR 71828, November 25, 2008 (¶700,094)—Implements and interprets the provisions of the DRA, and the Tax Relief and Health Care Act of 2006 (TRHCA). The DRA was amended by the TRHCA to include limitations on cost sharing for individuals with family incomes at or below 100 percent of the federal poverty line. A new section was added to the Social Security Act to provide state Medicaid agencies with increased flexibility to impose premium and cost sharing requirements on certain Medicaid recipients. Effective 60 days after publication in the *Federal Register*.

Also, amendments to 42 C.F.R. § 410.62 and 42 C.F.R. § 411.351, under the physician fee schedule update for 2009, are effective July 1, 2009, and, therefore would be subject to this review. ■

CCH Chicago Bureau, Jan. 22, 2009

FDA fails to provide sufficient oversight of clinical investigators

In fiscal year (FY) 2007, the Food and Drug Administration (FDA) did not ensure that sponsors submitted complete financial information for all of the clinical investigators involved in 119 marketing applications approved by the agency, according to an HHS Office of Inspector General (OIG) study. The FDA was unable to determine whether sponsors submitted financial information for all clinical investigators because: (1) only one percent of clinical investigators disclosed a financial interest; (2) over 40 percent of FDA-approved marketing applications were missing financial information; and (3) the FDA failed to take action on 20 percent of marketing applications with disclosed financial interests.

Prior to conducting clinical trials, sponsors are required to collect financial information from clinical investigators but they need not submit the financial information to the FDA until they submit their marketing applications to the agency at the conclusion of clinical trials. The FDA then assigns reviewers to evaluate the financial information for irregularities and minimize any potential bias related to the clinical investigators' disclosed financial interests.

Lack of financial information. The FDA was unable to determine whether sponsors had submitted complete financial information because the agency lacked a complete list of clinical investigators. Additionally, the FDA did not use onsite inspections to confirm that the information submitted was completed. Of over 29,000 clinical investigators, only one percent, or 206, disclosed any financial interests. These financial interests were associated with almost half of the marketing applications; the interests were generally payments from the sponsors for consulting services or general honoraria in the form of funds, stock options, or proprietary interests. The median reported payment was about $47,000, almost twice the $25,000 minimum payment reporting threshold.

The FDA was able to provide a complete list of clinical investigators for only seven percent of the marketing applications it received in FY 2007. The database that the FDA uses to capture demographic and inspection information was inadequate and cumbersome for compiling a list of clinical investigators per marketing application. The database did not list sub-investigators for two FDA centers and only included clinical inves-

continued on page 3

tigators listed for pretrial applications, foregoing the inclusion of investigators who may have been recruited once the clinical trials were underway.

FDA reviewers failed to take action on 20 percent of marketing applications with disclosed financial interests even though sponsors did not indicate taking action to minimize potential bias in these studies. The FDA did not provide information to its reviewers on how to review financial information and this was considered a major factor in the lack of action.

Recommendations. The OIG recommended that the FDA: (1) use a complete list of clinical investigators to check whether sponsors have completed financial information appropriately; (2) check that sponsors complete all attachments to financial forms; (3) update guidances for sponsors regarding the due diligence exemption; (4) add a review of financial information as a component of the onsite inspection protocol; and (5) provide adequate training for financial information reviewers. In addition to requiring that sponsors submit financial information during the pretrial application process, sponsors should be required to submit financial information with the marketing application. This would ensure that the FDA could review updated financial information for clinical investigators. The FDA did not agree with the final recommendation on submitting financial information at the start of the pretrial process contending that this would be burdensome. ■

OIG Report, OEI-05-07-00730, Jan. 13, 2009, Health Care Compliance Reporter, ¶530,716

ICD-10 implementation for medical data code sets delayed

The International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) and the International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS) code sets proposed implementation and compliance date of October 1, 2011, was delayed until October 1, 2013, by CMS. Concern raised by physicians and other providers in over 3,000 comments submitted about the cost and complexity of adjusting to the new codes led CMS to delay the implementation. The two medical data code set standards will be modified to implement certain provisions of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 (PubLNo 104-191) and will be concurrently adopted as standard code sets for coding diagnoses and inpatient hospital procedures.

Functionality exhausted. These new codes will replace the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM), Volumes 1 and 2, including the Official ICD-9-CM Guidelines for Coding and Reporting, which was developed nearly 30 years ago. In 2000, under authority provided by HIPAA, HHS adopted the ICD-9-CM code sets as the official standard medical data code sets for use in the health care administrative transactions to report diagnoses and inpatient hospital procedures. The functionality of ICD-9 codes, however, has been exhausted and the code set's basic structure is flawed and outdated, unable to accommodate new medical technology and terminology.

ICD-10 benefits. The ICD-10 code sets provide a standard coding convention that is flexible, with unique codes for all substantially different health conditions. It also allows new procedures and diagnoses to be easily incorporated as new codes for both existing and future clinical protocols. ICD-10-CM provide specific diagnosis and treatment information that can improve quality measurements and patient safety, and the evaluation of medical processes and outcomes.

Adoption of ICD-10 will provide the precision needed for a number of emerging uses such as pay-for-performance and biosurveillance; biosurveillance is the automated monitoring of information sources that may help in detecting an emerging epidemic whether naturally occurring or as the result of bioterrorism. ICD-10-PCS codes will not be used in outpatient transactions because the codes are limited to inpatient procedures. ICD-10 implementation will permit the United States to compare its data with international data to track the incidence and spread of disease and treatment outcomes because the United States is one of the few developed countries not using ICD-10. ■

Final rule, 74 FR 3328, Jan. 16, 2009, Health Care Compliance Reporter, ¶700,108

How to Tackle the Wreck of the RACs

by Fay Rozovsky, JD, MPH

In the last five years, two pieces of federal legislation took effect which dealt with the Medicare Recovery Audit Contractor or "RAC" program. The first, the Medicare Modernization Act of 2003[1] involved a demonstration project to help identify both improper overpayments and underpayments under Medicare. The second law, The Tax Relief and Health Care Act of 2006[2] made the RAC program a permanent feature for CMS, requiring CMS to expand the program to all 50 states by 2010.

On the surface, the RAC program appears to be a subject ripe for those in billing, coding, and regulatory compliance. Delving more deeply into the RAC program, however, it is apparent that the requirements are of great interest to those in risk management and health care facility financial management. Indeed, when coupled with the impacts of the inpatient prospective payment system (IPPS) "present on admission (POA)" and "serious preventable hospital acquired conditions (HACs)," the RAC program may be the tipping point to enterprise risk management (ERM).

As of this writing, the RACs program has been suspended pending resolution of a dispute raised by a firm that was not selected as a contractor for the Recovery Audit Program. There is little doubt that the program will take shape In the interim, the delay provides a good opportunity for compliance officers and risk managers to consider several things. For example, how will the RAC program operate? What is the period of financial risk exposure? What steps are needed now to address this emerging risk exposure? These issues are addressed in this article along with several risk management strategies for tackling the "wreck of the RACs."

The Rationale for the RAC Program

Over the last few years, there has been an evident shift from reimbursement for patient encounters under the Medicare program to "value based" purchasing. In other words, a patient visit must have clinical value. For Medicare, value-based purchasing includes many attributes of a revised public policy that includes financial rewards for those providers that achieve established benchmarks in terms of quality, safe, efficient, and effective care. Rewards can be realized through pay-for-performance reimbursement.

At the other end of the spectrum is the IPPS approach that precludes certain types of payments for conditions that were present on admission but not documented effectively and serious preventable hospital-acquired conditions. The IPPS approach is based on the same logic of payment only for value-based health care delivery.

The final facet in value-based reimbursement is the RAC program. It is a "claw-back" style process through which Medicare can recoup improper payments. It also affords those who received underpayments with remuneration. Payment for value is the underlying theme here as well.

The RACs system also highlights another interesting aspect of public policy, third party contractors that are paid on a contingency basis. That is, the RAC contractors receive a percentage of improper overpayments collected from providers.

Lest anyone doubt the financial success of the RAC program, one need only review the results of the demonstration project. According to a Medicare report as of March 27, 2008,

> ...RACs succeeded in correcting more than $1.03 billion in Medicare improper payments. Approximately 96 percent ($992.7 million) of the improper payments were overpayments collected from providers, while the remaining 4 percent ($37.8 million) were underpayments repaid to providers.[3]

The results involved a three-year interval. In the demonstration project, the great preponderance of overpayments were collected from inpatient hospital providers. Some 6 percent of overpayments were collected from inpatient rehabilitation facilities and just 4 percent from outpatient hospital providers. According to Medicare, most of the overpayments stemmed from providers submitting claims that were not compliant with Medicare coding policies or medical necessity requirements.

Extrapolating from the demonstration project, one can appreciate why there is much interest in expanding the RAC program. As CMS has noted, on an annual basis, Medicare processes over 1.2 billion claims from more than one million health care providers.[4]

The prospect of recouping large amounts of money paid in error by the cash-strapped Medicare program serves as a strong incentive for the recovery audit program. One also can see the strong financial incentive for third party contractors that participate in the RAC program.

The Nuts and Bolts of the RAC Program

A RAC contractor identifies claims overpayments and underpayments using two systems. One involves the use of proprietary software that pinpoints some type of claims errors. This is an "automated" review because it does not include a review of the patient's medical record.[5]

To use this approach it must be believed that the service was one for which there should not be benefit coverage or the claim was coded improperly. In addition, there must be something in writing from Medicare to support this determination. The documentation may include a Medicare coding guideline or Medicare policy statement.

The contractor can use the automated review even when Medicare has not issued written policies. Thus, the RAC contractor can use automated review to address duplicate claims and errors in pricing.

The RAC contractor also has at its disposal a "complex review" process.[6] In this instance there is a human review of the patient's medical record. As suggested by the American Hospital Association

> Complex review is used when there is a high probability (but not certainty) that a service is not covered or where no Medicare policy, Medicare article or Medicare-sanctioned coding guideline exists. In complex reviews, the RAC will need copies of medical records to provide support for its decisions.[7]

In those situations in which Medicare has not issued any policy or guidelines, a RAC may proceed with a complex review. This so-called, "individual claims determinations" process relies on medical literature and clinical judgement. The medical director of the RAC contractor must review the information used for this purpose.[8]

The RAC contractor may decide that a claim involves coverage issues, coding considerations, or that there were duplicative claims. The RAC contractor also may make other determinations involving improper application of a payment policy.[9] The focus is not on so-called "gotcha" issues such as missing dates or signatures.

One may wonder how the RAC contractor gains access to the medical record for complex reviews. The RAC contractor is permitted to go on-site to review and copy the medical records at the provider's location.[10]

Alternately, the RAC contractor may request that the provider mail, fax or "otherwise securely transmit" the medical records. Thus, imaged medical records on a CD or "digital video device" are permitted.[11]

Provision is made for the RAC contractors to pay for copies of the medical records made with respect to IPPS and long term care hospital prospective payment system (LTCH PPS) claims. When the on-site evaluation results in a determination of an improper payment, the RAC will make a copy of the pertinent sections of the medical record and retain this information.[12]

Some claims will not be subject to RAC contractor review. Termed "suppressed" files, these include those situation in which:

- a post payment medical review is in progress;
- claims are subjected to complex prepayment medical review;
- a fraud/benefits integrity review is in progress; or
- the AC (affiliated contractor) has been instructed by an outside agency (law enforcement, Office of Inspector General, Department of Justice) that an investigation is ongoing.[13]

In addition, RACs are prohibited from identifying improper payments in other situations. These include:

- services provided under a program other than Medicare fee-for-service;
- the cost report settlement process;
- claims more than three years past the date the claim was originally paid;
- claims paid earlier than October 1, 2007;
- claims for which the beneficiary is liable for the overpayment because the provider is without fault;
- clams that are randomly selected;
- claims involved in a Medicare demonstration or that have other special processing rules; and
- prepayment review.[14]

As one might imagine, questions might arise about the qualifications of those who make determinations based on the complex review process. When the issue in question is coverage or medical necessity, registered nurses or therapists make the determination. Coding determinations are made by certified coders. The credentials of those making the medical review decisions must be made available when requested by the provider. Also, the medical director of the RAC contractor must be available to communicate with the provider that is the subject of a claim denial.[15]

Overpayments may result in a partial denial or involve a full denial. The latter will result from a determination that the service provided was not reasonable or necessary "and no other service would have been reasonable and necessary."[16]

It is up to the RAC contractor to follow CMS requirements in seeking recoupment of Medicare overpayments of more than $10 in value. The term "recoupment" means:

> ...the recovery by Medicare of any outstanding Medicare debt by reducing present or future Medicare provider payments and applying the amount withheld to reduce the debt. The entire overpayment is recouped, but the overpayment should be net of the correct payment amount identified by the RAC.[17]

Withholds of present and future payments are managed by the Medicare fiscal intermediary, carrier, or other contractor. The withhold is applicable until the debt is satisfied. A payment plan can be used for this purpose. Interest, however, accrues on overpayments.[18]

In contrast, in an underpayment situation the RAC sends to the provider a written notification letter that describes rel-

evant claim details. When an underpayment is identified, the Medicare fiscal intermediary, carrier or contractor is notified and once validated, the payment is adjusted.[19]

There is an appeal mechanism built into the RAC contractor program. According to CMS:

> The Medicare Appeals process will remain the same for physicians under Part B and Part A non-inpatient claims. The only difference under Part A is for the inpatient hospital claims under the Prospective Payment System (PPS). In the current appeals process, the first level appeal will go to the Quality Improvement Organization (QIO); however, the RAC appeals will go to the Fiscal Intermediary that processed the claim.[20]

For their part, the RAC contractors are paid on a contingency basis. That is to say the RAC contractors receive a portion of the monies recovered for all accurately identified overpayments.[21] If the provider prevails on appeal, CMS is required to pay interest to the provider. The interest payment in this instance is determined by CMS' interpretations of the appeal regulations.[22] There are a number of guidance documents available on the Internet to help providers gain a much more detailed understanding of the RAC program. Some of these resources are listed at the end of this article.

The Financial Risk Exposure

The RAC program could pose serious financial risk exposure for health care entities, especially those challenged by poor documentation practices, inadequate coding and billing systems, and a lack of quality oversight for submitting health care claims information.

The looming burden of IPPS is another stress factor. Absent good documentation practices it is quite possible that a hospital will "miss" inappropriate Medicare claims for what was "present on admission." Similarly, inaccurate claims data for serious preventable hospital acquired conditions may be detected either through the automated or complex review RAC program. Either way, contested payments can result in a protracted appeal or recoupment payment plan.

The situation is one that raises the prospect of serious financial challenges. For example, assume it is 2010. A hospital chief financial officer (CFO) breathes a sigh of relief thinking that claims paid by Medicare two or three years ago are now a thing of the past. The three-year limitation period for the RAC program started in 2007, however, in this instance, the hospitals claims are still subject to a RAC review. Absent funding reserves to satisfy successful RAC findings, the financial projections for a health care facility may not be on solid footing. Even with an installment payment plan in place, there may be need to slash budgets, postpone new programs, or reduce staffing. In competitive markets with a thin operating margin, the financial pressures could prove challenging for a health care entity.

Flawed coding and billing and use of medically unnecessary tests or treatment can be the trigger for a watershed of serious consequences for a health care entity. As such, the RAC program may be the tipping point that helps accelerate the move to an enterprise risk management (ERM) model for health care organizations. Combining good business analytical tools, accurate clinical data, and effective coding, billing, and oversight, an enterprise-wide system would help to avert serious financial risk exposures.

An ERM model may require realignment in reporting structures, investment in good analytical tools, and more education than in the past for those involved in coding and billing. Oversight might require deployment of a team of clinicians to constantly review documentation. Software may be developed to help "flag" those cases or patterns of coding, billing, and service delivery that merit attention. The investment compared to the potential results of a RAC finding may more than justify such an approach.

ERM Strategies for the RAC Program

There are several enterprise risk management strategies to consider in ramping up for the RAC program. These strategies go well beyond clinical risk management and encompass the board of directors, senior management, medical staff, and those responsible for coding and billing practices.

1. Provide a practical educational program. Implement a user-friendly educational program on the RACs program that is appropriate for various segments of the health care facility. Consider for the board and, in particular, the finance committee of the governing body the questions that should be asked each month regarding coding and billing and financial projections. Think about specific programs for senior management health professional staff. Recognize that RAC education programming will require regular in-service sessions based on lessons learned from audits and correspondence from the RAC contractor.

2. RAC documentation 101. Offer the medical staff and coding and billing personnel "how to" training on documentation to avoid encounters with the RAC contractor for the region. Build into the training case studies that illustrate complex issues involving medical necessity, charting of present on admission, and hospital acquired conditions. Recognize that training should focus on accurate, descriptive entries that might serve as an invitation for review. Build into the electronic medical record (EMR) and electronic health record (EHR) systems useful glossaries and drop-down lists for accurate documentation.

3. The RAC QI team. Deploy a qualified RAC quality improvement team to serve as real time coaches for quality documentation and coding. Consider registered nursing personnel, certified coders, and physicians for this purpose. Ask them to identify patterns or trends that pinpoint the need for one-to-one education, in-service programs, or refinement of policies, procedures and practice routines.

4. Chain of command for coding and billing. Think about implementing a specific chain of command communication process for questions that arise about coding and billing. Consider a process that is comprehensive, contemplating the needs of nursing personnel, members of the medical staff and coding personnel.

5. RACs reserving program. Factor into financial projections the three-year "claw back" potential of the RAC program,

making certain that sufficient reserves are available to address all or a portion of a withhold or repayment requirement. Build into the RAC reserving policy a statement of philosophy on the use of installment payments for RAC repayment contingencies. Recognize that this approach also should address the issue of legal fees for appeals of withhold or repayment decisions. Note that this approach requires board approval.

6. RAC service sector alignment policy. Consider implementing a framework for aligning service sector billing and coding with possible RAC contractor activity. Review the regularly published CMS RAC reports and the Medicare Financial Management Manual to design the framework for areas that are apt to be "flagged" for either automated review or complex review. Consider as well new service lines that involve high risk, high volume, or high utilization that may come under RAC review and align these programs with the internal process used for quality improvement in documentation practices.

7. RAC auditing. Evaluate the idea of retaining an external RAC program level auditor to review coding and billing approaches. Use the results of the external audit to help drive refinement in documentation practices, RAC reserving policies, and educational offerings.

8. Address RAC program in e-discovery plans. Recognize the potential for a RAC contractor to request EHR or EMR data that would then trigger the health care facility's e-discovery plan. Work with health information management, information technology, and other key stakeholders on how to address RAC level data in the e-discovery plan. Involve legal counsel in the process, particularly as it relates to so-called "legal holds" for such information. Note that legal counsel may include corporate compliance counsel for this purpose.

Conclusion

The Recovery Audit Contractor Program is another element in the emerging public policy of Medicare value-based reimbursement. CMS wants to be certain that Medicare funds are spent wisely and that expenditures help beneficiaries achieve good outcomes. The goal is to use the RAC program to recoup improper overpayments while tackling the issue of underpayments.

Education is a must for all involved in the health care enterprise. Education, however, is just one important step. Effective communication and documentation are essential for avoiding improper Medicare claims. The board will need succinct, accurate reporting so that prudent decisions can be made about future spending and resource allocation. With input from coding, billing, risk management, quality, and the CFO, much can be done to create a composite dashboard for this purpose.

Time will tell to what extent the RAC program filters into possible litigation. Director and officer liability may be a risk exposure from the RAC program, particularly, if financial reserves and projections are not well marshaled by the board and senior management. Regulatory scrutiny also may emanate when a pattern emerges of improper claims.

The RAC program requires a concerted effort among key individuals in the health care facility Using an enterprise risk management approach may be an optimal solution for health care organizations trying to avoid entanglement in the RAC program.

Suggested Resource List:

- American Health Lawyers Association, www.ahla.org
- American Hospital Association Recovery Audit Contractor (RAC) Program Website, www.aha.org/aha/issues/RAC/index.html
- American Health Information Management Association, www.ahima.org
- Healthcare Financial Management Association, www.hfma.org
- The Medicare Record Audit Contractor Website, www.cms.hhs.gov/RAC

Fay Rozovsky, JD, MPH, is the President of The Rozovsky Group, Inc. and a faculty member in the Department of Legal Medicine at Virginia Commonwealth University Medical College and the Barton Certificate Program in Healthcare Risk Management. She has more than two decades of experience in health care risk management. She has published more than 500 articles on subjects in health law, risk management, patient safety, and medical ethics. Ms. Rozovsky is a member of the CCH Health Care Compliance Editorial Advisory Board.

[1] Medicare Modernization Act of 2003 (PubLNo. 108-173), §306.

[2] Tax Relief and Health Care Act of 2006 (PubLNo 109-432) §302.

[3] The Medicare Recovery Audit Contractor (RAC) Program: An Evaluation of the 3-Year Demonstration, June, 2008, 2.

[4] CMS Program Identifies $371.5 Million in Improper Medicare Payments in Three States," CMS Press Release, Feb. 28, 2008.

[5] CMS RAC Status Document FY 2007, February, 2008. *See also* Recovery Audit Contractor (RAC) Program, American Hospital Association (AHA), accessible at: www.aha.org/aha/issues/RAC/index.html.

[6] *Id*

[7] RAC Program, *Supra* n. 5..

[8] *Id.*

[9] *Id.*

[10] *Id.*

[11] *Id.*

[12] *Id.*

[13] CMS Medicare Financial Management Manual, Pub 100-06, Chap. 4- Debt Collection, §100.4 (Rev. 139, 07-11-08).

[14] RAC Program, *Supra* n. 5.

[15] *Id.*

[16] *Id.*

[17] *Id.*

[18] *Id.*

[19] *Id.*

[20] See CMS RAC Frequently Asked Questions at http://questions.cms.hhs.gov. Search by ID: 7730.

[21] http://questions.cms.hhs.gov. Search by ID: 9405. *See also* RAC Program, *Supra* n. 5.

[22] http://questions.cms.hhs.gov. Search by ID: 7736.

Fraud & Abuse

Former pharmaceutical execs exclusion affirmed

An administrative law judge (ALJ) affirmed the Office of Inspector General's (OIG's) 15-year exclusion of three former pharmaceutical executives who failed to prevent misbranding and fraudulent distribution of OxyContin from federal health care programs. The three men once served as corporate officers at Purdue Frederick, the manufacturer and distributor of OxyContin.

Corporate responsibility. The excluded officers are Michael Friedman, former chief operating officer and then chief executive officer; Paul Goldenheim, former chief scientific officer; and Howard Udell, former general counsel. All three pleaded guilty in 2007 as responsible corporate officers to misdemeanor misbranding. As a corporation, Purdue Frederick pleaded guilty to felony misbranding.

ALJ Carolyn Cozad Hughes found that the three men had a responsibility to prevent or correct the misbranding of OxyContin but failed to do so. She also noted the costs to the government were "astronomical" and that the failures of the officers "endangered the health and safety of program beneficiaries and others."

Misbranding. OxyContin, which is prescribed for patients with moderate to severe pain, is now regulated as a controlled substance with the same addictive potential as morphine. At the time it pleaded guilty, Purdue Frederick admitted that the company falsely claimed OxyContin was less addictive, less subject to abuse, and less likely to cause withdrawal symptoms than rival pain medications.

The OIG previously excluded Purdue Frederick for 25 years as part of a global resolution between the United States, Purdue Frederick, and Purdue Pharma, a related company. As part of a resolution with the United States, Purdue Frederick and Purdue Pharma, a related company, agreed to pay $600 million in restitution to settle their criminal and civil liabilities. Purdue Pharma also entered into a five-year corporate integrity agreement with OIG. ■

OIG Press Release, Jan. 23, 2009

In the News

RACs corrected improper Medicare payments

Updated appeals statistics have been added to the recovery audit contractor's (RAC) demonstration project evaluation report that indicate that from the beginning of the demonstration project through August 31, 2008, providers appealed 22.5 percent (118,051) of RAC determinations. RACs succeeded in correcting more than $1.03 billion in improper payments by Medicare during the demonstration project, of which approximately 96 percent were overpayments collected from providers and 4 percent were underpayments repaid to providers. The RAC demonstration project led CMS to incorporate several important components into the RAC permanent program, including (1) building cooperative relationships with Medicare claims processing contractors, fraud fighters, the Department of Justice, and appeals entities; (2) contracting with a RAC validation contractor to conduct independent third-party reviews of RAC claim determinations; (3) limiting the claim review look-back period to three years; (4) requiring each RAC to hire a medical director; and (5) conducting significant outreach to providers.

CMS Report, Jan. 2009, Health Care Compliance Reporter, ¶350,133

Electronic transaction standards updated

HHS has amended the regulations governing the standards for electronic transactions originally adopted as mandated under the provisions of the Administrative Simplification subtitle of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), The amended regulations include: (1) updated versions of the original electronic standards, (2) the adoption of a transaction standard for Medicaid pharmacy subrogation, and (3) two new standards for billing retail pharmacy supplies and professional service. The definition of "standard transaction" has been changed from "the applicable standard" to "an applicable standard" to reflect a policy change that allows for dual use of standards for billing retail pharmacy supplies and services. The final rule would become effective March 17, 2009, except for the provisions of the Medicaid pharmacy subrogation standard, which become effective January 1, 2010; however, the Obama administration has delayed the effective dates of final rules until the new administration has had an opportunity to review and approve them (see story on page 1).

Final rule, 74 FR 3296, Jan. 16, 2009, Health Care Compliance Reporter, ¶700,107

House bill aims to spur development of health IT

The House Ways and Means Committee has finalized a bill aimed at advancing the use of health information technology (IT) by requiring the government to develop national standards and invest $20 billion in IT infrastructure and incentives. The Health Information Technology for Economic and Clinical Health Act would require the government to develop standards by 2010 that allow for the nationwide electronic exchange and use of health information. It also establishes a voluntary certification process for health IT products and provides funding for health IT infrastructure, training, and dissemination of best practices. Under the bill, physicians would be eligible for financial incentives ranging from $40,000 to $65,000 for showing that they are using health IT meaningfully.

House Ways and Means Press Release, Jan. 16, 2009