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MONDAY
OCTOBER 5, 1998

Self-administered drug probe shifts to take-home drugs

Federal prosecutors in Ohio are backing off from their probe of whether hospitals improperly billed for self-administered drugs, *Compliance Hotline* has learned. The retreat comes after the Ohio intermediary has already audited five hospitals for such billing, and amid a promised OIG investigation of self-administered drugs nationwide.

But don't breathe a sigh of relief yet. Ohio investigators are now shifting their cross hairs to hospitals that billed Medicare for drugs that were given to patients to take home. These include, for instance, pills that a doctor hands a patient before sending him home, according to **Charles Cataline**, director of health policy for the Ohio Hospital Association.

Jim Bickett, the Assistant U.S. Attorney for Northern Ohio, who's spearheading the self-administered drug probe, says he dropped the investigation when he realized that hospitals were given bad guidance from the Ohio FI. Hospitals were advised in a memo in 1988 from the Ohio intermediary that any drugs administered at the hospital would not be considered self-administered. "Now the FI says that whoever sent that memo didn't know what he was talking about, and he was wrong," admits Bickett.

The carrier memo contradicts Medicare's traditional policy of classifying these drugs, which has tended to focus less on how and where the drugs are taken and more on whether they can theoretically be administered by patients themselves.

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Physician-owned ASC gets mixed approval from OIG

Can doctors set up their own ambulatory surgical center –and refer patients to it–without breaking federal laws that bar kickbacks for referrals? The latest advisory opinion from Office of the Inspector General of the Department of Health & Human Services gives a qualified yes to that question.

Yet it also raises the question of whether OIG is now intervening in the practice of medicine, says attorney **Bob Wolin**, at Baker Hostetler in

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A self-administered drug notice you can give patients

Given the crackdown on self-administered medication, many hospitals are choosing to give Medicare beneficiaries ABNs warning them they may have to pay for these drugs themselves, says **Charles Cataline**, health policy director for the Ohio Hospital Association. Even in Ohio, where the FI has said ABNs aren't needed for these drugs, it's still a good idea to give patients advance warning, Cataline adds. If for no other reason, it will help ease potential problems with patients who can't understand why they suddenly are paying for drugs they thought were covered.

With that in mind, one three-hospital system has devised a form that informs Medicare beneficiaries that they will have to pay for self-administered drugs. It may not always make patients happy to hear they might have to fork over cash, but "it's better to take your castor oil upfront," says **Dean Wiler**, compliance officer for

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Self-administered drug probe

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Medicare won't pay for drugs that patients should be able to take themselves, such as aspirin or some types of insulin, unless they are taken for diagnostic purposes and are given through injections or IVs, says Cataline. That has created confusion over whether, for example, a salve should be considered self-administered if it was spread by an ED nurse on the legs of an elderly burn victim who couldn't reach his legs, he adds.

Unfortunately for hospitals, investigators are discovering that billing for take-home drugs is actually a more widespread problem than self-administered medications. And while hospitals could claim they received poor guidance on self-administered drugs, they can't use the same alibi the second time around. The bottom sentence of that carrier memo explicitly warned hospitals not to bill for take-home medication, says Bickett.

The Justice Department will also have an easy time identifying its targets. "These are hospitals with large outpatient clinics that have a habit of passing out a lot of drugs," he says.

Several hospitals have voluntarily stepped forward to be audited, says Bickett, who declined to discuss the settlement negotiations. He did say that overbillings have ranged from $200,000 to amounts so small that one hospital was told it was off the hook. Strangely, even hospitals that know of the take-home drug probe have continued to bill for them. "We're still pulling claims for 1998," he muses.

Word of the investigations has prompted some hospitals to pay extra attention to the issue. MedCentral Health System, in Mansfield, Ohio, has its clinical auditors check all claims to ensure, among other things, that there are no bills for self-administered drugs, says compliance officer Dean Wiler.

Once the initial batch of settlements are done, a more wide-ranging investigation will begin in Ohio, though Bickett declined to estimate when that would be. Given the withering Congressional scrutiny of nationwide Justice Department investigations such as the lab unbundling crackdown, Bickett was careful to say that he was not coordinating a national probe. He did acknowledge that new Justice Department guidelines are having an effect on how prosecutors treat cases, by giving extra consideration to the clarity of guidance hospitals received from intermediaries, for example. "If it's a close call, you need to step back," he adds. "They provide a clear basis on when to say no or whether to proceed." ■

Carrier pays $38.5 million in whistleblower suit

In yet another qui tam suit against a carrier, Highmark Inc. – the former Pennsylvania Blue Shield – has agreed to pay $38.5 million. The civil suit alleged that in the early 1990s, Pennsylvania BS had failed to process secondary payor claims; didn't recover overpayments from computer errors; failed to properly screen lab claims involving kidney disease; and manually overrode computer payment safeguards. In addition, the carrier was accused of obstructing a federal audit of its performance.

The case follows a $144 million criminal and civil settlement in July against Health Care Service Corporation, the former BC/BS Part B Illinois contractor. HCSC pled guilty to falsifying its performance data as well as obstructing an audit.

The Justice Department has also levied criminal charges against a former Pennsylvania BS vice-president. Judith Krafsig-Kearney was charged with making false statements to HCFA during audits of the contractor. Krafsig-Kearney has agreed to plead guilty and to cooperate in the investigation, according to prosecutors. ■

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Drug notice you can give

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MedCentral Health System, Mansfield, Ohio.

MedCentral's form also informs beneficiaries that Medicare doesn't cover screening exams. The form says:

"As a Medicare beneficiary, it's important that you are aware of items that are not covered under Medicare. Self-administered drugs are not covered. These include most prescription drugs and medicines taken at home, including: aspirin and other pain relievers; cold medicines; suppositories; nicotine patches; and injections that can be self-administered, such as calcitonin or insulin. You are responsible for the cost of these medications.

"Medicare also does not pay for screenings, except for Pap smears and mammograms. When you come to a MedCentral facility and are undergoing a screening that is not covered by Medicare, you will be asked to sign a waiver and you will be responsible for the cost of the procedure.

"However the following items generally are covered: drugs that cannot be self-administered; blood-clotting factors for hemophilia; certain oral and anti-cancer drugs; injectable osteoporosis drugs; and immunosuppressive drugs used during the first year after an organ transplant. Also covered are prescription drugs received in a skilled nursing facility.

"This is not a change in Medicare policy, but these are rules you should be aware of, especially in light of the increased attention by the government to hospital billing procedures. MedCentral Health System also thinks it's important you know this because you will be responsible for the cost of items not covered by Medicare. ■

Physician-owned ASC

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Houston. The advisory opinion comes with a proviso that says the agency's approval is contingent upon how much ASC work the doctors perform, he adds.

The case that spurred the advisory involves five orthopedic surgeons and anesthesiologists who plan to create a joint venture ASC. The physicians asked OIG whether the profits they received would violate the anti-kickback statute.

OIG acknowledges that "it has long been concerned with the risk of abuse posed by health care joint ventures in which investors are also sources of referrals or suppliers of items or services to the joint venture." In particular, the government frowns on doctors who refer patients to facilities in which they have a stake, and thus effectively receive kickbacks through profit distributions. What it wants are operations that can function as independent businesses without being dependent on referrals from investors.

The proposed ASC doesn't meet the safe harbor that protects investors who make referrals to large, publicly traded companies, but own only a small percentage of shares. Nor does the deal fit the safe harbor for small ventures, because all of its investors will make referrals to the ASC, which in turn will get much of its business from investor referrals.

Nonetheless, OIG concluded the deal in question would violate the anti-kickback statute only if the physicians intended to send patients to the ASC to boost their incomes. The safeguards that reassured OIG included:

- The physicians are making substantial investments in the ASC and have exposure for the ASC's lease. This indicates the facility is not a sham operation.
- The doctors perform many ASC procedures and will perform most of their future ASC work at the site. All five physicians currently derive at least 40% of their practice income from ASC procedures.
- Medicare beneficiaries would account for only about 5% of the ASC's revenue. So, any income from Medicare referrals would be only a fraction of what the doctors would earn from private patients.
- Profit-sharing will be based on the size of each physician's investment rather than on the volume of referrals.
- Patients will be given a written disclosure of their doctor's interest in the ASC. This doesn't necessarily guard against fraud, but it does offer "some protection against possible abuses of patient trust," OIG notes.

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Physician-owned ASC

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But: Pay attention to footnote #4 of the opinion, warns Wolin. If income from performing ASC procedures drops below 33% of total medical practice income for any of the physician-investors, the opinion is invalid, according to OIG. This effectively means that OIG will dictate how a doctor practices medicine as a condition for a favorable advisory opinion. ■

Compliance part of Medicaid HMO regs

Medicaid HMOs are not escaping the federal government's new emphasis on managed care compliance. Proposed HCFA regs that would make it easier for states to place Medicaid beneficiaries in HMOs also contain a requirement for Medicaid HMO compliance. Section 438.606 of the regs, which were published in the Sept. 29 Federal Register, would require any managed care organizations to "have

administrative and management arrangements or procedures designed to guard against fraud and abuse." Any "credible information on violations of the law" by the HMO, its subcontractors and enrollees must be reported to the state, HCFA and OIG. However, HCFA does specify that information on enrollees need only be reported if the violations pertain to enrollment in the health plan, or provision of and payment for services. ■

Voluntary Disclosure Redux

OIG will be releasing new guidelines for its Voluntary Disclosure Program in about a month, says deputy IG **Lew Morris**. The guidelines will specify audit methodologies for providers who want to voluntarily confess their sins to OIG in return for a chance of more lenient penalties. Still, it's an open question whether the changes will revive a program that even Morris has admitted hasn't lived up to expectations. Only about a dozen providers have stepped forward, largely because health lawyers consider it folly to confess when the government offers no explicit guarantees that penalties will be mitigated. ■

OIG is looking for input for managed care model

OIG is soliciting input on what should go into its model compliance plan for managed care. More specifically, it wants input regarding Medicare+Choice organizations that offer coordinated care plans. Coordinated care plans, as defined by HCFA, comprise networks of providers that deliver benefits to an organization. These networks include HMOs, PPOs, PSOs, religious and fraternal benefit plans, and most other network plans. HCFA already mandates that Medicare+Choice groups have a compliance plan.

OIG's request reflects the agency's new policy of seeking industry guidance on model compliance plans, in contrast to past efforts where OIG devised the plan itself. That drew fire from providers who felt shut out. Now they have until Nov. 23 to submit their comments.

Nonetheless, managed care is likely to be the odd bird in OIG's flock of model plans, which have already been issued for labs, hospitals, and home health agencies. While the other plans focused on stopping overbilling, managed care compliance will most likely target denial of care as well as quality of care. Some federal prosecutors, such as Jim Sheehan in Philadelphia, argue that capitated plans that skimp on care are as equally guilty of fraud as fee-for-service providers who upcode.

Note that OIG does not want anyone to send a comprehensive compliance plan for the agency to look over. Instead OIG wants concise hints that specifically address what compliance risk areas exist for managed care groups, as well as how these groups can fit into the agency's seven-plank framework for a comprehensive compliance program. The seven points include: creating written policies; appointing a compliance officer and board; training employees in compliance; creating lines of communication such as hotlines; enforcing compliance standards; monitoring compliance through audits; and procedures to investigate and correct violations. ■