

# HEALTH LAW TRENDS

Spring 2000

## NEW DEVELOPMENTS IN MEDICARE MAXIMIZATION

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The Health Care Financing Administration (“HCFA”) has given providers and suppliers some relief in the tug of war that often occurs between State Medicaid programs and the Medicare program as a result of so-called “Medicare Maximization” or “Third Party Liability” (“TPL”) audits<sup>1</sup>. These audits, which often result in large recoupments against providers and suppliers, rest on the theory that services should have been paid for by Medicare or another third party payer, rather than by Medicaid, which by law is the payer of last resort. HCFA has now clarified that States may not recoup money as a result of these audits until third party liability is established. Further, states with subrogation rights may not seek recoupment from providers, but must look directly to the Medicare program.

The Medicaid program is a joint Federal-State program, under which the federal government provides matching funds to states that account for at least 50% of the state’s Medicaid budget. Therefore, if a state Medicaid program is successful in shifting the obligation to pay for services to a third party payer, such as Medicare, the Medicaid program saves money. However, this also increases the costs incurred by the Medicare program, since HCFA must pay the administrative costs of processing TPL claims.

Encouraged by a high rate of success before federal Administrative Law Judges, state Medicaid programs conduct or contract with private entities to conduct “Medicare Maximization” or “TPL” audits, to identify claims that can be billed to Medicare. The goal of these audits is to identify claims from providers such as home health agencies, skilled nursing facilities, hospices and assisted living programs for dually eligible patients that have been paid by the state Medicaid program, but which the state believes should have been paid by the Medicare program or other third party payers. The basis for these Medicaid overpayments is the language of the Social Security Act, which makes Medicaid the payer of last resort.

HCFA’s letter to State Medicaid Directors and Program Memorandum “urge” Medicaid programs that have paid providers for Medicaid services for “dually eligible” patients, i.e., patients who are covered by both the Medicare and Medicaid programs, not to recoup these payments from the providers “until the extent of legal liability, if any, is established on the part of a third party (such as Medicare) to pay for the services.” The relief is even more powerful in states such as Connecticut, Michigan, New York and Vermont where, as a result of various court decisions, these states have obtained the right of subrogation to pursue Medicare appeals of denied claims on behalf of dually-eligible patients. HCFA advised the Medicaid programs in these states that they cannot pursue recoupment from providers. In these four states, HCFA requires that once liability is established the Medicaid programs must recover directly from liable third parties and not from the providers. As explained in detail below, the federal regulations

<sup>1</sup> The relief is contained in a letter from HCFA to State Medicaid Directors dated December 3, 1999 and its accompanying Program Memorandum to Intermediaries and Carriers, Transmittal AB-99-88.

do more than “urge,” but instead prohibit Medicaid programs from recouping from providers where third party liability has not been established. HCFA has the power to enforce these requirements through a State Plan Compliance proceeding.

In order to participate in the Medicaid program and receive matching federal funds, a state must submit a Medicaid State Plan that contains state regulations enforcing certain federally mandated State Plan requirements. The State Plan requirements authorizing recovery from liable third party payers are set forth in 42 C.F.R. §§ 433.135 to 433.153. Those federal regulations require state Medicaid programs to submit to HCFA for approval a description of the procedures to be used by the Medicaid program to identify any liable third party payers prior to Medicaid paying the claim. This is referred to in the regulations as “cost avoidance.” 42 C.F.R. § 433.139. Cost avoidance requires the Medicaid program to establish any third party liability at the time the claim is filed by the provider with Medicaid. Thus, the Medicaid program is required to reject the claim and return it to the provider with information necessary for the provider to bill the third party. Some states have computer edits in their Medicaid billing systems that identify claims that may be covered by Medicare or other third party payers. The cost avoidance requirements prevent overpayment and recoupment actions by state Medicaid programs based on retroactive audits of old claims because the correct payer is identified before the claim is paid by Medicaid.

A state Medicaid program may request a waiver from HCFA of the cost avoidance requirement and pursue what is known as “pay and recover later” or “pay and chase.” Under pay and chase the Medicaid program pays the total amount allowed under its payment schedule and later, sometimes up to six years later, seeks recovery from a third party payer such as Medicare. Usually recovery is sought by requiring a provider or supplier to submit the claims to Medicare under threat of a Medicaid overpayment. According to regulations and as reiterated in the December 3rd HCFA letter to

Medicaid Directors, recovery must take place only *after liability has been established*. See 42 C.F.R. § 433.139(d). Problems have arisen for providers because some Medicaid programs are ignoring the cost avoidance regulatory requirements and pursuing a pay and chase methodology even though they do not have a waiver to do so. In addition, some states are ignoring the requirement that recovery is permitted only after third party liability is established.

For example, when a provider is the subject of a Medicaid Maximization or TPL audit by the state Medicaid program, the state will require the provider to submit the claims to the Medicare fiscal intermediary to determine if Medicare coverage is appropriate. If the fiscal intermediary determines that the claim is too old, it will refuse to process the claim as untimely and issue a “Time Reject Notice.” Under this scenario, third party liability has not been established and the state Medicaid program cannot recoup against the provider pursuant to the regulations discussed above. However, state Medicaid programs are recouping overpayments against providers in just such a scenario and triggering financial hardships, closures, and bankruptcies. In these disputes the provider becomes a bouncing ball between the Medicare program that refuses to process the claim, and the Medicaid program, which will proceed with its recoupment action even though Medicare’s liability has not been established.

HCFA’s December 3rd letter to the State Medicaid Directors addresses this problem by advising States not to recoup any Medicaid payments until the extent of legal third party liability, if any, is established. If Medicare refuses to process a claim as untimely, there is no determination of other third party liability. Therefore recoupment against the providers is prohibited. Although the HCFA letter “urges” states not to recoup against providers where third party liability has not been established, HCFA does have the authority to enforce compliance with its regulations. HCFA has the authority to initiate an action against a state Medicaid program for failure to comply with its State Plan requirements. HCFA is authorized to withhold its

payments to a state for its Medicaid program for non-compliance with its State Plan in practice, which includes “the State’s failure to actually comply with a Federal requirement, regardless of whether the plan itself complies with that requirement.” 42 C.F.R. § 430.35. A state does have the right to an administrative appeal of HCFA’s decision. Thus, although HCFA “urges” compliance, it does have the authority to implement compliance with its regulations that prohibit recoupment from a provider when third party liability has not been established.

The Medicaid programs in New England and New York State have been very active in pursuing Medicare Maximization and TPL audits conducted by state auditors or contingency fee contractors, such as the Center for Medicare Advocacy or Health Systems Management, Inc.<sup>2</sup> These organizations contract with different state Medicaid programs to identify possible third party claims, and contact providers to request that they develop and submit claims to Medicare. The requests to providers are made under the threat of a Medicaid overpayment and recoupment action. These audits are retrospective and may involve claims up to six years old. Providers are not compensated for their administrative costs in locating, developing, and submitting these claims to Medicare. The Medicaid auditors or their contingency fee contractors file “Statements of Intent to File Claims” with Medicare advising Medicare of the forthcoming claims.

The increase in TPL claims submitted to Medicare by providers and suppliers in response to Medicaid overpayments, and the increase in administrative costs to process these claims are among the reasons HCFA issued the December 3rd letter to the State Medicaid Directors and its accompanying Program Memorandum. The Program Memorandum

instructs fiscal intermediaries and carriers that they are not responsible for: 1) identifying providers and suppliers of TPL claims for the state Medicaid programs; 2) requesting that the provider or supplier submit the claim; or 3) requesting additional information from the provider or supplier to develop the claim. These functions are the responsibility of the Medicaid program, or its contingency fee contractor, which files a “Statement of Intent To File Claims” for these TPL claims.

HCFA’s December 3rd letter and Program Memorandum emphasizing long standing regulations will help providers and suppliers obtain some relief from a previously no-win situation between the Federal and state governments. ■

## NEW DEVELOPMENTS IN EMTALA ENFORCEMENT

*By Robert Wanerman, J.D., M.P.H.*

The Emergency Medical Treatment and Active Labor Act (“EMTALA”) has emerged as a new priority for the Department of Health and Human Services in an attempt to forge a closer link between quality of care and fraud and abuse enforcement. Two recent developments may make it easier for the government to initiate an EMTALA investigation, but may make it more difficult to impose sanctions against hospitals and physicians.

Under EMTALA, a hospital participating in the Medicare program must offer an appropriate medical screening examination to any patient seeking emergency services to determine whether or not an emergency medical condition exists. If an emergency medical condition is found, the hospital must either (1) provide stabilizing treatment within the capabilities of the staff and facilities at the hospital, or (2) if the patient cannot be stabilized, the hospital must arrange for an appropriate transfer of the patient, after considering the patient’s condition as well as the risks and benefits of the transfer.

2 HCFA refers to these private contractors with State Medicaid programs as contingency fee contractors because they are usually paid a fee for every potential third party claim they identify. HCFA has denounced the use of Federal matching funds for “county bounty” because these payments to contractors to identify third party liability claims are not authorized expenditures under Title XIX of the Social Security Act, the Medicaid Act. See 60 FR 35498, 35500 (July 10, 1995).

If a hospital fails to meet these obligations, it is subject to a civil monetary penalty of up to \$50,000 per violation, and may have its Medicare provider agreement terminated by the Secretary of HHS.<sup>3</sup> In certain circumstances, a hospital may also be fined for its failure to accept an appropriate transfer if it has the staff and equipment to treat the patient.<sup>4</sup> The increased pace of HHS's enforcement is striking: during the first 10 years of the law's existence, HHS collected a total of \$1.84 million in settlements and judgments; however, during fiscal 1998, it entered into 53 settlements and judgments totaling \$1.82 million, and collected \$1.725 million in 61 settlements and judgments in fiscal 1999.<sup>5</sup>

The total cost of compliance with EMTALA can be quite substantial, and may even be a disincentive for hospitals and particularly for physicians: in a recent study, the uncompensated cost to hospitals of EMTALA compliance in 1996 was estimated to be \$ 10.5 billion, and the uncompensated cost of physician care in emergency departments was estimated at \$426 million during the same year.<sup>6</sup>

In a recent Special Advisory Bulletin, the the HHS Office of Inspector General ("OIG") and the Health Care Financing Administration ("HCFA") jointly published guidelines governing the application of EMTALA to managed care plans and to voluntary withdrawal by patients before examination and treatment.<sup>7</sup> The Special Advisory Bulletin notes that EMTALA generally prohibits a hospital from either delaying a screening examination or providing stabilizing treatment to inquire into a patient's method of payment or insurance status. However, this may create a conflict with existing requirements under managed care contracts that hospitals obtain prior authorization

before examining or treating individuals coming to their emergency department. Whenever such potential conflicts arise, the Special Advisory Bulletin unequivocally states the Department's position that under EMTALA, the obligation to provide screening and stabilizing treatment cannot be delayed or denied based on financial concerns. Once the stabilizing treatment, if needed, has begun, the hospital may then initiate requests for payment authorization from the managed care plan. Similarly, the Special Advisory Bulletin advises that hospitals not attempt to delay screening services or stabilizing treatment in order to secure an advance beneficiary notice obligating the individual to pay for any non-covered services. In HHS's view, these practices may impede hospitals from complying with EMTALA, and may deter patients from receiving services. In order to avoid such problems, HHS recommends that if patients make inquiries about their coverage, the hospital's response should be delayed at least until the screening examination is complete.

A special concern addressed in the Special Advisory Bulletin covers "dual staffing" of emergency departments. Under these arrangements, a managed care plan furnishes physicians on its panel in a hospital's emergency department for the sole purpose of examining and treating individuals covered under that plan. While recognizing that this practice may make it more difficult for a hospital to meet its EMTALA obligations, HHS did not declare the practice to be illegal in all cases. Nevertheless, it warned that if the two emergency tracks did not provide the equivalent degree of access to screening and stabilizing treatment, the hospital could violate EMTALA. Examples of non-compliance could include significant delays in treatment in one staffing track, differences in operating protocols, or differences in the hospital's quality assurance prac-

3 42 U.S.C. § 1395dd.

4 See *St. Anthony Hospital*, HHS Departmental Appeals Board, Civil Remedies Division, DAB CR 620 (October 5, 1999).

5 See Office Of Inspector General, Semi-Annual Reports to Congress (October 1997- September 1999).

6 See American College of Emergency Physicians, *Defending America's Safety Net* 11-13 (1999).

7 64 Fed. Reg. 61,353 (Nov. 10, 1999).

tices based on the staffing track. As a result, even though a hospital might intend to operate more efficiently by adopting a “dual staffing” model, the costs of ensuring that equivalent services are always provided may be a significant disincentive.

The Special Advisory Bulletin also contains a warning to hospitals to guard against “voluntary withdrawal” of patients, noting that a hospital can violate the law if a patient leaves due to a delay in conducting the medical screening examination or if there is a pattern of unreasonable delay that causes patients to leave the emergency department. In such circumstances, HHS believes that the better practice is to inform patients of their right to receive further treatment, to explain the benefits of treatment and the risk of withdrawal, and to take reasonable steps to obtain written consent should the patient choose to refuse examination and treatment. Even though HCFA’s regulations obligate an emergency department to maintain a log of all emergency department visits, this advisory can be seen as adding a special requirement in potential withdrawal cases. Moreover, the agency cautions that the hospital bears the burden of showing that services were appropriately offered and knowingly refused. However, this may leave hospitals without an objective standard of what constitutes a reasonable time period within which to conduct the medical screening examination or to provide stabilizing treatment.

EMTALA also authorizes the OIG to impose civil monetary penalties of up to \$50,000 per violation on individual physicians who fail to provide appropriate screening examinations or stabilizing treatment. However, the agency’s ability to impose sanctions has been curtailed by the decision of the United States Court of Appeals for the Sixth Circuit in *Cherukuri v. Secretary of Health and Human Services*.<sup>8</sup> In that case, a general surgeon

elected to transfer two patients who had suffered head trauma and abdominal bleeding because his hospital lacked the equipment to safely monitor the administration of anesthesia under such circumstances. The Sixth Circuit reversed the agency’s civil monetary penalty of \$100,000, which had been the largest such penalty imposed to date. It found that the scope of the stabilization requirement demanded under EMTALA only requires that the hospital stabilize the patient within the capacity of the staff and equipment available, and that a review of the attending physician’s decision to either treat or transfer an unstable patient must be based on the circumstances and available information at the moment that the physician makes that decision. Under this standard, the court rejected the view that Dr. Cherukuri was obligated to perform the abdominal surgery before attempting a transfer. The court’s conclusion relied on the legislative history of the EMTALA statute, which had been cited with approval by the Secretary in an *amicus curiae* brief filed with the Supreme Court in *Roberts v. Galen of Virginia, Inc.*, 119 S. Ct. 685 (1999), which observed that “all participating hospitals must . . . provide further examination and treatment within their competence to stabilize the medical condition or provide treatment for the labor.”<sup>9</sup>

These changes do not necessarily mean that every hospital is subject to EMTALA sanctions. Nevertheless, both hospitals and the medical staffs that provide services in emergency departments should carefully evaluate their protocols and standards to determine whether or not HHS’s current interpretation of the law poses a significant risk of non-compliance. While HHS has articulated an expansive interpretation of the situations under which EMTALA’s obligations may be triggered, the standard for imposing sanctions set out in *Cherukuri* may make enforcement more problematic for the agency. ■

<sup>8</sup> 175 F.3d 446 (6th Cir. 1999).

<sup>9</sup> H.R. Conf. Rep. No. 453, 99th Cong., 1st Sess. 473 (1985)(emphasis added). In addition, one of EMTALA’s co-sponsors, Senator Dole, stated that “a hospital is charged only with the responsibility of providing an adequate first response to a medical crisis” which “means the patient must be evaluated and, at a minimum, provided with whatever medical support services and/or transfer arrangements that are consistent with the capability of the institution and the well-being of the patient.” 131 Cong. Rec. 28569 (1985).

## HEALTHCARE INTEGRITY AND PROTECTION DATA BANK

*By Jo An Leonce, Esq.*

In an effort to battle health care fraud and abuse, the Department of Health and Human Services (“HHS”) has launched the Healthcare Integrity and Protection Data Bank (“HIPDB”). Health plans using the data bank will be capable of more thorough checks on the qualifications of those with whom they seek to contract, employ, or credential. The purpose of the data bank is to effectuate the wide dissemination of information concerning providers’ offenses to government agencies and health plans in order to prevent providers from evading the consequences of their offenses by relocating to other states. The final rule implementing the data bank was published on October 26, 1999 in the *Federal Register*. The rule took effect on the date of publication.

### *Reportable Final Adverse Actions*

The following types of information will be included in the data bank:

1. Actions taken by federal or state agencies concerning the licensure of any health care provider, supplier or practitioner;
2. Federal or state criminal convictions against health care providers, suppliers or practitioners;
3. Civil judgments, except malpractice judgments, against health care providers, suppliers or practitioners that are related to the delivery of a health care item or service;
4. Exclusion of health care providers, suppliers or practitioners from participation in federal or state health care programs; and
5. “Other adjudicated actions or decisions,” which are defined as any final action taken by a federal or state government agency or health plan that provided some type of due process mechanism. Examples include suspension without pay, reductions in pay, termination, or other similar actions.

HIPDB complements the 10-year-old National Practitioner Data Bank (“NPDB”), which contains information such as reports of medical malpractice

payments, adverse licensing actions, adverse clinical privileges actions, and adverse professional society membership actions involving physicians, dentists, and other types of health care practitioners. The Health Resources and Services Administration (“HRSA”), which currently operates the NPDB, will also manage the new data bank.

Due to the overlap in the entities required to report, those authorized to query, and the types of actions reported to the two data banks, the NPDB-HIPDB Integrated Querying and Reporting Service (“IQRS”) has been created to report to and query both data banks on the Internet. Depending upon the action being reported and the applicable laws, the IQRS will automatically submit the report to the NPDB, the HIPDB, or both. Before access is authorized, those who use the data banks are required to register and certify eligibility to report or submit queries. The integrated web site can be located at [www.npdb-hipdb.com](http://www.npdb-hipdb.com). Entities required to report to the data bank must provide information on all reportable final adverse actions taken since August 21, 1996, the date of enactment of the Health Insurance Portability and Accountability Act of 1996 mandating the creation of HIPDB.

Final adverse actions are required to be reported, regardless of whether or not the action is being appealed by the subject of the report. Although settlements in which no findings or admissions of liability have been made will be excluded from reporting, any final adverse action stemming from such settlements that is otherwise reportable is to be reported to the data bank.

### *Who is Required to Report?*

The following entities are required to report to the data bank:

- State and federal law enforcement organizations;
- State and federal agencies that license and certify any type of health care practitioner, provider, or supplier;
- Federal agencies that administer or provide payment for health care; and
- Private health plans.

The regulation defines a health plan as any group, organization, or company providing health benefits directly or indirectly through insurance, reimbursement, or other methods. The term “health plan” is quite broad, and includes traditional health insurance plans as well as insurance agents, brokers, solicitors and consultants, insurance companies, self-insured employers, and health care purchasing groups.

Government agencies and health plans are required to report final adverse actions:

- 1) within 30 days of the date of the action;
- 2) within 30 days of the date that reporting entity became aware of the final adverse action; or 3) by the close of the entity’s next monthly reporting cycle, whichever is later.

If government agencies fail to report, the name of the agency will be published in a public report; however, health plans are subject to a civil monetary penalty of up to \$25,000 for each adverse action not reported. In order to avoid being penalized, health plans must devise systems that will flag the required information and assure that it is reported in a timely fashion.

#### *Whose Actions Must be Reported?*

Government agencies and health plans must report adverse actions taken against health care providers, suppliers, and practitioners. “Health care providers” include HMOs, PPOs, hospitals, skilled nursing facilities, home health agencies, hospices, group medical practices, and any other health care entity that directly or indirectly contracts to provide health care services. “Health care suppliers” include but are not limited to durable medical equipment suppliers, manufacturers of health care items, pharmaceutical suppliers and manufacturers, health record services, billing and transportation services suppliers, and any individuals licensed by the state or otherwise authorized to provide health care services. “Practitioners” are individuals licensed by the state or otherwise authorized to provide health care services.

#### *Who May Access the HIPDB?*

The general public does not have access to the data bank. According to the regulation, only the government agencies and private health plans required to report to the data bank have the authority to access HIPDB’s information. Subjects of reports may receive their own report. HIPDB information may be requested for the following reasons: privileging and employment, professional review, licensing, certification or registration, fraud and abuse investigation, and civil and administrative sanctions.

The operating cost of the data bank is covered by fees obtained for each query requested by a non-federal entity authorized to use HIPDB.

Individual practitioners, providers and suppliers making self-queries are charged \$10.00 per query per data bank for a total of \$20.00. Fee alterations will be announced through the *Federal Register*. A response to a self-query takes approximately 15-20 business days. In order to self-query, a practitioner must submit a signed and notarized Practitioner Response to Information Disclosure form, which is available on the website. However, to verify the information when the report is received, HIPDB will provide a complimentary copy of the report to the health care provider, supplier, or practitioner who is the subject of the report and to the reporter of the information.

#### *Correcting of Erroneous Information*

Agencies and health plans are required to correct erroneous information they submitted and to update changes in adverse actions. However, the final regulations do not stipulate a time period within which an error must be corrected. Agencies and health plans are penalized for failure to report, but there are no consequences for failure to promptly correct or update information. Moreover, individuals, entities, and their authorized agents are immune from civil liability if the report was submitted without knowledge that it was false. Therefore, entities do not have as strong a set of incentives to accurately report information as they could and as practitioners believe they should.

*Major Differences Between NPDB and HIPDB*

NPDB	HIPDB
<ul style="list-style-type: none"> <li>• Focuses on adverse disciplinary actions and malpractice payments</li> </ul>	<ul style="list-style-type: none"> <li>• Focuses on disciplinary and licensure problems (no malpractice information)</li> </ul>
<ul style="list-style-type: none"> <li>• Subjects are physicians and dentists</li> </ul>	<ul style="list-style-type: none"> <li>• Subjects of reports are health practitioners, providers, and suppliers</li> </ul>
<ul style="list-style-type: none"> <li>• Recipients of information primarily are credentialing committees and organizations seeking to employ or contract with physicians</li> </ul>	<ul style="list-style-type: none"> <li>• Recipients are credentialing entities and federal and state law enforcement officials</li> </ul>

**MIXED LICENSURE PRACTICES BECOMING MORE COMMON**

*By William A. Sarraile, Esq.*

Mixed licensure practices are becoming increasingly common in today's evolving health care environment. Although the regulatory environment is rapidly changing to become more supportive of mixed licensure practices, tricky legal, ethical, business, and cultural issues must be considered in evaluating whether to form a mixed licensure practice.

Mixed licensure practices exist in various forms. Common models include practices that combine ophthalmologists, optometrists and opticians; orthopedists, podiatrists and physical therapists; pain management anesthesiologists, psychologists and physical therapists; and psychiatrists and psychologists. Mixed licensure practices involve the allied health professional either being employed by the mixed licensure practice or, increasingly, the allied health professional serving as an equity

owner in the professional partnership, corporation, or limited liability company.

The growing popularity of mixed licensure practices is a reflection of many economic forces at work. Mixed licensure practices often reflect the desire to consolidate in order to control costs, to provide a continuum of care, to extend service areas, to increase patient volume, and to become better able to attract and serve payer contracts on a risk basis. Recent gains in the efforts of many allied health professionals to expand their scopes of practice, or their ability to secure direct reimbursement from the Medicare program and other payers through varying degrees of independent practice (including nurse practitioners, clinical nurse specialists and physician assistants), have been another powerful engine in support of mixed practice models.

State law often determines whether a mixed licensure practice can be created. Historically, state statutes governing the legal structure of health care entities and the disciplinary regulations promulgated by state boards of medicine and state boards governing allied health care practitioners prohibited mixed licensure practices, at least with respect to mixed licensure practices involving equity ownership by an allied health care practitioner. In some cases, state law even prohibits employment of a given class of health care provider by a practitioner from another class.

Many states have changed their regulatory and statutory frameworks to permit mixed licensure practices in response to the forces that have generated an interest in mixed licensure practices. Ohio is one of the states that did so last year. Some states that permit mixed licensure practices still have significant regulatory barriers. In California, for instance, although ophthalmologists and optometrists may share equity in a single corporate entity, there are limitations on the ratio of one class of practitioner to another and who may control the practice of each class of licensed practitioner.

Where state law permits mixed licensure practices, both federal and state anti-kickback and self-referral prohibitions and state fee split provisions will restrict the manner in which a mixed licensure must be formed and how it operates. Where equity ownership is contemplated and one class of practitioner is in a position to refer to the other, the grant of equity ownership interests for sums or assets that do not reflect fair market value in an arm's length transaction will invite scrutiny and exposure under the federal and state anti-kickback statutes, and, sometimes, state fee split laws. The federal government has long believed that at least some payments for goodwill constitute disguised payments for referrals. Third party independent appraisals can reduce this regulatory risk and help ensure a fair business deal. Once the formation of the mixed practice itself is completed, similar issues will be confronted in the articulations of how the practitioners will be compensated on an ongoing basis.

When referrals for a Medicare and Medicaid designated health service are made between different licensed practitioners, the transaction may have to fit within the "isolated transaction" exception. This exception does not permit installment payments or earn-out provisions. The mixed licensure entity also typically must be designed to fit within the "in-office ancillary services" exception and qualify as a "group practice," within the meaning of the Federal Self-Referral Law. These standards involve a stringent set of requirements that can be difficult to comply with in any practice. Additional or different restrictions may be imposed by state self-referral statutes that may apply to "all payers," not just the Medicare and Medicaid programs.

Important regulatory and tax consequences can also flow from the manner in which the mixed licensure practice is formed. One approach is to have the pre-existing practice entities come together in a formal merger. Another approach is for one practice entity to purchase the assets of the other entity. Successor liability for False Claims Act and other liabilities is a risk inherent in adopting the "merger" model, but asset purchases are more likely to have adverse tax consequences for the

entity selling the assets. Where an asset purchase occurs, there can also be exposure under medical record confidentiality rules in some states if patients do not specifically authorize the transfer of their medical records from the selling practice to the buying practice.

In some cases, however, the biggest obstacle to mixed licensure practices has nothing to do with statutes or regulations and everything to do with historic antagonisms and cultural differences between classes of providers. Like any relationship that works, mixed licensure practices must be founded on common goals that are clearly articulated and realized in a manner that is agreeable to all parties. Communication and a sense of respect are indispensable. Given the changes gripping health care, mixed licensure practices will continue to be an increasingly important model for the delivery of coordinated services. ■

### **MEDICAL WEB SITES UNDERGO INCREASED SCRUTINY AT FEDERAL AND STATE LEVEL**

*By Mark B. Langdon, Esq.*

The growing number of Web sites that offer consumers the opportunity to obtain prescription medications have recently been attracting considerable regulatory scrutiny from federal and state health officials.

On December 28, 1999, President Clinton announced a \$10 million initiative aimed at cracking down on illegal sales of prescription drugs over the Internet. The proposal would protect consumers from illegitimate Internet pharmacies that inappropriately prescribe medications, increase the risk of dangerous drug interactions, or sell potentially counterfeit or contaminated drugs. The proposal comes on the heels of Congressional hearings that were held on this subject late last year. The Clinton plan would allow the Food and Drug Administration (FDA) to start verifying the quality of hundreds of online companies that have emerged in the last year. Many of these companies

allow consumers to fill prescriptions without going to a traditional drugstore. In addition, some of these sites allow consumers to obtain prescription medication merely by filling out an online questionnaire.

If approved by Congress, the administration's proposal would create federal fines of up to \$500,000 for e-pharmacies that dispense drugs without first obtaining a valid prescription from the buyer. The proposal also would give the FDA new investigative authority through administrative subpoena, which the agency currently lacks. The initiative provides that the FDA will carry out a public education campaign on safe ways to purchase pharmaceuticals over the Internet. The FDA will enable consumers to identify legitimate Internet pharmacy sites that operate consistently with state and federal law. FDA would use part of the budget increase to develop a rapid response team and upgrade the FDA's computer technology to identify, investigate, and prosecute illegitimate Internet pharmacies.

The initiative represents the government's first attempt to regulate the growing e-health industry, and is significant because states are often powerless to bring enforcement actions against providers who are licensed in multiple states. However, since protecting the health of residents is a duty traditionally delegated to the states, the proposal is likely to generate controversy.

The FDA announced February 2 that it has sent electronic letters to at least a dozen foreign Web sites, warning them that their prescription drug sales to U.S. citizens potentially are illegal. This marks the first time the agency has sent warning letters over the Internet. The FDA said it may start using electronic warning letters to curtail illegal sales of prescription drugs from U.S.-based Web sites. The FDA seeks to at least cut in half the current number of illicit domestic sites.

The Clinton proposal comes after state attorneys general and pharmaceutical companies have pledged steps against online pharmacy fraud. Attorneys general from several states have taken action against online drugstores, charging some of them with being unlicensed and unregistered to do business in their states. In addition, several state medical boards have fined physicians and suspended their licenses for prescribing and dispensing medications to patients they have never seen.

In Kansas, the Attorney General last year filed civil petitions alleging violations of consumer protection laws against seven companies that were selling prescription-only medications, including Viagra and weight-loss drugs, over the Internet. The Attorney General alleged that prescription drugs were dispensed by a doctor or pharmacist who was not licensed in the state. The state went after not only the sites that prescribe the medications, but also three pharmacies that filled the prescriptions. If found liable, the companies could face penalties of \$5,000 to \$10,000 per violation.

In November 1999, a Missouri judge, responding to a suit brought by Attorney General Jeremiah W. "Jay" Nixon, issued a permanent injunction blocking an online Texas-based pharmacy and other defendants from engaging in the unlawful sale of prescription-only drugs to Missourians over the Internet. The pharmacy paid a fine of \$15,000, lawsuit costs, and restitution to Missouri residents. In response to a separate action brought by Nixon, the court issued a permanent injunction in October blocking a San Antonio, Texas-based pharmacy operator from filling or shipping prescriptions over [www.thepillbox.com](http://www.thepillbox.com) and required the defendants to pay \$15,000 in penalties and costs to the state.

In October 1999, Illinois Attorney General Jim Ryan filed four lawsuits against out-of-state Internet pharmacies and their physicians and operators, alleging that they were not licensed and registered to do business in the state. An Illinois physician

was also fined by the State Board of Medicine \$1,000 and placed on probation for two years for unprofessional conduct.

In December 1999, the Michigan Attorney General issued warnings to 10 online pharmacies for selling drugs to Michigan residents over the Internet. The suits allege violations of the state Consumer Protection Act, which carries a maximum penalty of \$25,000 per violation.

Enforcement actions have also recently been taken against Internet physicians and/or pharmacies in California, Ohio, Maryland, Colorado, Washington, Wisconsin, Wyoming, and Arizona. Further, there are at least 19 states that are expected to consider legislation regulating the sale of online prescription drugs.

In addition to these recent state enforcement activities, the American Medical Association (AMA) recently took the position that online physicians who write prescriptions without patient contact are in direct violation of AMA policy. At its convention last summer, the AMA called on state medical societies, government regulators, and licensing boards to investigate doctors who dispense pills to patients without examining them. Noting that no state laws directly address the issue of online prescribing, the AMA said that it would assist the Federation of State Medical Boards (FSMB) in developing them. But in the absence of state law, the AMA says that local medical boards should take action against doctors who are prescribing drugs for patients they do not know. The AMA Board of Trustees report, which was adopted by the House of Delegates, directs the AMA to work with the FSMB, the National Association of Boards of Pharmacy, and the Food and Drug Administration to curtail inappropriate online prescribing. Nevertheless, the report did recognize the growing use of the Internet in health care, and states that online transmission of prescriptions, order refills, and electronic consults may be appropriate if the physician and patient have a preexisting relationship.

The National Association of Boards of Pharmacy (NABP), which represents state pharmaceutical licensing authorities, has also taken the position that any site that uses a questionnaire without a legitimate patient-physician relationship is illegal. To help guide consumers, the pharmacy association developed a voluntary seal program called the NABP Verified Internet Pharmacy Practice Sites (VIPPS) which endorses sites that meet its criteria for dispensing drugs online. The VIPPS seal certifies that an online pharmacy is licensed by the appropriate state boards of pharmacy to dispense pharmaceuticals. To receive the VIPPS seal, sites must meet criteria involving licensure, information, communication, storage and shipment, over-the-counter products, and quality improvement programs. To date, only four sites have received VIPPS accreditation: cvs.com, drugstore.com, Merck-Medco.com, and PlanetRx.com.

As more and more consumers turn to the Internet as a cost-effective and convenient way to obtain medical information and fill prescriptions, federal and state officials will continue to scrutinize the growing number of Internet drugstores and doctors offices to ensure that consumers are adequately protected. The sites that are presently attracting the most attention from the FDA and state attorneys general are those that sell misbranded or adulterated drugs, those that do not require a physical examination of the patient by a physician prior to prescribing, and those that are not appropriately licensed. Additional issues that will likely face medical Web sites include: the effect of state confidentiality laws and the newly-proposed federal privacy regulations on the confidentiality of patient information; the effect of federal and state fraud and abuse laws on the financial arrangements involving Web sites, their contracted pharmacies and physicians, and providers (such as pharmaceutical manufacturers) who advertise on the site; and the effect of state and federal consumer protection and advertising regulations. ■

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**EDITORIAL NOTE**

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