CCH Healthcare Compliance LETTER

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Letters to the Editor

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Scirex recovers losses despite RNs' record keeping fraud

by Suzanne Himes, J.D., Contributing Editor

Four recent clinical trials to test the effectiveness of pain medications produced positive and promising results. However, the nurses' monitoring the study failed to follow established protocols and fabricated entries on patients' records. Thus, the research was declared useless.

Despite the invalidated study, the nurses' employer, Scirex Corporation, a clinical testing company, sought reimbursement for its losses from its insurance carrier. The U.S. Court of Appeals for the Third Circuit reversed the trial court's decision to deny insurance coverage for the dishonest actions of the nurses in each of the trials. The Third Circuit ruled, however, that the clinical testing company could recover only the policy limits under one of the insurance policies, because all of the defective studies were considered to be one occurrence.

Exacting work. According to the Third Circuit, the Food and Drug Administration's clinical testing requirements are exacting and inflexible. Furthermore, the court noted that any discrepancy between actual events and deceptive record keeping of such events has the effect of rendering clinical studies worthless. The judicial findings showed that the nurses from Scirex falsely recorded that they observed patients for eight hours after administration of an investigational drug, when in fact they often sent patients home after as little as an hour.

However, Scirex sought payment for the botched studies from its insurance carrier under a "blanket employee dishonesty" policy. At trial, the nurses defended their actions, contending that their conduct was not dishonest or wrongful. In addition, they asserted that they did not receive financial gain from the study, nor did the Scirex impose unreasonable and unnecessary restrictions on how clinical trials are to be conducted. Moreover, testimony by the nurses indicated that filling in patient records ahead of time are common practice shortcuts and a common business practice.

Decision. The Third Circuit ruled that the fictionalized records were flagrant misrepresentations in a field characterized by strict adherence to procedure, and the nurses' conduct was clearly dishonest, causing a direct loss to the company under its policy. Although there were four separate studies, the court concluded that the nurses themselves did not distinguish among the studies in terms of their responsibilities; therefore, it ruled that the nurses' conduct caused a single loss. ■

Scirex Corporation v. Federal Insurance Company, 3rd Cir., No. 02-1172, Dec. 23, 2002, ¶301,464

Unreleased HIPAA Security Rule continues to irritate

by Gordon R. Shea, J.D.

Concerns about the yet-to-be-issued administrative Security Rule of the Health Insurance Portability and Accountability Act (HIPAA) continue to roil the healthcare community.

In one of the most obvious and recent examples of this, the American Health Information Management Association (AHIMA) recently issued a strongly-worded public letter to both the Department of Health and Human Services (HHS) and the Department of Defense (DOD) complaining about what it called "the failure of the Department of Health and Human Services (HHS) to issue a final notice for HIPAA Security regulations - as anticipated in December 2002." New U.S. Senate Majority Leader and longstanding physician Bill Frist was copied on the AHIMA letter, as was Minority Leader Tom Daschle and House member F. Pete Stark, author of the well-known Stark law.

The letter, signed by Dan Rode, AHIMA's Vice President of Policy and Government Relations, "[o]n behalf of the 45,000-plus members" of the organization, also points to an incident that occurred on December 24, 2002, in which several hundred thousand military healthcare records were apparently stolen from a DOD contractor. "Both incidents raise serious concerns," Rode wrote, "regarding the willingness and commitment of the federal government to make [security] a key priority at a time when both the healthcare industry and the federal government are trying to address the need for and build a national healthcare information" system. "AHIMA's members are very concerned about these two incidents," Rode continues, "and the message they send to the public."

Rode's letter goes on to chastise both HHS and the DOD: "In 1998 there were fewer than 3,000 comments on the proposed rule and there was a general consensus that it would be moved forward quickly. Now, over 4 years later, the industry and the public wait while incidents like [the apparent DOD theft] erode confidence in both the government and the industry." The budgetary considerations that are often used as a justification for the delay, according to Rode, have become an "excuse."

"I must note," Rode continued, "that HHS staff has often told the public that the regulations are ready to" be released. He stated, "[i]f there is something that AHIMA can do to assist in the release of these regulations, please let us know." A copy of the letter is available at http://www.ahima.org/dc/AHIMA_Letter_Secretaries_HHS_DOD.html.

Frustration with the delay of the HIPAA Security Rule is not new. Recently, rumors circulated that the Rule would be released during the inconvenient holiday date of Friday, December 27, 2002. When that date came and went with the Rule nowhere to be seen, speculation put the Rule's release date at anywhere from January 27 to mid-June 2003. One recent posting at the website www.hipaadivsory.com suggests that a February 2003 release date was likely, although as most Security Rule watchers will say, that date is far from official or certain. ■

CCH Chicago Bureau, Jan. 24, 2003

Recent case suggests complexities of HIPAA preemption

by Gordon R. Shea, J.D.

A recent employee health benefits case before the United States Court of Appeals for the Ninth Circuit provides a glimpse of how at least one court handles the thorny issue of preemption of state laws. The case hints as to how preemption disputes involving the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA) may play out in the future.

FEHBA Background. The case, *Botsford v. Blue Cross and Blue Shield of Montana, Inc.*, is about the Federal Employees Health Benefits Act (FEHBA). Although the case is not a direct preemption challenge to the HIPAA Privacy Rule, it may provide some clues as to how courts may generally analyze HIPAA Privacy Rule issues as they filter into the legal system in coming months and years.

HIPAA's preemption issue springs from §264(c)(2) of HIPAA. This subsection states that HIPAA's privacy "regulation...shall not" be considered to "supercede a contrary provision of

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Hospital hurting from pain management fraud

by Geraldine S. Stroka, J.D., R.N.

Hospitals cannot continually ignore complaints about a physician, including the performance of unnecessary procedures, and expect to escape the government's wrath. United Memorial Hospital (UMH) of Greenville, Michigan, failed to control a physician, whose practice constituted approximately one-third of its income, and it will pay for its mistakes. UMH has agreed to plead guilty to wire fraud in connection with the services rendered by a hospital anesthesiologist it recruited and protected, despite numerous complaints from physicians, hospital staff and patients.

The money machine. UMH, hoping to improve its financial status, recruited an anesthesiologist, Dr. Jeffrey Askanazi, to provide full-time anesthesia services. Soon, he was performing pain management procedures, including invasive surgeries, despite his lack of training in this specialty. His lack of qualifications to perform these procedures did not hinder his practice at UMH, because as chairman of the anesthesiology department, he approved his own application for pain management privileges.

When the professional staff and patients complained about Dr. Askanazi, UMH's management team took actions to discourage complaints. The nurses repeatedly voiced their concerns about the number of patients receiving repeat procedures without any improvement; UMH told them to silence themselves or leave. Physicians' complaints about Dr. Askanazi's failure to properly examine patients and his clinical judgment were never followed-up. When complaints reached the Board of Trustees, it asked the Professional Activities Committee to review Dr. Askanazi's practice, and no action was taken.

Emboldened by his seemingly unstoppable ability to generate income, he formed a corporation with two other physicians, Doctors Seward and DeWys, and opened a surgery center. Despite their mutual financial interests and the protestations of other physicians, Doctors Seward and DeWys were members of committees that regulated Dr. Askanazi's practice. Dr. Askanazi reigned supreme; Dr. Seward suspended the hospital privileges of a physician who challenged Dr. Askanazi's qualifications.

Only a patient's death, as a result of one of Dr. Askanzai's procedures, caused UMH to review his practice. He continued working during the month-long review process and then voluntarily resigned after meeting with UMH's attorney. After his departure, a peer review organization reviewed his charts and generated a scathing report.

UMH's role. UMH admitted that its administrative and medical management team knew, or should have known, about the numerous medically unnecessary pain management procedures performed by Dr. Askanazi. It also acknowledged that it billed Blue Cross and Blue Shield and other private insurers for these medically unnecessary procedures.

Plea Agreement. The court will keep UMH's guilty plea under advisement for three years. At the end of the three-year period, the government will request a dismissal of the charges against UMH, if it has fully complied with the Agreement. The Agreement includes fines, reimbursement to insurers, the implementation of a compliance plan with yearly medical billing and coding audits supplied to the U. S. Attorney's Office, and the mandatory exclusion of Dr. Wys from any affiliation with UMH. ■

U.S. v. United Memorial Hospital, W.D. Mich., Southern Division, No. 1:01-CR-238, Jan. 8,2003, ¶305,237

Medicare co-payment waiver okayed for gov't clinical trial

by Geraldine S. Stroka, J. D., R.N.

Medicare patients who qualify for a government-sponsored scientific study may participate and receive all necessary medical supplies free of charge. The Office of Inspector General (OIG) has approved a waiver of the Medicare Part B copayment required for blood glucose testing supplies used in conjunction with a national clinical trial sponsored by the National Heart, Lung and Blood Institute (NHLBI), a part of the National Institutes of Health (NIH).

Government clinical trial. Approximately 3,900 of the 10,000 patients involved

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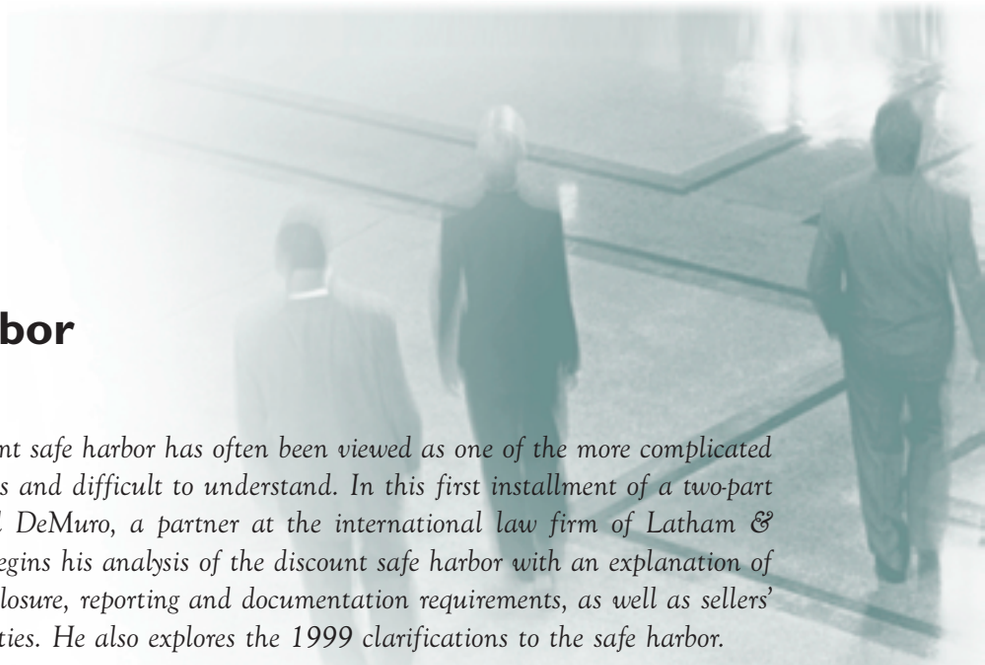

On The Front Lines

The Discount Safe Harbor

by Paul DeMuro, J.D.

The discount safe harbor has often been viewed as one of the more complicated safe harbors and difficult to understand. In this first installment of a two-part series, Paul DeMuro, a partner at the international law firm of Latham & Watkins, begins his analysis of the discount safe harbor with an explanation of buyers' disclosure, reporting and documentation requirements, as well as sellers' responsibilities. He also explores the 1999 clarifications to the safe harbor.

"Discount" Defined. The discount safe harbor has often been viewed as one of the more complicated safe harbors and more difficult to understand. A first inquiry in a review of a particular situation under the discount safe harbor is whether there is a discount for the purposes of the safe harbor. As a result, an analysis of the safe harbor should begin with the definition of the word "discount." The safe harbor provides that "the term discount means a reduction in the amount a buyer (who buys either directly or through a wholesaler or a group purchasing organization) is charged for an item or service based on an arms-length transaction."[1]

The safe harbor also provides that "the term discount does not include:

(1) Cash payment or cash equivalent (except that rebates[2] as defined [in the safe harbor] may be in the form of a check);

(2) Supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, unless the goods or services are reimbursed by the same federal healthcare program using the same methodology and the reduced charge is fully disclosed to the federal healthcare program and accurately reflected where appropriate, and as appropriate, to the reimbursement methodology;

(3) A reduction in price applicable to one payor but not to Medicare or a state health care program;

(4) A routine reduction or waiver of any insurance or deductible amount owed by a program beneficiary;

(5) Warranties;

(6) Services provided in accordance with a personal or management services contract, or;

(7) Other remuneration, in cash or in kind, not explicitly described [in this subsection]".[3]

Once the threshold questions are answered, whether there is an arm's-length price reduction, and whether the discount is a discount for the purpose of the safe harbor, then it is important to consider how the buyer is reimbursed under the Medicare and Medicaid programs. Is the buyer a health maintenance organization (HMO) or a competitive medical plan (CMP) acting in accordance with a risk contract? Is the buyer an entity that reports its costs on a cost report required by the Department of Health and Human Services (HHS) or a state healthcare program? Is the buyer neither an HMO, CMP nor a cost reporting provider, e.g., "the other category buyer"?

The Buyer. Depending upon the nature of the buyer, there are different disclosure, reporting and documentation requirements. The 1999 clarifications to the safe harbor made it clear that the safe harbor may apply to one party even if the other party is out of compliance. For example, if the seller has done everything in its power not to impede the buyer's compliance and has made all the requisite disclosures and otherwise complied with the safe harbor, the seller should be found to have complied with the discount safe harbor.

With respect to buyers, if it is an HMO or a CMP acting in accordance with certain risk contracts, or under another state healthcare program, it need not report the discount except as otherwise may be required under the risk contract.[4]

If the buyer is an entity that reports its costs on a cost report required by HHS or a state healthcare program, it must comply with all of the following four standards:

(1) The discount must be earned on purchases of that same good or service bought within a single fiscal year of the buyer;

(2) The buyer must claim the benefit of the discount in the fiscal year in which the discount is earned or the following year;

(3) The buyer must fully and accurately report the discount in the applicable cost report, and

(4) The buyer must provide, upon request by the Secretary of HHS or a state agency, information provided by the seller as specified in the safe harbor, or information provided by the offeror as specified in the safe harbor.[5]

For "the other category buyers" in whose name or claim or request for payment is submitted for the discounted item or service and payment may be made, in whole or in part, under Medicare or a state healthcare program, these buyers must comply with the following standards:

(1) The discount must be made at the time of the sale of the good or service or the terms of the rebate must be fixed and disclosed in writing to the buyer at the time of the initial sale of the good or service, and

(2) The buyer (if submitting the claim) must provide, upon request by the Secretary of HHS or a state agency, information provided by the seller as specified in the safe harbor, or information provided by the offeror as specified in the safe harbor.[6]

Basically, discounts have to apply equally, regardless of payor, and be on the same product. The federal government wants to ensure that it gets its share of the discount, assuming this is possible given the nature of reimbursement for the product and the type of provider.[7] Obviously, for providers who seek reimbursement for claims based on charges, assuring that the discount is passed on to the government in some manner is not generally possible.

The 1999 amendments to the discount safe harbor make it clear that cost-based providers and others can take advantage of rebates if the terms are set in advance and there is proper disclosure and documentation.

In addition, the government looks to the transparency of the discounting; that is, is there the proper disclosure and reporting to the government and can the government ensure that there has not been improper cost shifting and/or cost distortion?

The Seller. The seller's responsibilities under the discount safe harbor, if the seller wants to avail itself of that safe harbor, depend upon the type of buyer. A "seller" for the purposes of the safe harbor is defined as "an individual or entity that supplies an item or service for which payment may be made, in whole or in part, under Medicare or a state healthcare program to the buyer and who permits a discount to be taken off the buyer's purchase price."

A seller must comply with all of the applicable standards of the safe harbor within the following categories of buyers. If the buyer is an HMO or a CMP acting under a risk contract, or under another state healthcare program, the seller does not need to report the discount to the buyer.[8] If the buyer is a cost reporting entity, the seller must comply with either of the following two standards:

(1) Where a discount is required to be reported to Medicare or a state healthcare program by the buyer, the seller must fully and accurately reflect such discount on the invoice, coupon or statement submitted to the buyer; inform the buyer in a manner that is reasonably calculated to give notice to the buyer of its obligations to report such discount and to provide information upon request; and refrain from doing anything that would impede the buyer from meeting its obligations under the safe harbor, or

(2) Where the value of the discount is not known at the time of the sale, the seller must fully and accurately report the existence of a discount program on the invoice, coupon or statement submitted to the buyer; inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report such a discount and to provide information upon request; when the value of the discount becomes known, provide the buyer with documentation of the calculation of the discount identifying the specific goods or services purchased to which the discount will be applied; and refrain from doing anything which could impede the buyer from meeting its obligations under the safe harbor.[9]

If the buyer is an "other category buyer," the seller must comply with either of the following two standards:

(1) Where the seller submits a claim or request for payment on behalf of the buyer and the item or service is separately claimed, the seller must provide, upon request by the Secretary of HHS or a state agency, information provided by the offeror, such as informing the individual or entity submitting the claim or request for payment in a manner reasonably calculated to give notice to the individual or entity of its obligations to report such discount and to provide the information requested, or

(2) Where the buyer submits a claim, the seller must fully and accurately report such a discount in the invoice, coupon or statement submitted to the buyer; inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligation to report such discount and to provide information upon request; and refrain from doing anything that could impede the buyer from meeting its obligations under the safe harbor.[10]

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1 See 42 C.F.R. § 1001.952(h)(5).

2 "Rebate" is defined as "any discount, the terms of which are fixed and disclosed, in writing to the buyer at the time of the initial purchase to which the discount applies, but which is not given at the time of sale." See 42 C.F.R. § 1001.952(h)(4).

3 See 42 C.F.R. § 1001.952(h)(5).

4 See 42 C.F.R. § 1001.952(h)(1).

5 Id.

6 Id.

7 See 64 Fed. Reg. 63,518, 63,529 (1999).

8 See 42 C.F.R. § 1001.952(h)(2).

9 Id.

10 Id.

in the randomized study will be Medicare patients. This clinical trial, named "Action to Control Cardiovascular Risk (ACCORD)," will address whether improvements in the treatment of Type II diabetes patients can occur by lowering their blood glucose and systolic blood pressure to levels below currently recommended levels, as well as by administering drugs that modify their cholesterol and triglyceride levels.

All ACCORD patients will be required to monitor their blood glucose in compliance with the study's treatment protocol. Estimated usage of the self-monitored blood glucose (SMBG) supplies for each ACCORD patient will be 75 times per month for the duration of the study.

To encourage enrollment in ACCORD, NHLBI wants all care, including supplies, to be without charge. According to the proposed arrangement, the nationwide supplier will purchase SMBG supplies from a manufacturer and distribute them to all ACCORD patients for the length of the study. The supplier will then seek reimbursement from Medicare or Medicaid, or private or public health insurance programs.

Anti-kickback issues. On September 19, 2000, the Health Care Financing Administration issued a National Coverage Determination (NCD) designed to permit Medicare patients who participate in qualifying clinical trials to receive treatment on the same basis as they receive other Medicare-covered items and services. The concern is that although NHLBI wants all clinical trial patients to receive free care, enrollees might be induced to forego equally appropriate, if not more than appropriate care. Also, payments are often made to providers and patients who participate in clinical trials, further raising the risk for fraud and abuse.

Copayment waived. OIG permitted the proposed arrangement because it accommodated the needs of a large government-sponsored scientific study without posing a significant risk of Medicare fraud and abuse. OIG based its decision on the following: (1) ACCORD is government-sponsored; (2) ACCORD is not a commercial or a product-oriented study; and (3) NHLBI believed that the resolution of the issues addressed by ACCORD would have significant impact on the treatment of all patients, including Medicare beneficiaries.

OIG warned, however, that commercial studies posed different risks under the NCD and Medicare fraud and abuse statutes. Waivers of the cost-sharing obligations of enrollees in commercial studies would not necessarily be sheltered from anti-kickback sanctions or civil monetary penalties. ■

OIG Advisory Opinion 02-16, Jan. 3, 2003, ¶150,197

Ongoing challenges to attracting and keeping talent

by Judith A. Tichenor, J.D., L.C.S.W.

According to a recent study by Watson Wyatt Worldwide, approximately 81 percent of healthcare organizations that participated in Watson Wyatt's Strategic Rewards® survey said they are having difficulty attracting critical-skill employees. This figure is almost twice as high as that for all other industries (41 percent) who participated in the survey. Nearly three-quarters (72 percent) of the healthcare employers reported difficulty retaining critical-skill workers, compared with 21 percent of all other industries. A total of 44 of the 431 companies in the survey were healthcare organizations. Watson Wyatt Worldwide is an international human capital consulting firm that provides services in the areas of employee benefits, human resources technologies, and human capital strategies and is headquartered in Washington, D.C.

"The health care industry is facing a severe talent shortage due to the job requirements, the demographic shift in the labor pool, and the level of compensation," said Laura Sejen, national practice director of Strategic Rewards at Watson Wyatt. Part of the problem may be due to the special requirements indigenous to healthcare jobs, according to Sejen. "Generally, many positions in the industry require specific certification and licensures that must be obtained through formal school versus on-the-job training," she noted. Furthermore, Sejen added that "many jobs can also place an especially high physical, intellectual and/or emotional strain on workers," which may both discourage people away from health careers as well as create a rise in the number of workers leaving healthcare jobs.

According to the Watson Wyatt survey, as well as other sources, healthcare corporations routinely deploy more aggressive reward tactics than other industries in an effort to better manage costs while improving their ability to attract and keep critical skill workers. Nevertheless, recruitment and retention tactics that rely on increasing levels of compensation are insufficient to attract workers to these jobs quickly enough to meet the ever-growing demand, the study noted.

For example, 61 percent of healthcare companies in the survey offer compensation that is above market base pay, while only 28 percent of all other industries compensate their employees at a rate above market base pay. Similarly, while 35 percent of all other companies in the study reported offering employees a reduced workweek, 56 percent of the responding healthcare organizations indicated they made reduced workweeks available. Finally, while 81 percent of healthcare employers permit flexible work schedules, 68 percent of employers in other industries provided such a benefit.

The Watson Wyatt survey results are further supported by the federal government's GAO reports regarding nursing shortages, and by a survey of healthcare human resource professionals, conducted by CCH, Incorporated and reported in the CCH Healthcare Compliance Letter, Vol. 5, Issue 16 (Aug. 19, 2002). ■

CCH Chicago Bureau, Jan. 27, 2002

State law, if the provision of State law imposes requirements...that are more stringent than the requirements, standards, or implementation specifications imposed under the regulation." Theoretically, HIPAA's Privacy Rule preemption language is fairly straightforward; covered entities in states that have medical privacy laws stricter than HIPAA's Privacy Rule may rely on state law. In contrast, entities in states that do not have medical privacy laws, which are stricter than HIPAA's, will be bound by the Privacy Rule.

In practice, however, the mechanics of HIPAA preemption is not so easy. The language of HIPAA's preemption clause suggests that while some individual provisions of any state's given law will be considered more stringent than HIPAA (and will thus supercede HIPAA), other provisions of the very same law may not. In addition, the fact that HIPAA's preemption clause speaks in terms of state *law* indicates that HIPAA officers should not confine their analyses to state *statutes* on medical privacy. The reason is that the word "law" encompasses common law court precedents and administrative provisions, as well as statutes. Furthermore, HIPAA-covered entities that do business in more than one state must undertake preemption analyses for every state in which they operate.

Botsford. In the *Botsford* case, Mr. Bruce Botsford, who was covered by FEHBA, received a smaller-than-expected reimbursement check after undergoing medical treatment from a provider who was not a participant in Botsford's usual health plan. Botsford became convinced that his insurer, Blue Cross, had not followed through on reimbursement promises it advertised and filed a lawsuit alleging fraud in federal court. The court dismissed Botsford's case, saying that the matter was a contract dispute that belonged in state, not federal court.

The Ninth Circuit, however, reversed on preemption grounds. It began by approaching the case using the *de novo* standard of review — the legal standard under which a lower court's adjudication of the matter is entitled to very little deference. The Ninth Circuit then set the framework for its analysis: "[t]o preempt state-law causes of action completely." Judge Thomas G. Nelson, who wrote for the court, explained that the federal law at issue "must both: (1) conflict with state law (conflict preemption) and (2) provide remedies that displace state law remedies (displacement)."

As to the first prong of this analysis, the Ninth Circuit noted that FEHBA contains an express preemption clause. Interestingly, Judge Nelson also noted that, under FEHBA, the preemption clause had recently been narrowed by a congressional re-write. This was due to judicial rejection of the FEHBA law's original, much broader clause, which had "specified that only state and local laws and regulations were 'inconsistent with such contractual provisions' were preempted." Judge Nelson then said that FEHBA's new preemption clause "closely resembles" that of the Employee Retirement Income Security Act (ERISA), and that ERISA therefore "provides authority for cases involving the FEHBA provision."

Judge Nelson continued by reviewing the history of ERISA and FEHBA preemption clauses. That review showed that interpretation of ERISA's preemption language "has evolved from a plain language interpretation in which the statutes would have preempted nearly everything, to a more pragmatic interpretation in which courts seek to preserve the goals of Congress when it passed the statutes, while maintaining state control in traditional fields of state regulation." Nelson then went on to consider "Congress's stated goal when it enacted FEHBA in 1959" and whether the "application of different state standards would disrupt the nationally uniform administration of benefits" that FEHBA was enacted to accomplish.

As to the second prong, displacement, of the Ninth Circuit analysis, Judge Nelson found that "[t]raditionally, courts considering whether a federal statute displaces state remedies have examined a statute's civil enforcement scheme and its jurisdictional statement, as well as the legislative history" of the federal statute. Following this "well-traveled path," Nelson concluded that FEHBA did indeed displace state laws on the same topic. This was because FEHBA has "complex" and "detailed" civil enforcement provisions that vested the U.S. Office of Personnel Management (OPM) with the power to promulgate related regulations and enforce remedies against insurance carriers. FEHBA also contains a generally narrow jurisdictional statement that Judge Nelson wrote, "is as broad as it can be" within the context of the entire statute. Given this, Nelson held that Botsford's claim stood to "undermine the federal scheme" on the topic of federal employee health benefits. Thus, both prongs of the Ninth Circuit's preemption test were met and the federal FEHBA law was held to preempt Botsford's claim.

HIPAA compared. Comparing HIPAA to FEHBA, and the Ninth Circuit's analysis of it, on preemption grounds yields both some prominent parallels and some notable contrasts.

First, like FEHBA, HIPAA has a preemption clause that is considered "express," in that it explicitly states that it is preempting contrary state laws. Unlike FEHBA, however, HIPAA's preemption clause has remained unchanged since it was first enacted into law.

The next comparisons between the FEHBA situation and HIPAA are the most interesting. Although the Ninth Circuit was able to draw a close comparison between FEHBA and ERISA and rested much of its analysis on this parallel, it is debatable whether HIPAA has a similar counterpart anywhere else in the statute books.

To the extent it does, ERISA again seems the most likely candidate. Located at 29 USC §1144(a), ERISA's preemption clause states that "the provisions of this subchapter...shall supercede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan described" in the ERISA statute. This is similar to but

far more emphatic than HIPAA's preemption clause, which says that the Privacy "regulation...shall not" be considered to "supercede a contrary provision of State law, if the provision of State law imposes requirements...that are more stringent than" HIPAA. This comparison suggests that HIPAA's preemption language could be read liberally by courts, even more liberally than courts have read the similar but stricter ERISA language that has itself undergone a loosening of interpretation over time. To the extent that HIPAA does in fact echo ERISA's preemption language, the possibility is left open that interpretation of HIPAA's preemption language could, as happened in *Botsford*, "evolve from a plain language interpretation" in which HIPAA's preemption language is seen to preempt "nearly everything," to a "more pragmatic interpretation" in which courts seek to preserve what they see as the Congressional intent behind HIPAA. Courts would then also be free to inquire as to whether the "application of different state standards would disrupt the nationally uniform administration" of healthcare privacy policy.

As to the displacement prong of a preemption analysis, the HIPAA situation is again not unlike the FEHBRA situation. Like FEHBA, HIPAA could be said to have a "complex" and "detailed" civil enforcement scheme. Much as FEHBRA vested significant enforcement authority in OPM, HIPAA has vested similar authority within the Department of Health and Human Services's Office of Civil Rights (OCR). If courts see the matter this way, courts would stand — under a *Botsford*-like approach — to be significantly influenced by HIPAA's jurisdictional language when interpreting HIPAA's preemption clause.

There are two possible conclusions that could be drawn (i.e. liberal interpretation of HIPAA's preemption language, free judicial injury into congressional intent, national uniformity, close focus on jurisdictional language). The first is that HIPAA preemption questions may be less clear than many commentators have thus far suggested. The second is that HIPAA may preempt more state laws than has been generally believed thus far.

Caveats. Generally speaking, however, the extent to which the *Botsford* decision may truly presage future approaches to HIPAA preemption problems is uncertain. For one thing, there is an element of "apples and oranges" to the foregoing comparison, given that ERISA and FEHBA deal with contracts and benefits, while HIPAA deals with privacy. For another, the Ninth Circuit is rather notorious among legal scholars and practitioners for having its approaches and outcomes disputed by both other circuits and the U.S. Supreme Court. The Second, Fifth, and Sixth Circuits, in fact, have all recently disputed the Ninth Circuit's approach to state/federal conflicts in the specific context of ERISA. In addition, even to the extent that other courts found a HIPAA-*Botsford* comparison generally compelling, they might be likely to depart from direct parallels at any of the many steps of the comparative analysis. ■

Botsford v. Blue Cross and Blue Shield of Montana, Inc., 9th Cir., No. 01-36019, Dec. 23, 2002, ¶301,465

"HIPAA preemption is not so easy."

HHS schedules four Privacy Rule conferences

by Gordon R. Shea, J.D.

The Department of Health and Human Services (HHS) has announced that it will hold four one-day conferences on the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA) across the country in February and March of this year.

The conferences are scheduled as follows:

- February 5, 2003—San Diego, California
- February 18, 2003—Atlanta, Georgia
- March 1, 2003—New York City, New York
- March 2, 2003—Chicago, Illinois

The conferences are one-day events that HHS says, "are designed to provide an unprecedented opportunity to hear from and interact with officials who developed" the Privacy Rule and who "will be responsible for interpreting and enforcing" it. HHS's Office of Civil Rights (OCR) will also have what the agency is calling "expert faculty" on hand to take queries at question and answer sessions.

Thus far, registration has been scheduled for only the two February conferences. Registration can be made by visiting the website www.hhs.gov/ocr/conference.html.

Following NCVHS? HHS's scheduling of these four sessions follows two reports by the National Committee on Vital and Health Statistics (NCVHS). These reports warned HHS in November 2002 that there "is an extremely high level of confusion, misunderstanding, frustration, anxiety, fear, and anger as the April 14, 2003" Privacy Rule compliance date nears. NCVHS has also reported a troubling overall lack of Privacy Rule readiness, "high levels of confusion and frustration" with the Privacy Rule, and a "likelihood of widespread disruption" in the nation's health care system in conjunction with the April compliance date. NCVHS said that the OCR was a particular target of complaints that the Committee heard in field testimony. NCVHS said there was a need for massive training and outreach on the part of HHS, which the upcoming conferences seem tailor-made to meet.

It is far from clear, however, that the scheduled sessions will mollify concerned healthcare industry players. According to NCVHS, an overwhelming number of the witnesses it heard from late last year testified that "general guidance" was of limited use and that specifically tailored training from sources other than high-priced private consultants would be much more effective. ■

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