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THE NATION'S ESSENTIAL ALERT FOR HEALTHCARE COMPLIANCE OFFICERS

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New Stark regulations face another setback

Final rules dealing with physician practices, ancillary services, and other issues not likely before Labor Day

Health care providers anticipating the Health Care Financing Administration's (HCFA) final regulations on self-referral likely have another long hot summer ahead of them. The unofficial word from government sources is that it will be the end of the summer at the earliest before the so-called "Stark II" regulations — seven years in the making — finally emerge from the agency's bureaucracy.

In 1989, Congress passed the so-called "Stark I" regulation, named for the law's main sponsor, Rep. Pete Stark (D-CA), which sought to block physicians from inappropriately referring patients to facilities in which they had a financial interest. Four years later, "Stark II" extended those prohibitions to hospitals, home health agencies, and other providers, but HCFA never turned that law into regulations to guide providers.

Health care attorney **Sandy Teplitzky** of the Baltimore-based firm Ober Kaler, says there are four overriding areas where health care providers are still in the dark. "The first area where there is a lot of concern relates to the definition of a group practice and what was viewed as a very restrictive definition in the proposed regulations," he asserts.

Bob Homchick, a health care attorney with Davis Wright Tremain in Seattle says critical questions in this area include what it takes for a physician practice to qualify as a group practice

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HCFA surveyors target HHAs on OASIS compliance

Not long ago, home health agencies (HHAs) faced grueling audits by state surveyors under the Health Care Financing Administration's (HCFA) Operation Restore Trust initiative. According to veteran health care attorney **Frank Case** of the Washington, DC-based firm Schmeltzer, Aptaker & Shepherd, those audits often turned on highly technical interpretations of the home health conditions of participation, and varied dramatically from state to state.

Today, that compliance landscape is being

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Physician compliance plan gets qualified 'thumbs up'

Health care provider groups and attorneys say the Department of Health and Human Services' (HHS) Office of Inspector General's (OIG) 43-page draft compliance plan for physicians in solo or small group practices released June 7 is mostly good news for doctors, even though most of them were not eager to have such a plan in the first place. **(See *Compliance Hotline*'s special fax bulletin, June 8.)**

Aaron Krupp of the Englewood, CO-based Medical Group Management Association (MGMA) says his group — which represents mostly small practices — is relieved, but not overjoyed. "We have mixed opinions about it," he reports. "We are very pleased the OIG attempted to make the guidance flexible, but we still have concerns."

The OIG initiated the process last year by soliciting comments from physicians on what a compliance program should look like, as well as their overall level of interest. OIG General Counsel

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Stark regs

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and how multisite offices must be structured in terms of compensation. Other unanswered questions include how the group should handle overhead allocations and internal costs, he adds.

According to Teplitzky, a second key area deals with in-office ancillary services. Specifically, he says there is still confusion about what "directly supervised" means as it relates to the in-office services physicians are allowed to perform.

One issue that may be resolved by the final regulations is whether lithotripsy, a treatment of the urinary tract, will be considered a designated health service when provided as an outpatient hospital service. Currently, whenever anything is provided as an outpatient hospital service, regardless of the arrangement, the outpatient hospital service is considered a designated health service.

Homchick says that is particularly relevant for lithotripsy, because currently the only way you can bill for lithotripsy is as an outpatient hospital service. "You can't bill it for a freestanding ambulatory surgical center," he explains.

A third major concern is the fair-market value exception that was not in the statute, but was created by the proposed regulations, says Teplitzky.

Mary Grealy, president of the Washington, DC-based Healthcare Leadership Council, says the Department of Health & Human Services' Office of Inspector General's new interest in hospitals that sell physician practices for far less than they paid for them raises potential kickback concerns.

Homchick agrees that the recent pattern of hospital divestiture has potential Stark implications. "All these deals are unique," he says. But a number of them were structured in such a way that the physicians were employees of the hospital and the group practice exception was not required.

However, when those physician practice groups spin off and form new groups, they are no longer employees who fit within the exception and instead require the broader group practice exception. "Some of those deals will involve doctors moving into an equity position with respect to the practice," explains Homchick. "If the spin-off or dissolution is a return to physicians owning and operating their own groups, then those groups will likely need to qualify and start new practices."

Teplitzky says the fourth issue is simply what the current delay means for implementation of the statute. "There is still a question about whether the statute was self-enforcing or whether it can't be enforced until the regulations are out," he argues. That includes whether or not HCFA is going to take aggressive action to enforce the law even before implementing regulations.

Last year, HCFA deputy director Kathleen Buto promised House Ways & Means Health Subcommittee Chairman Rep. Bill Thomas (R-CA) the regulations would be completed this year. Last year, Thomas introduced legislation that would strip the compensation portion of Stark, which is widely considered the most problematic portion of the law.

That bill is busy collecting dust as Congress grapples with how to handle a Medicare prescription drug benefit. However, if the Republicans hold their majority in the House this November, Thomas could find himself chairman of the full Ways & Means Committee next year. Regardless of whether he takes over the full committee, a Ways & Means staffer predicted this week that it is only a matter of time before Thomas finds a vehicle to push his bill. "It is still on his agenda, and we may hear more about it before the end of the year," he asserts. ■

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Physician plan

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Mac Thornton said 83 comments were submitted in all, which encouraged his office to go ahead with the plan.

According to Krupp, most of the concerns harbored by MGMA center around whether small practices will have the resources required to implement all of the measures the OIG includes in the draft guidance. For example, Krupp says his group was concerned about the requirement included in the OIG's initial notice that each practice establish an 800-number. "A lot of practices clearly don't have the resources to establish something like that," he explains. But he says his group was encouraged by the OIG's decision to let an "open-door" policy satisfy that requirement.

However, Krupp says his group is still concerned about the OIG's requirement that practices maintain a current compilation of relevant regulations. In releasing the draft plan, Thornton highlighted that as a key task for practices. "That can place a tremendous burden on practices," warns Krupp. "It is hard enough for us to stay on top of all these regulations and understand them."

In addition, Krupp points out that while the guidance is not mandatory, the draft repeatedly refers to "essential" ingredients of an effective compliance program. "That sends a bit of a conflicted message," he argues. "That is why we were wary about this in the first place."

Yet another concern for Krupp is the lack of any definition about what constitutes "an individual or small group practice" covered by the plan. "You would think that they would have to clarify what constitutes a small group practice," he asserts. "But they don't." Thornton says the OIG deliberately left that vague in order not to set an artificial boundary that appeared to exclude certain physicians.

Health care attorney **Julia Krebs-Markrich** of Washington, DC-based Reed Smith also sees the draft plan as mostly good news. "What they are saying here is not unreasonable," she argues. For example, she notes, the OIG details what should be included in a periodic audit.

"I thought the first appendix regarding additional risk areas was also very helpful," she says. That section points out what physicians must do to comply with local medical policy reviews. "It also addresses professional courtesy and clarifies some of the concerns that have been raised about physicians extending professional courtesy to patients," says Krebs-Markrich.

The plan also addresses third-party billing services. "There has been some noise over the past few years about using a billing service where the physician pays the billing company on a percentage basis," says Krebs-Markrich. She says the draft plan offers useful clarification in that area by explaining that a physician may contract with a billing service on a percentage basis, but while highlighting practices that would raise problems.

"There is a degree of specificity here that has not been present before that is very helpful," she concludes. "I think they have tried very hard to be helpful."

The guidance, which also covers dentists, chiropractors, and others, is likely to be the last major compliance plan that emerges from the OIG, according to Thornton, who said physicians can expect to see a final plan early this fall.

The OIG's Compliance Program Guidance for Individual and Small Group Physician Practices was published in the *Federal Register* June 12, and carries an extended 45-day comment period. It is available on the OIG's Web site at http://www.hhs.gov/oig/new.html. ■

OASIS compliance

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transformed by the new requirements surrounding HCFA's Outcome and Assessment Information Set (OASIS). Case's colleague, **Denise Bond**, warns that while HCFA has instructed state surveyors to take a graduated enforcement approach to OASIS compliance, yet nobody knows what that will mean in practice.

"I think that means that they are not going to drop bricks on our head like they did in Operation Restore Trust surveys," she asserts. "But they have not really spelled that out." Bond says the good news is that HHAs now have a regulation that offers a blueprint surveyors will use to measure compliance under OASIS.

Last November, HCFA published instructions to state surveyors in the *State Operations Manual* to make sure HHAs are complying with the OASIS

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requirements that have been incorporated into home health conditions of payment. Bond says the main focuses for OASIS are data collection and reporting requirements.

Here is a rundown of key areas Bond says HHAs should pay close attention to:

For comprehensive assessments, HCFA instructed surveyors to examine a sample of patients to determine who conducted any initial patient assessment completed on or after July 19, 1999. According to Bond, surveyors will want to make sure that the homebound status of the patient was confirmed along with the dates of the referral and initial assessment.

Bond says HCFA also wants surveyors to ensure the timely completion of comprehensive assessments. Before they even go on site, she says, surveyors will determine if assessments are being completed within five days of the start of care. "Very often, what we see with this new type of survey is that they look for very simple things that have a time deadline or a documentation requirement," she warns. "That is easy to look for and easy to document if it is missing."

In addition, Bond says HHAs should pay close attention to the type of clinician that completes the start of care assessment. She adds that surveyors will check on-site visit records to determine who signed that record. "You want to make sure that when that person signs the assessment they include their title," she cautions. "The surveyor is not going to be able to tell that Jane Doe is an RN."

According to Bond, HHAs must also ensure that adequate data are included in the comprehensive assessment. For example, she notes that surveyors have been instructed to assess the agency's policy on readmitting patients after transfer, such as whether they are put on hold or discharged, and how the next assessment date is determined.

Bond also warns that agencies should review patient records to make sure they are collecting appropriate data every second calendar month, within 48 hours of return to service, and at discharge. She says this is another area easy for surveyors to gauge compliance because there are set time frames.

According to Bond, before surveyors visit an agency, HCFA wants them to review state data reports and make sure that the agency's encoding is completed within seven days after completing the OASIS data set. Once they are on site, she says, surveyors will choose an assessment completed in the last seven days and perform a home visit to make sure the patient's overall condition matches to clinical information in the patient's records. "Here they want to see if your OASIS data match the clinical records and, if not, whether the patient's condition changed in the last seven days," she asserts.

Bond says surveyors also will try to make sure the other clinical information in the patient's record does not contradict the OASIS data. "If you have an obvious contradiction, they will conclude your OASIS data are incorrect," she warns.

Surveyors also will be checking to make sure that agencies give existing patients privacy notification regarding OASIS data collection in addition to existing privacy notification requirements, as well as when that information was given to them.

Not only that, Bond says, HCFA wants surveyors to question patients to make sure patient confidentiality is maintained. She says that will include an interview with the HHA system administrator to make sure that person knows how to add, edit, and modify the encoded data. They will also check to see whether there is a procedure in place to assign passwords, she notes. ■

OIG advisory opinion statute set to expire

The legislation authorizing the Department of Health & Human Services' Office of Inspector General's (OIG) advisory opinion process is set to expire Aug. 21, throwing that program into jeopardy. OIG spokeswoman **Alwyn Cassil** says her office will continue to accept and process requests for opinions received prior to that date, it is unclear how the OIG will handle requests after Aug. 21 without a legislative mandate to extend the program. Since the program was authorized three years ago, the OIG has issued 41 opinions; and despite the OIG's initial resistance to the program, it now considers it useful and beneficial. Health care attorney **Sandy Teplitzky** of the Baltimore-based firm Ober Kaler, who was instrumental in passing the measure to begin with, says the advisory opinion program has become an integral component of the compliance process. ■