

CCH Health Care Compliance LETTER

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CMP authority expanded to all HIPAA violations

by Vanessa Skawski, J.D., Contributing Editor

Civil money penalties (CMPs) will be imposed on entities that violate the administrative simplification provisions of the Health Insurance Portability and Accountability Act (PubLNo 104-191) (HIPAA) under a final rule issued by CMS. The compliance and investigation provisions of 45 C.F.R. Part 160, subpart C will now apply to all HIPAA rules, rather than only HIPAA privacy standards.

Penalties for violations. Under the new rule, if the Secretary finds in a notice of proposed determination that a covered entity has violated an administrative simplification provision, he will be required to impose a penalty unless the entity establishes an affirmative defense. When more than one entity has violated a provision, the Secretary will be required to impose a penalty on each. A member of an affiliated covered entity will be jointly and severally liable for violating a provision unless it is established that another member of the affiliated covered entity is responsible. Maximum penalties of \$100 for each violation and \$25,000 a year for all violations of an identical requirement during a calendar year have been established. In addition, a covered entity will be held liable for a CMP based on the actions of any agent acting within the scope of its agency or employment unless the agent was a business associate and the covered entity was in compliance with HIPAA rules governing business associates.

Hearings. To achieve consistency in CMP decisions among different administrative law judges (ALJs), an ALJ decision no longer will be considered the final decision. Under the new rule, an ALJ decision will be considered the initial decision of the Secretary, which may be appealed to the Departmental Appeals Board (DAB) within 30 days. This change will permit a respondent to file a petition for judicial review after an ALJ decision has been reviewed by the DAB.

The final rule also has revised the regulations related to hearing procedures. The rule addresses rights of the parties, the authority of the ALJ, prehearing conferences, discovery rules, witnesses, evidence, motion, sanctions, statistical sampling, and filing instructions.

Changes to proposed rule. The final rule reflects changes made in response to comments to the proposed rule. Significant changes include the added requirement that, when statistical sampling is used, HHS provide an entity with a copy of the study on which its statistical findings are based with the notice of proposed determination. Comments to the proposed rule also led to the addition of the requirement that respondents intending to introduce evidence from a statistical expert at the hearing must provide the study prepared by the

expert to HHS at least 30 days prior to the hearing. Additionally, while the proposed rule provided 60 days for a respondent to file a request for a hearing, the final rule provides 90 days.

Finally, the proposed rule listed variables to count the number of violations of an identical requirement. The final rule, however, clarifies that the method for determining such violations is grounded in the substantive requirement violated. The final rule will be effective on March 16, 2006. ■

Final rule, 71 FR 8389, Feb. 16, 2006, ¶1700,006.

Proposed amendment to California law restrains flow of health information

Gené Stephens, J.D.,
Contributing Editor

An amendment to the California Confidentiality of Medical Information Act (CMIA) would restrain the flow of health information to consumers because the proposed bill would be more restrictive than the federal privacy rule under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (PubLNo 104-191), according to the Federal Trade Commission (FTC).

The proposed amendment to modify the CMIA would require pharmacies, subject to certain exceptions, to obtain a patient's "opt-in" consent before providing a patient with sponsored marketing communications in connection with a prescription drug. The proposed amendment also would require patient consent for pharmacy communications that recommend alternative or complementary prescription drugs or therapies that may be needed for a patient's treatment simply because the communication was sponsored by a drug manufacturer.

HIPAA privacy standards. The HIPAA privacy rule excepts from its definition of commercial and marketing promotions those communications that are for the treatment of an individual

or for case management, care coordination, or recommended alternative treatments. While HIPAA generally requires an individual's consent before the individual's health information can be used for marketing purposes, it does not require patient consent for the receipt of a marketing communication that may enhance a patient's quality of care or treatment regimen.

Restrictions of the amendment. The proposed bill would change the definition of marketing under the CMIA to include written communications provided to a pharmacy patient in conjunction with the dispensing of a prescription in which the sponsor's trade name or commercial slogan is included with the prescribed treatment or therapy. Thus, any sponsored communication from a manufacturer, labeler, or distributor that includes an advertisement or coupon for a specific over-the-counter or prescribed medication would be a prohibited marketing communication that would require the pharmacy to obtain the patient's consent.

FTC concerns for consumers. The FTC noted several concerns in its comments regarding the proposed amendment. First, the proposed bill would be more restrictive than HIPAA's privacy rule because HIPAA does not define a health care provider's message as a marketing communication. In addition, the bill would serve as restraint on a type of commercial speech that is not inherently unlawful or misleading and raises questions about the constitutionality of the restriction. Proponents of the bill expressed concerns that the sponsored communications might confuse consumers about the nature of the communications or imply that a pharmacist sanctions a suggested treatment over a doctor's advice.

Less restrictive alternative. As an alternative solution to the proposed amendment, the FTC suggested that a less restrictive measure could be taken, such as requiring a clear and prominent disclosure of a drug's sponsorship so that consumers would

not be misled regarding the source of or funding for the communication. The suggested alternative would allow patients to receive the provider communications without limiting consumer access to potentially useful health information. ■

Federal Trade Commission Comment, Letter to the Honorable Barbara S. Matthews, Jan. 20, 2006, Health Care Compliance Reporter, ¶1680,005.



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Unless otherwise noted, all paragraph references are to the CCH Health Care Compliance Reporter.

Agency access to PHI not barred by HIPAA

Vanessa Skawski, J.D.,
Contributing Editor

The confidentiality provisions of the Health Insurance Portability and Accountability Act (PubLNo 104-191) (HIPAA) and the Medicaid Act do not prohibit a state hospital and state training school from disclosing protected health information to a state protection and advocacy system (P&A) as long as the disclosure complies with the requirements of the Protection and Advocacy for Individuals with Mental Illness Act (PAIMI) and other related acts, according to the U.S. District Court for the District of Wyoming. Therefore, the agreement for access to medical records between the state hospital and state training school and the P&A could be implemented.

P&A access to medical records

The P&A requested medical information from a state hospital and a state training school as part of its federal mandate to protect and advocate for the rights of persons with disabilities. PAIMI, the Developmental Disabilities Assistance and Bill of Rights Act (DD Act), and the Protection and Advocacy for Individual Rights Act (PAIR Act) (collectively P&A acts) authorize the P&A to access medical records of disabled patients without their consent in certain circumstances. These circumstances include occasions when the P&A has received a complaint regarding the treatment of an individual in a facility and the individual either has no legal guardian or the legal guardian has chosen not to act on behalf of the disabled individual. The P&A also has authorization to access records when they have probable cause to believe an individual in a facility was subject to abuse or neglect.

Limits on release of medical records. After the state hospital and state training school denied the P&A's request to access the medical records of its disabled patients, both sides sought guidance on the extent to which HIPAA and the Medicaid Act affected the disclosure requirements of the P&A acts.

The court determined that the limits on the release of protected health information found in HIPAA and the Medicaid Act do not prevent the P&A from accessing protected health information. Under HIPAA, medical records may be released when required by another law. The P&A acts require the release of medical records in certain circumstances, satisfying requirements for release of the information under HIPAA.

The Medicaid Act allows the release of medical records in several situations, including when conducting or assisting an investigation, prosecution, or civil or criminal proceeding related to the

Medicaid plan. Because, as part of its procedures, the P&A requests records when investigating whether or not facilities provided adequate services or safeguards for Medicaid clients, the P&A meets the requirements for release of protected health information under the Medicaid Act. Because HIPAA and the Medicaid Act authorize the release of records to the P&A, the agreement between the P&A, state hospital, and state training facility for access to medical records could be implemented. ■

Protection & Advocacy System, Inc. v. Freudenthal, D. Wyo., No. 05CV0141, Jan. 6, 2006, Health Care Compliance Letter, ¶301,782.

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Internal Investigations— What You Don't Know Can Hurt You

by James M. Welch, J.D., and Kristalee Guerra, J.D., Contributing Editors

Investigations help organizations determine whether any reported or potential noncompliance exists in an organization. Once an issue is found to exist, further investigation can determine the depth, breadth, and impact of the issue and the optimal path to resolution. Health care organizations in particular should view internal investigations as a process designed to demonstrate their commitment to compliance while providing the ability to address potential noncompliance on their own terms.

Internal investigations are the processes all organizations use to gather and analyze information related to potential compliance problems or issues that may exist. Every investigation into a potential issue or problem should include certain goals to: (1) validate the existence of the reported issue; (2) determine the control that failed or did not exist; (3) assess the potential legal and economic impact; (4) develop a remedial action plan with internal and external responses; and (5) advance a recommendation regarding notification to the governmental authorities when appropriate.

In health care settings, internal audits, audits by Medicare contractors, government inquiries, and patient complaints commonly reveal potential compliance issues. Employees also offer insight into possible instances of noncompliance. Employees raise issues by reporting them to their supervisors, calling compliance hotlines, and participating in employee exit interviews and satisfaction surveys. Even employees that are complainers may be rightfully identifying important compliance issues.

What Should be Investigated

Health organizations should seriously evaluate all potential compliance issues regardless of whether they are discovered through audits, inquires, complaints, hotlines, or even disgruntled employees. The most inopportune way for an organization to discover a report of noncompliance is directly from a federal or state agency. A whistleblower lawsuit, government subpoena, search warrant, request for documents, or an in-person visit by government agents are obvious indicators that the organization's internal mechanisms for detecting and investigating noncompliance issues failed. For this reason, organizations should have multiple internal processes in place to detect and deter noncompliance.

Issues can, and will, arise out of these various inquiries. Each issue should be investigated at some level. The company also should properly document the investigation, regardless of its outcome—even if it resulted from a simple misunder-

standing. By doing this, employees know that their company values compliance and that all reports of potential noncompliance are taken seriously. If the investigation reveals the existence of an issue, the problem must be identified, evaluated, quantified, and corrected.

Every investigation has the potential to uncover compliance issues that can present significant legal and possibly economic consequences. For example, the government may insist upon pursuing an investigation of the very issues that were investigated internally, which creates the potential for the government to discover other unknown issues. Even more troubling, the government may insist on full cooperation, which usually means waiving legal privileges. For these reasons, the investigation's scope, project plan, and implementation should be carefully deliberated.

Advantages of an investigation. There are several positive outcomes of an investigation. Early discovery provides an opportunity to stop any violations, implement corrective actions, and demonstrate the effectiveness of an organization's compliance program. An effective compliance program also reduces the risk of future compliance issues.

Another advantage of conducting an internal investigation is that organizations can learn and develop facts and legal theories that would be helpful in addressing a government investigation. They can anticipate arguments and, if necessary, defend against claims asserted by the government. Further, organizations may be able to influence the government's investigation by getting a head start, evaluating the issue, assessing the underlying cause of the problem, and taking appropriate steps to remediate and correct the problem. When undiscovered problems exist, they should be addressed as soon as they are identified. It is far better to discover your problems and address them internally than to have the government find them. To the extent you can prevent or avoid a government investigation, internal investigations also can reduce or eliminate adverse publicity that sometimes accompanies those investigations.

Planning an Internal Investigation

The most important component of an effective internal investigation is planning. Planning begins with basic considerations, such as analyzing possible conflicts of interest, defining the scope of the investigation, and identifying personnel with knowledge of the issue.

Measure twice, cut once

The organization should appoint a leader for the investigation and pick the investigative team. The organization also should determine whether or not to protect the investigation from potential disclosure to third parties through the use of attorney-client privilege or the work product protection.

At the outset, an internal investigation requires certain basic considerations. First, if there are multiple entities that are impacted or involved, separate counsel and investigative teams may be required. Second, the scope of the issue—both temporal and subject matter—should be well thought-out and properly framed. Third, the company must identify all personnel who are or may be involved in the process. Once determined, these important issues often dictate the direction of the investigation and suggest the most appropriate person to conduct it.

Identifying the leader of the investigation and investigative team

In considering the most appropriate person to lead an investigation, an organization should contemplate the nature of the reported issue, the dollar amount at stake, its potential impact, and relevant organizational policies and processes. General counsel, the compliance officer, the internal audit department, outside counsel, consultants, or any combination of the above can play a role in investigations. Counsel is often selected to lead an investigation because only attorneys can conduct a privileged, or confidential and legally protected, investigation. In health care settings, however, corporate compliance officers usually direct the investigation.

Compliance officers generally are responsible for establishing, implementing, administering, and monitoring compliance with the policies and procedures of the organization. The compliance officer also monitors and ensures compliance with applicable laws, regulations, and standards in the industry. In addition, the compliance officer must properly investigate and be the champion of a plan to correct any suspected noncompliance. To do this, however, the compliance officer must possess complete authority to conduct a proper internal investigation. He or she must be equipped with sufficient influence, resources, and access to the most senior leaders in the organization. Only under these circumstances can they ensure that an investigation is impartial and independent. He or she should not be beholden to particular persons or organizational interests; rather, the compliance officer's only interest should be to work toward compliance in the organization.

After a team leader is chosen, the health care entity should identify the rest of the investigative team at the outset as part of the planning process. To avoid conflicts of interest and an ineffective team investigation, some stakeholders may not be able to be a part of the investigating team. These stakeholders might be less inclined to divulge the facts if they discover that an internal mechanism that was under their command failed.

Finally, the organization should select a document custodian from the team at this time. The document custodian will then be responsible for locating and collecting all relevant documents. He or she also will organize and maintain the documents obtained during the investigation.

Developing a plan

The team selected to conduct the investigation should construct a detailed and thoughtful workplan, which can and should be refined as it is executed and more information is discovered. Each team member should clearly understand his or her role and the role of others as well.

Noncompliant conduct. The first step on every workplan should be to cease any potentially noncompliant conduct. Noncompliance usually occurs unintentionally, but it often continues after it has been reported. So, all questionable conduct must be stopped. Regardless of what is known or even suspected at the outset, the team should conduct the investigation as if the results of the investigation will be disclosed to the government.

Documentation procedures. The plan also should outline a document procedure. The flow of documents and other information will be critical to conducting an efficient and effective investigation. Obviously, all affected people and departments must be instructed to preserve documents. In addition, all routine document destruction should cease until the investigation is complete. As documents are collected in an attorney-directed investigation, they should be marked attorney-client privilege or attorney work product as appropriate. Electronic files should be marked similarly to the extent appropriate. Any questions or concerns regarding document labeling or retention should be referred to the document custodian.

Lastly, the team should consider the possibility of attorney-client privilege and/or the work product doctrine. Waiver can occur either voluntarily or involuntarily.

Whether to protect the investigation from potential disclosure to third parties

The organization should seriously consider whether to conduct the investigation under privilege in order to protect the information it anticipates discovering from interested third parties. Several issues should be regarded when making this decision.

One issue to consider is whether to engage an attorney or a non-attorney consultant. If an attorney is conducting the investigation, the attorney's umbrella of privilege will cover all retained experts

and others working at his or her direction. A nonattorney consultant, however, cannot protect the investigation or its results with privilege. The team should be mindful that any unfortunate information uncovered during a nonprivileged investigation can be obtained by the government and other third parties. The potential for bad paper, therefore, should factor into who should lead the investigation.

Another issue organizations should recognize is that protecting privilege in an internal investigation enables employees to speak more freely. An effective investigation relies heavily on employees' abilities to speak candidly and confidentially about the matter of concern. On the flip side, the organization also must realize that a prosecutor may look favorably on an organization that identifies wrongdoers, waives attorney-client privilege and work-product protection, and discloses the results of its internal investigation.

Conducting an Internal Investigation Under Privilege

If the internal investigation is to be conducted under privilege, then the organization can choose to use its own in-house counsel or it can use outside counsel. Both choices have advantages and disadvantages.

In-house counsel

In-house counsel often have institutional knowledge about the organization and understand its operations and policies. They also are aware of company politics and relationships. Many have cultivated relationships within the organization such that they are able to obtain candid information from their colleagues. Furthermore, in-house counsel are often more cost-efficient because the investigating employees are on the organization's payroll. This saves money and time because the organization does not have to spend funds on hiring external help and the investigation can proceed immediately.

On the other hand, there are disadvantages to using internal resources. For example, the government may comprehend that the investigation lacked independence and impartiality. Furthermore, conflicts of interest can arise if the wrongdoer is a high-level stakeholder. Finally, although the financial cost may be lower using in-house counsel, the time internal personnel devote to an investigation is a significant organizational resource that is more difficult to quantify.

Outside counsel

Using outside counsel also has several advantages. The government often considers outside counsel to be independent and unbiased. Outside counsel usually can be more objective when assessing compliance issues because they generally have no loyalties or interests within the organization. As a result, counsel can act more decisively and cleanly maintain attorney-client privilege and work product protection. In addition, outside counsel usually have more breadth of experience with respect to legal compliance issues and can identify possible issues of administrative, criminal, or civil fraud. Additionally, they may have developed relationships with government agents from previous work.

There are two big disadvantages to utilizing outside counsel to lead and conduct an investigation. First, it will cost significantly more. Second,

outside counsel have a steeper learning curve when learning and attempting to understand the structure and character of the organization.

Privilege and its use

Regardless of whether in-house counsel or outside counsel conducts the investigation, one of the main reasons for using an attorney is to protect the information learned during the investigation. This allows the organization to decide the circumstances under which it wants to reveal the results. Absent some form of protection, the results could become available for both the government and private litigants to use in current or future investigations or litigation.

Organizations can take advantage of two primary protections: the attorney-client privilege and the work product doctrine. These protections (and others in some jurisdictions) vary depending on the jurisdiction, but the general concepts are similar.

Attorney-client privilege. The attorney-client privilege protects all communications between an attorney and the client. Its purpose is to promote the full and frank communication between attorneys and their clients. *Upjohn v. U.S.*, 449 U.S. 383, 389 (1981). Privilege cannot, however, be used to prevent the dissemination of factual information. For example, pre-existing documents that are analyzed during an investigation are not privileged. Employees should understand that documents they give to counsel during an internal investigation may not be privileged. Nonconfidential matters of employment or communications made in furtherance of a crime also are not privileged.

Once the privilege is established, the organization must protect it. First, the organization must implement internal mechanisms to ensure effective reporting on noncompliance issues. Second, the organization must assure its employees that they can speak candidly about compliance issues without worry of retaliation. Third, the organization must maintain and protect its documents in an orderly fashion to ensure that privilege is not waived by accident or on purpose. In sum, assertive steps must be taken to protect this privilege.

Work product doctrine. The work product doctrine covers work relating to preparation of the case. It is another protection that can be used by an organization that wants to protect the information discovered during an investigation. Work product includes material prepared or mental impressions developed in anticipation of litigation or for trial. Generally speaking, work product refers to an attorney's or organizational agent's mental impressions, opinions, conclusions, or legal theories.

Joint defense privilege. The joint defense privilege is another commonly used privilege that arises when parties agree that they can share an attorney, or when parties agree that their respective attorneys can share information in defense of common claims against them. The parties also consent to exchange confidential information for their mutual benefit and agree to protect this information from disclosure. This is a judicial doctrine derived primarily from the attorney-client privilege. A disclosure made in the confidence of a jointly privileged communication is not a waiver of the privilege.

Whether or not to waive any of these privileges is a serious consideration. Privilege can protect against "bad paper" and can allow employees to be more candid in their interviews. This could result in a more fruitful investigation. If there is wrongdoing, though, the government looks favorably on organizations that identify

wrongdoers, waive the attorney-client privilege and work-product protection, and disclose the results of their internal investigation. All members of the investigative team should seriously contemplate the advantages and disadvantages of waiving privilege.

Conducting the Investigation

Conducting an investigation requires several important steps, including notification of employees; identification of potential witnesses; establishment of interview teams and identification of who will be interviewed; documentation of all of the steps taken to conduct the interview; and evaluation of the processes and creating a solution.

First, any employees who could be affected by the investigation should be notified about it. Each of them should be made aware in general terms of the investigation. The investigator also should inform the employees that they are expected to cooperate fully with the process, that truth and candor are necessary to the success of the process, and that information will only be given on a "need to know basis." This is important to mention, especially to high-level employees. No employee outside the investigative team, regardless of senior or superior positions, should expect regular updates on investigative actions or findings. Keeping the results of the investigation within the confines of the team helps reduce the potential for conflicts of interest and waiver of privilege.

Second, the investigator should identify all the potential witnesses. Witnesses, for example, can be the complainant, parties with knowledge of relevant facts, parties named in the complaint or in any related documents, and third parties. After determining this, the lead investigator should create a strategy to gather this information.

Third, the investigative team leader must carefully plan the interview teams and decide who to interview. This is important because employees may be hesitant to be candid if their immediate supervisor is appointed to talk to them. Employees may fear for their jobs or believe that their work environment would be threatened if they voiced a complaint about a particular process or person.

The interviewer must make it clear that his or her client is the organization, not the employee. The employee must know this and understand that he or she can retain their own counsel if they feel the need to do so. The interviewer also should inform the witness about the purpose of the investigation and reveal that the conversation is protected by the attorney-client privilege, unless the organization waives that privilege. Regardless of what the organization does with the information, the employee should be instructed to keep the information confidential. Lastly, the interviewer should admonish the employee to be truthful and that his or her employer expects truthful responses during the interview.

Fourth, the investigator must document all steps taken to complete the investigation. For example, the investigator should note who was interviewed, which documents were reviewed, and which regulations were analyzed, and maintain the notes and impressions gathered during the interviews. The investigator must maintain all the relevant documents separately. These documents must be protected to maintain privilege. They also must be protected to ensure that no evidence is tampered with or destroyed.

Finally, the investigator should evaluate the entire processes to determine whether any acts of noncompliance occurred and develop a solution.

Conclusion

The internal investigative process is a complicated process that requires considerable experience, thought, and resources to execute. Organizations should thoughtfully consider the potential scope of the problem, the personnel involved, the potential conflicts, the best person to lead the investigation, and whether and how to conduct the investigation under privilege.

Simply validating the existence of an issue regularly requires substantial work. Once validated, the issue must be thoroughly investigated. Based on the documents reviewed, the information obtained from witness interviews, relevant research relating to the issue being investigated, and working with the people with ultimate responsibility, the investigative team can define the extent of the noncompliance and its impact on the organization. Only then can an organization determine whether and the manner in which it should remedy or disclose the issue. ■

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Trends

Senators question safety of specialty hospitals

Gené Stephens, J.D.,
Contributing Editor

Ranking Senate members questioned the Secretary about patient safety and quality of care in physician-owned specialty hospitals after an 88-year-old woman died at an Oregon specialty hospital. The hospital should not have qualified for Medicare participation because it opened during a federal moratorium on new specialty hospitals imposed under the Medicare Modernization Act of 2003. The purpose of the moratorium was to determine if such hospitals caused harm to patients and federal health care programs. The senators called on the Secretary to investigate why the Oregon facility was allowed to open during the federal moratorium and determine whether other specialty hospitals were opened during the moratorium period.

Adequacy of patient care. Senators commented that patients should expect to receive a full range of medical services at specialty hospitals rather than receive care as if they were at a clinic. At the Oregon facility, there was no doctor on site when the woman suffered a cardiac arrest following an elective back surgery. Nurses at the specialty hospital had to call 911 for additional medical assistance because there was no emergency department. Information from investigative reports revealed that nurses made multiple unsuccessful calls to several physicians for assistance just before the patient stopped breathing. The senators questioned whether the surgery was appropriate given the patient's abnormal laboratory values prior to the surgery.

Hospital procedures, policies. The Oregon case highlights the concern regarding emergency care policies of specialty hospitals. Senators have called for an investigation of physician-owned specialty hospital procedures including the dissemination of patient disclaimers regarding hospital procedures in the event of a life-threatening emergency. The senators also asked CMS to answer questions concerning whether federal health care program funds should be paid to specialty hospitals that lack either a physician on duty or a physician on call. ■

CCH Chicago Bureau, Feb. 14, 2006.

In the News

Lawmakers seek changes to improve Medicare Part D

Several lawmakers from both chambers, including House Democratic Leader Nancy Pelosi, (D-Cal) and Sen. Richard Durbin (D-Ill) are calling for changes to the Medicare Part D prescription drug benefit. "The Republican prescription drug benefit is confusing and complicated," Pelosi said on February 15. What seniors "have today is a confusing benefit, a law that prohibits Medicare from negotiating with pharmaceutical companies and a plan that guarantees drug companies billions of dollars in profits," according to Durbin. House and Senate Democrats held events during the President's Day work period and discussed problems seniors and those with disabilities face with the system. They plan to offer a series of proposals to improve the program. ■

CCH Washington Bureau, Feb. 15, 2006.

IPA, FTC settle on price fixing charges

A physicians' independent practice association (IPA) in Texas has agreed to settle Federal Trade Commission charges that it engaged in unlawful collective bargaining with health insurance plans. The IPA claimed it employed a messenger model process to negotiate contracts; however, if properly orchestrated, a messenger model process does not restrain competition. If approved, the consent order would prohibit the IPA from entering into or facilitating agreements: (1) to negotiate with payors on any physician's behalf; (2) to deal, refuse to deal, or threaten to refuse to deal with any payor; (3) to designate the terms upon which any physician deals or is willing to deal with any payors; or (4) not to deal individually with any payor, or to deal with any payor only through any arrangement involving the IPA. ■

FTC Consent Order, Feb. 13, 2006, Health Care Compliance Reporter, ¶1680,006.

Revised Part D formulary guidelines

The U.S. Pharmacopeia (USP) has revised the Medicare prescription drug benefit Model Guidelines for 2007. Under the Medicare Modernization Act, the USP is responsible for creating Model Guidelines and revising the guidelines when necessary "to reflect changes in therapeutic uses of covered part D drugs and additions of new covered part D drugs." The new guidelines include eight additional therapeutic categories and have eliminated twenty pharmacological classes. The revised Model Guidelines, Model Guidelines Version 2.0, may be used by drug plans as they design their formularies for the 2007 benefit year. ■

USP Press Release, Feb. 1, 2006.

Tenet settles Florida RICO suit

Florida's Attorney General announced that an agreement has been reached with Tenet Healthcare Corporation resolving allegations that Tenet violated the federal and Florida Racketeer Influenced and Corrupt Organization (RICO) Acts. Tenet was accused of artificially increasing charges to improperly access the Medicare Outlier Fund. Public hospitals depend on the Outlier Fund, to obtain reimbursement for expensive procedures whose costs greatly exceed Medicare's standard reimbursement rates, such as coronary bypass surgery. Under the settlement, Tenet will contribute close to \$6 million to be disbursed to public hospitals according to the level of indigent care and expensive procedures provided by each facility and will repay the state approximately \$1 million for costs of the investigation. The settlement ends all investigations of Tenet by the Florida Attorney General, including two Medicaid billing cases. ■

Florida Attorney General Press Release, Feb. 21, 2006.