CCH Healthcare Compliance LETTER

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The CCH Healthcare Compliance team welcomes comments or questions regarding articles published in the CCH Healthcare Compliance Letter. Send comments to Sharon Sofinski, Coordinating Editor, at sofinsks@cch.com. For more information about the CCH Healthcare Compliance Portfolio visit our online store at http://health.cch.com.

Thomas challenges tax exemption for nonprofit hospitals

by Catherine Hubbard, MA, Contributing Editor

Congress needs to review Internal Revenue Code Sec. 501(c) to determine whether nonprofit hospitals deserve their tax breaks, House Ways and Means Committee Chairman William Thomas, R-Calif., said at a June 22 oversight subcommittee hearing. During the hearing, he questioned whether nonprofits provide more charity care than for-profits and whether the preferred status is appropriate. "Is the difference between the tax treatment of not-for-profits and for-profits justified?" he asked. He also requested that subcommittee chairman Amory Houghton, R-N.Y., continue holding hearings on the entire (c)(3) code section. "I hope this is the beginning of a long process," he said.

Thomas said the exemption for nonprofit hospitals has not been reformed significantly since the 1950s, yet it represents 41 percent of all expenditures resulting from the code section. Thomas added that it's difficult for consumers to distinguish between for-profit hospitals and not-for-profits based on their facilities, treatment options and prices. "If there's no real difference between the two, why the expenditures?" he questioned. "We don't know," he said, adding that Congress owes it to the taxpayers to answer that question.

Health Subcommittee Chairman Nancy Johnson, R-Conn., also questioned the tax status of nonprofit hospitals. "What does the status gain us?" she said. "We need to understand the effect of the nonprofit tax structure," she added.

Thomas asked a panel of witnesses whether there is a difference between the amount of community service provided by for-profits v. nonprofits. While several witnesses agreed that nonprofits do provide more uncompensated care, only the Democrat's witness, Karen Davis, president of The Commonwealth Fund, said the tax break is justified. Other witnesses, including Nancy Kane, a professor at Harvard Business School in Boston, said there isn't enough data to determine whether the tax break is appropriate. ■

CCH Washington Bureau, July 9, 2004

Banner Health to pay $6.1 million settlement

by Sharon Sofinski, Coordinating Editor

The Department of Justice (DOJ) announced that Banner Health has agreed to pay $6.1 million to settle allegations that it submitted false claims to Medicare for reimbursement for home health care visits by its Wyoming facilities.

Banner is alleged to have filed claims that were not reasonable or not necessary, or for which the amount, frequency and duration of services were not reasonable or necessary.

A former Banner employee filed a lawsuit regarding the false claims in the U.S. District Court for the District of Wyoming. Under the settlement, the whistleblower will receive $1 million of the settlement proceeds.

Banner Health, formerly known as Lutheran Health Systems, is based in Phoenix, Arizona, and is one of the largest nonprofit health care systems in the country. The DOJ's press release on the settlement is at http://www.usdoj.gov/opa/pr/2004/June/04_civ_448.htm. ■

CCH Chicago Bureau, July 12, 2004

OIG demand letter seeks penalties from PharMerica

by Sharon Sofinski, Coordinating Editor

In a demand letter to PharMerica Drug Systems, Inc., dated June 17, 2004, the Office of Inspector General (OIG) seeks $21.8 million in civil monetary penalties and damages and a ten-year exclusion from participation in federal health care programs for alleged kickback violations.

According to the OIG, PharMerica agreed to buy a Virignia pharmacy, Hollins Manor I, LLC, for an excessive price in exchange for the sellers' agreement to refer their Medicaid patients' pharmacy business to PharMerica for the next seven years. The pharmacy sellers also owned 17 nursing homes and eight assisted living facilities. The agreement violated the anti-kickback statute's prohibition on payment to induce the referral of health care patients or business, the OIG charged. Under the exclusion sought by the OIG, PharMerica would be excluded from all federal health care programs, including Medicare and Medicaid, for ten years.

PharMerica is a wholly owned subsidiary of AmerisourceBergen Corporation, a global supplier of pharmaceuticals, medical and surgical supplies, and specialty healthcare products. PharMerica has 83 pharmacies throughout the country and is based in Tampa, Florida. ■

CCH Chicago Bureau, July 12, 2004

Wal-Mart, Rite Aid settle false claims charges

by Sharon Sofinski, Coordinating Editor

Wal-Mart Stores, Inc., and Rite Aid Corporation have agreed to pay the United States to settle charges that they submitted false prescription claims to government health insurance programs, according to the Department of Justice (DOJ).

Wal-Mart, which operates retail pharmacies throughout the United States, will pay $2,866,904 to settle allegations that its pharmacies dispensed partial prescriptions due to insufficient stock yet billed government health insurance programs for the full quantities prescribed. The settlement covers the period from January 1990 to December 2000.

Rite Aid will pay $5.6 million to the United States and $1.4 million to participating states to settle charges that it billed government health insurance programs for drugs that were never delivered to beneficiaries of those programs and were later returned to stock. The Rite Aid settlement covers the period from January 1997 to December 2001.

Under the provisions of the False Claims Act, the whistleblowers who brought the suits against Wal-Mart and Rite Aid will share in the settlement proceeds. Both Wal-Mart and Rite Aid have entered into Corporate Integrity Agreements with the Office of Inspector General of the Department of Health and Human Services. The agreements address each company's prescription billing procedures and other compliance-related issues. For copies of the DOJ's press releases on the settlements, see http://www.usdoj.gov/opa/pr/2004/June. ■

CCH Chicago Bureau, July 12, 2004

CCH Healthcare Compliance LETTER

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Business associate agreements present HIPAA challenge

by Harris Beach, LLP

Practitioners interviewed regarding compliance have repeatedly complained that business associate agreements are one of the biggest compliance challenges under the Health Insurance Portability and Accountability Act (HIPAA), for a variety of reasons. Perhaps the biggest complaint has been that indemnity clauses are difficult to draft, negotiate, and implement.

One of the initial problems many covered entities discovered while striving for compliance under the Privacy Rules was that they did not have any business associate agreements in place, and that such agreements were quickly executed simply for the purpose of compliance. It is fairly certain that covered seeking to comply with the Security Rules will have as few, if not fewer, business associate agreements in place. Furthermore, covered entities that had business associate agreements in place by October 16, 2002, had an extra year following the original compliance date—until April 14, 2004—to amend their agreements; small health plans also had an extra year to comply with all provisions of the Privacy Rules. Under the Security Rules, there is no such liberality or grandfathering; business associate agreements must be in place by the compliance date.

Standard forms. There are many standard and adaptable business associate agreement forms available in print publications and on the Internet. Large organizations most probably have already negotiated and revised every agreement to deal with the business associate rules. Even those covered entities that have existing business associate agreements must spend considerable amounts of time checking the existing language, and possibly have to negotiate and amend the agreements to ensure the security provisions also are taken into account.

A major developing problem is that each party to a business associate agreement has its own form. Thus, parties often do not dispute what should be in the form, but rather which form should be utilized. This could lead to increased legal costs for either or both parties not only upon the initial review, but also where boilerplate model agreements that do not allow modifications result in difficulties after some period of time.

Furthermore, some covered entities or service providers attempt to modify a model agreement by including what could be termed "extraneous clauses" that are not relevant to the business associate agreement. Again, this can lead to prolonged negotiations, increased attorneys' fees, and in the worst case, a severing of the original underlying agreement resulting in the covered entity having to procure a new company's services.

Health lawyers generally take the position that business associate agreements should simply set forth the rights and responsibilities of the covered entities and their business associates to ensure that privacy rights of patients are not breached, and should not be cluttered with unrelated matters. These same lawyers, however, are being paid to advocate for their clients, and must negotiate the new agreements (or changes to existing agreements) with other attorneys, also being paid by their clients. The result is often that the best intentions become protracted battles over issues unrelated to the HIPAA Rules.

Indemnity clauses. The most significant problem associated with business associate agreements is the issue of adding indemnity clauses that shift responsibility from one party to another. This issue can cause negotiations to become serious and divisive.

Because indemnity clauses may include limitations of liability, and due diligence issues like the right of the covered entity to inspect the operations of the business associate, the parties often begin to seek concessions in return for the addition of indemnity clauses, or refuse outright to include such clauses.

The problem becomes even more pronounced when practitioners attempt to use certain form agreements and shift the entire cost of compliance to one side. This may be compounded when attempts are made to redefine terms that are defined in the Privacy and/or Security Rules. Some practitioners report that proposed agreements included language that would have broadened the meaning of "protected health information," which clearly exceeds the scope of the intentions of the regulations.

Shifting liability. The changes under business associate agreements can

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Monitoring medical necessity in hospitals: A compliance imperative and new challenge in hospital-medical staff relations

by Timothy P. Blanchard, JD, MHA, FHFMA

The hospital-medical staff relationship that developed many decades ago in the United States as the vehicle for the supervision and delivery of hospital-based care has often been the source of tension and conflict among the parties to that relationship. This venerable construct is likely to be stressed yet again by hospital compliance programs to address the risk of enforcement actions seeking to hold hospitals responsible for physician decisions regarding what services are medically necessary and appropriate.

The first wake-up call for hospitals regarding this looming threat was the government's investigation into patient care and billing practices of Dr. Jeffrey Askanazi at a pain clinic he operated at United Memorial Hospital (UMH) in Michigan between 1994 and 1996. The investigation resulted in charges that Dr. Askanazi had performed medically unnecessary pain management procedures in order to increase payments from Medicare and other payors. In December 1998, Dr. Askanazi was convicted of 32 counts of fraud and sentenced to three years in prison.

That was not the end of the matter, however—a federal grand jury handed down indictments against UMH, the physician who had served as UMH Medical Staff Chief of Staff, and the physician who had served as Chair of the Professional Activities Committee. The indictments charged that the defendants had allowed Dr. Askanazi to perform multiple unnecessary pain management procedures at the hospital, and that they had obstructed the government's investigation into Dr. Askanazi's practice.[1] According to the U.S. Department of Justice (DOJ), the UMH action was the first criminal prosecution of a hospital in the history of the DOJ's health care fraud efforts.

On January 8, 2003, UMH entered into a plea agreement, pleading guilty to one count of mail fraud, paying fines in excess of $1,000,000, and agreeing to affiliate with a health care entity or health care management company acceptable to the United States for the purpose of implementing an appropriate compliance plan.[2] The two physicians individually indicted also pled guilty to misdemeanors.

Meanwhile, in California, an investigation stemming from a 2002 whistleblower complaint under the False Claims Act alleging numerous unnecessary invasive cardiac procedures by two cardiovascular surgeons at Redding Medical Center in Northern California was proceeding. In 2003, the investigation was settled with payments to state and federal governments of $54 million in fines and the institution of special monitoring of cardiac procedures performed at the facility.

Once again, however, that was not the end of the matter for the hospital. The Office of the Inspector General (OIG) notified the hospital that the OIG intended to exclude the hospital from participation in the Medicare and other governmental programs based on the alleged provision of unnecessary cardiology services at the hospital. Exclusion would have a devastating financial impact on the hospital and the community, but the issue was resolved through a divestiture agreement.[3] This case makes it clear that the OIG is prepared to wield its exclusion authority when it believes allegations regarding the provision of unnecessary services at hospitals.

"[T]he OIG is prepared to wield its exclusion authority when it believes allegations regarding the provision of unnecessary services at hospitals."

While hospital executives, hospital boards and compliance officers may prefer to view these cases as aberrations, they represent yet another form of assault that hospitals must be prepared to defend against. Regardless of how one analyzes the facts in these cases, whistleblower actions patterned after these examples are likely to proliferate because such allegations are easy to make but, given the nature of medical necessity issues and differences in medical opinion, far more difficult to defend. The best defense to such challenges is the implementation of compliance program procedures tailored to address and avoid allegations of medically unnecessary care in the first place. This, however, may be easier said than done in practice.

Although physicians continue to have the final say as to what care is provided to patients (subject, of course, to patient

consent), there is growing risk that a hospital will be held responsible, not just for potential malpractice liability, but for administrative, civil and even criminal fines and penalties, based on the professional medical decisions of the physicians practicing on their medical staffs. Indeed, it appears that a hospital might only avoid such liability by actively challenging the judgment (or perhaps the honesty) of its medical staff physicians and taking action to prevent the provision of services that might later be considered unnecessary or inappropriate. Those with experience handling medical staff credentialing and privileging disputes understand that taking such actions in the context of medical staff bylaws and hospital regulations will usually be very difficult. Indeed, physicians enjoy considerable due process rights in connection with actions that would limit, revoke or deny privileges to practice or perform certain services in a hospital. These rights are derived not only from bylaws specific to the hospital but also from state law.

Responsibility for governing the practice of medicine in a hospital through credentialing and the granting of privileges is vested initially with the medical staff of the hospital. It is not uncommon for members of a medical staff or its executive committee to disagree with hospital administration and a hospital governing body regarding questions of clinical competence or medical judgment. While, in most cases, the hospital's governing body (board of trustees or board of directors) retains authority to take action contrary to determinations of the medical staff or when the medical staff fails to act in certain circumstances, such actions are not to be taken lightly and will almost certainly result in litigation against the hospital by a physician seeking to protect his license, reputation, savings, and perhaps liberty.

Adding to the complexity of such matters are longstanding "turf wars" between physician specialties that have different views regarding the appropriate treatment of certain conditions (medical vs. surgical, conservative vs. aggressive). In these cases, both sides are typically able to present compelling positions, and credible "expert witnesses" that are professionally and ethically sound. Even in the absence of conflicts of interest (*e.g.,* Dr. Kildare is the highest admitter to the hospital's surgical service), hospital administrators and compliance officers are not generally well-equipped to resolve these disputes on the merits. Furthermore, the patients of the physician in question may be completely satisfied—indeed delighted—with the care provided, and may even have had favorable clinical results.

At issue in these cases is not malpractice or clinical competence, but rather whether the services were reasonable and necessary under applicable government or third-party payor rules and interpretations. In such situations, a hospital may be faced with conflicting professional assessments, a medical staff that will likely give the treating physician the benefit of the doubt, and satisfied patients. Unfortunately, these facts may not be enough to enable a hospital to avoid liability for false claims if the services in question are ultimately found not to have been medically necessary by the government in an audit or investigation in response to a qui tam whistleblower suit.

In such cases, the threshold issue is whether the services were unnecessary, but the ultimate question for purposes of Medicare overpayment recovery and false claims liability will be whether the hospital knew or should have known that the services were not necessary.[4] When neither the provider nor the Medicare beneficiary knew or should have known that the services at issue were considered unnecessary, the Medicare program is to pay for the services, under a provision known as "limitation of liability," notwithstanding the finding that they were not reasonable and necessary.[5] Conversely, a hospital may be liable under the False Claims Act and Civil Money Penalty Law if the government can prove that the hospital had actual knowledge that the specific services furnished by members of its medical staff were not necessary, **or** that the hospital kept itself deliberately ignorant of that fact, **or** that the hospital acted with reckless disregard for the facts when billing for the services.[6]

"In most cases, a hospital will not have actual knowledge that unnecessary services are being provided."

In most cases, a hospital will not have actual knowledge that unnecessary services are being provided. A hospital is not licensed to exercise medical judgment and must therefore act through the members of its medical staff, or on the advice of outside physician experts. While, in a particular case, a hospital might be held to have had actual knowledge based on statements of the treating physician in question regarding services he or she thought to be medically unnecessary, even such conclusions could be disputed based on evidence to the contrary—the physician may be wrong in the belief that particular services were in fact not reasonable and necessary in a particular case. Accordingly, a hospital's exposure will more likely arise from allegations of deliberate ignorance or reckless disregard.[7] Fortunately, these are sources of exposure that can be addressed through compliance program efforts.

The starting point for hospital compliance with the obligation to submit claims only for services that were reasonable and necessary and compliance with the reasonable and necessary representation on each claim is an effective peer review program. A hospital's peer review program should be structured in accordance with applicable state peer review laws and the medical staff bylaws. This is important to secure

available immunities and evidentiary exclusions for the peer review activities. The hospital must also be careful in handling peer review information to avoid inadvertently compromising the privilege in the particular case. Remember that in any situation involving allegations of unnecessary services there will not only be government investigators to contend with, but a potential line of plaintiff's attorneys waiting in the wings to allege, if not malpractice, battery (lack of informed consent) or consumer fraud.

It is not sufficient for the hospital to have merely a nominal peer review program. The governing body should be sure that the hospital's medical staff takes its peer review obligations seriously, that the process is free from conflicts of interest that could affect the validity of peer review determinations and recommendations, and that appropriate documentation of peer review activities is prepared and maintained.

Moreover, a hospital should not rely solely on medical staff peer review to protect itself against allegations of providing and billing for unnecessary services. For one reason, medical staff determinations can be time consuming and can become tied up in administrative process and appeals for extended periods of time. It is also possible, depending on applicable state peer review rules, that only very limited information may be conveyed to the compliance officer with regard to such reviews. Accordingly, the hospital's compliance office should develop a system for monitoring at least identified high-risk services for indications of over-utilization or inappropriate care. While such processes may not be able to definitively determine whether particular services are medically necessary, such procedures may enable a hospital to identify cases that may be questionable. While such cases might ultimately be found to be appropriate, such compliance reviews can identify cases in which clinical documentation should be improved to better reflect the medical support for the services and claims in question and possibly resolve an issue without a lengthy and expensive investigation.

"It is not sufficient for the hospital to have merely a nominal peer review program."

Several different approaches are possible depending on the organization of the particular hospital services to be monitored. Procedures for monitoring surgical services, for example, may not be as well suited to monitoring nonsurgical admissions or diagnostic services. There are also various sources for norms or standards that can be used in the development of internal utilization screens. Because determinations regarding medical necessity in individual cases are not as straightforward as some in government appear to believe,[8] these factors should be carefully developed, preferably in consultation with the hospital's medical staff, to identify potential problems. It is important to remember that the purpose of a screen is not to determine whether a service is inappropriate—even presumptively—but rather to identify services for further review. One way to think about it is that the purpose of utilization screens in a hospital's compliance program is to identify situations that might appear to be inappropriate to an outsider who is inclined to jump to adverse conclusions. The hospital should consider how the most likely sources of investigations—Medicare reviewers or qui tam whistleblowers—would view the data.

It is also important to remember that utilization monitoring is just the beginning of the process. As a starting point, a hospital should honor the "treating physician" rule, which recognizes that the physician who has met and examined the patient—as opposed to the hospital compliance office or medical staff office—is in the best position to make medical necessity and treatment determinations with the patient.[9] Establishing and maintaining this basic mind-set within the organization and explaining it to physicians is important to maintaining good medical staff relations and securing the cooperation regarding these compliance program efforts. The treating physician rule is an appropriate presumption that cannot properly be rebutted based solely upon utilization screens, however well constructed.

When cases are identified using internal review screens, the hospital must follow up promptly. Because, in practice, the hospital will not be able to control the timing or rigor of a medical staff review in a particular case, and because there is no sound basis for triggering a traditional medical staff review based on the evidence at this stage, the compliance office should independently request and review the hospital medical records supporting the services in question. It may not be necessary at this stage to consult with a physician reviewer. It may be clear that the case is well-documented. Whether the treating physician should be advised of the review at this stage is a matter of organizational culture and possibly the legal relationships involved. Since most of these reviews are not expected to reveal problems (*i.e.*, because there will be adequate documentation to support the medical necessity of the services provided and no other reason to suspect unnecessary services), there is no reason that the treating physician would necessarily need to be made aware of this routine preliminary review.

If it appears that the medical record documentation may be inadequate to support the medical necessity of the services, the compliance officer will need to consider how best to arrange for a review of the record by a physician who is qualified to make that determination for use by the compliance office. Here again, while it may be possible to use the hospital's medical staff (or members thereof) to conduct that review, the hospital should consult legal counsel familiar with applicable peer review rules to understand the implications of a course of action upon the availability of peer review privileges and immunities.

In some cases hospital compliance officers may want, or need, to retain outside experts to conduct review of cases to avoid compromising the hospital's general peer review process or to secure prompt unbiased opinions. Unless there is a basis for

On the Front Lines (cont.)

conducting such reviews under the direction of an attorney and steps are taken to establish and maintain that privilege, it is likely that an outside consultant's report would be discoverable. This could be problematic, because, depending on the facts of the case, corrective action might include payment refunds by the hospital, compliance training for the physician and referral to the medical staff for review and potential discipline. Maintaining appropriate privileges may be important to effectively managing such corrective actions.

Hospital compliance officers sometimes fear that the medical staff may reach conclusions contrary to those of the compliance office (or outside experts) upon review of a case. While this is true, it is not a reason to avoid review if it is indicated in the first place. The hospital must take steps to avoid allegations that it was intentionally ignorant or—worse—recklessly disregarded the issues. If such differences of opinion exist, there is exposure to challenge based on medical necessity allegations. Forewarned is forearmed, however. At a minimum, such cases frequently will warrant efforts to improve the documentation supporting similar services in the future.

It is likely that these cases will need to be carefully evaluated on a case-by-case basis. Because of likely collateral consequences and complicated legal implications that may be involved in reconciling rights and obligations under applicable law, contracts (physician and/or payor), government provider agreements, medical staff bylaws, databank reporting requirements, and tort law (vis-à-vis potential patient claims or physician claims for defamation or related torts), legal counsel should be consulted in these situations. In any event, the compliance officer should document the basis for corrective action and for closing the matter so that the hospital will be able to demonstrate that it followed its compliance program and acted reasonably—rather than recklessly—under the circumstances.

Finally, because of the many interconnected regulatory provisions and the many important rights and obligations that are implicated by procedures for hospital review of medical necessity issues, hospitals should consider these issues and make appropriate revisions to their compliance program procedures before they are confronted with a case with a face—a case involving a known individual. These procedures should be well publicized within the hospital and medical staff and should be implemented consistently across the board. Any conflicts of interest should be identified and promptly addressed. As with all compliance program elements, these steps, or other approaches to monitoring these evolving issues within the organization, should be well documented and reviewed periodically by the compliance officer, administration and the governing body.

Timothy P. Blanchard, JD, MHA, FHFMA, is a partner in the Los Angeles office of McDermott Will & Emery LLP and practices health care law with an emphasis on fraud and abuse, health care regulation and payment issues, including medical necessity. He is a member of the Board of Directors of the American Health Lawyers Association, a Fellow of the Healthcare Financial Management Association, and a member of the American College of Healthcare Executives.

1 See Indictment, *United States v. United Memorial Hospital,* No. 1:01-CR-238 (W.D. Mich. 2001).

2 See Plea Agreement, *United States v. United Memorial Hospital,* No. 1:01-CR-238 (W.D. Mich. Jan. 8, 2003), CCH HEALTHCARE COMPLIANCE REPORTER, ¶305,263.

3 See http://www.oig.hhs.gov/publications/docs/press/2003/121103release.pdf.

4 42 U.S.C. §1320a-7a(a)(1)(A) and (E) ("a pattern of medical or other items or services that a person knows or should know are not medically necessary"); 31 U.S.C. §3729.

5 See 42 U.S.C. §1395pp; Medicare Claims Processing Manual, CMS Pub. 100-4, Chap. 30, §30; see *also* Blanchard, "'Medical Necessity' Denials As A Medicare Part B Cost-Containment Strategy: Two Wrongs Don't Make It Right Or Rational," 34 ST. LOUIS U.L.J. 939 at 979-981, 1012-1015 (1990).

6 42 U.S.C. §1320a-7a(i)(7); 31 U.S.C. §3729(b).

7 Indeed, a hospital could face anti-kickback or patient inducement exposure if were intentionally providing even unnecessary services to patients without charge on a routine basis. See OIG Draft Supplemental Compliance Program Guidance for Hospitals, 69 Fed. Reg. 23012 at 32025 (June 8, 2004); OIG Special Advisory Bulletin: Offering Gifts And Other Inducements To Beneficiaries (August 2002), http://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf.

8 The OIG suggested in its Compliance Guidance for Hospitals that the compliance officer should simply compile a clear comprehensive summary of applicable medical necessity criteria for dissemination within the organization—a task that even CMS has, to date, been unable to accomplish. See 63 Fed. Reg. 8987 (1988); *see generally* Blanchard, *Medicare Medical Necessity Determinations Revisited; Abuse of Discretion and Abuse of Process in the War Against Medicare Fraud and Abuse,* 43 St. Louis U.L.J. 91, 117-121.

9 See *generally* Blanchard, "'Medical Necessity' Denials As A Medicare Part B Cost-Containment Strategy: Two Wrongs Don't Make It Right Or Rational," 34 ST. LOUIS U.L.J. at 988-990.

HIPAA (cont.)

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also include attempts to shift liability from one party or another. Again, such an attempt generates legal fees and can be destructive to otherwise healthy business relationships.

The underlying cause for this attempted shift is obviously an attempt to limit damages for an unauthorized release of PHI. Because it is unlikely under the Privacy and Security Rules that covered entities may shift the liability, difficult negotiations may result in unenforceable contract provisions.

Preemption issues. The issue of underlying state laws that may or may not be applicable depending upon HIPAA preemption increases the complexity in the business associate agreement. As states continue to pass privacy and security rules that are more stringent than HIPAA, the cost of attorney research and drafting increases because the business associate provisions must take into account these provisions. Of

course, the parties may differ about whether a state law is substantive or procedural and if it, in fact, preempts HIPAA.

This issue becomes more complicated where a company has locations in multiple states. Due diligence is difficult for a single location, but companies with multiple locations must seek competent legal advice in each jurisdiction.

At the same time, the business associate agreement forces the covered entity to review state laws in light of HIPAA. While such a review may seem like a given in the context of compliance, it is questionable whether all covered entities are in fact complying with this difficult task.

An example is that of California's security breach reporting law (Cal. Civ. Code Section 1798.82). This law states that security breaches should be reported "[i]n the most expedient time possible and without unreasonable delay; the California Office of Privacy Protection recommends notification within 10 days." The Privacy Rules state that a covered entity has 60 days to comply with an accounting of what it did with a patient's protected health information. Covered entities can have an additional 30 days after the 60 days if they have not yet received the information, but they have to inform the patient. This law will also impact Security Rules compliance in that security breaches must be logged.

Clearly, it appears that the more stringent state law should apply. At the same time, however, practitioners are seemingly ignoring the state law, especially those who are from out of state.

Litigation can reasonably be expected at some point, and the business associate agreement will be the underlying trigger. During negotiations about the agreement, parties are attempting to expedite or prolong the reporting time period. The timeframe, however, is prescribed by statute and the covered entity, not the business associate, will be the party sanctioned if regulatory consequences if late; the business associate could be liable only under contract law, and thus covered entities seek to utilize the agreement in order to potentially recoup losses.

End result. The party with the most bargaining strength generally wins the negotiations. It is difficult to predict with certainty which party will ultimately have the upper hand in negotiations of indemnification clauses in business associate agreements as it is simply an economic end game. If the supply of business associates is greater than the demand, the covered entity will prevail. An additional factor, however, is the difficulty involved in switching from one business associate to another. Furthermore, a preferred business associate may understand its powerful position within an entity, and take advantage of this by refusing to negotiate on key points. This puts the covered entity in a difficult position, as the expense and complications caused by switching may ultimately not be worth the trouble, as negotiations with other business associates may prove no less fruitful. ■

Adapted from the CCH HIPAA Security Guide

FCC: Telecommunications Relay Services do not violate HIPAA

by Sharon Sofinski, Coordinating Editor

The use of Telecommunications Relay Services (TRS) programs for telephone calls between healthcare providers and hearing or speech disabled patients does not violate the Privacy Rule of the Health Insurance and Portability and Accountability Act (HIPAA), according to a notice published by the Federal Communications Commission (FCC) in the July 8 *Federal Register.*

TRS, which is mandated by Title IV of the Americans with Disabilities Act, allows those with hearing or speech disabilities to communicate via the telephone system. At TRS facilities, trained communications assistants use technology to relay conversations between those using various types of assistive communication devices (for example, a text telephone, or TTY) and those communicating by voice. The communications assistant relays the conversation between the parties without alteration. The concern among some healthcare providers has been that discussions through TRS may violate the Privacy Rule because a third party—the TRS communications assistant—may hear an individual's protected health information while relaying the call.

Although a covered entity such as a doctor can contact a patient using TRS without the need for a business associate contract under the Privacy Rule (45 C.F.R. 164.510(b)), some providers have been requiring TRS communication assistants to sign disclosure forms before using TRS to contact patients. The FCC's notice clarifies that covered entities under HIPAA do not need to require TRS facilities or TRS communications assistants to sign a disclosure agreement before contacting hearing or speech disabled patients.

The *Federal Register* notice is at http://www.access.gpo.gov/su_docs/fedreg/a040708c.html. ■

CCH Chicago Bureau, July 12, 2004