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DMEPOS accreditation, competitive bidding rules finalized

by Gené Stephens, J.D., Contributing Editor

The new regulations governing Medicare durable medical equipment, prosthetics, and supplies (DMEPOS) competitive bidding program and accreditation procedures and requirements will improve DMEPOS items and services for Medicare beneficiaries, according to CMS. The regulations have been included with the inpatient rehabilitation facility prospective payment system *Final rule*, which is scheduled to be published in the *Federal Register* on August 18, 2006. The *Final rule* implements the DMEPOS provisions of the Medicare Modernization Act of 2003 (MMA) (PubLNo 108-173).

Competitive bidding program. The purpose of the competitive bidding program is to utilize marketplace dynamics that will yield incentives for suppliers to provide quality items and services in an efficient manner and at a reasonable cost. The MMA requires competition under the bidding program to be phased in beginning in 2007 in ten of the largest Metropolitan Statistical Areas (MSAs). Of the remaining MSAs, 80 MSAs will be phased in during 2009 and all other areas will be phased in after 2009. It is expected that savings to taxpayers will exceed over $1 billion annually within five years of the program's implementation.

Suppliers desiring to participate in the competitive bidding program will be required to submit bids for selected DMEPOS items. The bids will be used by CMS to establish Medicare payment amounts for the selected bid items.

Suppliers of DMEPOS under Medicare Part B who submit bids in the first phase of the competitive bidding process will need to be accredited in early 2007; those in the second phase of bidding will need to be accredited by the winter of 2007.

To assist with the implementation of the competitive bidding program, CMS also will contract with Competitive Bidding Implementation Contractors (CBICs). The CBICs will prepare DMEPOS supplier requests for bids, perform bid evaluations, select qualified suppliers, set single payment amounts for all competitive bidding areas, and monitor the program for effectiveness, access, and quality. The CBICs also will oversee an education program for beneficiaries, suppliers, and referral agents concerning the new competitive bidding process.

Quality standards. In response to the MMA's requirements regarding the establishment and implementation of quality standards, CMS will publish quality standards through program instructions. Draft instructions were published on the CMS Web site at www.cms.hhs.gov/CompetitiveAcqfor DMEPOS/ on September 25, 2005. CMS has considered the public comments on the draft and will provide final quality standards that will be available at the Web site. The quality standards will become a part of the accreditation process when posted.

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Accreditation organizations. According to the advance document, quality standards will be applied by recognized independent accreditation organizations. CMS has included in the regulations the application and reapplication procedures for CMS-approved accreditation organizations. In addition to the application procedures, CMS has codified ongoing responsibilities of accreditation organizations, including providing CMS with information about surveys and accreditation decisions, complaints regarding a supplier, denial of accreditation, and any changes in processes. The advance document indicates that accreditation organizations must provide a detailed description of their dispute resolution process and have a policy and procedure in place to allow suppliers to dispute a negative accreditation survey or survey findings. The regulations also establish specific criteria and procedures for continuing oversight of accreditation organizations, including a validation survey, and withdrawing deeming authority from an approved accreditation organization.

CMS also plans to:

(1) select several accreditation organizations to induce competition and assist in decreasing accreditation costs;

(2) ask accreditation organizations to include a plan that outlines their methodology to reduce accreditation fees for small or speciality suppliers and suppliers that have multiple locations;

(3) encourage accreditation organizations not to expand on streamlined quality standards;

(4) clarify the role of the accreditation organizations; and

(5) utilize an unannounced survey process to reduce costs and survey preparation time.

CMS expects to approve several accreditation organizations before the bidding dates.

Accreditation of suppliers. Under the regulations as provided in the advance document, all suppliers of DMEPOS and other items must be accredited by a CMS-approved accreditation organization. CMS is phasing-in the requirement for suppliers to become accredited consistent with the statutory phase-in of the competitive bidding program and will provide guidance as to the date by which all suppliers will need to be accredited at a future time.

Suppliers must comply with quality standards and accreditation requirements to receive or retain a provider or supplier billing number for Medicare reimbursement of claims. In addition, all DMEPOS supplier locations must meet quality standards and be separately accredited to bill Medicare. An accredited supplier can be denied enrollment or enrollment can be revoked if CMS determines that the supplier is not in compliance with the DMEPOS quality standards.

The accreditation must indicate the specific products and services for which the supplier is accredited for the supplier to receive payment for those specific products and services. If a supplier adds a new product line after enrollment, the supplier must notify the accrediting body of the new product or service so that the supplier can be re-surveyed and accredited for these new products or services. Also, DMEPOS suppliers must notify their accreditation organization when a new DMEPOS location is opened.

CMS hopes to minimize the burden and duplication of efforts for suppliers that have been accredited, Medicare-certified, or licensed under state law by taking into consideration any previous findings that indicate that quality standards are being met at the time the accreditation organization surveys the supplier.

Education and outreach campaign. An extensive education campaign will be conducted to ensure that Medicare beneficiaries receive timely, reliable, and understandable information about the competitive bidding program. CMS will use such resources as its 1-800 hotline and web site to promote information and educate consumers about the DMEPOS competitive process. In addition, suppliers will receive extensive education, including opportunities to attend special bidders conferences to ensure that they are fully aware of the aspects of the program.

CMS believes that the new bidding process requirements will promote improved quality of DMEPOS items and services and reduce unnecessary costs in providing such medical equipment to program beneficiaries.

The proposed rule on the DMEPOS competitive bidding program and accreditation procedures and requirements was published in the May 1, 2006, *Federal Register* (see *Health Care Compliance Reporter* ¶730,008). ■

CCH Chicago Bureau, Aug. 9, 2006.

CCH Health Care Compliance Letter

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Similarities found in nonprofit hospitals executive pay practices

by Anuradha Gupta, J.D., Contributing Editor

Although a Government Accountability Office (GAO) survey identified similarities in certain nonprofit hospital systems governance and compensation policies and practices, the GAO drew no conclusions as to whether hospital systems are complying with applicable laws and regulations or if their individual policies and procedures are adequate. Senator Charles Grassley (R-Iowa), Chairman of the Committee on Finance, was instrumental in initiating the GAO study, which highlights current executive compensation practices among nonprofit hospital systems throughout the country.

Study components. The GAO was asked to review executive compensation issues at selected private, nonprofit hospital systems to gain an understanding of the policies and practices related to the salaries, benefits, travel, gifts, and entertainment expenses paid by these hospital systems. Using the American Hospital Association's AHA Guide (2005), the GAO identified 172 hospital systems as private, nonprofit systems out of the top 200 private hospital systems identified from the guide and selected 100 hospital systems to participate in the study. An electronic survey was used to ask primarily closed-ended questions and hospital systems were given the opportunity at the end of the survey to provide comments. Responses were received from 65 of the 100 hospital systems.

Corporate governance. Over two-thirds of the hospital systems reported having written criteria for selecting members of the committee that governs executive compensation, and half of those hospitals reported that the criteria address the knowledge, skills or experience of members. Additionally, all of the hospital systems have conflict of interest policies in place that cover members of the executive compensation committee and require disclosure of potential conflicts.

Basis for compensation. All of the hospitals systems reported the ability to use outside consultants to advise on compensation matters and benefit issues and nearly all of the hospital systems have utilized these outside consultants since January 1, 2004. Prior to determining compensation packages for chief executive officers (and the next four highest paid executives), most hospitals relied upon comparable market data of total compensation and benefits as a basis for determining compensation.

In addition, most hospital systems have an executive compensation committee that is responsible for approving the executives' base salary, bonuses, and perquisites (other nonsalary benefits). Most hospital systems also provide supplemental executive retirement plans (deferred compensation plans) to the top five executives. A majority of hospital systems reported that since January 1, 2004, a top executive has left the system and half of the systems made a severance payment when the executive was involuntarily terminated.

Perquisites. Hospital systems commonly reported that they pay for executive expenses related to transportation; membership in recreational or social clubs; entertainment, which may include sporting events, theatre productions, company parties, and off-site activities; and travel. About half of the systems conducted an internal audit of automobile-related expenses and costs of membership in recreational or social clubs. Almost all hospital systems provide payment for entertainment expenses and have conducted an internal audit of entertainment expenses since January 1, 2004.

Written policies covering travel expenses for executives are in place at a majority of hospital systems, although they vary significantly among hospital systems. Other perquisites that may be provided to executives include: financial or tax planning, tax preparation, attorney fees, and personal travel expenses for spouses. Additional travel or recreation expenses for spouses and family members generally were not provided as perquisites for executives.

Congressional thoughts. The adequacy of oversight, reporting requirements, and overall governance of nonprofit and tax-exempt organizations has been subject to harsh criticism by Congress in recent years. Commenting on the survey's results, Senator Grassley, emphasized that there is much room for improvement and stated that "It's clear much more needs to be done to ensure that nonprofit hospital executives are not being paid extravagant amounts and are being held accountable for what they're paid." ■

GAO Report, GAO-06-907R., June 30, 2006; Senate Finance Committee News Release, July 28, 2006.

When and Why: Choosing Self-Disclosure in 2006

by Stacey Fahrner J.D., M.P.H., Contributing Editor

During his address at the American Bar Association's physician legal issues conference in Chicago Illinois, Lewis Morris, Chief Counsel to the Office of Inspector General (OIG), discussed the OIG's ongoing efforts to combat fraud and abuse in the federal health care programs. In particular, he stressed the importance of working with the OIG through the Provider Self Disclosure Protocol (SDP) when fraudulent activities occur in the organization. Since its debut in the 1995 pilot program, the OIG has worked to make the SDP an attractive alternative. This article will review the history and progression of the SDP, as well as outline the steps an organization must take in making a self disclosure based on guidance from CCH's Corporate Governance Manual.[1]

Before the adoption of the Self Disclosure Protocol (SDP), the Office of Inspector General (OIG) worked for years on an informal basis with providers and suppliers that came forward to cooperate with the OIG to resolve billing, marketing, and quality issues within their respective organizations. In 1995, the Department of Justice (DoJ) and OIG announced a voluntary disclosure pilot program, called "Operation Restore Trust" initiative, which gave qualifying entities a formal mechanism for disclosing and seeking the resolution of matters relating to the Medicare and Medicaid programs.

Pilot program. The pilot program was initially limited to five states (New York, Florida, Illinois, Texas, and California) and four types of providers (home health agencies, skilled nursing facilities, durable medical equipment suppliers, and hospice providers). To be eligible under the pilot program, a participant had to disclose a matter that was not under investigation by or known to a federal or state law enforcement authority, and the participant was required to sign an agreement to fully cooperate with authorities. Although participation in the pilot program was limited, the experience provided OIG with insight as to what influenced the decision to make a disclosure to the government.

Issuance of the SDP. In 1998, OIG published in the *Federal Register* the SDP, which included some, but not all, of the elements in the pilot program.[2] For example, under the SDP there are no pre-disclosure requirements, applications for admission, or preliminary qualifying characteristics. The SDP is open to all providers, including both individuals and entities, and is not limited to any particular industry, medical specialty, or type of service. A written agreement setting out the terms of the self-assessment is no longer required. Finally, a provider who is the subject of a government inquiry, including investigations, audits, or routine oversight activities, is not automatically precluded from participating in the SDP.

Open Letters. Initially, the SDP was directed at resolving a provider's permissive exclusion liability resulting from the submission of false claims in violation of the False Claims Act (FCA). In 2001, in keeping with its commitment to promoting "an environment of openness and cooperation" among providers, the OIG issued an Open Letter in which it discussed concern regarding the financial impact of corporate integrity agreements (CIAs) on providers. In particular, the OIG announced that it would modify billing reviews and the use of independent review organizations to reduce their financial impact.[3]

In 2006, the OIG further expanded the SDP to include an initiative promoting the use of the SDP to resolve civil money penalty (CMP) liability under the physician self-referral and anti-kickback statutes for financial arrangements between hospitals and physicians.[4] Under the current SDP, the OIG will waive it exclusion authority concurrent with the resolution of monetary liability under the FCA and CMP laws when providers demonstrate the requisite level of trustworthiness and have in place, or are willing to develop, an effective compliance program.

When to Follow the Protocol

While the decision to make a voluntary disclosure rests ultimately with the provider, the OIG offered some guidance on what the provider should consider before making a disclosure. First, a provider that uncovers an ongoing fraud scheme within its organization should contact the OIG, but should not follow the SDP's suggested steps to investigate or quantify the scope of the problem.

If the provider follows the SDP in this type of situation without prior consultation with the OIG, there is a substantial risk that the government's subsequent investigation will be compromised. Second, the OIG anticipates that a provider

will apply the SDP's suggested steps only after an initial assessment substantiates there is a problem with noncompliance with program requirements. The initial identification of potential risk areas should be less intensive and need not conform to the SDP's suggested procedures.

Other considerations. The OIG recognizes that it may require access to certain documents that are covered by the attorney work product doctrine. In that respect, the OIG has stated that it is prepared to work with the provider's counsel on ways to gain access to that information without the need to waive any privileges. The organization, however, should take steps to appropriately segregate privileged communications and protected work product from information that it intends to share with the OIG.[5]

Finally, the OIG warns in the 1998 notice that it is not bound by any findings made by the disclosing provider under the SDP and is not obligated to resolve the matter in any particular manner. Upon review of the provider's disclosure, the OIG could conclude that the disclosed matter warrants a referral to DoJ for consideration under its civil and criminal authorities. The provider also may request the participation of a representative of DoJ or a local U.S. Attorney's Office in settlement discussions to resolve potential liability under the FCA or other laws. In his address to the ABA, Morris suggested that full cooperation in good faith with the OIG should only aid the provider in resolving any issues with the DoJ.

The disclosure report should simply and factually convey an honest accounting of the matter and include the information outlined in the SDP.

The Protocol

The SDP was designed to expedite the OIG's verification process and diminish the time resolution of matters under investigation. The SDP provides "guidance" to providers on voluntary disclosure and, therefore, does not contain rigid requirements or limitations.

Initial communication with the OIG. Once it is determined that a disclosure should be made, the provider should write an introductory letter to notify the OIG of the provider's intention to voluntarily disclose and request OIG forbearance while the provider complies with the SDP. The letter should identify the disclosing entities and provide a general description of the noncompliant circumstances.

Internal investigation and self assessment. The disclosing provider will be expected to conduct an internal investigation and a self-assessment of the financial impact of the fraudulent activities and report the findings to the OIG. The internal review may be conducted after the initial disclosure, and the OIG will generally agree to forego an investigation for a reasonable time if the provider agrees to conduct the internal investigation in accordance with the OIG guidelines set out in the SDP.[6]

Self-assessment work plan. The provider also will need to submit to the OIG a work plan describing the self-assessment process. Because the OIG will verify the provider's calculation of program losses, it is strongly recommended that the provider conform to the guidelines in the SDP. The OIG is not obligated to accept the results of the provider's self-assessment. Consequently, findings based on the procedures outlined in the SDP will be given substantial weight in determining the amount of overpayments to the provider.

Disclosure report. To the extent possible, the disclosure report should simply and factually convey an honest accounting of the matter and include the information outlined in the SDP. The report also should succinctly address the nature and scope of the noncompliance and why the organization believes there is a potential violation.

While failure to conform to each element of the SDP is not fatal to the disclosure, the OIG stresses that it will likely delay the resolution of the matter. OIG guidance states that the report should demonstrate that a full examination has been conducted and suggests that the report:

- identify the potential causes of the incident;
- describe the incident or practice in detail, including how the incident or practice arose and continued;
- identify the division, departments, branches or related entities involved or affected;
- identify the impact on, and risks to, health, safety, or quality of care posed by the matter disclosed with sufficient information to allow the OIG to assess the immediacy of the impact and risks, the steps that should be taken to address them, as well as the measures taken by the disclosing entity;
- delineate the period during which the incident or practice occurred;
- identify the corporate officials, employees or agents who knew of, encouraged, or participated in, the incident or practice and any individuals who may have been involved in detecting the matter;
- the corporate officials, employees or agents who should have known of, but failed to detect, the incident or practice based on their job responsibilities; and
- estimate the monetary impact of the incident or practice upon the federal health care programs, pursuant to the Self-Assessment Guidelines.

The report should relate the circumstances under which the matter was discovered. Measures taken to address the problem and prevent future problems should be fully documented as well. OIG guidance suggests that the report include:

- a list of all individuals interviewed in connection with the matter;
- a description of files, documents and records reviewed; and
- a summary of auditing activities and a summary of documents relied upon in support of the estimation of losses.

In addition, the report must include a "Certification of Truthfulness" signed by a person who is responsible for handling the matter. The report should be sent to the OIG's Assistant Inspector General for Investigative Operations, with courtesy copies to any Office of Counsel to the Inspector General (OIG-OCIG) Attorneys or OIG Special Agents, or other government representatives who have been assigned to the case.

Verification. After the disclosure report is submitted an OIG Special Agent and an attorney from the Office of Counsel to the Inspector General (OCIG) will be assigned to verify the information. There may be other participants depending on the nature and scope of the matter. The OIG agent is responsible for interviewing witnesses, reviewing documents, validating the voluntary disclosure report, and doing general investigative work. It is incumbent on the provider to set the tone of this relationship by cooperating as fully as reasonably possible, being forthcoming at all times, and offering necessary and relevant information.[7]

Upon completion of the initial investigation, the OIG agent provides feedback to the OIG-OCIG attorney. The OIG-OCIG attorney reviews and weighs the OIG agent's recommendations and then decides on an appropriate course of action. The final stage of this process usually involves a discussion with the provider to negotiate the next steps or a resolution.[8]

Benefits of Disclosure

Because the provider's disclosure could involve anything from simple error to fraud, the OIG cannot make firm commitments as to how a matter will be resolved or what benefits will be achieved from the disclosure. In general, self-disclosure leads to a less restrictive three-year certification of compliance agreement rather than a corporate integrity agreement (CIA), which last five years and requires an independent review organization to conduct and verify audits or claim reviews. According to Daniel Levinson, HHS Inspector General, who spoke on April 24, 2006, at the opening session of the Health Care Compliance Association's 10th Annual Conference in Las Vegas, provider liability falls along a continuum. When an organization follows the SDP, the multiplier is at the lower level of the continuum. The hope is to settle at the lower level of the continuum, Levinson said.

Corporate integrity agreements. The November 20, 2001, Open Letter continues to guide the OIG in determining whether to require a CIA and the terms of those agreements. First and foremost, the OIG will consider whether the provider self-disclosed the alleged misconduct. In addition, the OIG will consider (1) the monetary damage to federal health care programs; (2) whether the case involves successor liability; (3) whether the provider is still participating in the federal health care programs or in the line of business that gave rise to the fraudulent conduct; (4) whether the alleged conduct is capable of repetition; (5) the age of the conduct; (6) whether the provider has an effective compliance program and would agree to limited compliance or integrity measures and would annually certify such compliance to the OIG; and (7) other circumstances, as appropriate.

Conclusion

During fiscal year 2004, the OIG excluded a total of 3,293 individuals and entities, barring them from participating in Medicare, Medicaid, and other federal and state health care programs. In addition, HHS collected $141.4 million in disallowances of improperly paid health care funds, based on OIG recommendations.[9] Clearly, seeking out and combating waste and abuse of federal health care funds continues to be a top priority of OIG. While prevention of fraud and abuse through an effective compliance program should be the primary approach to addressing these issues, providers need to be familiar with the SDP process should a situation arise in their organization that requires disclosing.

1 *Corporate Governance Guide for Health Care*, by Frank Sheeder, a partner at the law firm of Brown McCarroll, LLP in Dallas, Texas and Albert Lin, an associate at the law firm of Brown McCarroll, LLP in Austin, Texas.

2 *Notice*, 63 FR 58399, Oct. 30, 1998, *Health Care Compliance Reporter*, ¶156,019.

3 See Open Letter to Providers, Nov. 20, 2001, *Health Care Compliance Reporter*, ¶530,090.

4 See Open Letter to Health Care Providers, April 24, 2006, *Health Care Compliance Reporter*, ¶530,391.

5 See *Corporate Governance Guide for Health Care*, Chapter 3.4.

6 See *Notice*, 63 FR 58399, Oct. 30, 1998, *Health Care Compliance Reporter*, ¶156,019.

7 See *Corporate Governance Guide for Health Care*, Chapter 3.4.

8 See *Corporate Governance Guide for Health Care*, Chapter 3.4.

9 Health Care Fraud and Abuse Control Program, Annual Report for FY 2004, Department of Health and Human Services and Department of Justice, September 2005, *Health Care Compliance Reporter*, ¶370,017.

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Specialty hospital plan focuses on payment reform, physician investments

by Gené Stephens, J.D., Contributing Editor

CMS' strategic and implementing plan addresses concerns over physician investment in speciality hospitals and the development of a more accurate payment system for services performed in specialty hospitals; however, Senators Charles Grassley (R–Iowa) and Max Baucus (D–Montana) expressed concern that the plan was based on insufficient information. Section 5006 of the Deficit Reduction Act of 2005 (DRA) (PubLNo 109-171) required CMS to develop a plan for specialty hospitals in response to concerns that specialty hospitals, which may be owned by physicians, solicit more profitable cases, leaving sicker and poorer patients to be treated at community hospitals.

Medicare program officials have been conducting a survey of both specialty and "competing" hospitals as part of their effort to develop the plan. Survey findings included in CMS' final report revealed information concerning the impact of speciality hospitals on quality of care to Medicaid and uninsured patients, as well as information related to physician investments, distributions, loans, patient discharge rates, and the availability of emergency departments at specialty hospitals.

Major elements of the plan. The final report outlines CMS' strategic and implementing plan and includes: (1) an emphasis on the need for major hospital and ambulatory surgery payment reforms; (2) new opportunities for hospitals and physicians to work together to improve patient care; (3) clarification of the requirements for charity care patient emergency services whenever a hospital has the capacity to provide appropriate care; (4) requirements regarding the disclosure of physician investments and compensation arrangements in specialty hospitals; (5) CMS' position on the enforcement of Stark Law and anti-kickback rules for any improper or disproportionate physician investments or arrangements; and (6) details of CMS actions to enforce the 18 month moratorium on payments to certain speciality hospitals furnished to Medicare beneficiaries.

Payment reforms. The Strategic Plan (Plan) provides that CMS will continue working to make the hospital inpatient prospective and ambulatory surgical center payment systems more accurate. In addition, CMS will work with the Medicare Payment Advisory Commission to address physician incentives to form, or invest in, specialty hospitals.

Support opportunities and emergency services. Because of concerns by traditional, full-service hospitals that specialty hospitals promote better coordination between the facility and staff physicians due to the opportunity of physician ownership, CMS will implement demonstration programs to improve hospital-physician collaboration. The demonstration programs include a gainsharing demonstration and the use of other CMS authorities.

In addition to hospital and physician collaboration, the final report clarifies the requirements related to hospital emergency services. Under the new Emergency Medical Treatment and Labor Act (EMTALA) requirements, hospitals must accept transfers of cases when they have the capacity to provide care, regardless of whether the hospital has an emergency department. As a result, specialty hospitals will be forced to take less profitable cases.

Transparency of investments. Under the Plan, hospitals will be required to disclose information concerning physician investments and compensation arrangements. Specifically, hospitals that have not yet responded to the CMS survey on hospital investment will be required to disclose such information. Hospitals that do not respond timely will be subject to large penalties, including a fine of up to $10,000 for each day that the survey response is late. In addition, specialty hospitals will be required to disclose to patients that their staff physicians have an investment interest in the hospital in advance of providing care. Finally, CMS will change the hospital enrollment for the Medicare program to better identify speciality hospitals.

Improper investments. The final report presents CMS's plans to take appropriate action against any disproportional or nonbona fide arrangements that may violate the physician self-referral laws or that are, or that potentially could become, suspect under the anti-kickback statute. In partnership with the Office of Inspector General, CMS will require disclosure of financial arrangements and investment relationships to identify potential violations of the Stark laws and assess which of these relationships requires further investigation.

MMA moratorium. The Plan calls for continued enforcement of the 18 month moratorium on payments to certain speciality hospitals for services furnished to Medicare beneficiaries. CMS identified ten hospitals that may have been subject to a moratorium, as directed under the Medicare Modernization Act of 2003 (MMA) (PubL-No 108-173). In July of this year, letters were sent to the hospitals requiring information concerning the ownership of the hospital and the nature of services performed. Of the ten hospitals to which letters were sent and information received by CMS, it was determined that four hospitals were subject to the MMA moratorium. Additionally, overpayment notices of approximately $12.1 million were sent to the hospitals.

Legislative reaction. Grassley and Baucus noted that the problem with the information CMS gathered is that some of the hospitals selected for the survey to represent hospitals that compete with specialty hospitals are not even located in a state in which specialty hospitals are allowed to operate, while some traditional hospitals that compete directly with specialty hospitals have been left out of the survey all together.

Grassley pushed for additional legislative reforms concerning specialty hospitals to further safeguard and strengthen the nation's hospital system and commented that such additional reforms should include "the repeal of the whole hospital exception for specialty hospitals." Likewise, Baucus commented, "I'm concerned that a survey of just 140 facilities was used to develop policy for the roughly 4000 hospitals reimbursed by Medicare." Both Senators plan to keep a close watch on CMS's implementation plan as they push for added legislation concerning specialty hospitals. ■

CCH Chicago Bureau, Aug. 9, 2006; Final Report to the Congress and Strategic and Implementing Plan, Aug. 8, 2006, Health Care Compliance Reporter, ¶350,011.

Information Tech

Guidance describes EHR certification body requirements

by Stacey Fahrner, J.D., M.P.H., Contributing Editor

An entity that wishes to be recognized as a certification body for electronic health records software to ensure interoperability must meet the requirements that the Office of the National Coordinator for Health Information Technology (ONC) will use to determine whether to recommend that the HHS Secretary recognize a body for certification. The requirements and application procedures are included in an interim guidance issued by ONC following the August 8, 2006, publication of the Office of Inspector General (OIG) and CMS final rules governing the donation of health information technology.

Requirements. According to the guidance, a recognized certification body should, for example:

- have a transparent and well documented process;
- be able to adapt its process to emerging certification criteria;
- be able to accept and respond to public comment on its certification process;
- have a steering committee comprised of a diverse group of industry stakeholders;

The complete list of characteristics can be viewed at www.hhs.gov/healthit.

Application process. To be considered for review and recommendation to the Secretary, a letter must be submitted by a senior officer of the body seeking review either in writing or electronic format. The officer should have the authority to commit the body to fulfilling the obligations of a recognized certification body and make representations about the body's characteristics and operations. In addition, the letter should contain explanations as to how the body meets the characteristics specified in the guidance document.

The interim procedures should be followed until HHS formalizes the procedures in a final rule through notice and comment rulemaking. Comments on the guidance document will be accepted through October 3, 2006. ■

Notice, 71 FR 44296, Aug. 4, 2006, Health Care Compliance Reporter, ¶760,057.

In the News

NAS awarded first MAC contract

CMS has awarded the first of 15 Part A/Part B Medicare Administrative Contractor (A/B MAC) contracts to Noridian Administrative Services, LLC, (NAS), headquartered in Fargo, North Dakota, to handle Medicare Part A and Part B claims for six states. No later than March 2007, NAS will assume full responsibilities for claims processing and paying fee-for-service claims from hospitals and other institutional providers, physicians, and other practitioners in Arizona, Montana, North Dakota, South Dakota, Utah and Wyoming. The contract, which includes a base period and four one-year options, will provide NAS with an opportunity to earn award fees based on its ability to meet or exceed CMS performance requirements. CMS must award first round MAC contracts by 2011 and must put up the contracts for competitive bidding at least every five years.

HHS Office of External Affairs, July 31, 2006.

Emergency medical services shortage examined

The House Ways and Means Health Subcommittee examined the declining supply and increased demand of emergency medical room services (EMS) to develop a plan to address the issue at a July 27, 2006, hearing. An Institute of Medicine (IOM) report indicated that demand for EMS has increased in recent years, capacity has been reduced, patients are often "boarded" until inpatient beds become available, and diversions to other hospitals frequently occur. Gail Warden, president emeritus of Henry Ford Health System, urged Congress to (1) regionalize the system so that neighboring hospitals, EMS, and other agencies work together to provide emergency care to everyone in that region, and (2) make the system accountable to determine the performance of the different components of the system and report that performance to the public. Alan Levine, CEO of North Broward Hospital District, Fort Lauderdale, Florida, supported IOM's recommendations, including national standards with state flexibility, transparency using consistent measures, review of antitrust laws that would allow hospitals to regionalize call coverage, and enhanced use of information technology.

CCH Washington Bureau, July 28, 2006.

GSK settles allegations of inflating drug prices

GlaxoSmithKline (GSK), a leading pharmaceutical manufacturer, will pay over $41 million to resolve allegations that it inflated the price of certain drugs. GSK allegedly made false statements that inflated the average wholesale price (AWP) of anti-emetics and other drugs, causing government health plans and consumers to overpay. Government health plans overpaid because they reimbursed pharmacies and doctors at the inflated price; Medicare beneficiaries overpaid because they paid, as coinsurance, a percentage of the inflated amount. In addition, an inflated AWP allowed GSK to market the drugs to health care providers with the promise that they could keep the spread between the drug's actual price and its inflated rate, creating a financial incentive for doctors to choose GSK's drugs over competitors' products. Under the settlement, which was in conjunction with a Department of Justice and the National Association of Medicaid Fraud Control Units settlement, GSK will pay over $1 million in restitution to New York's Medicaid program, which represents New York's share of an agreement involving over 40 states and $940,000 to Medicaid for claims relating to payments for an antibiotic. Under a separate settlement of a private class action suit in federal court in Boston, GSK will establish a national restitution fund of approximately $40 million.

Office of New York Attorney General Eliot Spitzer News Release, Aug. 10, 2006.