CCH Health Care Compliance LETTER

Volume 10, Issue 17 health.cch.com August 21, 2007

FTC antitrust ruling leaves hospital merger intact

by Valerie L. Witmer, J.D., Contributing Editor

Evanston Northwestern Healthcare (ENH) will not have to divest Highland Park Hospital ("Highland Park"), despite the Federal Trade Commission's (FTC's) finding that the transaction violated antitrust laws. According to the FTC's August 2, 2007, ruling, the merger gave ENH the ability to raise prices through the exercise of market power but nevertheless did not warrant divestiture.

Antitrust allegations. In 2000, ENH merged with Highland Park. Prior to the merger, ENH owned Evanston Hospital and Glenbrook Hospital. Four years after the transaction closed, the FTC filed an administrative complaint challenging ENH's acquisition of Highland Park under §7 of the Clayton Act. Following the merger, ENH substantially raised its prices and negotiated a single contract for all three of its hospitals with each of its managed care organization (MCO) customers. The FTC alleged that the merger eliminated significant competition between ENH and Highland Park, allowing ENH to exercise market power against MCOs.

ENH argued that it increased its prices because information about Highland Park's rates showed that Evanston had been charging rates that were below competitive levels for several years. ENH also contended that the merger-related price increases in part reflected increased demand for Highland Park's services because of post-merger improvements at the hospital.

The administrative law judge (ALJ) who initially heard the case found that the transaction violated §7 of the Clayton Act and ordered ENH to divest Highland Park. (See *Health Care Compliance Letter*, Vol. 8, Issue 22, Nov. 3, 2005). ENH appealed the ALJ's decision to the full FTC.

FTC decision. The Commissioners agreed with the ALJ that the ENH-Highland Park merger violated the antitrust laws. They found that "the evidence demonstrates that the transaction enabled the merged firm to exercise market power and that the resulting anticompetitive effects were not offset by merger-specific efficiencies."However, the Commissioners did not agree that ENH should be forced to divest Highland Park, citing "the potentially high costs inherent in the separation of hospitals that have functioned as a merged entity for seven years."

The Commissioners instead ordered ENH to modify its contract negotiating procedures. ENH will be required to establish separate and independent negotiating teams – one for Evanston and Glenbrook Hospitals and one for Highland Park. According to the Commissioners, "While not ideal, this remedy will allow MCOs to negotiate separately again for these competing hospitals, thus re-injecting competition between them for the business of MCOs."■

In re: Evanston Northwestern Healthcare, FTC Action No. 9315, Aug. 2, 2007, Health Care Compliance Reporter ¶650,041.

Wolters Kluwer Law & Business

HIM, coders should prepare for new DRGs

by Catherine Hubbard, M.A., Contributing Editor

As CMS considers changes that would add nearly 200 new Medicare severity diagnosis related groups (MS-DRGs), health information management (HIM) and coding professionals will need to increase training, make sure coding is up to date, evaluate any policy and procedural changes needed, and ensure that documentation is thorough, experts advised at an American Health Information Management Association (AHIMA) audio seminar held on June 26, 2007. Gail Garrett, a coding compliance expert who works for a large health care organization, and Gloryanne Bryant, Corporate Director of Coding and HIM Compliance for Catholic Healthcare West, San Francisco, California, reviewed the code combinations and comorbid conditions that will affect DRG assignment and compared and contrasted the current 530 DRGs and the 743 proposed MS-DRGs.

The CMS rule is expected to be implemented this fall, Bryant said. She explained that under last year's proposed rule, CMS granted a contract to RAND Corporation to study a variety of grouping systems for severity capturing. The study is not due until around September, and the rule is expected to be implemented October 1, 2007. Bryant noted that CMS could adopt another severity system based on the RAND report the following year, which could mean even more changes.

New DRGs. CMS has proposed 743 MS-DRGs to replace the 538 current DRGs. The proposed rule would create new MS-DRGs as well as consolidate current DRGs. The new MS-DRGs are intended to improve CMS' ability to (1) identify groups of patients with varying levels of severity using secondary diagnoses; and (2) do a better job of identifying technology, Bryant noted. "It's a refinement of the base DRGs."

According to Bryant, in many cases, CMS would subdivide each base DRG into subclasses based on secondary diagnosis codes known as comorbid conditions (CCs) and major comorbid conditions (MCCs). A CC is defined as a condition (pre-existing or arising during a hospital stay) that prolongs the length of the stay by at least one day in approximately 75 percent of cases. The presence or absence of a secondary diagnosis code can have an impact on the DRG assignment. Specifically, the proposed rule would create up to three payment tiers for each DRG based on the presence or absence of a CC or MCC.

Examples of CCs include respiratory infection and inflammation, unstable angina, heart disease with heart failure or renal failure, and acute exacerbation of chronic bronchitis. Examples of MCCs include sepsis, acute myocardial infarction, acute/chronic diastolic/systolic heart failure, cardiac arrest, pneumonia, and acute respiratory failure.

CMS also has proposed to delete such conditions as dehydration, acute/chronic blood loss anemia, and angina from the current CC list, Bryant warned. A lot of clinicians, however, are saying that these conditions do impact the stay. "We'll see what happens with this proposed deletion from the current CC list and what CMS decides to keep and remove," she said.

The proposed CC list is comprised of significant acute diseases, acute exacerbation of significant chronic diseases, advanced or end-stage chronic diseases, and chronic diseases associated with extensive debility, Bryant explained. CMS reviewed the 13,549 current secondary diagnosis codes and removed many common secondary diagnoses and found that it could narrow down the list from 3,326 CCs to 2,583 in the proposal, she noted. "We are going to see a significant drop in CCs," Bryant predicted.

The CCs on the revised list require intensive monitoring, expensive and technically complex services, or extensive care involving multiple caregivers. Significant acute manifestation of the disease, an advanced stage of the disease, and chronic diseases are associated with extensive debility, she added.

When documenting secondary or other diagnoses, facilities must include conditions that affected patient care in terms of requiring clinical evaluation, therapeutic treatment, diagnostic procedures, extended length of stay, or increased nursing care or monitoring, Bryant noted. Facilities also must

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CCH Health Care Compliance Letter is published 24 times a year by CCH, a Wolters Kluwer business, 4025 W. Peterson Avenue, Chicago, IL, 60646. Subscription rate is $305 per year. First-class postage paid at Chicago, Illinois, and at additional mailing offices. POSTMASTER: SEND ADDRESS CHANGES TO *CCH Health Care Compliance Letter*, 4025 W. PETERSON AVENUE, CHICAGO, IL 60646. Printed in U.S.A.

document all conditions and diagnoses in a proprietary business document that should not be copied or distributed outside of the system without express written permission. "If it's not documented it cannot be coded," Bryant emphasized, adding, "Physician documentation is essential to capture patient comorbid complications."

Payment cuts. According to Garrett, CMS' proposal also includes a 2.4 percent cut to both operating and capital payments in fiscal years 2008 and 2009. The cuts are expected to save $24 billion over a period of five years. The rule also proposes improved payment based upon patient severity and resources, Garrett said.

CMS also has recommended reducing the amount of a proposed Inpatient Prospective Payment System (IPPS) payment when a full or partial credit towards a replacement device is made, the device is replaced without cost to the hospital, and there is a full credit for the removed device, Garrett said.

CMS identified 13 IPPS conditions present on admission (POA) that could have an impact from the reimbursement perspective. Those conditions include:

- catheter-associated urinary tract infection;
- pressure sores;
- object left in surgery;
- air embolism;
- delivery of ABO-incompatible blood products;
- staphylococcus aureus septicemia;
- ventilator-associated pneumonia;
- vascular catheter-associated infection;
- clostridium difficile-associated disease;
- methicilllin-resistant staphylococcus aureus infection;
- surgical site infections;
- surgery on wrong body part, patient, or wrong surgery; and
- patient falls.

CMS is seeking public comment to determine which of these measures to implement. Garrett noted that CMS must implement at least two of the measures and is likely to outline those conditions in the final rule. She added that the IPPS rule will address whether an unexpected event that occurs during a hospital stay results in additional revenue to the provider. "CMS believes this impacts quality of care," she said.

Preparing for DRG changes. To prepare for the potential IPPS changes, HIM and coding professionals should avoid becoming dependent on encoding software. "Coders need to review carefully the final code that the encoder software is providing," Garrett advised. They should use the ICD-9-CM code book and make sure that documentation supports the assignment of the code. "Coding from memory is dangerous," she cautioned.

To face coding guidelines changes, HIM professionals should continue to educate themselves and coders, have coding staff "shadowing" while on clinical rounds, re-audit documentation and coding, audit POA reporting, make physicians aware of POA reporting, increase anatomy and physiology knowledge, and increase knowledge of disease processes and anatomy and physiology as well as pharmacology. They also should recognize that core coding concepts remain the same: focus on accurate and complete coding.

HIM professionals should become experts on MS-DRG methodology and related changes and "[k]eep up with industry information," Garrett recommended. They should be aware of senior management, information systems personnel, department directors, the financial team, and the local contract team, she said.

Prior to implementation of proposed changes, more training and education will be needed, Garrett said. Professionals also should: (1) work to ensure coding is up to date prior to transition; evaluate any necessary change in any processes, policies, and procedures; (2) assess gaps in medical record documentation; and (3) continue emphasizing medical staff responsibilities.

"This is really not new to us," Garrett stressed. She noted that over the past couple of years, CMS has changed the major cardiovascular DRGs. "Hospitals are already coding as carefully and accurately as possible because of other incentives in the system to do so, such as risk adjustment in various quality reporting systems.... This is very similar in concept. This is going to be a very easy transition," she predicted.■

CCH Washington Bureau, July 17, 2007.

Requirements for reporting clinical trial incidents to OHRP: What research institutes need to know

by Patricia L. Brent, J.D., M.P.H., Contributing Editor

The correct and timely filing of reports related to unanticipated problems experienced by human subjects participating in clinical trials is essential for minimizing harm to other participants in similar trials. The complexity of the regulations, as well as separate agency reporting requirements (e.g., Food and Drug Administration (FDA) and HHS), however, has created uncertainty and frustration within the research community charged with their compliance. This article describes new and updated guidances provided by the Office of Human Research Protections (OHRP) in an effort to clarify procedures related to reporting requirements for unanticipated problems experienced during clinical trials.

Requirements for reporting incidents related to unanticipated problems experienced by human subjects participating in clinical trials, serious or continuing noncompliance with HHS regulations at 45 C.F.R. Part 46 or Institutional Review Board (IRB) requirements, and suspension or termination of an IRB approval have been a confusing web of procedures for institutions that conduct the trials. This confusion is aggravated by imprecise or undefined terminology; the proliferation of multi-centered clinical trials where issues of ultimate responsibility, authority, and procedures for reporting incidents are often vague; and separate HHS and FDA regulatory and policy requirements regarding reporting of unanticipated problems. This confusion has created uncertainty in the interpretation of the regulations and added an additional layer of complexity to an already complex regulatory system. In an effort to clarify procedures related to reporting requirements, the OHRP recently provided new guidances or updated versions of existing guidances on the following topics:

- applicability of incident reporting requirements;
- information to be included in incident reports;
- time frames for reporting incidents;
- OHRP focus on corrective actions when reviewing incident reports;
- OHRP's response to incidence reports; and
- additional guidance related to problems associated with the conduct of clinical trials.

The correct and timely filing of reports related to problems experienced by human subjects participating in a clinical trial is especially important to minimize any possible harm to other subjects participating in similar trials, when similar risks might be expected, even if they have yet to be encountered.

From an institutional perspective, the lack of reporting of unanticipated problems or serious or continuing noncompliance with the HHS regulations at 45 C.F.R. Part 46 may result in the suspension or termination of the clinical trial itself or the suspension or termination for a particular institution (and its researchers) in a specific clinical trial, resulting in the loss of funding for the program. All of these consequences have enormous implications for an individual subject participating in a clinical trial or the research institution. In addition, noncompliance of reporting requirements may subject the institution or a particular researcher to fraud-related charges. This article summarizes the primary reporting requirements for unanticipated problems, serious or continuing noncompliance, and suspension or termination of IRB approval.

Background

HHS regulations at 45 C.F.R. §§46.103(a) and (b)(5) require that institutions have written procedures to ensure that the following incidents related to research conducted under an OHRP-approved assurance are promptly reported to OHRP:

(a) any unanticipated problems involving risks to human subjects or others;
(b) any serious or continuing noncompliance with the policy or the requirements or determinations of the institutions' IRB; and
(c) any suspension or termination of IRB approval.

Applicability

In general, these reporting requirements apply to all nonexempt human subjects research that is conducted or supported by HHS; conducted or supported by a non-HHS federal department or agency that has adopted the Common Rule and is covered by a Federalwide Assurance (FWA) determined to be appropriate for such research; or covered by a FWA, regardless of the funding source.

Federal departments or agencies other than HHS that have adopted the Common Rule may determine that the FWA is not appropriate for certain research that they conduct or support. OHRP has noted that these incident reporting requirements are not applicable to such research. In these cases, however, the

institution should contact the non-HHS department or agency that supports the research about reporting requirements.

Reporting requirements for unanticipated problems involving risks to subjects or others

On January 15, 2007, the OHRP released the "Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events."[1] This Guidance is intended to ensure that the review and reporting of unanticipated problems and adverse events occur in a timely, meaningful way so that human subjects can be protected from avoidable harms, while at the same time reducing the unnecessary regulatory burdens that typically fall on investigators and their IRBs.

Although not specifically defined in the HHS regulations, the term *unanticipated problem(s)*, in general is considered to include any incident, experience, or outcome that meets all of the following three criteria:

(1) unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

(2) *related or possibly related* to participation in the research (where the term *possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

(3) suggestions that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.[2]

It is important to note that HHS also does not define or use the term adverse event, nor is there a common definition of this term among government and professional entities. In an effort to harmonize the FDA's definition with OHRP's terminology, the 2007 Guidance uses the term adverse event very broadly and includes any event that meets the following definition:

> Any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (*e.g.*, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.[3]

Adverse events encompass both physical and psychological harms. They occur most commonly within the context of biomedical research although, on occasion, they can occur within the context of social and behavioral research.

For unanticipated problems involving risks to human subjects and others, OHRP requires the following information to be included in incident reports:

- name of institution (*e.g.*, university, hospital, foundation, school, etc.) conducting the research;
- title of the research project and/or grant proposal in which the problems occurred;
- name of the principal investigator on the protocol;
- number of the research project assigned by the IRB and the number of any applicable federal awards(s) (*e.g.*, grant, contract, or cooperative agreement);
- a detailed description of the problem; and
- corrective actions the institution is taking or plans to take to address the problem (*e.g.*, revise the protocol, suspend subject enrollment, terminate the research, revise the informed consent document, inform enrolled subjects, increase the frequency and/or type of monitoring of subjects, etc.).

Reporting requirements for serious or continuing noncompliance

Both the Common Rule and FDA regulations require that IRBs have written procedures for principal investigators to report promptly to the IRB, appropriate institutional officials, OHRP and the FDA any serious or continuing noncompliance with the regulations or the requirements or determinations of the IRB.[4] It is not uncommon that the time frame for "prompt" reporting of any serious or continuing noncompliance is different than the reporting time frame for "unanticipated problems" and is often related to the seriousness or the risks associated with the noncompliance. For example, when the subject matter of the suspected noncompliance is more clinical in nature, the time frame for reporting is usually quite short, whereas the time frame for reporting administrative issues typically is longer.

Actions (or inactions) related to noncompliance, generally, are more likely to occur with principal investigators. Examples may include such actions as not obtaining informed consent from the human subject, modifying the informed consent document or not using an approved version, modifying the protocol without obtaining IRB approval for the modifications, and continuing to conduct research after the IRB approval expires.

IRBs also may be guilty of noncompliance. Some common examples of IRB noncompliance include inappropriate use of expedited review procedures; lack of an IRB committee quorum, and the existence of conflict of interest issues related to the institution, researchers, or IRB members.

There is no definition for what is considered "serious noncompliance" in either the OHRP or FDA regulatory schemes. IRBs have the discretion to define the terminology and devise a process for determining when it occurs. If serious, however, noncompliance occurs within the context of the IRB's definition and, then, it is reportable.

If noncompliance is determined to be "continuing," then it also is considered to be reportable. As with the above issue of "serious noncompliance," there is no regulatory definition of "continuing noncompliance" within this context. Continuing noncompliance may arise with a research

investigator's activities (or his or her inactions) or it may occur by the IRB. Repeated instances of failure to meet the requirements of federal regulators (or the institution's IRB policies and procedures) are generally considered to be the working definition of "continuing noncompliance."

For serious or continuing noncompliance, the following information must be included in the incident report to OHRP:

- name of the institution conducting the research;
- title of the research project or grant proposal in which the noncompliance occurred;
- name of the principal investigator on the protocol;
- number of the research project assigned by the IRB and the number of any applicable federal awards;
- a detailed description of the noncompliance; and
- corrective actions the institution is taking or plans to take to address the noncompliance (*e.g.*, educate the investigator, educate all research staff, suspend the protocol, suspend the investigator, conduct random audits of the investigator or all investigators, etc.).

Reporting requirements for suspension or termination of IRB approval

Simply, "prompt reporting" to the institution, HHS, and OHRP or the FDA is required when any suspension or termination of IRB approval is made. Suspension or termination of IRB approval commonly arises when a significant adverse event occurs that is likely to be deemed as an unanticipated problem. Again, while there is no definition of "prompt," the appropriate time frame for satisfying the requirement of "prompt" reporting will vary, depending on the specific nature of the problem and the entity to which reports are to be submitted. For example, an unanticipated problem that results in a subject's death or life-threatening situation will require a shorter time frame for reporting than events that are not considered life-threatening. OHRP recommends the following guidelines for prompt reporting:

(1) Unanticipated problems that are serious adverse events should be reported to the IRB within one week of the investigator becoming aware of the event.

(2) Any other unanticipated problem should be reported to the IRB within two weeks of the investigator becoming aware of the problem.

(3) All unanticipated problems should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and OHRP within one month of the IRB's receipt of the investigator's report of the problem.[5]

In some cases, the requirements for prompt reporting may be met by submitting a preliminary report to the IRB, appropriate institutional officials, the supporting HHS agency head (or designee) and OHRP, with a follow-up report submitted at a later date when more information is available. The primary consideration in making these judgments is the need to take timely action to prevent avoidable harms to other human subjects participating in similar clinical trials. For suspension or termination, the following information must be conveyed to OHRP:

- name of institution conducting the research;
- title of the research project and/or grant proposal in which the noncompliance occurred;
- name of the principal investigator on the protocol;
- number of the research project assigned by the IRB and the number of any applicable federal awards;
- a detailed description of the noncompliance; and
- corrective actions the institution is taking or plans to take to address the noncompliance (*e.g.*, educate the investigator, educate all research staff, suspend the protocol, suspend the investigator, conduct random audits of the investigator or all investigators, etc.).

Summary

The newly published "Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects and Others and Adverse Events" represents a milestone in clarifying the confusion among researchers, their IRBs, and their institutions for reporting incidents that may have life-threatening or serious implications for human subjects participating in clinical trials. The Guidance provides researchers with clear examples of determining what type of event has occurred, what the review and reporting requirements are, and how OHRP expects similar incidents to be handled. Moreover, the accurate and timely reporting of incidents, when made to the appropriate review board or agency, creates an important database for use in determining the safety and efficacy of a trial while it is ongoing. Another goal of the Guidance is to reduce the amount of reports an IRB must manage. It remains to be seen if the Guidance is able to help IRBs cope with the ever-expanding number of reports they must manage, but the Guidance is a good beginning.■

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1 OHRP, *Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events*, Jan. 15, 2007 (*hereinafter* Guidance), *available at* http://www.hhs.gov/ohrp/policy/AdvEvntGuid.htm (last visited June 13, 2007).

2 Guidance at 4.

3 Note that this definition is modified from the one outlined in the 1996 International Conference on Harmonization E-6 Guidelines for Good Clinical Practice.

4 45 C.F.R. §46.103(b)(5); 21 C.F.R. §56.108(b).

5 Guidance at 14.

6 A more complete discussion on reporting time frames and reporting mechanisms is included in the Guidance.

OIG approves drug subsidy, donation, rejects CHF assessment proposal

by Matthew E. Mann, J.D., Contributing Editor

In recent advisory opinions, the Office of Inspector General (OIG) determined that an organization's proposed subsidy of beneficiary expenses associated with prescription drugs and a foundation's proposed donation of money to a retirement facility would pose minimal risk of abuse to the federal health care programs. The OIG determined, however, that a proposed arrangement to provide free congestive heart failure (CHF) assessments to Medicare and Medicaid beneficiaries could generate prohibited remuneration in violation of the anti-kickback statute. The OIG explained its position on each of these proposals in three advisory opinions issued on July 23, 2007.

Prescription drug subsidy. A tax-exempt charitable organization's proposed arrangement to subsidize cost-sharing and premium obligations owed by financially needy beneficiaries with certain chronic diseases would not constitute grounds for civil monetary penalties and, while the arrangement could potentially generate prohibited remuneration, the OIG would not impose administrative sanctions under §1128(b)(7) or §1128A(a)(7) of the Social Security Act. Under the arrangement, the organization would operate a series of individual charitable funds for patients with certain serious diseases and would provide financial assistance for out of pocket expenses associated with outpatient prescription drug treatment.

The organization was developed and established by employees of a health care consulting company with commercial clients that include pharmaceutical manufacturers whose products are used or might be used by patients under the agreement. The design and administration of the arrangement make it unlikely that donor contributions would influence any patient's selection of a particular provider, practitioner, supplier, or product. No donor would exert direct or indirect control over the organization or its programs, assistance would be awarded in a truly independent manner without regard for donor interests and would be based on a uniform measure of financial need, and no data would get back to donors that would allow them to correlate the amount or frequency of donations to the use of products or services.

In addition, the organization's proposed subsidy of insurance premiums and cost-sharing obligations is not likely to improperly influence any beneficiary's selection of a particular provider, practitioner, supplier or product. It would assist all eligible applicants, all of whom are under the care of a physician with a treatment regimen in place. Once covered by Medicare or Medicaid, a patient would be able to select any provider, practitioner, or supplier regardless of whether the provider, practitioner, or supplier has made contributions to the organization's support programs.

OIG Advisory Opinion No. 07-06, July 23, 2007, Health Care Compliance Reporter ¶500,162.

Charitable donation. A proposed donation of money to a retirement community by a foundation that was formed and initially funded by a health system that could potentially provide items and services to the retirement community is unlikely to result in fraud or abuse under the anti-kickback statute. Although the arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals were present, the OIG would not impose administrative sanctions under §1128(b)(7) or §1128A(a)(7) of the Social Security Act.

The donation is unlikely to result in fraud or abuse under the anti-kickback statute because (1) it was unrestricted as to the use of the funds and neither the foundation nor the health system would exert any influence over the retirement community's use of the funds; (2) the donation constituted a one-time fixed payment and the foundation certified that neither the amount nor the offer was determined in a manner that took into account the volume or value of any referrals to the health system; and (3) the retirement community has implemented and will maintain safeguards designed to prevent improper influence by the health system.

OIG Advisory Opinion No. 07-07, July 23, 2007, Health Care Compliance Reporter ¶500,163.

CHF assessments. A durable medical equipment (DME) supplier's proposed arrangement to provide free in-home CHF assessments to Medicare and Medicaid program beneficiaries could constitute grounds for the imposition of civil monetary penalties, generate prohibited remuneration under the anti-kickback statute, and invite administrative sanctions. Pursuant to the proposed arrangement, the DME supplier would provide patients diagnosed with CHF an assessment with oximetry testing, free of charge.

The Medicare and Medicaid programs cover oximetry tests at an estimated value of $22. The value of the assessment is more than nominal and the supplier proposed to deliver the testing in a manner that would lead a reasonable beneficiary to believe that he or she is receiving a valuable service. Further, the remuneration provided would be likely to influence beneficiaries to select the supplier for Medicare goods and services because typically a beneficiary's physician will have recommended the supplier for the CHF assessment, leading the beneficiary to assume that the physician also was recommending the supplier's goods.■

OIG Advisory Opinion No. 07-08, July 23, 2007, Health Care Compliance Reporter ¶500,164.

Quality of Care

New bill sharpens focus on quality of care

by Valerie L. Witmer, J.D., Contributing Editor

The Continuing the Advancement of Quality Improvement Act of 2007 (CAQI) will overhaul the Quality Improvement Organization (QIO) program and refocus the program's efforts on ensuring that Medicare beneficiaries receive quality care, according to Sens. Charles E. Grassley (R-Iowa) and Max Baucus (D-Mont.), who introduced the legislation on August 2, 2007.

According to Grassley and Baucus, the reform initiatives are based on several reports, including the findings and recommendations of a study conducted by the Institute of Medicine of the National Academy of Sciences, which was mandated by the Medicare Prescription Drug, Improvement and Modernization Act of 2003. The reforms include:

- focusing the role of QIOs to be technical assistants for quality improvement and performance measurement;
- improving the beneficiary complaint review process;
- prioritizing QIO technical assistance to providers in rural or underserved areas, in financial need, having low performance measures, or having a significant number of beneficiary complaints;
- promoting competition by allowing other types of organizations to serve as QIOs and eliminate noncompetitive renewals;
- enhancing board governance requirements and requiring CMS to establish mechanisms to address conflicts of interest; and
- requiring the HHS Secretary to perform interim and final evaluations of effectiveness at the individual QIO and program levels.

Baucus said the bill "puts QIOs in a better position to add value to the health care system [and] illustrates our commitment to improving quality and moving the health care system forward." Grassley added, "Improving the quality of health care services is an important job, and it needs to be done right."■

U.S. Sen. Chuck Grassley News Release, Aug. 2, 2007 .

In the News

Troy sworn in as HHS Deputy Secretary

Tevi Troy was sworn in on August 6, 2007, as HHS' 23rd Deputy Secretary. Troy "brings solid policy experience and expertise to this position, as well as a strong commitment to improving the health of our nation,"according to a statement by HHS Secretary Michael Leavitt. Troy had been the deputy assistant to the President for domestic policy. In that capacity, Troy made significant contributions on such issues as health information technology, public health and childhood obesity, food and drug safety, welfare, and family and community services. Senate Finance Committee Chairman Max Baucus (D-Mont.) said in a July 25, 2007, statement following Troy's nomination for the position that he expects Troy "to be impartial and put politics aside."

HHS News Release, Aug. 7, 2007; CCH Washington Bureau, July 25, 2007.

OIG approves Nevada, New York FCAs

Senator Charles E. Grassley (R-Iowa), ranking member of the Committee on Finance, expressed his pleasure on Thursday that New York and Nevada's state False Claims Acts received the Office of Inspector General (OIG) approval and encouraged other states to do the same. "By passing state laws that are similar to the federal False Claims Act, these states are now qualified for a greater share of any Medicaid dollars recovered in their states. I'm glad to see the efforts of New York and Nevada and encourage other states to take advantage of this provision and join the nine other states that now have qualified state False Claims Acts."Grassley authored two key provisions in the Deficit Reduction Act of 2005 (PubLNo 109-171) that enhanced the ability of states and the federal government to collect Medicaid dollars lost to fraud by making states with OIG approved false claims acts eligible to receive a 10 percent increased share in amounts recovered through action under their state false claims acts.

U.S. Senate Finance Committee News Release, Aug. 9, 2007.

Weems considered for key CMS role

The Senate Finance Committee on July 25, 2007, considered the nomination of Kerry Weems, a 24-year veteran of HHS, to serve as Administrator of CMS. As the head of CMS, Weems "would be responsible to more than 85 million beneficiaries who rely on the agency for their health care," Committee Chairman Max Baucus (D-Mont.) said. He added, "I am counting on Mr. Weems to be fair and even-handed. I do not believe that CMS has been putting beneficiaries' needs first recently. And that has to change." Weems said he is aware that the Committee is frustrated with a lack of access to information from CMS on issues such as Medicare Part D premiums withheld. "You will have the same information that I do," he vowed. Weems would replace Mark McClellan, who left the agency in October of 2006. Acting Administrator Leslie Norwalk has been serving in the role ever since.

CCH Washington Bureau, July 25, 2007.