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OIG condemns hospital-physician gainsharing

New advisory bulletin surprises health care experts with claim that gainsharing violates anti-kickback laws

If you're involved in a gainsharing relationship with a local hospital, be warned: A new special advisory bulletin from the Department of Health and Human Services' Office of Inspector General (OIG) makes it clear that federal investigators now consider such arrangements to be little more than elaborate kickback schemes.

The bulletin defines gainsharing as an arrangement in which a hospital pays physicians a percentage of any reduction in the hospital's costs for patient care attributable to the physician's efforts. The goal in pushing such arrangements is to get physicians on board with the hospital's cost-cutting efforts, particularly when it comes to Medicare and Medicaid reimbursement.

According to the advisory bulletin, however, while the OIG recognizes that hospitals have a legitimate interest in enlisting physicians in their efforts to eliminate unnecessary costs, gainsharing arrangements are prohibited by Section 1128A(b)(1) of the Social Security Act. That section essentially prohibits hospitals from paying physicians, either directly or indirectly, to reduce or limit services to Medicare or Medicaid beneficiaries under the physician's direct care. The OIG argues that for gainsharing relationships to become legal, Congress would have to amend current laws and regulations, particularly the physician incentive provision under the civil monetary penalty statute.

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AMA calls on government to regulate Internet prescribing

At its annual meeting in Chicago last month, the American Medical Association (AMA) highlighted the problem of on-line prescribing by calling on government regulators, state medical societies, and licensing boards to step up efforts to investigate physicians who dispense drugs to patients over the Internet without benefit of a face-to-face examination.

Anecdotal evidence suggests that at least some state medical boards already have made this practice a top investigative priority. Recently, for

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New bill could derail privacy regulations, critics say

A last-minute addition to the sweeping Financial Services Bill (HR 10), passed last week in the House of Representatives, could further slow the momentum for passing comprehensive medical records privacy legislation and even prevent the Department of Health and Human Services from issuing regulations on the matter, critics say.

The Financial Services Bill, different versions of which have now passed in both the House and Senate, would allow insurance companies to exist as part of an operating entity that includes banking and securities firms. The medical privacy provision, introduced in the Commerce Committee by Rep. Greg Ganske (R-IA) is, proponents say, merely an attempt to prohibit such entities from disclosing patients' medical information without their consent.

Barbara Levering, Ganske's press secretary, says the provision's opponents fundamentally misunderstand its intent. "Some people say that it

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Gainsharing

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That's shocking news to some health care experts, who had previously assumed that gainsharing arrangements weren't prohibited under federal law, says **Pat Smith**, director of government affairs at the Medical Group Management Association in Englewood, CO. "A lot of attorneys were fooled by it," he says. Indeed, only a few weeks before the advisory bulletin was released, a health care attorney who had spoken to OIG officials about gainsharing had offered assurances that OIG was only looking at the practice and wasn't likely to issue anything. "He said they're not really very concerned about it," Smith says. "Then, boom!"

Smith says no data exist on just how many physicians are involved in gainsharing relationships with hospitals, but anecdotal evidence indicates that the practice is "somewhat widespread," he says. Since the advisory bulletin was released, his office has been flooded with calls about the OIG's stance. "They ask, 'Do you think this is going to affect me?' And pretty much the answer is 'Yes.'"

Much of the reason for concern is that the OIG's new position on gainsharing seems to have come virtually out of the blue, says **Robert Homchick**, a partner with the Seattle-based law firm Davis, Wright, Tremain.

Although the OIG is attempting to support its stance by citing the Social Security Act provision, Homchick argues that the regulations based on that provision do little to explain what arrangements would be acceptable or offer substantive guidance in this area. "Essentially nothing has been done in terms of enforcement activity or interpretive guidance on these regulations and statutes," he says.

In addition to gainsharing, the advisory also casts aspersions on clinical joint ventures involving physicians and freestanding hospitals. The OIG argues that hospitals typically market such ventures only to physicians who are in a position to refer patients to the venture. According to the OIG, these arrangements are structured to take advantage of an exception in the physician self-referral law and, like gainsharing arrangements, "may induce investor-physicians to reduce services to patients through participation in profits generated by cost savings in clinical care." Therefore, they also may violate the anti-kickback statute.

The special advisory comes in the wake of seven requests for advisory opinions about the legality of these arrangements based on fears that these arrangements could trigger the anti-kickback statute or Stark anti-self referral laws. "We have determined that gainsharing arrangements raise significant issues that cannot be resolved through the advisory opinion process," HHS Inspector General June Gibbs Brown said in a prepared statement. "Without adequate safeguards, gainsharing could pose a risk of abuse, could adversely affect patient care, and could be manipulated to reward physicians for patient referrals."

"The statutory proscription is very broad," argues the OIG. "The payment need not be tied to an actual diminution in care, so long as the hospital knows that the payment may influence the physician to reduce or limit services to his or her patients."

The advisory adds that there is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. "In short, any hospital incentive plan that encourages physicians through payments to reduce or limit clinical services directly or indirectly violates the statute," the advisory concludes.

The advisory bulletin will be published as a *Federal Register* notice later this month. It's available on the Internet at www.os.dhhs.gov/oig. ■

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Privacy provision

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would prevent passage of comprehensive medical privacy legislation, but that is total poppycock. It's only germaine to HR 10 and doesn't cover a lot."

In a letter to other members of Congress, Ganske stressed that the provision would not:

- Pre-empt state privacy laws or obstruct future state privacy laws;
- Satisfy the requirements for comprehensive medical privacy legislation under the Health Insurance Portability and Accountability Act of 1996 (HIPAA);
- Block the Secretary of HHS from promulgating regulations on health information privacy;
- Create a disincentive for comprehensive medical privacy legislation.

But a top aide to Sen. Patrick Leahy (D-VT) disputes virtually all of those statements, claiming the provision represents an attempt to indefinitely stall any type of legitimate, comprehensive privacy legislation. That's because of one thing Ganske admits the provision will do: It will "cease to be effective on or after the date on which legislation is enacted that satisfies the [HIPAA] requirements."

That means that the provision essentially will serve as stopgap privacy legislation, effectively scrapping the Aug. 21 deadline dictated by HIPAA, opponents argue. With the deadline out of play, HHS would be prevented from drafting medical privacy regulations. "The provision doesn't say it will sunset when regulations are passed, or when the HIPAA requirements [for a privacy bill] are satisfied," says Leahy's aide. "It says it will sunset when legislation is enacted, and that is how it vitiates the deadline."

The provision has other problems as well, Leahy's office argues. While it restricts insurance companies from releasing medical information without the patient's consent, once the information's gotten out, the provision doesn't place any restrictions on how it's subsequently used. "Once it's released for one purpose, there's nothing that would bar it from being released for any other purpose whatsoever," Leahy's aide says. "It essentially allows unfettered redisclosure of health information." The bill also includes numerous exceptions to disclosure without patient consent, including cases in which information is requested by law enforcement officials.

The privacy provision is contained only in the House version of the Financial Services Bill. The version approved by the Senate contains no such language. Now it's up to a conference committee to hammer out differences in the bill, a process likely to extend well beyond the Aug. 21 deadline, given the complexity of the overall bill. Leahy already has vowed to fight to strip the privacy provision in conference.

Given the current impasse in formulating comprehensive privacy legislation, some in Congress have floated the idea of approving an extension of the Aug. 21 HIPAA deadline but Leahy and his Democratic colleagues are fighting that as well, having already sent a letter to President Clinton formally requesting that he veto any such extension. Their argument is that if HHS is forced to formulate regulations without benefit of a law, "at least there would be something out there that would be broad based to provide consumer protections," the aide says. "Congress can still continue its current movement on getting legislation passed. The deadline doesn't stop Congress from acting." ■

Internet prescribing

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example, the Illinois Department of Professional Regulation in Chicago suspended the license of a physician who prescribed Viagra on-line to patients he never examined. The department also imposed a $1,000 fine. At least 10 other state boards are investigating Internet prescribing.

In Kansas, the Board of Healing Arts in Topeka took an even bolder step, filing petitions in district court against two out-of-state physicians who had dispensed drugs to patients in Kansas without an examination.

The physicians were charged with practicing medicine without a license in the state of Kansas. The board won an injunction against the physicians.

"Theoretically, a criminal case could have been filed," says **Mark Stafford**, JD, the board's general counsel. "But realistically, it would have been a Class B misdemeanor, and it's hard to get extradition for something like that. The formalities are incredible."

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The Kansas case highlights the problems inherent in taking action against such prescribing schemes, since many are conducted by fly-by-night organizations that use the Internet to hide their identity and location.

One Web site mentioned by the AMA, "get-it-on.com," which sold Viagra, already has folded. What remains at the site is a link to cybrxpress.com, which advertises itself as "the premier online source for Phentermine, Meridia, Xenical, Valtrex, and Zyban." The main page boasts that "no visit to your doctor's office or pharmacy" is necessary and that there's "no charge if you are not approved for the medication." A counter on the site indicates that it's received almost 50,000 hits.

According to the AMA, at least 14 Web sites are probably involved in sight-unseen on-line prescribing.

"In many of these cases, there is no real physician involvement," Stafford says. "In some of the cases we've dealt with, the physician involvement was in name only. The order comes in for the drug and the marketing company simply fills the order. The doctor doesn't normally see the patient information."

Patricia Beatty, assistant vice president of communications at the Federation of State Medical Boards in Euless, TX, notes that boards can't take action against a physician simply for issuing prescriptions over the Internet. "They would have to take an action for unprofessional conduct, depending on how they define that in their board order," she says. Besides, she says, the real problem is the lack of physician-patient relationships, and even regulating that can pose problems for medical boards and state and federal lawmakers.

"It's written in a lot of medical practice acts that you have to have a good faith exam or [establish] a physician-patient relationship," Beatty says. "But how that's defined becomes a gray area." Most statutes are very specific about what's required, primarily because, before the Internet came along, it was difficult to prescribe drugs or otherwise treat a patient without a face-to-face encounter. Even now, enacting effective legislation is difficult "because it would have to get very specific, and might not stand the test of time as technology continues to change."

Currently, a committee established by the Federation of State Medical Boards is examining the issue and preparing recommendations it hopes will be generic enough to be used by all state medical boards. The recommendations will be presented at the federation's next house of delegates meeting in April 2000. ■

Physician billing company settles $15M fraud charges

Jacksonville, FL-based Gottlieb's Financial Services, Inc. (GFS) and its parent company, Medaphis Physician Services Corporation of Atlanta, have agreed to pay the federal government and 35 fives states $15 million to settle charges that GFS submitted false claims to various federal health care programs, including Medicare, Medicaid, and TRICARE, as well as the Federal Employees Benefits program.

The U.S. Attorney's Office for the Western District of Michigan, which brokered the settlement, alleges that GFS submitted false claims to the health care programs on behalf of emergency department physicians and emergency room staffing companies around the country. According to the U.S. Attorney's Office, GFS used computer software to systematically upcode claims and billed for services to make it appear that more extensive services were rendered than were actually provided by the physicians.

Although staff members were required to identify and input data into the computer software system, the program itself automatically assigned CPT-4 codes, regardless of the documentation of physician services present in the chart, according to the official complaint.

A spokesman for the U.S. Attorney's office declined to say how many emergency physicians may have been involved in the scheme, or whether charges are pending against them.

The agreement settles a dispute with GFS and Medaphis originally brought as a qui tam case in U.S. District Court in Grand Rapids, MI. The whistleblower, Greg Robinson, who was a vice president with GFS in the mid-1990s, will receive $2.4 million in the settlement. He remains under contract with GFS as a consultant. ■