

HCCH Health Care Compliance LETTER

Volume 9, Issue 7

health.cch.com

April 3, 2006

On The Front Lines 4

HHS recognizes value of measured approach to enforcement in HIPAA final rule

by **Sanford V. Teplitzky, Esq.**
and **John F. Lessner, Esq.**,
Contributing Editors

Charity Care 1

- Illinois' proposed charity care law draws national attention
- Grassley urges AHA to be more active in nonprofit reform

Antitrust 3

- Physician's antitrust challenge focuses on HCQIA immunity, level of scrutiny
- FTC reforms the merger review second request process

Fraud and Abuse 8

- Thomas calls on OIG to finalize excessive claims rule

In the News 8

Illinois' proposed charity care law draws national attention

by **Stephen K. Cooper, Contributing Editor**

In a closely watched battle between Illinois state regulators and the nonprofit hospital industry, Attorney General Lisa Madigan is seeking an answer to the question of whether taxpayers are receiving their money's worth in return for the tax exempt benefits that hospitals enjoy. Madigan's legislation, the Tax-Exempt Hospital Responsibility Act (HB 5000), would require hospitals to spend eight percent of their operating costs on free care for the roughly 1.8 million poor and uninsured citizens in Illinois.

Hospitals' response. For their part, Illinois hospitals are warning of a pending financial catastrophe from the legislation and have made its defeat one of their top agenda items this year. Hospital representatives say they currently are providing \$1.2 billion annually in free care and they are unable to spend another \$739 million to meet the requirements of HB 5000.

The Illinois Hospital Association estimates that of the 133 hospitals affected by the legislation, approximately 28 hospitals would lose \$158 million and 45 hospitals would actually face operating deficits and be forced to cut back on other services.

The potential for that much red ink is making the bond market jittery and affecting hospitals' ability to borrow money, said Theresa Hoban, vice president and general counsel of Northwest Community Hospital in Arlington Heights, Illinois. Hoban spoke at a teleconference hosted by the American Health Lawyers Association (AHLA) in March.

Madigan's position. Those arguments have failed to dissuade Madigan from attempting to set a bright line for the amount of charity care that hospitals should provide. Madigan believes that pursuing legislation is the most transparent way to bring needed change and, thus, she has stopped short of threatening litigation. Instead, she is counting on cutting a deal with hospitals that fear losing the substantial financial benefits from property, sales and income tax-exemptions, and from financing capital projects with tax-exempt bonds.

"Hospitals that benefit from huge tax breaks have an obligation to give back to the community," said Madigan, who has criticized hospitals for providing stingy health care to the state's most vulnerable citizens. "It is clear that we must create standards and hold hospitals accountable to fulfill their charity care responsibilities."

In addition to the legislation, Madigan has begun investigating 42 hospitals in the state. The investigations address issues such as hospital billing, pricing, and charity care delivery, according to AHLA speaker Anne M. Murphy, who is senior counsel to the Illinois Attorney General Office. In 2003, tax-exempt hospitals in

Illinois devoted less than one percent of hospital charges to the delivery of charity care, Murphy noted.

Federal oversight. The developments in Illinois are part of a national trend, which includes recent scrutiny by Congress and the Internal Revenue Service (IRS) over the benefits of federal tax-exemption, said Bernadette M. Broccolo, McDermott Will & Emery LLP in Chicago, who also spoke at the AHHA teleconference.

Last May, IRS commissioner Mark W. Everson told lawmakers on the powerful House Ways and Means Committee that the IRS needed greater flexibility to deal with nonprofit hospitals that mimic their for-profit counterparts in most respects, including providing too little charity care and too much executive compensation.

In addition, Senate Finance Committee Chairman Charles E. Grassley (R-Iowa) sent a letter to 10 hospitals and hospital systems last year seeking an explanation of how their charitable activities balance with their tax exempt status. "It's my duty to make sure charitable donations actually help those in need," Grassley said. "It's also my job to make sure charities are earning their generous tax breaks. Tax-exempt status is a privilege. Unfortunately some charities abuse that privilege."

Illinois legislation. Under Madigan's bill pending in the Illinois House, citizens who earn less than 150 percent of the federal poverty threshold would receive free care from nonprofit hospitals, while citizens earning up to 250 percent of that level would see discounts of 65 percent to 80 percent on the cost of care they receive. Certain hospitals, such as those located in rural areas or owned by the government, would be exempt from the legislation.

As a sweetener to hospitals, the legislation would define charity care more broadly than in current law. The new definition would include charity provided at medical clinics sponsored by a hospital and the shortfall in federal Medicaid payments. A hospital also would be allowed to classify care as charity well after the service is rendered, thereby allowing hospital bad debt to count towards the legislation's eight percent threshold.

According to the hospital association, those changes are not quite broad

enough. Hospitals remain adamantly opposed to this legislation, said Hoban. The charity care definition also should include money losing services such as trauma care, emergency care, burn units and neonatal intensive care. Other hospital services that should qualify are research and development of new drugs, physician and nurse training, and community health education programs to name a few. In addition, it should include losses that hospitals face from underpayments by the federal Medicare program.

Madigan fully intends to negotiate the specifics of the charity care bill with hospitals before making a legislative push to win passage from state lawmakers, Murphy said.

Bond market reacts. So far, the legislation is receiving a lukewarm response from the bond market, which sees the potential for red ink, according to both Hoban and Murphy. Two hospital bond deals are on hold, pending the outcome of the legislation. The bond market typically requires a hospital credit assessment as part of the underwriting process, and some hospitals have been told that the legislation, if passed, would not allow enough money in the budget to pay their operating costs, Hoban said. "The bond market goes elsewhere when regulatory risk affects financing," he added.

Madigan has had a number of discussions with bond insurers and underwriters and other state regulators in an effort to reassure the capital markets that the legislation is still in the process of negotiation. Murphy said Madigan recognizes the financing concerns, but fully expects that the potential risk will be evaluated at each stage of the legislative process.

CCH Washington Bureau, March 22, 2006.

Grassley urges AHA to be more active in nonprofit reform

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

Although the American Hospital Association (AHA) demonstrated "leadership" by suggesting substantive proposals for nonprofit hospital reform, Sena-

tor Charles E. Grassley (R-Iowa), chair of the Senate Finance Committee, in a March 8, 2006, letter, urged the AHA to take a "more active and serious role" in the discussion.

Grassley said he might include provisions in upcoming exempt-organization reform legislation that focuses on better transparency and board governance of tax-exempt hospitals, particularly in the area of self-dealing, private inurement, and excessive compensation. He also expressed con-

continued on page 3



Portfolio Managing Editor
Pamela K. Carron, J.D., LL.M

Coordinating Editors
Susan Smith, J.D., M.A.
Stacey Fahrner, J.D., M.P.H.

CCH Washington Bureau
Paula Cruickshank
DOJ, FTC—John Scorza
SEC—Peter Feltman

Health Law—Catherine Hubbard, M.A.
Tax—Jeff Carlson, Steve Cooper

Designer
Don Torres

Requests for information about article submission and comments from readers are welcome and should be directed to Susan Smith at susan.smith@wolterskluwer.com, Tel. 847-267-2780, Fax 847-267-2514. Customer service inquiries should be directed to 800-449-9525.

CCH Health Care Compliance Letter is published 24 times a year by CCH, a Wolters Kluwer business, 4025 W. Peterson Avenue, Chicago, IL, 60646. Subscription rate is \$305 per year. First-class postage paid at Chicago, Illinois, and at additional mailing offices. POSTMASTER: SEND ADDRESS CHANGES TO *CCH Health Care Compliance Letter*, 4025 W. PETERSON AVENUE, CHICAGO, IL 60646. Printed in U.S.A. ©2006, CCH. All rights reserved.

No claim is made to original government works; however, the gathering, compilation, and arrangement of such materials, the historical, statutory and other notes and references, as well as commentary and materials in this Product or Publication are subject to CCH's copyright.

This publication is designed to provide accurate and authoritative information in regard to the subject matter covered. It is sold with the understanding that the publisher is not engaged in rendering legal, accounting or other professional service. If legal advice or other expert assistance is required, the services of a competent professional should be sought.

For more information about the CCH Health Care Compliance Portfolio, please visit our online store at <http://health.cch.com>.

Charity Care (cont.)

cern about the lack of common policy among hospitals and encouraged tax-exempt hospitals to come forward with substantive proposals for common definitions and reforms in areas such as community benefit, charitable care, charges to the uninsured, debt collection, and joint ventures.

AHA's proposed options. The AHA proposed several options in response to Grassley's call to action. Legislative Option One requires hospitals to provide discounts to all uninsured patients of limited means and make that discount publicly available. Grassley requested that the AHA explain how to calculate the discount and how to define those of limited means, as well as whether the medically indigent (i.e., persons having financial difficulty be-

cause of a catastrophic illness) should be included.

AHA's proposed Option Two requires hospitals to use a common definition of community benefit and makes publicly available the amount of community benefit provided by the hospital. This option is based on the model of the Catholic Health Association and Voluntary Hospitals of America, Inc. (VHA). The letter asked how and when AHA will present the model to members. In addition, the letter requested information regarding the guidance AHA plans to provide to its members on the calculation of charity care and community benefit and the criteria used to classify AHA's members into separate constituencies.

Finally, the third option suggested by the AHA adopts the June 2005

recommendations on strengthening transparency, governance, and accountability of charitable organizations made by the Panel on the Nonprofit Sector. Grassley requested that the AHA specify which of the recommendations should be legislated.

Nonprofit hospitals' practices in other areas also are cause for serious concern, according to Grassley. He requested advice and current best practices on, for example, investments in joint ventures, taxable subsidiaries, and billing and debt collection practices. The full text of the letter is available at the AHA website at www.aha.org/aha/advocacy-grassroots/advocacy/hillletters/2006/060309_grassley2aha.html. ■

CCH Chicago Bureau, March 21, 2006.

Antitrust

Physician's antitrust challenge focuses on HCQIA immunity, level of scrutiny

by **Gené Stephens, J.D.**,
Contributing Editor

The Third Circuit's interpretation of the Health Care Quality Improvement Act (HCQIA) will allow hospitals to enjoy blanket immunity from antitrust laws when they assert that their restraints on physician competition would further the quality of health care or protect patients, according to the claims of a physician. The physician submitted this and other antitrust arguments in a petition for writ of certiorari to the U.S. Supreme Court.

The physician additionally presented questions regarding (1) whether hospital contracts imposed on a physician that prohibit competitively important information are entitled to the same deferential antitrust scrutiny as a nonprice vertical agreement even when the hospital and physician do not stand in a vertical relationship as surrogates protecting consumer interests, and (2) whether agreements between two competitors may be subject to enhanced

antitrust scrutiny when one of the competitors has not yet entered the marketplace or commenced business operations.

Physician-hospital relationship.

The physician, an ophthalmologist and surgeon, performed cataract surgeries using the modern "phaco" procedure. The procedure became the preferred procedure for ophthalmologists in the area because it allowed for a shorter recovery

time with less risk of complications. A competing physician in the area, however, who used an older procedure to remove cataracts, falsely advertised that he performed the modern procedure.

The physician entered into a contract with the hospital agreeing that he would not inform anyone of the differences between his procedure and
continued on page 7

CCH Health Care Compliance Editorial Advisory Board

Timothy P. Blanchard, Esq.
McDermott, Will & Emery

Patricia L. Brent, J.D., M.P.H.
President, Morgan Hill Associates

Neil B. Caesar, Esq.
President
The Health Law Center

Paris Cavic, Esq.
Albany, New York

Michael E. Clark
Partner
Hamel Bowers & Clark LLP

Bill Dacey, MBA, MHA, CPC
President
The Dacey Group

Allan P. DeKaye, MBA, FHFMA
DeKaye Consulting, Inc.

Paul R. DeMuro, J.D., MBA
Partner
Latham & Watkins

Louis H. Feuerstein
Corporate Compliance Program National Leader
Ernst & Young

Cynthia Reaves, Esq.
Honigman Miller Schwartz and Cohn

Fay A. Rozovsky, J.D., M.P.H.
Quality Medical Communications, LLC

William P. Schurgin, Esq.
Seyfarth, Shaw, Fairweather & Geraldson

John E. Steiner, Jr., Esq.
Chief Compliance Officer for
Cleveland Clinic Health System

Sanford V. Teplitzky, Esq.
Ober, Kaler, Grimes & Shriver

HHS recognizes value of measured approach to enforcement in HIPAA final rule

by Sanford V. Teplitzky, Esq. and John F. Lessner, Esq., Contributing Editors

In this article we will illuminate the government's approach to Health Insurance Portability and Accountability Act of 1996 (HIPAA) compliance as reflected in the final enforcement rule. Additionally, we will explain the provisions addressing the two modes of compliance review, enforcement through "informal means," the imposition of civil money penalties, the abilities of covered entities to demonstrate affirmative defenses to the imposition of civil money penalties, and notice and hearing requirements for imposition of civil money penalties. Covered entities should familiarize themselves with these new provisions to make any adjustments and fine tune their HIPAA compliance efforts as necessary.

The Department of Health and Human Services' (HHS) long awaited final rule on the Health Insurance Portability and Accountability Act of 1996 (HIPAA) administrative simplification enforcement provisions was published on February 16, 2006.¹ This final rule amends the existing rules relating to the enforcement of privacy noncompliance rules, applying them to all of the HIPAA administrative simplification provisions, e.g. the privacy, security, and transaction code set standard rules.

The final enforcement rule provides details about the investigation process, the basis for civil money penalty (CMP) liability and determining civil money penalty amounts, and generally provides certain procedural protections and provisions with regard to HIPAA covered entities. The effective date of the final rule is March 16, 2006.

Resolution by "Informal Means"

As HHS notes in the preamble to the final rule, one of the department's fundamental considerations in shaping the final rule was to facilitate the movement from non-compliance to compliance by promoting and encouraging voluntary compliance with the HIPAA administrative simplification provisions. This consideration is reflected in HHS' scaled approach to enforcement. As the final rule provides, when HHS identifies a covered entity's noncompliance through either a complaint investigation or a compliance review, HHS must attempt to reach a resolution of the matter by informal means.

The rule explains that "informal means" may include demonstrated compliance by the covered entity, a completed corrective action plan, or other satisfactory resolution of an alleged or identified violation. The significance of this aspect of the final rule is that the government is codifying its tiered approach to HIPAA enforcement by encouraging compliance by covered entities through cooperation in the

form of action plans or plans of correction rather than imposing compliance by resorting to punitive enforcement actions, such as civil money penalties.

Notification of resolution or request for additional evidence. If an alleged or identified violation is resolved by informal means, HHS is required to inform the covered entity and the complainant of the resolution in writing. If the matter is not resolved by informal means, HHS must inform the covered entity and provide it an opportunity to submit evidence of mitigating factors or affirmative defenses that would potentially resolve the issue informally. Such response by the covered entity to HHS must be submitted within 30 days of HHS' notice to the covered entity.

Notification of findings. After any submitted information is received and reviewed by HHS. If HHS finds that a civil money penalty should be imposed, HHS will inform the covered entity of its findings through a notice of proposed determination sent by certified mail. Conversely, if, based on the covered entity's submission, HHS finds there was no evidence of noncompliance; HHS will inform the covered entity and the complainant of its findings.

Statistical support for measured approach. With respect to its intended approach to HIPAA enforcement, in the preamble, HHS notes that as of October 31, 2005, it had received over 16,000 privacy complaints from health care consumers. It further notes that 60 percent of these cases have been resolved informally or otherwise closed to date, indicating that HHS is receiving cooperation from covered entities and that covered entities are quickly addressing compliance problems through corrective action. Thus, with these statistics as support, it appears that HHS recognizes the value in taking a measured approach to HIPAA enforcement, rather than immediate corrective action through the imposition of civil money penalties.

HHS Review

As noted above, the HIPAA enforcement rule contemplates two ways in which a covered entity may be subject to review by HHS. First, HHS will investigate complaints that are lodged against covered entities by health care consumers or other individuals. Even in the absence of a specific complaint, however, HHS may conduct a “compliance review” of covered entities.

The government most likely gave itself this ability to conduct compliance reviews of covered entities’ HIPAA programs to address issues that can often be brought to HHS’ attention regarding a covered entity’s operational practices but have not necessarily been identified by an individual or do not stem from a specific complaint. For example, the media sometimes identify particular concerns or issues with operational aspects of health care providers’ practices that may raise HIPAA concerns. In that event, HHS has enabled itself to review a covered entity’s compliance so that it can take appropriate enforcement action if violations are identified.

Covered Entity Liability for Violations

The final enforcement rule outlines the methods for imposition of civil money penalties. These new provisions provide that if HHS determines that more than one covered entity was responsible for a violation, it will impose a civil money penalty against each of the covered entities. In addition, the rule provides that a covered entity that is a member of an affiliated covered entity is jointly and severally liable for a civil money penalty for violation of the rules unless it is established that one particular member of the affiliated covered entity was responsible for that violation.

Workforce violations. The final rule further provides guidance for covered entities with respect to their liability for their workforce’s compliance violations. Significantly, the stated basis for a civil money penalty sanction includes specific reference to the federal common law of agency. This provision provides that covered entities are liable for a violation of the HIPAA rules based on the acts or omissions of any agent of the covered entities, including a workforce member, who is acting within the scope of his or her agency.

Business associates. The rule explicitly excludes business associates from such direct liability, assuming that the covered entity has complied with the applicable requirements pertaining to business associate agreements and business associates’ obligations under the administrative simplification rules, and provided that the covered entity did not know of a pattern of activity or practice of the business associate nor failed to act upon such pattern or practice if it did know. In such cases, a covered entity will not be held liable for acts or omissions of its business associate.

Amount of Civil Money Penalty

HHS may not impose a civil money penalty that is more than \$100 for each violation or in excess of \$25,000 for identical violations during a calendar year. The enforcement rule provides, however, that if a requirement or prohibition in one administrative simplification provision is repeated in a more general form in another provision under the same subpart, a civil money penalty may be imposed for a violation of only one of those administrative simplification provisions.

Calculating the amount of the penalty. With respect to calculation of the amount of the civil money penalty, the rule notes that in the case of continuing violations of the provisions, a separate violation occurs each day the covered entity is in violation of the provision. Consequently, even though the actual amount of a civil money penalty is limited to \$100, that \$100 may be assessed on a daily basis for the period of time a covered entity is out of compliance with the provision.

As noted above, however, the total violation is limited to no more than \$25,000 for the same violations in a calendar year. Moreover, in assessing the number of violations that have occurred, the rule requires HHS to base its assessment on the nature of the covered entity’s obligation to act or not act under the provisions violated. For example, HHS must assess whether the violation involved the failure to respond within a certain time frame or acting or not acting with respect to certain persons.

Mitigating factors. In determining the amount of the civil money penalty, the provisions permit, but do not require, HHS, to consider certain aggregating or mitigating factors. The factors HHS may consider in assessing a civil money penalty include:

- (1) the nature of the violation; and
- (2) the circumstances of the violation, including:
 - the time periods during which it occurred,
 - whether the violation caused any physical harm,
 - whether the violation hindered any individual’s ability to obtain health care, and
 - whether the violation resulted in any financial harm.

Additional factors HHS may take into consideration include the degree of culpability of the covered entity, including whether the violation was intentional and whether it was beyond the direct control of the covered entity and any prior compliance history of the covered entity, including previous violations, the financial condition of the covered entity, and other matters “as justice may require.”

Affirmative Defenses

Importantly, the final rule makes available to covered entities three affirmative defenses, which if established, prevent

HHS from imposing a civil money penalty. The basis for the affirmative defenses includes:

- (1) a violation of an act punishable under 42 U.S.C. § 1320d-6 (the statutory provisions outlining criminal penalties for wrongful disclosure of individually identifiable health information);
- (2) violations about which the covered entity did not have knowledge (“determined in accordance with the federal common law of agency”) and, by exercising reasonable diligence, would not have known; and
- (3) the violation was due to reasonable cause, not willful neglect, and was corrected during a 30-day period beginning on the date the covered entity knew or should have known that the violation had occurred.

These affirmative defenses are significant because covered entities that conduct regular and ongoing compliance and promptly address HIPAA issues when they are identified, will have positioned themselves well for establishing an affirmative defense if a complaint is lodged and HHS investigates.

Notice of Intent to Impose a Penalty

The enforcement rule provides appropriate provisions for notice to the covered entity of HHS’ intention to impose a civil money penalty. Such notice must be sent by certified mail, return receipt requested, and must include the statutory basis for the penalty, a description of the findings of fact regarding the violations, the reasons the violations subject the covered entity to a penalty, the amount of the proposed penalty, any factors HHS considered in assessing the amount and instructions for responding to the notice, including the covered entity’s right to a hearing.

Hearing Rules and Procedures

The covered entity must request a hearing before an administrative law judge within 90 days of the notice. The final rule contains the procedures for the hearings, including provisions for pre-hearing conferences, discovery, exchange of witness lists, statements and exhibits, subpoenas and attendance at hearings, motions, evidence and establishing the hearing record.

Rules for statistical sampling. Of particular note are the provisions addressing statistical sampling. The hearing rules specifically permit HHS to introduce results of a statistical sampling study as evidence of the number of violations of the rule that was used in determining the amount of the civil money penalty.

The rule provides that the statistical study must be based upon an appropriate sampling and computed by valid statistical methods, in which case it constitutes prima facie evidence of the number of violations. As a result of these provisions, HHS is permitted to estimate the number of

violations, rather than prove the exact number that occurred, arguably granting HHS significant discretion in determining civil money penalty amounts.

Further appeal rights. Finally, the hearing rules ultimately provide that the administrative law judge’s decision may be appealed to the Departmental Appeals Board and, if the covered entity is dissatisfied with the decision of the Board, the covered entity may request judicial review in federal district court.

Conclusion

While the final enforcement rules grant a certain amount of discretion to the government in the oversight of the administrative simplification provisions, they nevertheless reflect a certain willingness on the part of the government to recognize covered entities’ good faith attempts at HIPAA compliance. These provisions should serve to encourage covered entities to continually review and update their HIPAA compliance efforts to demonstrate to the government that they make good faith efforts not only to prevent violations, but to timely correct them when they are identified. If a violation is identified by HHS, such compliance efforts should have a significant impact on HHS’ ultimate decision as to whether to resolve the issue informally or to impose civil money penalties.

¹ *Final rule*, 71 FR 8389, Feb. 16, 2006, *Health Care Compliance Reporter*, ¶730,006. An interim final rule promulgating procedural requirements for imposition of civil money penalties, *Civil Money Penalties: Procedures for Investigations, Imposition of Penalties, and Hearings* was published on April 17, 2003 (68 FR 18895), and became effective on May 19, 2003, with a sunset date of September 16, 2004 (as corrected at 68 FR 22453, April 28, 2003). The sunset date of the April 17, 2003, interim final rule was extended to September 16, 2005, on September 15, 2004 (69 FR 55515), and was further extended to March 16, 2006, on September 14, 2005 (70 FR 54293).

Sanford V. Teplitzky is a Principal and Chairman of the Health Law Department of Ober, Kaler, Grimes & Shriver and is resident in the Baltimore office of the firm. His clients are typically large health care companies and delivery networks that seek help with fraud and abuse problems and representation in federal or state investigations. He is a former president of the American Health Lawyers Association and a frequent writer and lecturer on various health care fraud and abuse issues. Mr. Teplitzky can be contacted at (410) 347-7364 or by e-mail at teplitzky@ober.com.

John F. Lessner is a Principal in the law firm of Ober, Kaler, Grimes & Shriver in Baltimore. Mr. Lessner focuses his practice on regulatory matters involving Medicare/Medicaid issues and state licensure of hospitals, nursing homes, assisted living facilities, group homes, home health agencies, laboratories and other health facilities. He advises and represents clients on Medicare and Medicaid cost reimbursement issues, conditions of participation, certification, privacy, e-health, advance directive and freedom of choice issues in institutional settings. Mr. Lessner can be reached at 410-347-7683 or by e-mail at jflessner@ober.com.

the competing physician's or expressing any concern about the procedure used by the competing physician. After the physician told a patient that the competing physician misrepresented the cataract removal procedure the competing physician had performed, the hospital revoked his privileges. The physician claimed that the contract imposed by the hospital violated §1 of the Sherman Act.

The physician's motion for summary judgment on his Sherman Act claims was denied. The Third Circuit labeled the relationship between the hospital and an independent physician as a "vertical" relationship such that the agreement would be subject to review under a rule of reason analysis. In addition, the court concluded that a hospital that imposes restraints on a physician is immune from antitrust damage claims whenever the hospital asserts that its actions would benefit patients.

HCQIA. The HCQIA provides a narrow grant of immunity to health care entities, such as hospitals, health maintenance organizations, and group medical practices that use peer review to maintain the delivery and quality of care. The grant of immunity is limited, however, to certain professional review actions. The physician argued that the Third Circuit's expansion of immunity to hospitals conflicted with the plain statutory language of HCQIA and asked whether such professional review actions, which were designed to protect competition, remained viable.

Level of scrutiny. The physician argued that the Third Circuit misstated the level of scrutiny applicable to hospital-physician agreements and that such agreements are horizontal in nature because:

1. hospitals and physicians provide different complementary services to patients;
2. the interests of hospitals are aligned with consumers; and
3. the hospital-physician relationship is complicated by the direct competition that physicians enter into with hospitals by taking substantial steps to open

facilities, such as free-standing surgical centers and specialty hospitals.

He further argued that the information restraints contained in the hospital's contract had a net anticompetitive effect, which would prevent the physician from providing both information and services to patients. ■

Gordon v. Lewistown Hospital, Petition for Writ of Certiorari to the U.S. Supreme Court, No. 05-1000, Feb. 6, 2006.

FTC reforms the merger review second request process

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

In an effort to reduce the time and expense associated with merger review investigations under the Hart-Scott Rodino (HSR) Act, the Federal Trade Commission (FTC) has announced reforms to the controversial second request process. Last year, the FTC formed the Merger Review Task Force to assess the entire merger review process.

This initial set of reforms is directed at the second request process because it has been the area of greatest concern due to rapidly rising costs to both the agency and the parties involved in the transaction. According to Commission Chairman Deborah Platt Majoras, the reforms are "designed to facilitate rapid identification of the relevant issues, preparation of focused second requests, and the use of consistent investigation timetables."

Merger review process. The HSR Act, enacted in 1976, increased the FTC's ability to enforce antitrust laws with respect to mergers and acquisitions. The Act imposes a 30 day waiting period on the completion of transactions of a certain size and requires parties to notify both the FTC and the Department of Justice (DOJ) of the intended merger or acquisition.

In some instances the FTC determines that additional review is necessary and issues a second request. While only a small number of transactions require a second request, approximately two to four percent of all transactions, the process historically has been very controversial.

The DOJ, FTC, and the parties involved in the transaction often spend millions in collecting, reviewing, and analyzing responsive materials. In addition, second request investigations can take from six to nine months to complete. In recent years, the process has become more cumbersome due to changes in antitrust analysis and technology. In particular, the review has become more fact intensive and the number of potentially relevant documents has increased exponentially. In the last fiscal year, the FTC was involved in nine second request investigations having document productions of over a million pages.

Process reforms. In general, the reforms will turn accepted best-practices into formal components of the merger review process. The main objective is to lower the costs of investigations by reducing the volume of materials the parties must produce in response to a second request. Under the reformed process, the Bureau of Competition and Economics will:

1. not require a party to search the files of more than 35 employees provided the party complies with certain conditions,
2. reduce the relevant time period for which the party must submit documents from three years prior to the second request to two years prior to the second request,
3. allow a party to produce fewer backup tapes and produce documents on those tapes only when responsive documents are not available through more accessible sources, and
4. significantly reduce the amount of information parties must submit regarding documents they consider to be privileged.

The reforms are considered "presumptions," and as such are not binding on the Bureau. The FTC has noted that there is no one size fits all approach to the review process. For example, some investigations may require a search group of more than 35 employees. The reformed procedures took effect for all HSR filing submitted on or after February 17, 2006. ■

FTC Announcement, Feb. 16, 2006.

Fraud & Abuse

Thomas calls on OIG to finalize excessive claims rule

by Catherine Hubbard, M.A.,
Contributing Editor

The Office of Inspector General (OIG) needs to finalize its rule proposed in 2003 that would have established a benchmark for determining an excessive level of charges submitted by a provider or supplier to the Medicare and Medicaid programs relative to the rates paid by the private sector, House Ways and Means Committee Chairman William Thomas (R-Calif.) wrote in a March 10 letter to HHS Secretary Michael Leavitt. OIG's failure to establish a framework for overcharges has cost taxpayers \$9 billion, Thomas noted.

Funding for fraud and abuse programs. OIG's failure to define excessive charges has raised the concern that HHS is not committed to reducing wasteful health care spending, Thomas said. As the committee reviewed the HHS budget, the question arose as to whether Congress should increase funding for the Health Care Fraud and Abuse Control program.

Hospital charges have become grossly inflated above their private market prices, said Thomas, adding that without a market-based benchmark, President Bush's recent initiatives to increase health care price transparency will fail.

Proposed rule provisions. The proposed rule, which was published in the *Federal Register* on September 15, 2003, would amend OIG exclusion regulations addressing excessive claims, by including definitions for the terms "substantially in excess" and "usual charges," and by clarifying the "good cause" exception. Under the proposed rule, OIG would be able to exclude an individual or entity that has submitted or caused to be submitted, bills or requests for payments under Medicare or any state health care programs containing charges or costs for items or services substantially in excess of the individual's or entity's usual charges or costs for the items or services. ■

CCH Washington Bureau, March 15, 2006; Proposed rule, 68 FR 53939, Sept. 15, 2003, Health Care Compliance Reporter, ¶730,006.

In the News

CMS to post hospital charges on Internet

The Bush administration plans to publish on the Web the prices hospitals charge Medicare for certain elective medical procedures, such as knee and hip replacement in an effort to provide better information for consumers to compare prices. The prices should be posted in a matter of weeks, according to a CMS spokesperson. The government eventually also plans to post the rates negotiated by the Defense Department and the Federal Employees Health Benefits Program, the spokesman stated. At a recent Federation of American Hospitals meeting, Allan Hubbard, a key economic and policy advisor to President Bush and head of the White House's National Economic Council, said that it is "indefensible" for hospitals not to provide consumers with price information about hospital services. Hubbard said the government needs to release price information on out-of-pocket costs. CMS Administrator Mark McClellan said insurers and health care purchasers can help in the effort. ■

CCH Washington Bureau, March 22, 2006.

State FCA laws must comply with DRA, stresses Grassley

The statutorily mandated review of state False Claims Acts (FCAs) to determine if they qualify for the increased share of recoveries should include assurances that state FCAs contain the requirements set forth in §6032 of the Deficit Reduction Act of 2005 (DRA), including the qui tam provisions, according to a request made by Senator Charles Grassley (R-Iowa), chairman of the Committee on Finance. Grassley made his request in a letter to Daniel Levinson, HHS Inspector General and Alberto Gonzales, Attorney General, Department of Justice. Under the DRA, states have been provided with an incentive to enact state FCAs modeled after the federal FCA. Specifically, if a state has in effect a law relating to false or fraudulent claims that meets the requirements, the state will receive a 10 percent increase to the state share of any recovery obtained under the state FCA. Grassley noted his concern that states that modify or deviate from the qui tam requirements may ultimately undermine the ability of whistleblowers to file qui tam complaints on behalf of the government. ■

CCH Washington Bureau, March 17, 2006.

Prior state suit bars federal charity care claims

A federal appeals court has upheld the dismissal of a lawsuit alleging that Baptist Health System Inc. of Birmingham, Alabama violated its obligation as a charitable organization under the federal tax exemption laws by charging uninsured patients more than insured patients. The court found that the claim was barred by prior state court litigation regarding the unpaid medical bills of the uninsured patients. Although the two suits were premised on different legal theories, the issue in both cases was whether or not the patients were denied charity care. The ruling was the first issued by a federal appeals court in a series of lawsuits filed across the country beginning in June 2004 attacking the tax exempt status of not-for-profit hospitals under federal law. ■

Kizzire v. Baptist Health System, Inc., 11th Cir., March 9, 2006, Health Care Compliance Reporter, ¶1800,103.