CCH Health Care Compliance LETTER

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Recent changes to the U.S. Sentencing Guidelines

by Gene' Stephens, J.D., Contributing Editor

On November 1, 2005, the United States Sentencing Commission (USSC) issued amendments to the Federal Sentencing Guidelines. The recent amendments respond to the continued regulatory and government focus on corporate responsibility, fair competition, and intelligence reform. Additionally, the latest amendments compliment the seven fundamental elements of an effective health care compliance program by providing heightened penalties for antitrust violations involving price-fixing schemes and intellectual property offenses for pre-released works. To provide further guidance to corporate officers and compliance professionals, the antitrust amendment provides a new "volume of commerce table" that recognizes the depreciation in the value of the dollar in response to data indicating that the financial magnitude of antitrust offenses have increased significantly over the years.

Emergency amendments. Two emergency amendments to the Sentencing Guidelines became effective on October 24, 2005. These emergency amendments included changes to the crimes for obstruction of justice and intellectual property rights. The emergency amendment for obstruction of justice provides a twelve-level increase in the base offense level when the statutory maximum term of imprisonment relating to international or domestic terrorism is applicable. The base level increase was intended to provide parity with the treatment of the federal crime of terrorism within the limits of the eight-year statutory maximum penalty allowed by the Intelligence Reform and Terrorism Prevention Act of 2004. The amendment also ensures a five-year sentence of imprisonment for offenses that involve international or domestic terrorism.

The second emergency amendment implements the directive in the Family Entertainment and Copyright Act of 2005 that required the USSC to review and amend, where appropriate, the Sentencing Guidelines and policy statements for persons convicted of intellectual property rights crimes. The amendment provides a two-level enhancement for intellectual property offenses involving a pre-released work. For such cases, the infringement amount is determined by using the retail value of the infringed item, however, the amendment allows the courts flexibility to make a reasonable determination of the infringed amount.

Additional amendments. In addition to the emergency amendments, the USSC promulgated a new guideline for aggravated identity theft. The new guideline, which is consistent with statutory provisions recently enacted by Congress, provides for consecutive mandatory minimum sentences of two and five year for identity theft offenses dependent upon the underlying associated offense involving the misuse of stolen identification. The USSC also has increased the penalties for person who unlawfully obtain or misuse means of identification by abusing or exceeding the authority of their position.

Trends (cont.)

The most significant enhancement to the Sentencing Guidelines that coincides with the roles of corporate compliance officers is the amendment to the antitrust guidelines, which provides an increase in the maximum term of imprisonment for Sherman Act violations from three years to ten years. The purpose of the heightened penalties for antitrust violations was to serve as a deterrence to large-scale anticompetitive arrangements and crimes. This amendment directly relates to the recent onset of cases involving investigations by the Federal Trade Commission against provider and physician group practice price-fixing schemes.

Compliance professionals should review their current corporate operating standards and procedures against these latest amendments to test the effectiveness of their compliance programs. ■

United States Sentencing Commission, Federal Sentencing Guidelines, November 2005.

Tax Exempt

IRS to conduct compliance checks of exempt entities in 2006

by Angela Johnson, Contributing Editor

At the ALI-ABA conference on Tax-Exempt Charitable Organizations held in Washington, DC on December 1, Eric San Juan of the Treasury Department's Office of Tax Policy and Marvin Friedlander, Chief of the Exempt Organizations (EO) branch of the IRS joined in presenting a review of the recent developments at Treasury and the IRS.

San Juan focused on proposals of the President's Advisory Panel on Tax Reform's recommendations that would impact exempt organizations, including recent guidance of a variety of issues affecting charitable organizations, and stated that guidance will be issued over the course of the next year.

Friedlander reviewed structural changes in positioning the IRS to manage current issues. He covered EO workplans over the next year, the opening of a new compliance office and an office to review operations.

Work plan. Marvin Friedlander explained that the Fiscal Year 2006 Exempt Organizations Implementing Guidelines (work plan), released in late October, spells out some major changes in the division. The changes are being made in response to the extraordinary amount of scrutiny of the EO sector being seen in the popular press. He added that the scrutiny is "fueled by one scandal after another ... watch dog groups, reporters, and our friends in Congress have no problem pointing this out to the IRS."

Compliance office created. Friedlander stated that a new compliance office is opening in Exempt Organizations to help examine, investigate, analyze data, and record-keep for the division. He said the group's major responsibility will be to examine large-scale statistics on EOs for abuse patterns and grey areas, and to spearhead large-scale compliance checks. He also hopes that, with the addition of this office and its reports, the criminal investigation units will be more understanding of the gravity of abuse seen in EOs.

In addition, Friedlander reported that there will be a new office known as "ROO," short for Review of Operations. This group will look for "gaps" in the EO processing system, such as exemptions that were granted, but with questions about the validity of the grant, or when new information comes to light after tax-exempt status is given. Friedlander said that the group will cross-check the charity's information with its Form 990 for verification.

Friedlander took pains to mention that other areas in the Exempt Organizations division will suffer. He said that private letter rulings will not go out as quickly and that pre-rulings will be considered a low-priority. To aid organizations through this priority change, Friedlander told the group that exempt applications will remain a high priority, with an easy applications complete in as little as 30 days. He also mentioned the implementation of a "cyber assistant" to aid, although not solve, a time-lag problem for the longer applications. ■

CCH Washington Bureau, December 2, 2005.

CCH Health Care Compliance Letter

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Executive compensation and excess benefit transactions draw IRS scrutiny

by Andrew Maschas, Contributing Editor

In light of recent scandals involving large compensation packages paid to officers and directors of tax-exempt organizations, Internal Revenue Service (IRS) Manager David Fish reported at a DC Bar Tax luncheon on November 20, 2005, the IRS is updating forms and issuing new regulations in order to ensure compliance with laws already in place to prevent such abuses.

Determining problem areas. Fish reported that before taking action by starting to update forms and regulations, the IRS first contacted over 1800 exempt organizations to determine the problem areas. Of these contacts, 1200 were compliance checks. Some of the triggers that led to the IRS contacting an organization included filed forms that had some questions unanswered or without explanation and forms that failed to list compensation paid to a director. Fish stated that the letters sent at the start of an IRS exam were much more detailed than a typical tax return. They usually involved questions such as how compensation is established and the duties and responsibilities of the organization's officers.

Fish highlighted some observations the IRS discovered after contacting tax-exempt organizations. He emphasized that compliance check letters were working. The IRS has found that exempt organizations are making substantial loans to insiders, fragmenting an officer's compensation among related organizations, and inaccurately reporting deferred compensation. He also admitted that there is a general lack of clarity in the forms and instructions.

Formulating appropriate compensation. Galina Kolomietz, a General Attorney in the IRS Chief Counsel's Office, also spoke, giving practitioners advice on establishing compensation. She emphasized that board oversight is extremely important and that this can be done in several steps. First, the board should establish legal protection by meeting the rebuttable presumption of reasonableness when setting compensation. Second, the board should make sure that forms are timely filled out properly to avoid any automatic excessive benefit transactions. Last, she stated that transparency is important, that even though boards are in the practice of delegating duties, it is still ultimately responsible for any compensation decisions.

Both Fish and Kolomietz discussed the changes to 2005 Form 990, including a clarification to the total number of directors to be listed, and payment of compensation. The revised Form 990 also includes a table for former officers and directors that are receiving compensation. Schedule A to Form 990 currently has a table to include compensation to the five highest paid independent contractors for professional services; the 2005 form will include a table for independent contractors for other services in addition.

Fish and Kolomietz also reviewed the recently proposed regsec 1.501c(3) issued in September. The regs are divided into 3 parts. The first and third parts contain examples of when exemption status will be revoked and the second part lists factors the IRS will consider when revoking exemption status. Kolomietz emphasized that it was important for organizations to put mechanisms in place to correct over-compensation problems and to contact the IRS if an organization feels that cannot correct its compensation structure. The proposed regs remain open for comment until December 8, 2005. In the meantime, instructions to Form 990 are being formulated right now and will be issued shortly. ■

CCH Washington Bureau, December 2, 2005.

On The Front Lines

We've Complied with HIPAA; now What? Preparing for and Responding to HIPAA-Related Complaints and Government Investigations

by W. Andrew H. Gantt III, J.D. and Anthony B. Casarona, J.D.

Part II of this article discusses government investigations and what to expect following a government investigation. If, instead of a third party complaint, a covered entity receives notice of a government investigation, including a compliance review, or a "surprise visit" by a government official, again, the first plan of action is to follow the procedures that have been put in place for this type of situation.

The first step in being prepared to respond to a government investigation is to make sure that an individual has been appointed to coordinate the covered entity's response to the investigation. This will likely be the covered entity's privacy or security officer. However, it is important that this individual be calm under pressure, so it may be necessary to appoint someone else if the covered entity's privacy or security officer do not posses this trait.

The designated individual should first verify the identities and authority of the investigators and attempt to ascertain the nature of the investigation and the alleged violations that are the basis for the investigation. In addition, the designated individual should attempt to determine whether there are any law enforcement personnel present, which will help in making an initial assessment of the severity of the situation. Once this information has been obtained, the designated individual should alert outside legal counsel and other key personnel to coordinate the covered entity's response and to ensure that everyone within the organization is aware of the situation and is receiving consistent information.

After ascertaining the authority of the investigators and the basis for the investigation, the designated individual must begin the balancing act of cooperating with investigators while also ensuring that only that information which is specifically sought is disclosed. The first step in this process is to determine which workforce members are needed to comply with the investigator's requests. Ideally, this will be the designated individual and as few additional people as possible. Members of the workforce who are not necessary to the investigation should be kept out of the way of investigators, if possible, to ensure that the investigators are receiving consistent information and to establish that, unless otherwise directed by a subpoena or required pursuant to applicable law, there will be one point of contact. Of course, those members of the workforce who are present and must interact with the investigators should be cooperative and instructed not to hide or conceal facts or otherwise mislead investigators. The next step in this process is to demand inspection of any warrant, subpoena, or other authority for the investigators being present, to verify, with the assistance of legal counsel, the authority of the investigators (e.g., to verify that the information being sought is directly related to a legitimate investigatory purpose).

Once investigators have verified their identities and have also verified their authority, HIPAA requires that PHI that is the subject matter of the investigation, or reasonably related to the investigation be provided to them in accordance with the covered entity's notice of privacy practices and applicable federal and state law. However, specificity is critical here and only those records specifically identified in a warrant, subpoena or other authority need be surrendered or provided for review. A covered entity should also be aware of other federal or state laws which could limit the extent to which the records sought may be disclosed. If the investigators seek records that are not specifically described in a warrant, subpoena or other authority, the covered entity may decline to provide them and ask for a request in writing so there will be no misunderstanding about the documents that are being sought. While it is important to render courteous cooperation with the investigators, a covered entity is not required to leave investigators alone to "look around." The designated individual or another authorized member of the covered entity's workforce should escort and monitor the investigators at all times while they are present and document the areas searched and a list of information seized.

When the investigators have completed their work onsite, the designated individual should promptly request an exit conference in order to learn additional details of the investigation, if any violations have been discovered, and if the company will be involved in any further investigative activity. While all of this information may not be provided or even known at the time the investigators complete their search, anything obtained from them will be beneficial as the covered entity and its legal counsel devise a strategy for dealing with the investigation.

What to Expect Following a Government Investigation

In general, if no violations are discovered following an investigation by the Office for Civil Rights (OCR) or CMS, the covered entity will be notified in writing and the matter will be considered closed. If, however, a violation or violations are discovered, the covered entity will be given an opportunity to resolve the matter through informal means such as a corrective action plan. Although HHS has stated that it will attempt to resolve HIPAA compliance matters by informal means wherever possible, a covered entity may face significant penalties and fines if such informal resolution is not successful.

The Enforcement Rule emphasizes that violations may occur when a covered entity takes an action prohibited under HIPAA, as well as when a covered entity fails to take an action which is required under HIPAA. Covered entities may be subject to civil monetary penalties ("CMPs" of not more than $100 for each violation of the Privacy Rule or Security Rule up to a maximum of $25,000 for all violations of the same provision or requirement in a calendar year (a single action may violate more than one provision of the Privacy Rule and/or Security Rule and could, therefore, constitute a separate violation for each provision violated). In determining the amount of CMPs, HHS may consider the following factors: (1) the nature of the violation; (2) how the violation occurred; (3) the covered entity's degree of culpability; (4) the entity's history of prior offenses; (5) the entity's financial condition; and (6) such other matters as justice may require. However, the Enforcement Rule provides for several affirmative defenses, the existence of which will prohibit the imposition of CMPs. In particular, CMPs may not be imposed if: (1) the violation is an act punishable under HIPAA's criminal penalty provisions; (2) the covered entity establishes, to the satisfaction of HHS, that it did not have knowledge of the violation and, by exercising reasonable due diligence, would not have known that the violation occurred; and (3) the violation is due to circumstances that would make it unreasonable for the covered entity to comply with the provision violated and was corrected within thirty days of the date the covered entity became aware of the violation or such additional period as HHS determines to be appropriate under the circumstances. The government also has the authority to negotiate a settlement with the covered entity, a fact which further emphasizes the importance of cooperating with the government from the outset of any investigation. Under the Enforcement Rule, the imposition of CMPs will be made known to certain state and local agencies, as well as the general public through posting on HHS' website, publication in the Federal Register or other means of disseminating such information as HHS deems appropriate.

The Enforcement Rule provides for a detailed administrative hearing and appeals process with respect to the imposition of CMPs. Significantly, the rule adopts the doctrine of collateral estoppel, which means that once a matter has been decided pursuant to HHS' administrative procedures, it may not be readdressed by the same parties in any other matter involving HIPAA violations. Thus, in the event that CMPs are imposed, a covered entity should appeal the decision of the administrative law judge if it has any doubt regarding the outcome of the hearing. Otherwise, it will be precluded from doing so later based on the doctrine of collateral estoppel. In instances where a violation is found, but no CMPs have been assessed, a covered entity does not have a right to appeal the determination. Thus, a covered entity that wishes to challenge the findings of the administrative law judge should raise objections in order not to be precluded from later doing so under the doctrine of collateral estoppel.

Under the Enforcement Rule, the ability to impose CMPs is in addition to, not exclusive of, any other penalties prescribed by other federal or state laws, with certain exceptions. One notable exception provides that CMPs may not be imposed in respect of an act that constitutes an offense punishable by criminal penalties under HIPAA. HHS may impose criminal penalties against anyone who knowingly obtains, uses or discloses PHI in violation of HIPAA. Significantly, the Department of Justice has indicated that the "knowingly" element of a HIPAA criminal offense does not require knowledge that the offensive conduct violated HIPAA, but, instead, requires only proof of knowledge of the facts that constitute the offense.

Conclusion

Although thousands of complaints have been filed with the OCR, the number of HIPAA violations to date have been few and the number of HIPAA-related criminal actions has been even less. However, it is inevitable that, as the government shifts its focus from implementing to enforcing the Privacy Rule and Security Rule, the number of violations and criminal actions will rise.

In addition to a comprehensive HIPAA compliance plan, a well though out plan for responding to HIPAA complaints and government investigations can serve as the first line of defense for covered entities when they are faced with such actions. With some advance planning and preparation, covered entities will find themselves in the best position to dampen the initial shock and conclusive impact of HIPAA-related complaints and government investigations. ■

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On The Front Lines (cont.)

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[1] 70 FR at 20,226.

[2] *Id.* at 20,229.

[3] *Id.* at 20,234.

[4] *See id.* at 20,235.

[5] *Id.* at 20,236-39.

[6] *Id.* at 20,240.

[7] *Id.* at 20,240.

[8] *Id.* at 20,242.

[9] *Id.* at 20,240.

[10] *Id.*; 42 U.S.C. § 1320d-5(b)(1).

[11] 42 U.S.C. § 1320d-6(a).

[12] *Id.* at § 1320d-6(b).

[13] See Memorandum dated June 1, 2005, from U.S. Department of Justice, Office of Legal Counsel to Alex M. Azar II, General Counsel, Department of Health and Human Services and Timothy Colemen, Senior Counsel to the Deputy Attorney General re: Scope of Criminal Enforcement Under 42 U.S.C. § 1320d-6 (available at http://www.worldprivacyforum.org/pdf/hipaa_opinion_06_01_2005.pdf.

Fraud & Abuse

Guidance issued for PHS grant recipients

by Gené Stephens, J.D., Contributing Editor

In coordination with the National Institutes of Health (NIH) and other Public Health Service (PHS) agencies, the Office of Inspector General issued a draft guidance to encourage the use and development of internal controls by PHS grant recipients for the effective monitoring of NIH biomedical and behavioral research program related requirements and regulations. The guidance provides research institutions with methods for avoiding criminal and civil fraud investigations related to the misuse of program grant funds. The OIG further recommended that recipients of PHS research awards use the seven fundamental elements of an effective compliance program as a guide for the development of internal controls. The elements include: (1) implementing written policies and procedures; (2) designating a compliance officer and committee; (3) conducting effective training and education; (4) developing effective lines of communication; (5) conducting internal monitoring and auditing; (6) enforcing standards through well-publicized disciplinary guidelines; and (7) responding promptly to detected problems and undertaking corrective action. An eighth element, defining roles and responsibilities, was added to the list by the OIG for PHS grant recipients and is believed to be especially important for research institutions. Finally, the guidance provides information on financial support reporting and stresses the importance of properly reporting the allocation of grant funds and charges. ■

Notice, 70 FR 71312, Nov. 28, 2005.

Drug manufacturer PAPs for Part D enrollees present anti-kickback risk

by Sheila Lynch-Afryl, J.D., Contributing Editor

Arrangements that subsidize the cost-sharing obligations of patients covered under the Medicare Part D prescription drug plan through the use of patient assistance programs (PAPs) that are affiliated with pharmaceutical companies present heightened risks for fraud and abuse under the anti-kickback statute, according to a Special Advisory Bulletin published by the Office of Inspector General. Types of abuse that may occur as a result of the manufacturer giving subsidies to beneficiaries to use its products include increased costs to the Medicare program, steering beneficiaries to a

OIG 2006 work plan targets vulnerabilities in Medicare Part D

by Sheila Lynch-Afryl, J.D., Contributing Editor

During fiscal year (FY) 2006, the Office of Inspector General (OIG) will focus its investigations of fraud and misconduct on pharmaceutical fraud and vulnerabilities in the Part D program. Because of the business relationships that will be formed under Part D, the OIG is anticipating violations such as kickbacks, billing for services not rendered, false statements, prescription shorting in institutional settings, and telephone scams. Audits and inspections will focus on the administration of the Part D program, including CMS program integrity safeguards for Medicare drug plan applicants and beneficiary awareness of the Part D low income subsidy. Other areas that the OIG will focus on in FY 2006 include: (1) adjustments for graduate medical expenses; (2) home health outlier payments; (3) oversight of hospice providers; and (4) Medicare drug reimbursement. In addition to the projects outlined in the work plan, the OIG will continue its oversight of HHS programs relating to Hurricanes Katrina and Rita, but the planning for this area was in progress at the time the document was finalized.

OIG Work Plan Nov. 19, 2005, ¶540,043.

particular drug, and reducing beneficiaries' incentives to locate and use less expensive, equally effective drugs.

Cost-sharing subsidies provided by *bona fide*, independent charities that are unaffiliated with pharmaceutical manufacturers, however, should not raise anti-kickback concerns, even if the charities receive contributions from the pharmaceutical manufacturer.

There are nonabusive alternatives available. For example, nothing in the Part D program, laws, or regulations prevents pharmaceutical manufacturers from providing assistance to uninsured patients or from waiving cost-sharing amounts owed by Medicare beneficiaries on the basis of a good faith, individualized assessment of the patient's financial needs, as long as the waiver is neither routine nor advertised. In addition, PAPs may elect to provide free drugs to financially needy Medicare Part D enrollees outside of the Part D benefit.

PAPs need not disenroll all Medicare beneficiaries from their existing PAPs to be compliant with the fraud and abuse laws. Enrollment in Part D is voluntary; therefore, existing PAPs may continue to provide free or reduced price out-patient prescription drugs to Medicare beneficiaries who have not yet enrolled in Part D. ■

Notice, 70 FR 70623, Nov. 22, 2005, CCH Health Care Compliance Reporter, ¶760,011.

Release bars employee from filing qui tam action

by Catherine Geraghty, J.D., Contributing Editor

A former hospital employee was denied relief against a hospital corporation that provided management services to his employer because he signed a severance agreement with the employer that barred him from filing suit under the *qui tam* provision of the False Claims Act (31 U.S.C. § 3730(b)), which allows a private citizen to file suit on behalf of the federal government when fraud is alleged to have occurred. The employee agreed to release the hospital and its officers and agents from "any and all claims, demands, actions, and causes of action of any kind or nature, known or unknown, arising or existing until the date of this instrument" in exchange for the hospital's payment of more than $124,000. The employee alleged that during his employment with the hospital from the mid-to-late 1990's through part of 2000, the corporation was responsible for improperly billing: (1) charges not permitted under the Medicare Bulletin 1836, (2) durable medical equipment, (3) observation room services, (4) Medicare services provided without physician's orders, (5) cardiac rehabilitation services, and (6) mental health unit services. Public policy did not bar enforcement of the contract under the particular facts of this case because disallowing a litigant who has agreed to release his right to serve as a relator from maintaining a *qui tam* action, who then seeks to renege on the agreement, does not discourage those with relevant information concerning fraud against the government to come forward. Moreover, the employee did not have a public duty to bring the *qui tam* action and Congress did not provide private citizens with an unfettered right to proceed as relators. The hospital corporation's motion to dismiss was granted. ■

U.S., ex rel. Ted Whitten v. Triad Hospitals, Inc., Oct. 27, 2005, CCH Health Care Compliance Reporter, ¶800,062.

HIPPA

Constitutional challenges to release of PHI without consent invalid

by Andra Popa, J.D., LL.M, Contributing Editor

Constitutional challenges to the Secretary's amendment of a mandatory rule that patient consent must be obtained before the routine use of protected health information (PHI) to a permissive rule were invalid because state action requirements were not met. A patient advocacy group alleged that the covered entities' disclosure of PHI without patient consent violated due process and freedom of speech rights.

The advocacy group challenged the amendment on the basis of the alleged injury caused by private entities using and disclosing PHI without patients' permission and against their will. The Constitution protects only against state interference with these rights and, to meet state action requirements, the Secretary's promulgation of the amended rule must permit covered entities to engage in behavior prohibited prior to the amendment.

The amended rule does not compel covered entities to use PHI without patient consent, but states that these entities "may" obtain consent. Accordingly, covered entities must continue to honor routine requests for privacy and applicable state privacy laws, and the amended rule retains most of the Health Information Portability and Accountability Act (HIPAA) (PubLNo 104-191) privacy protections of the original rule. In addition, the advocacy group's HIPAA claims were invalid because the Secretary did not exceed the regulatory authority granted by HIPAA and did not eliminate rights in amending the original rule because the rule was not in effect when it was amended.

The Secretary promulgated the amended rule through the proper administrative rulemaking process by demonstrating: (1) a rational connection between the final rule and the relevant data that informed the decision and (2) adequate notice to the public of his intention to rescind the consent requirement. The district court's grant of summary judgment on all claims was affirmed. ■

Citizens for Health v. Leavitt,, U.S. Court of Appeals for the Third Circuit, Oct. 31, 2005, ¶800,054.

Ordinance regulating hospital construction not an antitrust violation

by Sheila Lynch-Afryl, J.D., Contributing Editor

An ordinance that required county approval for the construction of new health care facilities did not violate the Sherman Act because it merely required obedience with the regulatory commands of a local government and did not constitute a conspiracy, according to the U.S. District Court for the Southern District of Indiana.

The county, which owned and operated a hospital, passed an ordinance imposing a moratorium on the construction of specified health care equipment and facilities in the county until December 31, 2005, and required the county commissioners to approve the construction of such facilities after that date. When the ordinance took effect, the only other hospital in the county had incurred costs and entered into an agreement for a $40 million expansion project, which the ordinance stalled.

The hospital alleged that the ordinance was preempted by §1 of the Sherman Act because it compelled the hospital to enter into a horizontal conspiracy to allocate the market for health care in the county. The court held that the county's actions to protect its hospital from competition were not protected by the state action doctrine because of the state's preference for competition in health care. Neither a contract nor conspiracy existed, however. Enactment of and compliance with a local ordinance, even if the effect is to restrain trade, amounts to obedience with the regulatory commands of a local government and does not constitute a conspiracy for Sherman Act purposes.

The court also found that (1) the state home rule act preempted application of the ordinance to hospital construction and expansion due to state regulations on the construction of new and expanded hospital facilities, and (2) the hospital's rights were not violated under the Religious Land Use and Institutionalized Persons Act because the hospital failed to establish that the ordinance imposed a "substantial burden." ■

Sisters of St. Francis Health Services, Inc. v. Morgan County, Indiana, S.D. Ind., Nov. 2, 2005, CCH Health Care Compliance Reporter, ¶800,059.

E-record plans for gulf

CMS has entered into agreements with two organizations to coordinate the planning for the digital recovery of patient records destroyed during the recent hurricanes in the Gulf Coast region and develop a prototype of health information sharing and electronic health record support that can be replicated throughout the affected Gulf Coast region. The instant destruction of paper records during the recent hurricanes demonstrated the need for an interoperable electronic health care records system, particularly since most providers and payers using electronic medical records were able to preserve their systems and patient information. The agreements establish a task force of local and national experts that will assist providers to turn to electronic medical records as they rebuild. These initiatives complement recent announcements related to the national advancement of electronic health records and the sharing of health information from the Office of the National Coordinator for Health Information Technology, including efforts related to the certification of electronic health records and the development of standards for interoperability. ■

CMS Press Release, Nov. 17, 2005 .

Final rule for e-prescribing and the prescription drug program

The adopted electronic prescribing standards address system and software requirements that will permit communications between providers, dispensers, and prescription drug plan sponsors. The requirements are considered "foundation standards" and represent the first step in an incremental approach to implementing electronic prescribing, which is expected to promote efficiencies and cost saving in the delivery of care. All plan sponsors are required to support and comply with the e-prescribing standards. Although prescribers are not required to write prescriptions electronically, those that conduct electronic prescription transactions are required to comply with the rule. Furthermore, certain Stark exceptions and anti-kickback safe harbors are anticipated to encourage providers to participate in e-prescribing incentive programs. The rule also addresses preemption of state laws and applies the Medicare Modernization Act of 2003 (PubL No108-173) preemption provision to all beneficiaries who are eligible to participate in the drug benefit regardless of their enrollment status. ■

CMS Press Release, Nov. 17, 2005, CCH Health Care Compliance Reporter, ¶700,003.