CMS Issues Stark II Phase II Final Rules: Summary of Key Changes and Clarifications
by Robert M. Portman

I. Introduction
The Centers for Medicare and Medicaid Services ("CMS") of the U.S. Department of Health and Human Services recently issued its long-awaited Phase II regulations on the Stark II physician self-referral law. These regulations, which were issued as an interim final rule with a 90-day comment period, supplement the Phase I final rules that were issued in January, 2001. The rules contain many significant changes and several new exceptions from the proposed rules issued in January, 1998 and the Phase I rules. The Phase II rules went into effect on July 24, 2004.

The Phase I rules covered the following provisions of the Stark statute:
• the general prohibition on physician self-referrals;
• the definitions of key terms, including "group practice" and "designated health services"; and
• the general exceptions that apply to both ownership and compensation relationships, including the in-office ancillary services exception and several new regulatory exceptions.

The Phase II rules cover:
• responses to and changes based on public comments on the Phase I regulations;
• the remaining provisions of the statute, including exceptions for ownership and investment interests and compensation arrangements such as personal service agreements and space and equipment leases, reporting requirements, and sanctions;
• additional definitions; and
• additional new regulatory exceptions, including an exception for professional courtesy.

In general, the Department has tried to reduce regulatory burdens and add flexibility by using the Secretary’s discretionary authority under the statute to create exceptions that pose no risk of fraud or abuse. However, the rule still contains many traps for the unwary. This article summarizes the basic Stark prohibition and the highlights of the Phase II rules. A more detailed summary of the Phase I and Phase II final rules is available on the Jenner & Block website.

II. Basic Prohibition of Stark II
Stark II prohibits a physician from making a referral to an entity for the furnishing of "designated health services" ("DHS") covered by Medicare if the physician (or an immediate family member of the physician) has a financial relationship with that entity, unless a statutory exception exists. The statute also prohibits an entity from submitting a claim to Medicare, or to any other person or entity, for DHS provided pursuant to a prohibited referral. Other sections of the Social Security Act apply the self-referral ban to Medicaid services.

The statute lists 11 categories of DHS, including:
1. clinical laboratory services;
2. physical therapy services;
3. occupational therapy services;
(4) radiology services;
(5) radiation therapy services;
(6) durable medical equipment (DME) and supplies;
(7) parenteral and enteral nutrients, equipment, and supplies;
(8) prosthetics, orthotics, and prosthetic devices and supplies;
(9) home health services;
(10) outpatient prescription drugs; and
(11) inpatient and outpatient hospital services.

A financial relationship is defined to be a direct or indirect ownership interest or compensation arrangement. The statute contains numerous exceptions that apply to ownership and compensation arrangements, and some that apply to both. Prohibited referrals are not reimbursable, and knowing violations of Stark II carry severe monetary penalties and in some cases exclusion from Medicare.

It is important to note that Stark II is separate from the Medicare-Medicaid anti-kickback law, which broadly precludes payments in exchange for referrals of program-related items or services. Compliance with Stark II does not necessarily ensure compliance with the anti-kickback statute and vice versa. In addition, Phase II declines to adopt a blanket Stark II exception for conduct that meets an anti-kickback safe harbor, although it does create some specific exceptions that effectively adopt certain anti-kickback safe harbors. Compliance with the anti-kickback law is also a condition for meeting several Stark II exceptions.

In response to comments on the Phase I final rules, Phase II made several important changes and clarifications. Specifically, it:

- Clarifies that a financial relationship with an entity that provides DHS implicates the statute even if it is wholly unrelated to the DHS, for example where the financial relationship only involves private pay business.
- Confirms that payment may be made to a DHS entity that receives a prohibited referral if the entity did not have actual knowledge, and did not act in reckless disregard or deliberate ignorance, of the identity of the physician who made the referral, and the claim complies with all other applicable federal laws, rules, and regulations.
- Confirms that DHS personally performed by the referring physician is not covered by the definition of “referral,” but clarifies that this exclusion does not apply to DHS performed by the physician’s co-owners, employees or independent contractors. One effect of this clarification is that productivity bonuses can be paid without violating Stark II for DHS personally performed by physicians. Productivity bonuses may also be based on “incident to” DHS for physicians in group practices that otherwise meet the group practice requirements.
- Excludes from definition of radiology services those radiology procedures that are does create some specific exceptions that effectively adopt certain anti-kickback safe harbors. Compliance with the anti-kickback law is also a condition for meeting several Stark II exceptions.

III. Highlights of Phase II Final Rules

Phase II first provides clarifications and modifications in response to comments on the Phase I final rules. It also creates final rules for the existing statutory exceptions not covered by Phase I; and third, it establishes several new regulatory exceptions under CMS’s authority to create new exceptions that do not pose a risk of program or patient abuse. Lastly, it establishes final rules for the reporting requirements and sanction provisions of Stark II. The highlights of Phase II follow.

A. Changes in Response to Comments on Phase I Rules

In response to comments on the Phase I final rules, Phase II made several important changes and

clarifications. Specifically, it:
integral to the performance of a nonradiological medical procedure either during the procedure, or immediately following the procedure to confirm placement of an item positioned during the procedure.

- Confirmed that PET scans and other nuclear medicine procedures are not DHS, but said it was still considering whether these procedures should be covered by Stark II.

- Further broadens and clarifies the in-office ancillary services exception, which is designed for group practices that order, provide, and bill for DHS. Among other things, Phase II creates a more liberal test for one of the location requirements of the exception—i.e., where the services must be performed to qualify for the exception; clarifies that a solo practitioner may provide DHS through a shared facility, as long as the supervision, location, and billing requirements of the in-office ancillary services exception are satisfied; and confirms that leased employees can be members of group practices if they meet the IRS definition of employee.

- Clarifies the rules for determining whether an indirect ownership interest or compensation arrangement exists and when the indirect compensation exception applies.

- Permits percentage-based compensation arrangements if certain conditions are met and confirms that per-service, time-based, and unit-based compensation provisions are permissible under certain circumstances. This change will allow physicians to enter into personal service agreements and leases with percentage-based, per-service, and per-click compensation provisions.

- Creates specific safe-harbor methodologies for calculating an hourly payment for physician services that will be deemed to meet the fair market value requirements of various Stark II exceptions.

- Clarifies that an arrangement that meets an ownership or investment interest exception does not also have to meet a compensation exception to protect profit distributions, dividends, or interest payments on secured obligations.

- Changes the definition of "commercially reasonable," a term used in several compensation exceptions, to "An . . . arrangement [that] would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician (or family member or group practice) of similar scope and specialty, even if there were no potential DHS referrals."

In addition, Phase II retains the following exceptions from the Phase I final rules of special interest to many physicians:

- The definition of DHS excluding services provided as part of a composite rate, such as an ambulatory surgical center ("ASC") rate, but declines to create an exception for radiology procedures performed in ASCs and billed for outside the composite rate.

- The exception for non-monetary compensation from DHS entities to physician up to $300. Phase II agrees to index this limit for inflation.

- The exception for incidental benefits provided to hospital medical staff. Phase II will index for inflation the $25 per occurrence limit on expenditures and makes additional changes to clarify the type of benefits covered. Phase II also excepts the listing or identification of physicians on hospital websites (but advertising or promoting a physician’s private practice on the hospital’s website is not excepted), deletes the requirement that benefits be of a type offered to medical staff members at other local hospitals or by comparable hospitals in comparable regions, and clarifies that the exception applies to other institutions, such as long term care facilities, federally qualified...
health centers ("FQHCs"), and other health care clinics as long as they have bona fide medical staffs.

B. Final Rules for Ownership and Compensation Exceptions

Phase II also created final rules for several ownership and compensation exceptions created by the statute or proposed rules that were not addressed by Phase I. The key changes or clarifications for these exceptions are as follows:

- **Publicly-Traded Securities and Mutual Funds.** The statutory exception for ownership in certain publicly-traded securities and mutual funds requires that the securities be available for purchase on terms generally available to the public. Phase II interprets this provision to mean availability at the time of a DHS referral rather than time of purchase of the security, as was originally proposed. This change means that stock purchased during a private offering may be eligible for the exception if the company goes public before a DHS referral is made. In addition, ownership in stock options received as compensation will not be considered to be ownership or investment interests until the time they are exercised.

- **Rural Providers and Hospital Ownership.** Phase II implements the temporary exclusion of specialty hospitals from the exception for ownership or investment interests in rural providers (defined as providers outside metropolitan statistical areas) and the exception for ownership of U.S. hospitals, as mandated by the Medicare Prescription Drug Improvement, and Modernization Act of 2003. Otherwise, these exceptions are unchanged.

- **Rental of Office Space and Equipment.** As noted above, Phase II clarifies that percentage-based and per-click leases are permissible as long as methodology for calculating the compensation is set in advance, objectively verifiable, and does not change over the course of the arrangement in any manner that reflects the volume and value of referrals or other business generated by the referring physician. In addition, Phase II provides that:
  - leases or rental agreements may be terminated with or without cause as long as no further agreement is entered into within the first year of the original lease term and any new lease between the parties meets an exception (the government believes termination without cause provisions are subject to abuse because they permit the parties to circumvent the requirement that the term of a lease, or personal services agreement, be at least one year);
  - month-to-month holdover leases are permitted for up to 6 months if they continue on the same terms and conditions as original lease;
  - there will be no distinction between capital and operating leases (the proposed rule would have excluded capital leases from this exception);
  - the requirement that the lessee have exclusive use of the property or equipment during the period of use will be met as long as the lessee or sublessee does not share the rented space or equipment with the lessor (or any entity related to the lessor) during the time it is rented or used by the lessee or sublessee.
• **Bona Fide Employment Relationships.** This exception is unchanged from the Proposed Rule, except, consistent with the Phase II determination that services personally performed by physicians are not referrals, Phase II permits payment of productivity bonuses to employed physicians based on any services that they personally perform, including DHS. The Proposed Rule would have precluded productivity bonuses based on DHS personally performed by employed physicians. Productivity bonuses still may not be paid to employed physicians based on supervision of “incident to” DHS services, unless done so under the in-office ancillary services/group practice exception.

• **Personal Services Arrangements.** Phase II makes several clarifications to the exception for personal service agreements. Specifically, it states that:
  - the exception covers services provided by the referring physician or his or her immediate family member and/or through technicians or employees (or through a wholly-owned subsidiary), but not through independent contractors; except that *bona fide locum tenens* may be used in referring physician’s absence;
  - personal services mean any kind of services personally performed, not just generic Medicare services;
  - a personal services contract can be between a DHS entity and an individual or the individual’s group practice;
  - as with leases, percentage-based, per-service, or time-based compensation are permissible as long as the methodology and/or amount is set in advance and does not vary with the volume or value of DHS referrals; hourly payments can be structured under the new safe harbor discussed above;
  - as with leases, termination without cause clauses are permitted as long as the parties do not enter into the same or substantially same arrangement during the first year of the original term and any subsequent agreement fits on its own terms in an exception;
  - personal service agreements may include equipment that the physician needs to provide services; separate equipment leases are not required;
  - to meet the statutory requirement that the agreement cover all services provided by a physician to a DHS entity, Phase II requires either that the multiple agreements incorporate one another by reference or that each agreement cross-reference to a master list of agreements that is maintained and updated centrally. Such master lists must be made available for inspection by the Secretary upon request and the list or lists must be maintained in a manner that preserves the historical record of contractual arrangements between the parties.

• **Remuneration from Hospitals to Physicians Unrelated to Provision of DHS.** Phase II clarifies that this exception applies only to remuneration that is wholly unrelated to provision of DHS—e.g., rental of residential property. Any cost that can be allocated, in whole or in part, to Medicare or Medicaid, will be treated as related to the provision of DHS. Also, any remuneration will be treated as related to DHS if it is furnished directly or indirectly, explicitly or implicitly, to medical staff or other physicians in a position to make or influence referrals in any manner that is selective, targeted, preferential, or conditional. Phase II clarifies that this exception does not apply to remuneration to family members.

• **Physician Recruitment.** This exception allows for
remuneration provided by a hospital to a physician to induce the physician to relocate to the geographic area served by the hospital to be a member of the hospital's medical staff. Phase II creates a new test for determining relocation eligibility, which changes the focus from the relocation of the physician’s residence to the relocation of his or her practice. Among other things, Phase II also permits, in limited circumstances, payments to medical groups, rather than individual physicians, and retention payments for physicians who practice in health professional shortage areas. Hospitals making recruitment payments cannot prevent physicians from obtaining staff privileges at, and/or referring to, other hospitals, but hospitals may still have reasonable credentialing restrictions with respect to numbers of procedures performed at the hospital, etc.

- **Isolated Transactions.** This exception permits isolated transactions, such as a one-time sale of property or a practice, in certain circumstances. Phase II reverses the proposed rule by permitting these transactions to include installment payments if the total aggregate payment is set before the first installment payment is made and does not take into account, directly or indirectly, referrals or other business generated by the referring physician. In addition, the outstanding balance must be secured by a third party, promissory note, or other mechanism to guarantee payment. Post closing adjustments are permitted within 6 months of date of the purchase or sale transaction if they are commercially reasonable and not dependent on referrals or other business generated by the referring physician. Phase II also clarifies that this exception covers any isolated transaction, not just those that involve DHS or Medicare.

- **Payments Made by Physician for Items and Services.** This exception protects items or services purchased by physicians from DHS entities at a price consistent with fair market value. Phase II extends this exception to cover purchases by a physician’s family members. It also removes a proposed exception for items or services purchased by physicians at a discount.

### C. New Regulatory Exceptions

Phase II creates several new exceptions intended to protect practices that are not considered to be improper or abusive. For instance, the new rule includes the following exceptions:

- **Noncompliance Grace Period.** Creates a 90-day grace period for certain arrangements involving temporary noncompliance for reasons beyond the control of the entity furnishing DHS, and the entity promptly takes steps to come back into compliance. The exception may only be used by an entity once every 3 years with respect to the same referring physician. It also does not apply to arrangements that previously complied with the exceptions for non-monetary compensation up to $300 or incidental medical benefits.

- **Professional Courtesy.** Creates a narrow exception for professional courtesy offered by a DHS entity to a physician or a physician’s immediate family member or office staff if the professional courtesy is offered to all physicians on the entity’s medical staff or in the entity’s local community or
service area without regard to the volume or value of referrals or other business generated between the parties, is not offered to a federal health care program beneficiary unless there has been a good faith showing of financial need, and several other conditions are met.

- **Intrafamily Referrals in Rural Areas.** Creates a new exception for certain referrals from a referring physician to a DHS entity with which his or her immediate family member has a financial relationship, if the patient being referred resides in a rural area and there is no DHS entity available in a timely manner in light of the patient’s condition to furnish the DHS to the patient in his or her home (for DHS furnished to patients in their homes) or within 25 miles of the patient’s home (for DHS furnished outside the patient’s home).

- **Anti-kickback Safe Harbors.** Adopts the Medicare anti-kickback safe harbors for referral services and obstetrical malpractice insurance as new Stark II exceptions.

- **Other New Exceptions.** Creates new exceptions for retention payments to physicians in underserved areas, charitable donations by physicians, and community-wide information systems.

### D. Reporting Requirements and Sanctions

The final rule generally requires entities that provide DHS to retain reportable information and furnish it to HHS upon request. This is a substantial improvement from the Proposed Rule, which would have imposed very onerous affirmative reporting requirements on DHS entities that would have applied with or without a government request. Still, the regulations will require medical practices to maintain specified information on each of its physicians’ ownership or compensation relationships that are covered by Stark II, except for shareholder information relating to ownership interests that satisfy the exceptions for publicly-traded securities and mutual funds. The specific requirements are included in Section 411.361 of the rule and listed in the detailed summary available at www.jenner.com. The failure to respond to a request for information from the Secretary within 30 days is subject to a fine of up to $10,000 per day.

Phase II makes no change in the sanctions for Stark II violations, which include nonpayment of claims resulting from prohibited referrals or require refunds of amounts paid on prohibited claims. Individuals or entities that knowingly violate the prohibition are subject to civil monetary penalties.

### IV. Conclusion

The Phase II final rule contains many changes that should be helpful to physicians and entities that furnish DHS in their efforts to comply with this law. However, the final rules are still enormously detailed and complex, creating many traps for the unwary. Physicians and DHS providers should take care to consult with experienced legal counsel before entering into any business or professional arrangements that implicate the statute.

### Endnotes


6 With the exception of prepaid health plans, Phase II does not include provisions elaborating on the application of Stark II to Medicaid. CMS indicated that it will publish rules on this issue at a future date.

7 See 42 C.F.R. § 1001.952(f) and (o).
At the end of its recent 2003-04 term, the U.S. Supreme Court shed further light on the scope of the preemptive effect of the Employment Retirement Income Security Act of 1974 (ERISA) on state health care liability claims against insurers. In *Aetna Health Inc. v. Davila* and *CIGNA Health Care, Inc. v. Calad*, the Supreme Court ruled in a unanimous decision that patients cannot use state health care liability laws to sue the administrators of ERISA-regulated employee benefit plans for claims relating to the denial of coverage of treatment or services. In both cases, an HMO, acting as plan administrator, denied physician-recommended treatment because it determined that the benefit sought was not covered by the plan. In reaching its conclusion, the Court, speaking through Justice Thomas, reasoned that allowing the plaintiff’s state law claims would interfere with Congress’ intent to create a uniform scheme for the regulation of employee benefit plans and therefore the claims were completely preempted by ERISA. The effect of the Court’s decision will likely be to shift the focus of future legal battles over coverage denials by ERISA-regulated employer-provided health plans administered by an HMO. In *Davila*, the physician recommended Vioxx for arthritis pain. However, Aetna refused to pay for the recommended drug. Davila took a different medication and suffered a severe reaction requiring hospitalization and extensive treatment. In *Calad*, the physician recommended an extended hospital stay following a scheduled surgery. CIGNA determined that Calad did not meet the plan’s criteria for an extended hospital stay and refused to cover it. Calad suffered post-surgery complications. Both Davila and Calad brought suit under the Texas Health Care Liability Act (THCLA), claiming that the HMOs’ refusal to authorize benefits proximately caused their injuries and therefore constituted a breach of the THCLA duty to exercise reasonable care.

*Aetna* and *CIGNA* removed the state actions to federal court on the basis that Davila and Calad’s claims were completely preempted by the civil enforcement provisions found in Section 502 of ERISA. The district courts ruled in favor of the HMOs and because the plaintiffs refused to amend their complaints to bring claims under ERISA, the courts dismissed the cases with prejudice. Davila and Calad both appealed to the Fifth Circuit Court of Appeals where their cases were consolidated (as *Davila*) along with several others raising similar issues. The Fifth Circuit ruled for the plaintiffs, holding that their state causes of action were not preempted by ERISA because the actions were:

(i) mixed eligibility and treatment cases not subject to ERISA;
(ii) pleaded in tort rather than ERISA breach of contract language; and
(iii) sought tort damages under an independent statutorily-imposed duty of ordinary care rather than for the collection of benefits.

The Court of Appeals reasoned that complete preemption under ERISA

---

**History**

Both *Davila* and *Calad* involved employer-provided health plans administered by an HMO. In *Davila*, the physician recommended Vioxx for arthritis pain. However, Aetna refused to pay for the recommended...
is limited to cases in which states duplicate causes of actions available under ERISA and because the Texas health care liability law does not provide an action for collecting benefits, the plaintiffs’ claims fell outside of ERISA. The HMOs appealed to the Supreme Court and were granted certiorari.

**Summary of the Decision**

The Supreme Court first notes that the purpose of ERISA is to provide a uniform regulatory scheme over employee benefit plans and that ERISA § 514 specifically includes broad preemption provisions to serve that end. As further evidence of Congress’ intent to create a comprehensive statute for the regulation of employee benefit plans, the Court points to the existence of carefully integrated, albeit limited, civil enforcement remedies in ERISA Section 502(a). Although Section 502(a) does not provide all potential remedies, the Court, quoting its previous decision in *Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 504 (1981), notes that the statute’s explicit remedies represent a “‘careful balancing of the need for prompt and fair claims settlement procedures against the public interest in encouraging the formation of employee benefit plans. ... [and] provides strong evidence that Congress did not intend to authorize other remedies that it simply forgot to incorporate expressly.’” Therefore, the Court concludes that “any state law cause of action that duplicates, supplements or supplants the ERISA civil enforcement remedy conflicts with the clear congressional intent to make the ERISA remedy exclusive and is therefore preempted.” In addition, the Court confirmed that causes of action within the

... because plaintiffs’ causes of actions were brought to remedy only the denial of benefits under ERISA-regulated benefit plans, their state law claims ... were completely preempted by ERISA.

The plaintiffs contended that their HMOs’ actions violated legal duties that arose under Texas law independently of ERISA or of the terms of the employee benefit plans at issue. Specifically, they claimed that the Texas health care liability law created a duty for managed care entities to exercise ordinary care when making health care treatment decisions. However, the Court concluded that the essential actions complained of were the HMOs’ refusal to approve payment for particular treatments because they were not covered by the plaintiffs’ respective ERISA-regulated employee benefit plans. Therefore, because plaintiffs’ causes of actions were brought to remedy only the denial of benefits under ERISA-regulated benefit plans, their state law claims fall within the scope of ERISA’s civil enforcement mechanism and were completely preempted by ERISA.

In permitting the suit to go forward outside of ERISA, the court of appeals had found significance in the fact that the plaintiffs had alleged a tort claim for tort damages rather than a contract claim for contract damages and were not seeking reimbursement for benefits denied. The high court rejected this reasoning as putting form over substance and allowing the evasion of ERISA’s preemptive scope by merely re-labeling contract claims as tortious breach of contract claims. Likewise, the mere
fact that a state law authorizes remedies beyond those available under ERISA cannot alter ERISA’s preemptive scope and effect.

The Court also rejected the plaintiffs’ claim, raised for the first time in the Supreme Court, that the Texas statute is a law that regulates insurance and therefore falls within the “business of insurance” exception from ERISA preemption under § 514(b)(2)(A). Following Pilot Life and other precedents, the Court found that “even a state law that can arguably be characterized as ‘regulating insurance’ will be preempted if it provides a separate vehicle to assert a claim for benefits outside of, or in addition to, ERISA’s remedial scheme.”

Lastly, the Court distinguished its decision in Pegram v. Hedrich, 530 U.S. 211 (2000), which held that ERISA did not preempt claims that involved mixed eligibility and treatment decisions by an HMO acting through its physicians. In such cases, ERISA does not apply because HMOs are not acting in their fiduciary capacity. The Court emphasized that Pegram only applies in situations where the alleged “negligence plausibly constitutes medical maltreatment by a party who can be deemed to be a treating physician or such physician’s employer.” (citation omitted) This case, by contrast, involved pure eligibility decisions by HMOs acting in their fiduciary capacity, even though those decisions might involve medical judgments. And it did not involve the plaintiffs’ treating physicians or their employers. Thus, the Court appears to have significantly narrowed its holding in Pegram in order to distinguish it from the facts in Davila.

…the decision is likely to shift the focus of future litigation in coverage denial cases from preemption of state remedies to the scope of remedies available under ERISA.

Impact of the Decision

Davila represents a significant clarification of the scope of ERISA’s preemptive effect. The case restricts participants contesting coverage decisions under employer-provided health plans to bringing suit under ERISA. Therefore, despite state laws attempting to fill the void, plan participants’ ability to recover compensation for damages that result from the denial of claims is essentially capped. HMO administrators cannot be sued for refusing pay for benefits that the plan has not chosen to provide – despite the fact that not providing certain benefits may proximately cause injury to a plan participant. Certain benefits simply are not covered. At the same time, the Court’s decision leaves the door open to, and Justice Ginsburg’s concurrence explicitly calls for, broader remedies under ERISA itself. Thus, the decision is likely to shift the focus of future litigation in coverage denial cases from preemption of state remedies to the scope of remedies available under ERISA.

Concurrence

Justice Ginsburg’s concurrence, joined by Justice Breyer, attempts to shift the battle from ERISA preemption to ERISA remedies. She warns that the Court’s strong ERISA preemption doctrine coupled with a “cramped construction” of ERISA’s equitable remedies leaves many plaintiffs without access to make-whole relief. As a result, Justice Ginsburg calls on Congress and/or the Supreme Court “to revisit what is an unjust and increasingly tangled ERISA regime.” She urges both institutions to take steps to broaden ERISA’s equitable relief and specifically to reconsider the provision of consequential damages under ERISA. She points out that the Government’s amicus brief suggests that the Act as currently written and interpreted leaves room for some type of “make-whole” relief against a breaching fiduciary. She hints that others in plaintiffs’ situation may want to bring claims under ERISA for such relief, which, she notes, is a traditional remedy against fiduciaries under trust law.
Federal Court of Appeals Rules on HIPAA Privacy Regulations

by Edward F. Malone

The United States Court of Appeals for the Seventh Circuit recently issued one of the first decisions by a federal court of appeals interpreting the HIPAA privacy regulations. In Northwestern Memorial Hospital v. Ashcroft, 362 F.3d 923 (7th Cir. 2004), the Seventh Circuit reviewed a district court order quashing the government’s subpoena to Northwestern Memorial Hospital to produce the medical records of certain patients who had received late term abortions using a medical procedure banned under the Partial-Birth Abortion Ban of 2003 (“the Act”). The documents were subpoenaed in a lawsuit challenging the constitutionality of the Act that was brought by the physician who had performed the procedures. The district court held that the HIPAA statute directed the court to resolve the issue under Illinois state law, because Illinois law governing the production of medical records in litigation is “more stringent” than the HIPAA regulations, and therefore should be applied to prohibit the disclosures. The Seventh Circuit held that the district court erred in holding that the Illinois privilege governing medical records barred disclosure in this case.

HIPAA had the district court not found that a provision of the Illinois Code of Civil Procedure governing such disclosures – 735 ILCS 5/8-802 – was “more stringent” than the HIPAA regulations, and therefore should be applied to prohibit the disclosures. The Seventh Circuit held that the district court erred in holding that the Illinois privilege governing medical records barred disclosure in this case.

It reasoned that the Illinois rules created a state evidentiary privilege that does not apply in a federal case challenging the constitutionality of a federal statute. The court explained that the HIPAA regulation governing disclosure merely “create[s] a procedure for obtaining authority to use medical records in litigation.” We do not think HIPAA is rightly understood as an Act of Congress that creates a privilege.

Despite its disagreement with the district court’s interpretation of the HIPAA regulations, the Seventh Circuit agreed with the lower court’s conclusion that the subpoena should be quashed. Instead of resolving the issue under HIPAA or Illinois law, however, the court held that burden of compliance with the subpoena would exceed the benefit of production, and thus the subpoena should not be enforced under Fed. R. Civ. P. 45(c)(3)(A)(iv), the federal procedural rule governing third-party subpoenas. In short, the court found that the medical records were unlikely to be of much value to the Government… while the potential loss of privacy resulting from the disclosure of the records would be significant.

... the court found that the medical records were unlikely to be of much value to the Government ... while the potential loss of privacy resulting from the disclosure of the records would be significant.
court reasoned, “even if there were no possibility that a patient’s identity might be learned from a redacted medical record, there would be an invasion of privacy.” *id.* at 929, comparing the harm of disclosure to harm that might result from the publication of anonymous, nude pictures of the patient. The court identified the cost of production to be the “potential psychological cost to the hospital’s patients, and a potential cost in lost goodwill to the hospital itself, from the involuntary production of the medical records, even as redacted....” *id.* at 930.

At the end of the day, while the Seventh Circuit concluded that neither the HIPAA regulations nor the Illinois Code of Civil Procedure barred production of the records, its conclusion that the subpoena was unenforceable was informed by the privacy policies established by HIPAA and Illinois law, which have created strong expectations about the privacy of medical records among patients, physicians, and hospitals that should not be upset without a compelling reason.