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Proposed rule targets Stark loopholes, quality reporting, e-prescribing fax exemption

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

The Medicare Physician Fee Schedule 2008 proposed rule represents "a further step in Medicare's efforts to ensure that payment policies provide incentives to improve the quality of care," according to CMS, which issued the proposed rule on July 29, 2007. CMS has proposed revision of several policies affecting Medicare Part B payment for physicians and other providers, including: (1) modification of certain physician self-referral provisions; (2) inclusion of new quality measures in the Physician Quality Reporting Initiative (PQRI); and (3) elimination of the computer-generated fax exemption from the e-prescribing standards related to prescriptions under Medicare Part D.

Physician self-referral provisions. The rule proposes a number of physician self-referral provisions that would close loopholes that have made the Medicare program vulnerable to abuse, according to CMS. These provisions include:

- *"Anti-markup provision."* This provision would define "net charge" to prevent physicians from inflating their charges to cover space or equipment costs. It also would expand the anti-markup rules to apply to the professional component of a purchased test, all arrangements not involving a reassignment from a full-time employee of the billing entity, and the technical component of tests performed in a centralized building. Independent labs that have not ordered the technical component would be exempt from these expanded rules.
- *Burden of proof.* This provision would clarify that, in any appeal of the denial of payment on the basis that the service was furnished pursuant to a prohibited referral, the burden is on the entity submitting the claim for payment to establish that the service was not furnished pursuant to a prohibited referral.
- *Obstetrical malpractice insurance subsidies.* This provision would list specific requirements necessary to safeguard against program or patient abuse when a hospital provides remuneration to a physician in the form of an obstetrical malpractice insurance subsidy.
- *Unit-of-service payments in space and equipment leases.* Under this provision, space and equipment leases may not include unit-of-service-based payments to a physician lessor for services rendered by an entity lessee to patients who are referred by the physician to the entity. CMS is soliciting comments on whether it should prohibit time-based or unit-of-service-based payments to an entity lessor by a physician lessee for services rendered to patients sent to the physician by the entity.

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- *Period of disallowance for noncompliant financial relationships.* CMS is soliciting comments on (1) how to set the period of disallowance for arrangements that implicate, but do not satisfy, an exception to the physician self-referral rules; (2) whether it should allow the period of disallowance to terminate when the parties have returned, or paid back the value of, the consideration; and (3) whether to impose a period of disqualification from invoking an exception when an arrangement has failed to satisfy the requirements of that exception.
- *Ownership or investment interest in retirement plans.* Under this provision, ownership and investment interests would not include an interest in a retirement plan offered by an entity to a physician or immediate family member as a result of the physician or family member's employment with the entity.
- *"Set in advance" and percentage-based compensation arrangements.* The proposed rule would clarify that percentage-based compensation arrangements may be used only for paying for personally performed physician services and must be based on the revenues directly resulting from the physician services.
- *"Stand in the shoes."* Under this provision, when a DHS entity owns or controls an entity to which a physician refers Medicare patients, the DHS entity would stand in the shoes of the entity that it owns or controls and would be deemed to have the same compensation arrangements with the same parties and the same terms as does the entity that it owns or controls.
- *Alternative criteria for satisfying certain exceptions.* To address inadvertent and trivial violations of the physician self-referral statute, CMS is considering amending certain exceptions to provide an alternate method for satisfying the exceptions. For example, if a hospital failed to obtain a signature on a personal services agreement with a physician, the parties would be in compliance so long as there was full disclosure, the missing signature was inadvertent, and the other conditions for alternative compliance were satisfied.
- *Services furnished "under arrangements."* The proposed rule would revise the definition of "entity" such that a DHS entity would include both the person or entity that performs the DHS and the person or entity that submits claims or causes claims to be submitted to Medicare for the DHS.

Quality measures. CMS has outlined quality measures from seven categories for inclusion in the 2008 PQRI. The measures would be included so long as they are either endorsed by the National Quality Forum (NQF) or adopted by the AQA Alliance. The proposed rule also would retain the 2007 PQRI measures to the extent that they have been NQF-endorsed. In addition, CMS is proposing to extend voluntary quality reporting bonus payments into 2008.

CMS Acting Administrator Leslie Norwalk stated, "We think the early work on the PQRI program is one of those reforms that could help lead us to a point where we can promote better quality care and more efficient care."

E-prescribing. The proposed rule contains a provision that would eliminate the exemption for computer-generated faxes from the e-prescribing standards applicable to physicians and suppliers in connection with prescriptions under Medicare Part D. The standards included a SCRIPT standard for communications between physicians and pharmacies regarding prescription information.

Entities transmitting prescriptions via computer-generated faxes were exempt from using the SCRIPT standard, but CMS expected that these entities nevertheless would adopt the use of the SCRIPT standard over time. This has not occurred to date. Accordingly, CMS is proposing to eliminate the computer-generated fax exemption to encourage prescribers and dispensers to adopt the SCRIPT standard as quickly as possible. According to CMS, use of the SCRIPT standard will eliminate the administrative cost of keying prescription information into the pharmacy system and minimize data entry errors that may have an adverse impact on patient safety.

Comments on the proposed rule will be accepted until August 31, 2007. A final rule will be published later in the fall and will be effective for claims submitted on or after January 1, 2008. ■

CMS Press Release, July 2, 2007; Proposed rule, 72 FR 38122, July 12, 2007, Health Care Compliance Reporter, ¶730,021.

CCH Health Care Compliance Letter

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HHS fights DME fraud in Florida, California

by Catherine Hubbard, M.A., Contributing Editor

CMS is embarking on a two-year effort to further protect the Medicare program and its beneficiaries from the fraudulent business practices of suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). The initiative, which involves the enrollment of DMEPOS companies in Medicare, "is aimed at ... stopping durable medical equipment fraud before it happens," HHS Secretary Michael Leavitt stated when he announced the implementation of the demonstration project on July 2, 2007.

Implementation. The project is focused on deceptive practices of DMEPOS suppliers in South Florida and Southern California. These areas have been identified as high risk areas for fraudulent billing by DMEPOS suppliers due to the large number of Medicare beneficiaries, growth of DMEPOS providers (the number has nearly doubled over the past two years), and disproportionately high Medicare billing from suppliers in these areas.

Within the last 18 months, CMS and the Office of Inspector General (OIG) have identified and documented a significant amount of fraud committed by DMEPOS suppliers in Southern Florida and the Los Angeles metropolitan area. The types of fraud committed by the companies included: (1) billing for services not rendered (including claims for power wheelchairs, scooters, nutritional products, orthotics, prosthesis, hospital beds, etc.), and (2) billing for services that were not medically necessary.

HHS, in conjunction with the Department of Justice, formed a Medicare Fraud Strike Force comprised of federal, state, and local investigators, to combat fraud through real-time analysis of billing data. Over the course of just three months, 56 individuals have been charged in the Southern District of Florida with fraudulently billing Medicare for more than $258 million.

Additionally, last December, federal officials contracted with the National Supplier Clearinghouse (NSC) to conduct visits to 1,472 DMEPOS suppliers in Southern Florida. Through on-site investigations, 634 supplier billing numbers were revoked, saving Medicare a projected $317 million. A similar initiative was implemented in the Los Angeles area last year. There, investigations of 2,000 DMEPOS suppliers resulted in about 770, or 37 percent of them, losing their billing privileges.

Project requirements. There are three major components of the demonstration project: (1) immediate submission of a Medicare enrollment application; (2) revocation of billing privileges under certain circumstances; and (3) enhanced review of DMEPOS suppliers that have retained their Medicare billing privileges.

CMS will require DMEPOS suppliers in Florida and California to reapply for participation in the Medicare program to maintain their billing privileges. A DMEPOS supplier's Medicare billing privileges will be revoked if the supplier:

- fails to submit an enrollment application with 30 days after the NSC requests it;
- fails to report a change in ownership or address at least 30 days prior to the effective date of the change;
- fails to obtain accreditation from an approved DMEPOS accrediting organization within 90 days of notification from the NSC to do so;
- has an owner or managing employee that has had a felony conviction within the last 10 years; or
- no longer meets all criteria required for enrollment as a DMEPOS supplier.

DMEPOS suppliers whose billing privileges have not been revoked will be subject to an enhanced review by the NSC. The NSC will use a fraud level indicator for each DMEPOS supplier, and in doing so will consider several factors:

- experience as a DMEPOS supplier with other payers;
- prior Medicare experience;
- specific supplier location;
- fraud potential of products and services listed;
- site visit results;
- inventory observed and contracted; and
- the supplier's accreditation.

"The concept is straight forward and will be effective," CMS Acting Administrator Leslie Norwalk predicted. "Enhancing our review of these suppliers will go a long way to ferret out those who do not meet the needs of beneficiaries and the promises of Medicare." CMS will evaluate the effectiveness of the demonstration project and, based on those results, might implement the initiative nationwide. ■

CMS Press Release, July 2, 2007; CMS Fact Sheet, July 2, 2007.

Looking at executive compensation in nonprofit health care organizations from a compliance perspective, Part III

by Albert Y. Lin, Esq., Contributing Editor

To assist the compliance officer in understanding all of the issues impacting executive compensation in nonprofit health care organizations, this article provides a succinct, yet comprehensive, overview of the legal and practical considerations in evaluating the nonprofit health care organization's executive compensation package.

Part I of this three-part article discussed the legal meaning of executive compensation as it relates to health care organizations, which includes the compensation of medical staff physicians, who may not be "executives" in the common sense meaning, but nevertheless constitute a significant portion of payroll. Parts I and II also discussed the legal framework for analysis of executive compensation in the context of nonprofit organizations. Part III concludes the article by offering compliance suggestions for the nonprofit board.

Practical compliance suggestions for the nonprofit board

Clearly, the nonprofit health care organization should have a well-drafted mission statement, conflicts of interest policy,[15] code of ethics, and compensation committee with a written charter. It also should be transparent in its decisions to the extent possible. What follows are other specific suggestions for the compliance officer to elevate compensation compliance practices from good to great.

Monitor legal developments

Regular media and legislative coverage of developments in the nonprofit segment and hospital industry make it easy for the compensation committee and board to be informed. In addition to popular news outlets, the Internal Revenue Service (IRS) and the Independent Sector have useful web sites that publish regular articles on developments within the charitable and nonprofit industries and provide advance notice of upcoming compliance forms and legislation. Proper diligence almost requires compensation committee members to be skeptical academics.

Document facts and circumstances supporting both reasonableness of compensation and community need

The nonprofit organization bears the burden of proof in establishing that executive compensation is reasonable.[16] Consequently, it is necessary to have contemporaneous documentation in establishing decisions.

Reasonable compensation

The IRS does not rule on whether or not compensation is reasonable; all it can do is provide guidelines, and all compliance officers can do is be prepared to document the analysis and show that the factors discussed below were carefully considered.

General factors

Quite simply, the analysis conducted by the compensation committee when evaluating pay should be written up in the form of minutes or internal memoranda. A paramount and repetitive theme is that compensation decisions must be made pursuant to a written conflicts of interest policy. Documenting compliance with the policy (by stating the names of the parties involved, recusals of persons in conflict, etc. in committee minutes) is very important.

Once that preliminary step is accomplished, the nonprofit organization should consider the nature of the duties for the specific position, the candidate's background and experience, and his or her demonstrated knowledge of the business and academic and professional credentials.

The candidate's qualification for the organization's size, involvement in the community, time devoted to the business, and overall economic conditions are other relevant factors. Documentation of the arms-length nature of negotiations can be done by noting in the memorandum or minutes the names of independent counsel representing the hospital and the physician or executive. These steps may seem tiresome at first, but it is far easier to do them concurrently than retroactively during an IRS audit.

Health care-specific factors

IRS authority and recommendations are scattered throughout the IRS' administrative rulings and internal continuing professional education (CPE) materials. The following summarizes some particular, nonexhaustive recommendations for meeting the burden of proof that compensation is reasonable.

1. *There should be a ceiling or reasonable maximum that the physician can earn.* In practice, a dollar amount ceiling might be hard to justify, but a percentage cap might be considered.[17]

2. *There should be no reduction in charitable programs.* An increasing level of compensation, coupled with decreasing charity care statistics, is one item the IRS and the media may pounce upon.
3. *Incentive bonuses should be based in part on measures such as quality of care and patient satisfaction.* Discretionary bonuses should be tied to documented surveys or evaluations substantiating these factors, and preferably capped to a fixed maximum.
4. *If the bonus is net revenue based, expect red flags and be prepared to show that the arrangement accomplishes a charitable purpose (such as keeping expenses within budgeted amounts).* The IRS does not prohibit net revenue-based payments[18] (gross revenue less certain adjustments such as bad debts) outright, but bonuses based on net profits (gross revenue less expenses) are prohibited as private inurement by definition. The IRS has permitted net revenue-based bonus arrangements but has strictly scrutinized the reasonableness and arms-length nature of such arrangements.[19]
5. *The arrangement should not be a substitute for a joint venture.* Physician compensation arrangements should not consist of income diverted from, for example, an imaging center or a pharmacy. Those arrangements need to be structured separately and comply with the separate set of rules and administrative rulings on physician joint ventures with tax-exempt organizations.
6. *The compensation should reward physicians for services performed.* There should be no possibility that the compensation arrangement rewards the physician for activities beyond his or her control.

In addition to the factors identified in the IRS CPE materials, hospitals are expanding health care-specific factors to include other objective forms of performance. By measuring performance in less quantifiable areas, such as safety and patient satisfaction, as well as evaluating compensation based on financial goals, compensation committee discussions will further demonstrate best practices and appease regulators.[20]

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Community need for physicians

The best source of authority for the IRS' position on balancing community need with physician recruiting incentives to justify recruiting incentives is in a September 16, 1994, IRS "Closing Agreement" with Hermann Hospital of Houston, Texas. While not strictly precedential authority, the Closing Agreement is definitely another "best practices" guideline for those drafting physician recruiting arrangements. Given the activity in executive compensation, a review of the agreement is worthwhile because it is important to recall what factors the IRS will consider when reviewing compensation to medical staff physicians.

The Closing Agreement required the adoption of "Physician Recruitment Guidelines." Pursuant to the guidelines, a physician recruiting incentive is not permissible unless one of the following factors is demonstrated:

- A population-to-physician ratio in the community that is deficient in the recruited physician's particular specialty area (using Graduate Medical Education National Advisory Committee reports).
- A demand for a particular medical service in the community coupled with a documented lack of availability for the service or long waiting periods for the service.
- HHS designation of the community as a Health Professional Shortage Area at the time the recruiting agreement is executed.[21]
- A demonstrated reluctance of physicians to relocate to the hospital due to the physical location, such as when the hospital is in a rural or economically disadvantaged inner city area. In such cases, document the rejections.
- A documented, expected reduction in the number of physicians in the specialty area to due retirement within the next three years.
- A documented lack of physicians serving indigent or Medicaid patients in the hospital service area (provided that the recruits commit to serving a substantial number of such patients).

Conclusion

This article hopefully has relayed the considerations in evaluating executive compensation for the nonprofit health care organization. It has summarized the broad legal scheme and highlighted the plethora of authorities that influence the decision on what to pay. The nonprofit health care compliance officer should consider state nonprofit statutes and administrative guidelines. The executives should be aware of the duties they owe to the organization. The federal tax laws of exempt organizations, dry as they may be, need to be explained to and understood by the executives. The overall governance structure of the organization directly and indirectly contributes toward ensuring that executive compensation is fairly determined.

There is much to be considered, but clearly, the law and the media demand deliberate, careful consideration of these

issues. That seems to be the only real protection against future issues and problems. Those who lead nonprofit health care organizations should derive satisfaction out of their position for reasons other than compensation — this is the moral ideal. And, without a tongue in cheek, "Money" magazine recently named the "nonprofit executive" as the top job in 2007 for those "Over 50, But Not Over the Hill." If the executive can deal with the compliance headaches, a happy medium between compensation and job satisfaction can be reached in the nonprofit health care industry. ■

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[15] The IRS has stopped short of an absolute requirement for a conflict of interests policy on its Form 1023, but in practice health care nonprofits have been told to have a written and updated conflicts of interest policy prior to the IRS actually granting a favorable tax-exempt determination letter. Moreover, a conflicts of interest policy that is written and followed is one of three factors that create a *rebuttable presumption* that compensation paid to a disqualified person is reasonable. (The other two factors are approval based upon comparability data and concurrent, adequate documentation.) Treas. Reg. §53.4958-6(e).

[16] *People of God Community v. Comm'r*, 75 T.C. 127 (1980).

[17] IRS Gen. Couns. Mem. 39,498 (Jan. 28, 1986); IRS Gen. Couns. Mem. 39,670 (Oct. 14, 1987); IRS Gen. Couns. Mem. 39,674 (Oct. 23, 1987).

[18] See Rev. Proc. 97-13, 1997-1 C.B. 632.

[19] Rev. Rul. 69-383, 1969-2 C.B. 113.

[20] See Christopher Rowland, *Hospitals Tie CEO Bonuses to Safety*, The Boston Globe, May 5, 2007, *available at* http://www.boston.com/news/nation/articles/2007/05/05/hospitals_tie_ceo_bonuses_to_safety/.

[21] See http://hpsafind.hrsa.gov/for a searchable database of such areas.

Fraud & Abuse (cont.)

GHB manufacturer settles criminal misbranding allegations

by Matthew Mann, J.D., Contributing Editor

Jazz Pharmaceuticals, Inc. (Jazz) has agreed to pay $20 million in penalties and restitution to resolve civil claims and criminal charges arising out of the illegal marketing practices of its subsidiary, Orphan Medical, Inc. (Orphan). Orphan pled guilty in New York federal district court to felony misbranding of the prescription drug Xyrem® in violation of the Food Drug and Cosmetic Act. Jazz and Orphan also entered into a settlement agreement to resolve civil False Claims Act (FCA) allegations stemming from public and private reimbursement for prescriptions of the drug for off-label uses.

Criminal misbranding. Orphan admitted to engaging in a scheme to promote Xyrem®, also known as gamma-hydroxybutyrate (GHB), for unapproved uses. GHB is a central nervous system depressant that has been approved by the Food and Drug Administration (FDA) for only two medical uses: (1) treatment of cataplexy, a condition associated with narcolepsy and characterized by weak or paralyzed muscles; and (2) treatment of excessive daytime sleepiness in narcolepsy patients. Xyrem® has been subject to abuse as a recreational drug and is classified by HHS as a "date rape" drug. It also bears a "black box" warning label, the most serious warning placed in the labeling of a prescription medication, indicating that Xyrem® is capable of inducing sleep very quickly and causing serious side effects.

Orphan sought to expand the market for Xyrem® by promoting its use for the treatment of conditions not related to an approved use, including fatigue, insomnia, chronic pain, weight loss, depression, bipolar disorders, and movement disorders such as Parkinson's Disease.

The company induced physicians to write prescriptions for Xyrem® that were not reimbursable by private health insurers or public insurance programs like Medicare and Medicaid, causing millions of dollars of losses to these insurers. Orphan promoted the drug for off-label uses by (1) making sales calls to physicians for the specific purpose of promoting off-label uses of the drug; (2) distributing written materials concerning unapproved uses; and (3) paying a psychiatrist a substantial sum of money to give presentations promoting Xyrem's® off-label uses and provide advice on how to conceal off-label prescriptions to ensure reimbursement.

Penalties and restitution. The investigation into Orphan's sales practices was launched following a private whistleblower lawsuit by a former sales representative. Pursuant to the guilty plea, Jazz has guaranteed Orphan's obligation to pay the government and private insurers approximately $12.2 million in restitution for improper payments, as well as a $5 million criminal fine. The companies also agreed to pay $3.75 million in fines, plus interest, to settle the civil FCA allegations.

In additon, Jazz agreed to implement the terms of a corporate integrity agreement constructed by the HHS Office of Inspector General, implement a code of conduct prohibiting off-label promotion of drugs, require compliance training for promotional speakers and sales representatives, and replace Orphan sales managers who oversaw representatives who engaged in improper conduct.

Assistant Attorney General Peter Keisler said the settlement "sends a clear message to the pharmaceutical industry that the Justice Department will not tolerate these deceptive and illegal marketing practices." Kim Rice, Special Agent-in-Charge, FDA Office of Criminal Investigations, added, "The FDA will continue to seek the type of criminal resolutions and stiff sanctions involved in this agreement when pharmaceutical companies seriously undermine the drug approval process by dangerously promoting drugs for unapproved uses." ■

DOJ Press Release, July 13, 2007.

Board's duty to oversee quality explained by OIG, AHLA

by Susan Smith, J.D., M.A., Contributing Editor

With the current focus on quality of care and patient safety, the emergence of quality as an enforcement priority for health care regulators, and the effect quality of care has on reimbursement, oversight of quality is becoming a core fiduciary responsibility of the board of directors of health care organizations, according to the draft of an educational resource co-sponsored by the Office of Inspector General (OIG) and the American Health Lawyers Association (AHLA). Compliance with standards and regulations applicable to the quality of services delivered to health care organizations is essential for the lawful behavior and corporate success of such organizations, the authors noted.

The purpose of the OIG and AHLA collaboration is to provide a resource to help corporate directors ask appropriate questions related to health care quality requirements, measurement tools, and reporting requirements and help demonstrate that they have followed a reasonable quality oversight process. The resource, entitled "Corporate Responsibility and Health Care Quality: A Resource for Boards of Directors," was discussed in detail at the AHLA Annual Meeting on June 27, 2007, by authors Arianne N. Callender, J.D., Senior Counsel, OIG; Douglas A. Hastings, Esq., Epstein Becker & Green PC, Washington, D.C.; Michael C. Hemsley, Esq., General Counsel and Vice President Corporate Compliance, Catholic Health East; Lewis Morris, Esq., Chief Counsel to the Inspector General; and Michael W. Peregrine, Esq., McDermott Will & Emery LLP, Chicago.

Board's duties. According to the experts, the responsibility for oversight of quality of care arises under the duty of care and, for nonprofit boards, under the duty of obedience to corporate purpose and the charitable mission as set forth in the organization's articles of incorporation or bylaws.

Under the duty of care, the "reasonable inquiry" standard applies. Board members are required to actively inquire into the aspects of corporate operations where appropriate, the resource states. Directors' obligations under the duty of care come up in two distinct contexts: (1) the decision making function, and (2) the oversight function. The duty of care with respect to quality of care also arises in the related context of the board's duty to oversee the compliance program, according to the resource.

Board members may be expected to exercise general supervision and oversight of quality of care and patient safety issues. Their oversight responsibilities may include being sensitive to the emergence of quality of care issues, being attentive to the development of specific quality of care measurement and reporting requirements, and requesting periodic updates on quality of care initiatives and how the organization intends to address legal issues associated with the initiatives.

Definition of quality of care. The resource includes the recognized standard for quality of care as developed by the Institute of Medicine (IOM). The six-part definition includes the terms safe, effective, patient-centered, timely, efficient, and equitable. Because this standard is being adopted by payers, providers, and regulators, experts advise that boards "be mindful" of the implications of the definition.

Government's role. The resource points out that federal and state governments regulate the delivery of care in a manner designed to promote quality and provide a baseline for assessing the level of care provided as well as determining reimbursement. Specifically, the Medicare and Medicaid conditions of participation require hospitals to monitor quality through medical staff credentialing and maintenance of effective quality assessment and performance improvement programs. Under the rules, the medical staff is accountable to a hospital's governing body for the quality of care provided to patients.

The OIG, Department of Justice, and state Attorneys General are actively working together with health care regulatory agencies to address the provision of substandard care by individuals and institutions. The resource outlined a number of the government's theories of liability along with examples, including (1) submission of claims for the provision of medically unnecessary services and failure of care; and (2) provision of care so deficient that it amounts to no care at all. As part of its enforcement efforts, the government is scrutinizing quality reporting data. The experts noted that the data submitted to the government must be accurate, or it may result in misrepresentation of patients' status, submission of false claims, and potential enforcement action.

Systematic failure to follow regulatory requirements and provide care of acceptable quality can result in sanctions such as heightened oversight, monetary penalties, and exclusion from federal health care programs. In addition, the OIG has negotiated several quality of care corporate integrity agreements, which may entail board-level obligations to ensure the organization's commitment to the delivery of quality of care.

Questions for boards. The experts developed ten sets of questions for boards to ask as they examine the scope and operation of their organization's quality and safety initiative. Among the questions are:

- What are the goals of the organization's quality improvement program?
- How does the organization measure and improve the quality of patient/resident care?
- How are the organization's quality assessment and improvement processes integrated into overall corporate policies and operations?
- Does the board have a formal orientation and continuing education process that helps members appreciate external quality and patient safety requirements?

"Health care organization boards have distinct responsibilities in this area [quality of care] because ... promoting quality of care and preserving patient safety are at the core of the health care industry and the reputation of every health care organization," the experts emphasized. "Effective compliance in the quality arena is an asset for both the organization and the health care delivery system." ■

CCH Chicago Bureau, July 13, 2007; Corporate Responsibility and Health Care Quality: A Resource for Boards of Directors, June 27, 2007, ¶530,602.

Clinical Trials

Revised NCD expands access to clinical trials

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

CMS has made two significant changes to the Clinical Trial Policy (CTP) National Coverage Determination (NCD), which addresses Medicare coverage when beneficiaries participate in clinical research trials. CMS' final decision memorandum, issued on July 9, 2007, in response to public comments regarding its April 10, 2007, proposed decision, preserves the status quo with the exception of these two changes.

First, CMS is modifying language in the CTP that could be read to restrict payment for the item or service under investigation to the extent that the item or service would be covered outside of the clinical research trial. The final decision clarifies that these items or services would be covered if they would be covered outside of the clinical research trial.

Second, CMS is adopting the proposed addition of Coverage with Evidence Development (CED) to the CTP. CED is for items and services in clinical research trials for which there is some evidence of significant medical benefit, but for which there is insufficient evidence to support a "reasonable and necessary" determination. Coverage under CED is for items and services that would not be covered otherwise. By adding CED to the CTP, items and services furnished to Medicare beneficiaries under CED will be deemed reasonable and necessary.

CMS Acting Administrator Leslie Norwalk said, "This decision will expand access for Medicare beneficiaries to participate in clinical trials that seek to establish better evidence for the management of care and treatment of Medicare beneficiaries."

In addition to the final decision on the current reconsideration of the CTP, CMS plans to reopen the CTP NCD and post a new proposed decision memorandum for a 30-day public comment period. The proposed decision memorandum will build upon the extensive public comments already received. ■

CMS Press Release, July 10, 2007; Decision Memo for Clinical Trial Policy, CAG-00071R, July 9, 2007.

In the News

P4P demonstration improves quality, savings

All participating physician groups improved the clinical management of diabetes patients in the first year of the three-year Medicare Physician Group Practice demonstration. The demonstration, which began April 1, 2005, rewards providers for coordinating and managing the overall health care needs of Medicare patients with chronic conditions. Physician groups continue to be paid on a fee-for-service basis and have the opportunity to share in savings generated from enhancements in care management. All 10 of the participating physician groups achieved benchmark or target performance on at least seven of the 10 diabetes clinical quality measures. Two physician groups met all 10 benchmarks. HHS Secretary Michael Leavitt said, "This demonstration project provides new evidence that paying for quality of care instead of volume of services helps the program, physicians, and patients."

CMS Press Release, July 11, 2007.

OIG, DME company settle kickback claims

Advanced Neuromodulation Systems, Inc. (ANS), a medical device manufacturer specializing in spinal cord stimulation used for pain management, has agreed to pay $2.95 million to resolve kickback allegations concerning its marketing program and entered into a three-year corporate integrity agreement with the Office of Inspector General (OIG) that includes reviews of the company's arrangements with physicians. The OIG alleged that ANS engaged in a marketing program pursuant to which several physicians were paid $5,000 for every five new patients tested with an ANS product, and that the program did not have any significant clinical value but rather served as a marketing tool to increase ANS sales. OIG also alleged that perks such as sports tickets, trips, dinners, grants, and other gifts were provided by ANS sales and marketing personnel to physicians free of charge.

OIG News Release, July 2, 2007.

NPPES errors might result in claim rejections

Physicians, providers, and suppliers who submit claims to Medicare fee-for-service contractors and durable medical equipment contractors should validate their National Plan and Provider Enumeration System (NPPES) data to assure claims are processed timely and correctly, according to a recent *MLN Matters* article. CMS has identified frequent errors providers have been making when applying for National Provider Identifiers (NPIs). These errors, which may result in claim rejections, include: (1) errors in reporting an Employer Identification Number when applying for an NPI; (2) incomplete or invalid data within the "Other Provider Identifiers" section of the NPPES online application; (3) reporting an incomplete Medicare legacy identifier; (4) having more than the twenty allowable legacy numbers; and (5) listing legacy numbers that do not belong to the applicant. Failure to properly submit the NPI also might cause claims to reject. Providers billing for Part B services are encouraged to verify that their NPI/legacy identifier combinations are valid in NPPES.

MLN Matters, SE0725, July 5, 2007.