CCH Health Care Compliance LETTER

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Medco relator's counsel advises case management to smooth negotiation process

by Catherine Hubbard, M.A., Contributing Editor

Attorneys in the recent false claims suit against Medco Health Solutions took several steps that made negotiations go more smoothly, starting with negotiating the order governing discovery. Marc Raspanti, relator's counsel and founding shareholder of Miller Alfano & Raspanti, Philadelphia, Pennsylvania, discussed his litigation strategies at an event sponsored by the American Health Lawyers Association on December 13, 2006. According to Raspanti, simple steps such as videotaping depositions can help keep the process on track.

Medco false claims suit. On October 23, 2006, the Department of Justice (DOJ) announced that Medco, a pharmacy benefit management company, agreed to pay $155 million plus interest to settle allegations that they submitted false claims to the federal government, solicited and accepted kickbacks from pharmaceutical manufacturers to favor their drugs, and paid kickbacks to health plans to obtain business. The government required that Medco enter into a corporate compliance agreement.

Lessons learned. "With relators, we thought through the details of how the discovery was going to take place, how the motions were going to happen and what the depositions were," said Raspanti.

Raspanti discussed other helpful steps, including videotaped depositions. "With videotape on major depositions, the behavior of the lawyers changes," he noted. "They're somewhat more civilized with each other because they know they are being recorded."

"Also with videotape, the only time that counts is the time that's on the tape," Raspanti said. "In many depositions, it reduced the amount of friction." He explained that with a third party announcing how much time was left, squabbles over insignificant matters were reduced. Moreover, there were rules for how objections were to be phrased, conferences with the court, and use of magistrates to resolve discovery disputes.

"We really did think it through," said James Sheehan, DOJ assistant U.S. attorney for the Eastern District of Pennsylvania. "I think that everyone, including the Medco lawyers, would agree that it was helpful," he said. Without a case management order, "difficult depositions ... would have been even worse," Sheehan added, noting there were about 100 fact depositions and 20 experts. "It was a very helpful thing and something everyone should consider for any complex piece of litigation." ■

CCH Washington Bureau, Jan. 2, 2007.

Wolters Kluwer Law & Business

Medicare Part D sponsor compliance efforts fall short

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

The compliance plans created by Medicare Part D drug plan sponsors (PDPs) are lacking a significant amount of the content required by CMS guidance, according to a December 2006 report by the Office of Inspector General (OIG). While all PDPs had compliance plans in place, 91 percent of those plans failed to address all the necessary requirements.

Compliance requirements. Under the Part D regulations, PDP compliance plans must contain eight elements addressing concerns such as fraud and abuse, internal monitoring and auditing, training and education, and procedures for response to detected offenses. Additional guidance from CMS in the *Prescription Drug Benefit Manual* helps PDPs address the eight core elements by identifying 17 requirements for compliance plans. The manual also contains 11 recommendations specific to the detection, correction, and prevention of fraud.

Findings. The OIG found that 72 of the 79 PDPs did not address all of the seventeen elements required under CMS guidance documents. A median of only 13 of these elements were addressed. Many compliance plans did not address requirements related to designation of a compliance officer and committee, and procedures for internal monitoring and auditing. Furthermore, only 15 of 79 plans addressed all 11 recommendations regarding fraud detection, prevention, and correction. Plans most often did not address CMS recommendations regarding fraud detection procedures, fraud awareness training, and efforts to cooperate with CMS and law enforcement entities regarding potential fraud.

OIG recommended CMS ensure that PDP compliance plans address all requirements and encouraged PDPs to provide sufficient detail to clearly demonstrate how they are implementing compliance plan requirements. ■

OIG Report, No. OEI-03-06-00100, Dec. 1, 2006, Health Care Compliance Reporter, ¶530,495.

Administration

Panel discusses merits of pay-for-performance in Medicare

by Catherine Hubbard, M.A., Contributing Editor

Incentive payments for physicians and hospitals to provide higher quality and more efficient care may not work equally for all providers, according to a panelist who spoke at a recent event held in Washington, D.C. by the Alliance for Health Reform and the Commonwealth Fund.

Shortly before adjourning, Congress approved a change to the Medicare physician payment schedule to prevent a 5 percent reduction to Medicare physician payments in 2007 while establishing a quality reporting system beginning in July of 2007. Doctors and other eligible practitioners who submit data on applicable quality measures will receive bonus incentive payments of 1.5 percent for covered services.

One problem in selecting pay-for-performance opportunities is that the marginal rewards or penalties do not have an equal impact on hospitals and physicians, said Bob Berenson, senior fellow of the Urban Institute. One point five percent "is a big deal for hospitals or health plans" that have margins in the one to three percent range, he said. Physician margins, however, are about 40-percent, he noted. One point five percent for a physician "may be trivial and you're not going to get the same behavior change you're likely to get from a hospital."

Stuart Gutterman, senior project director on Medicare's future at the Fund, disagreed, stating that one percent of payments is a lot of money to providers. "There are a lot of very vicious fights over 1 percent more or less ... on the provider level, so I suspect it is a bigger incentive than we think," he said.

Berenson believes that rather than focusing entirely on pay-for-performance, Medicare should fine-tune basic incentives. "Measuring performance is difficult. Changing incentives is a different story. And I think we should be changing incentives," he said. For instance if the fee-for-service payment for primary care

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physicians does not support what clinicians should be doing, then the system should be changed. Berenson warned, "Don't expect pay-for-performance to solve the problem."

According to Berenson, in a reformed system, pay-for-performance can play a significant role. He suggested Medicare look at changing how it pays primary care physicians and take lessons from European systems that combine fee-for-service, capitation, and pay-for-performance.

Gail Wilensky, senior fellow of Project HOPE, noted that different aspects of health care, such as quality, efficiency, and patient-centeredness, should be included when designing awards. She explained that rewarding only efficiency would lead to less spending and less care. "We need to encourage ... high quality, efficiency, and patient centeredness," Wilensky said, adding that an Institute of Medicine (IOM) study released in September concluded that Medicare is a broken payment system. "We need to make changes, see the results, modify the system in response to the results, and continue on that process."

The IOM study recommended a phased approach. "We don't recommend jumping full-blown into a pay-for-performance system that would have a major shift in reimbursement," Wilensky noted. "Initially the funds ought to be provider specific. So any redistribution among hospitals ought to come from hospital funds and any redistribution under pay-for-performance for homecare ought to come from money that is part of homecare." Wilensky added, "Ultimately if you want to try to have a shared accountability, you will need to have consolidated pools of funding in order to reward the groups, individuals and institutions that are providing the care."

IOM also has recommended a voluntary basis for the first three years followed by an assessment, Wilensky noted. "Physicians need to be brought in slowly because their measurement sets are frankly far less developed."

Dr. Robert Galvin, director of global health care at General Electric, said 100,000 avoidable deaths occur in U.S. hospitals every year. In addition, a patient has a 50 percent chance of getting the right care when at the doctor's office, and there is a minimum of 25 percent waste in the system in terms of variation and duplication. He mentioned a physician who complained that she will be out of business if she continues to treat patients effectively by taking quality steps such as discussing care with patients over the phone when possible, discussions that are not charged, rather than requiring unnecessary visits to her office. "You have a system today that has all the wrong incentives," Galvin said. ■

CCH Washington Bureau, Jan. 4, 2007.

HIPAA

HHS issues new guidance for accessing electronic PHI

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

In response to recent security breaches related to the use of laptops and other portable devices used to store protected health information (PHI), the Department of Health and Human Services (HHS) has issued additional guidance on the security rule of the Health Insurance Portability and Accountability Act (HIPAA). The guidance reinforces ways in which a covered entity can protect PHI when it is accessed or used outside the organization.

The guidance stresses that covered entities should restrict offsite use of PHI except when absolutely necessary. Examples of appropriate offsite uses include: home health nurses collecting patient information, physicians accessing e-prescribing applications on hand held devices, and transportation of enrollee data by health plan employees. While the guidance identifies specific risk management strategies for consideration, covered entities should evaluate their own needs for offsite use, analyze the risks associated with that use, and develop corresponding risk management policies. Organizations should consider their size, capabilities, and complexity; their technical infrastructure, hardware, and software security capabilities; the costs assoiated with security measures; and the probabilty of risks to electronic PHI.

HHS identified three areas that should be addressed in any covered entity's security policy: access, storage, and transmission.

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Compliance risks arising from the safe harbor and Stark II exceptions allowing donations supporting e-prescribing and electronic health record systems, Part I

by Timothy P. Blanchard, J.D., Contributing Editor

This article is Part I of a three-part series that identifies compliance issues and risks resulting from significant limitations that remain in the new regulations, and proposes potential approaches for use by compliance professionals in assisting their organizations to navigate around those compliance traps.

On August 8, 2006, the Department of Health and Human Services (HHS or the Department) issued two long-awaited final regulations[1] intended to facilitate the development of electronic prescription (e-prescribing) and interoperable electronic health record (EHR) capability by specifying the circumstances under which the donation of e-prescribing and EHR technology and training services would be permissible under the federal anti-kickback statute[2] and the federal physician self-referral prohibition.[3]

Although CMS and the Office of Inspector General (OIG) obviously considered the feedback they received during the comment periods for the proposed rules and incorporated some of the feedback into the final rules, it remains a matter of debate (and outside the scope of this article) whether the new regulatory scheme has gone far enough to protect potential donors of equipment, software, and services to encourage them to engage in projects of the scope and expense required to meaningfully advance e-prescribing and EHR. While the public policy arguments in favor of e-prescribing and EHR systems are very strong, the protection offered in the regulations is limited. CMS and OIG have made clear their belief that they have expanded the regulatory protections about as far as they are permitted under the governing statutes, and compliance officers should expect strict scrutiny under the rules as written, not leniency based upon public policy considerations or even common sense.

The fraud and abuse laws

The anti-kickback statute

The anti-kickback statute (AKS) prohibits knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce referral or recommendation of items or services reimbursable under Medicare, Medicaid, or any other federal health care program, unless the arrangement falls within one of the regulatory "safe harbors" promulgated by OIG.[4] Prohibited remuneration includes not only kickbacks and bribes, but also anything of value, in cash or in kind, given directly or indirectly to a potential referral source. Even though the principal reasons for the donation of e-prescribing or EHR technology by a health care provider or plan may be improved efficiency and patient safety, the provision of such technology without charge or at less than fair market value would constitute prohibited remuneration to a referral source in violation of the AKS if it could be shown that one purpose[5] of the donation was to induce referrals.

Stark II prohibition against self-referral

The federal prohibition against self referral (Stark II) prohibits physician referrals to entities with which the physician (or a close family member of the physician) has a financial relationship, if the referral is for a "designated health services" (DHS) payment for which the Medicare program is responsible, and the referral does not qualify for an enumerated regulatory exception.[6] Stark II also prohibits the submission of claims to Medicare for DHS furnished as a result of a prohibited referral.[7] Arrangements for the donation of e-prescribing or EHR technology would create a financial relationship between the donor and the referral source for purposes of the Stark prohibition.

Need for reform

Although it may have been possible to structure certain arrangements for the provision of e-prescribing or EHR technology to qualify for protection under pre-existing AKS safe harbors and Stark exceptions, as a practical matter the prohibitions presented a roadblock to donations of the scope and kind that many comprehensive e-prescribing and EHR programs would have required.

When Congress expanded the Medicare program to include the Part D prescription drug benefit under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), it also adopted standards for e-prescribing and required the promulgation of a safe harbor and Stark exception designed to permit donations of e-prescribing technology to prescribing physicians, practitioners, and others involved in transmitting and receiving electronic prescription information.[8] While developing the required e-prescribing rules,

CMS and OIG recognized the need for a safe harbor and Stark exception for donations of other technology that would facilitate development of EHR. As a result, there are four new provisions: CMS's Stark rule for e-prescribing; CMS's Stark rule for EHR; OIG's anti-kickback rule for e-prescribing; and OIG's anti-kickback rule for EHR.

The regulations

As noted above, the MMA required the addition of a safe harbor under the AKS (which is within the jurisdiction of OIG) and an exception to the prohibition against physician self-referral (which is within the jurisdiction of CMS), and CMS and OIG added those provisions for e-prsecribing and EHR. Because there were two separate agencies with jurisdiction, two separate rulemaking processes were required. However, the agencies sought to make the resulting rules as consistent as possible, given the differences in their underlying statutes.[9]

Each agency's regulations address e-prescribing[10] and EHR[11] technology donations separately, defining the circumstances under which entities may become technology donors, which technology may be donated, to whom it may be donated, and under what conditions. Because the requirements of OIG's safe harbor regulation and CMS's Stark exception regulation are virtually identical, this article refers to the safe harbor and Stark exception regulations collectively as the "Rules," unless a specific reference to the safe harbors or Stark exceptions is required by context. Because the more liberal EHR Rules will probably be of greater interest to most health care organizations, this article discusses the compliance issues presented by both sets of Rules in the context of the EHR Rules.[12]

Differences between e-prescribing and EHR rules

Although the agencies worked to make the e-prescribing and EHR safe harbor and Stark exception rules consistent, it is important to remember the differences in scope between the Rules.

The e-prescribing Rules apply to prescriptions for medication and other items or services routinely ordered by prescription, such as durable medical equipment (DME) and laboratory tests.

- The e-prescribing Rules are broader than the EHR Rules in that the e-prescribing Rules permit donation of equipment, while the EHR Rules do not.
- The e-prescribing Rules do not require cost sharing by recipients; the EHR Rules mandate it.
- The e-prescribing Rules require that the donated technology be necessary and used solely for transmitting or receiving electronic prescription information, not for additional EHR functions.

The latter difference is likely to significantly limit the practical use of the e-prescribing Rules' protections because the most desirable electronic information systems serve multiple functions or can be used for applications beyond e-prescribing.

The EHR Rules permit donation of software and related training for the transmission, storage, and receipt of EHR information.

- The EHR Rules permit donation by a broader range of donors to a broader range of recipients.
- The EHR Rules permit the inclusion of multifunctional software and services, provided the predominant use of the donated technology is for EHR purposes.[13]

Scope of protected technology types

The e-prescribing and EHR Rules both protect only in-kind donations: hardware (e-prescribing Rules only), software, training, and information technology services. Permitted technology donations include interface and translation software; rights, licenses, and intellectual property related to software; connectivity services (including broadband and wireless internet services); maintenance services; secure messaging; training and support services; and clinical support and information services related to patient care.

Other items and functions that might be integrated with these systems but are not related to the core EHR functions, such as human resources or payroll software, software packages focused primarily on practice management or billing, or software used to conduct personal business, are excluded from the Rules' protections.[14]

The "necessary" criterion

The Rules permit donation of technology to the extent that it is "necessary" to create, maintain, transmit, or receive EHR. The donated technology must not be technically or functionally equivalent to technology already owned by the recipient.

The proposed rules would have required recipients of donated technology to certify that the donated items and services were "necessary," and not merely disguised payments or inducement for recipients to refer reimbursable business to donors. Because of concerns that potential recipients might not be able to make the technical determinations necessary to make such certifications without the assistance of expert consultants, certification is not required under the final Rules. Instead, the protection of the safe harbors and Stark exceptions is available if the donor "does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the recipient possesses or has obtained items or services equivalent to those provided by the donor."[15]

Donors now have the burden of determining that donated technology is not duplicative of the recipient's existing technology—and thus "necessary"—creating a challenging compliance issue for donors. Neither OIG nor CMS provided guidance concerning the facts and circumstances relevant to determining whether technology the recipient already possesses is

"equivalent" to the proposed donations—for example, is the determination to be based on a comparison of features and functions, the technology platform, or specific system architecture? The agencies have clarified, however, that the "necessary" standard does not preclude upgrades to enhance functionality or achieve greater standardization between donors and recipients.

In the preamble to the proposed rules, OIG and CMS expressed concern that prospective recipients might intentionally divest themselves of their existing EHR or e-prescribing technology in order to shift the cost of new technologies to donors (and thereby to payors).[16] This concern appears more likely to arise in connection with hardware donations under the e-prescribing Rules than under the EHR Rules, which do not protect equipment donations, because divestiture or redeployment of hardware appears the most likely circumstance in which such a concern could arise as a practical matter. Neither CMS nor OIG imposed any specific requirements with respect to this concern in the final Rules.[17] In response to comments, OIG did note the requirement that donors not shift costs to federal health care programs. (The implications of this requirement are discussed below.) Further, apparently as a result of the stated concern, the Rules do not protect a donation of personnel to assist recipients with necessary office functions, regardless of their relation to EHR systems. Accordingly, provision of personnel to transfer paper records to an electronic format is not protected by the Rules,[18] even though such assistance would clearly promote the development of EHR systems.

Questionnaires

OIG and CMS did recommend that donors make and document inquiries made to potential recipients concerning the "necessary" criterion. Donor compliance professionals should, in fact, consider developing standardized questionnaires for potential recipients as a tool to conduct and document reasonable "necessity" inquiries.

Moreover, notwithstanding the elimination of the recipient certification requirement from the final Rule, donors are free to include, and should consider including, some form of certification on the questionnaire to assure at a minimum the factual accuracy of the statements upon which the donor must rely with respect to the necessity of the technology donations.

Surveys

Organizations considering donations of EHR technology also may wish to consider having technically-qualified staff conduct detailed surveys of existing EHR technology at potential recipients' sites within the area to be covered by the contemplated donation program. Such surveys not only would confirm information required to evaluate the necessity of the technology to be donated, but also would record the state of existing equipment, including hardware, to determine whether the contemplated donations can be used with the existing equipment or whether additional investments outside the Rule would be essential before the donated technology could be used, thereby substantially contributing to donation program planning.

Because a potential recipient would need to provide the donor survey staff access to its premises and information systems for such a survey, the potential recipient should establish the potential donor (or survey organization, if separate) as a HIPAA business associate for purposes of evaluating the compatibility of existing information systems with the contemplated donations. The donor likely would need to incorporate general confidentiality provisions into the HIPAA business associate agreement to facilitate the survey so that even general information regarding individual recipients' information systems would be shielded from competitors. The donor organization should include strict confidentiality in its policies and procedures and workforce training prior to initiating such surveys, to prevent HIPAA violations or disclosure of competitive information regarding potential recipients. Finally, survey personnel would need to refrain from providing information systems advice to potential recipients prior to formalizing donation arrangements because such consulting advice could be interpreted as a "free" service that would not be protected by the Rules.

The "used predominantly" criteria

Under the EHR Rules, only technology that is "used predominantly" for EHR purposes will qualify for protection. This standard allows greater latitude than the "used solely" standard applicable under the e-prescribing Rules. The EHR Rules protect elements of an EHR system that incidentally facilitate other administrative functions, such as software with built-in diagnosis coding for billing purposes.[19] To satisfy this criterion, "the core functionality of the technology must be the creation, maintenance, transmission, or receipt of individual patients' electronic health records."[20] The EHR Rules also require that the donated EHR technology include an e-prescribing component that meets the technical standards established under the e-prescribing Rules.

The EHR Rules protect donations of software packages that include other functions, such as patient scheduling, billing, and clinical support, so long as the EHR function is predominant. Connectivity services and software to facilitate internet access and wireless networking technology can also be protected under the Rules when donated in connection with technology, but as noted above, donation of networking hardware such as modems and routers is not protected by the EHR Rules.

Conclusion

Part I of this article provided background on the fraud and abuse laws and the safe harbor and Stark exception regulations for e-prescribing and EHR, and focused on the scope of protected technology and the "necessary" and "used predominantly" criteria under the new regulations. Part II will discuss the range of protected donors and recipients of e-prescribing and EHR technology, as well as the interoperability requirement. Part III will address recipient solution considerations and other implications of the new regulations, including tax-exemption and state law issues. ■

On the Front Lines (cont.)

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[1] *Final rule*, 71 FR 45140, Aug. 8, 2006 (codified at 42 C.F.R. Part 411, Subpart J, issued by CMS); *Final rule*, 71 FR 45110, Aug. 8, 2006 (codified at 42 C.F.R. §1001.952(x), issued by the Office of Inspector General (OIG)).

[2] 42 U.S.C. §1320a–7b(b).

[3] 42 U.S.C. §1395nn; *see also* 42 U.S.C. §1396b (extending the prohibition to federal financial participation for Medicaid services furnished pursuant to a prohibited referral).

[4] 42 U.S.C. §1320a-7b(b).

[5] Courts have held the AKS to be violated if "one purpose" of the remuneration under an arrangement with a current or potential referral source is to compensate for past referrals or to induce future referrals. *See United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68 (3d Cir.), *cert. denied*, 474 U.S. 988 (1985).

[6] 42 U.S.C. §1395nn(a)(1)(A); 42 U.S.C. §1396b.

[7] 42 U.S.C. §1395nn(a)(1)(B).

[8] Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173) §101 (MMA) (adding §1860D to the Social Security Act).

[9] The principal difference between the two authorities is that the Stark referral prohibition applies only to referrals from physicians, while the anti-kickback statute applies more broadly. In addition, referrals and billings under arrangements that do not qualify for a Stark exception constitute violations of the law. Arrangements that do not fit within a safe harbor are not necessarily illegal under the AKS; they are subject to case-by-case review under the statute to determine the parties' intent.

[10] 42 C.F.R. §§411.357(v), 1001.952(x).

[11] 42 C.F.R. §§411.357(w), 1001.952(y).

[12] *See* 42 C.F.R. §§411.357(w)(8), 1001.952(y)(7).

[13] EHR is broadly defined as a "repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions." *See* 42 C.F.R. §§411.357(w)(8), 1001.952(y)(7).

[14] 71 FR at 45124-25 ("The safe harbor protects arrangements involving software packages that include other functionality related to the care and treatment of individual patients (e.g., patient administration, scheduling functions, billing, and clinical support) … We interpret the scope of covered electronic health records technology to exclude: Hardware (and operating software that makes the hardware function); storage devices; software with core functionality other than electronic health records (e.g., human resources or payroll software or software packages focused primarily on practice management or billing); or items or services used by a recipient primarily to conduct personal business or business unrelated to the recipient's clinical practice or clinical operations. Further, the safe harbor does not protect the provision of staff to recipients or their offices. For example, the provision of staff to transfer paper records to the electronic format would not be protected.").

[15] 42 C.F.R. §411.357(v)(8) (e-prescribing Stark exception); 42 C.F.R. §1001.952(y)(7) (e-prescribing safe harbor). *See* 42 C.F.R. §§411.351, 1001.952(x).

[16] *See Proposed rule*, 70 FR 59015, 59018, Oct. 11, 2005; *Proposed rule*, 70 FR 59182, Oct. 11, 2005.

[17] 71 FR at 45123-24.

[18] *Id.* at 45125.

[19] *Id.* at 45124.

[20] *Id. See also* 42 C.F.R. §1001.952(y).

HIPAA (cont.)

- **Access.** Data access policies and procedures should ensure that users accessing data are appropriately authorized. Remote access to PHI should be granted to authorized users based on their role in the organization and need for access.
- **Storage.** Storage policies and procedures should address security requirements for media and devices containing PHI that are moved beyond the organization's physical control.
- **Transmission.** Transmission policies and procedures should focus on ensuring the integrity and safety of PHI sent over networks.

Risk management policies should address training and awareness. Training should address the risk areas specific to the covered entity's needs and should provide clear instructions for storing, accessing, and transmitting PHI. In addition, employees should be trained on password management procedures. Finally, organizations need to ensure their workforce is aware of policies that prohibit leaving devices unattended in cars, transmitting electronic PHI over open networks, and downloading PHI to public computers.

A complete risk management policy also should address procedures in the event of a security breach. Incident procedures should specify the actions to be taken to manage the effects of a loss. Procedures may include securing and preserving evidence, managing the effects of improper use or disclosure, and notification to affected parties. A sanction policy should be included to communicate to the workforce the consequences of failing to comply with security policies and procedures related to offsite use of PHI.

Covered entities that are capable of implementing all the specific strategies listed in the guidance are strongly encouraged by HHS to do so. According to HHS, CMS may rely on the guidance document in determining whether the actions of a covered entity are reasonable and appropriate for safeguarding PHI. The guidance also may be given deference in an administrative hearing. However, the guidance is not exhaustive, and covered entities should evaluate their own needs in creating a risk management strategy. The guidance can be accessed at www.cms.hhs.gov/EducationMaterials/. ■

HIPAA Security Guidance for Remote Use of and Access to Electronic Protected Health Information, Jan. 4, 2007.

Tax-Exempt

Hospital settles with uninsured patients

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

A California hospital network settled with a class of uninsured patients alleging they were charged inappropriately high prices for services because of their uninsured status. The uninsured patients argued that they were gouged for services despite the hospital network being a charitable organization and reporting record profits during the class period.

Complaint. According to the complaint, the hospital network violated the state unfair competition act by holding itself out as a provider of charity care while charging unreasonable and inflated prices for medical care to those least likely to be able to pay those charges. Further, the complaint alleges that the hospital network then pursued aggressive collection techniques against uninsured patients that often resulted in lawsuits, garnishments, and bankruptcies. The uninsured patients also argued that the hospital network's practices were deceiving in that the hospital represented itself as a not-for-profit entity while profiting off the members of the community. Finally, the uninsured patients argued that the hospital network offered an insufficient amount of charity care.

Settlement terms. Under the terms of the settlement agreement, uninsured patients who received care between July 1, 2001, and September 25, 2006, and had $250,000 or less in gross annual household income in the calendar year in which they received hospital services are eligible to receive discounts or refunds. The hospital network also is required to provide financial counseling to uninsured patients, and hospital employees are required to inform uninsured patients of the discount policy and the patient assistance program. Finally, the hospital network's compliance officer must supply the uninsured patients' attorneys with a semi-annual report documenting the number of uninsured patients who have received services and the dollar value of those benefits. ■

Dancer v. Catholic Healthcare West Settlement Agreement, California Superior Court, Jan. 11, 2007.

In the News

Health care ranks 4th on NCSL's top 10 policy issues forecast

Health insurance ranks fourth out of ten among the predictions of state priorities for 2007, the National Conference of State Legislatures (NCSL) announced on January 4. Even though health care costs continue to strain state budgets, state legislatures may be focusing their attention on expanding coverage to the 46.6 million—or one out of every six—Americans the U.S. Census Bureau says were without health insurance in 2005, NCSL said. States may be looking at the plans Massachusetts and Vermont approved last year to ensure all state residents have health insurance, NCSL noted. "Look for states to continue looking at ways to reduce costs, such as seeking lower prices for medicine and health care procedures," it added.

National Conference of State Legislatures Press Release, Jan. 4, 2007.

Families USA backs drug price negotiation

As the House prepared to introduce legislation to allow the government to negotiate prescription drug prices under the Medicare Part D plan, Families USA, a consumer advocacy group, released a report showing that Part D drugs can cost twice as much as drugs under the Veterans Affairs (VA) program. In a report released on January 9, 2007, Families USA said that for each of the top 20 drugs prescribed to seniors, the lowest price charged by any of the top Part D insurers is higher than the lowest price secured by the VA. The report revealed that the median difference between the lowest Part D plan price and the lowest VA price is 58 percent. The VA is able to secure lower prices for prescription drugs because it negotiates prices with drug companies; but the 2003 Medicare Modernization Act (PubLNo 108-173) prohibits the government from negotiating prices under Part D.

CCH Washington Bureau, Jan. 12, 2007.

. . . but CMS says government negotiations will not lower costs

Independent actuaries at CMS concluded that government negotiations for Medicare Part D drugs as proposed in a recent House bill would not produce any savings. "Although the bill would require the Secretary to negotiate with drug manufacturers regarding drug prices, the inability to drive market share via the establishment of a formulary or development of a preferred tier significantly undermines the effectiveness of this negotiation," explained Paul Spitalnic, Director of the Parts C and D Actuarial Group in the Office of the Actuary. "Manufacturers would have little to gain by offering rebates that aren't linked to a preferred position of their products, and we assume that they will be unwilling to do so." "The actuaries expect that the Part D plans will continue to be the source of meaningful negotiations with manufacturers as they will continue to have the authority to establish formularies and define a preferred tier," he continued.

CMS Press Release, Jan. 11, 2007.