Final Self-Referral Rule Will Prompt Contract Reevaluation

BY ALICIA AULT
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In the third phase of the final regulations implementing the physician self-referral rule, known as Stark III, published in the Federal Register on Sept. 5, physicians will be considered to be "standing in the shoes" of the group practice when their investment arrangements are evaluated for compliance.

The Stark law governs whether, how, and when it is acceptable for physicians to refer patients to hospitals, laboratories, or other entities in which they may have ownership.

This is among the most important changes in the 516-page document, said Daniel H. Melvin, J.D., a partner in the health law department of McDermott, Will & Emery's Chicago office, in an interview. "The application of exceptions will be different going forward."

Most physicians with referral arrangements will have "a lot of contracts that will have to be looked at and possibly revised," said Amy E. Nordeng, J.D., a counsel in the government affairs office of the Medical Group Management Association.

Under Stark II—an interim policy that began in 2004—physicians were considered to be individuals, outside of their practices. Exceptions were evaluated using an indirect compensation analysis, which was the subject of many complaints. In comments on Stark II, physician groups, hospitals, and other facilities urged CMS to revert to the old policy.

CMS came to see the indirect compensation analysis as a loophole that allowed potentially questionable arrangements to slip through, said Mr. Melvin.

In the Stark III rule, CMS wrote the change in policy means that, "many compensation arrangements that were analyzed under Phase II as indirect compensation arrangements are now analyzed as direct compensation arrangements that must comply with an applicable exception for direct compensation arrangements."

There were several other notable changes in Stark III.

In one clarification, physicians who administer pharmaceuticals under Medicare Part B (like chemotherapy or infusions) or who prescribe physical therapy, occupational therapy, and speech-language pathology, are entitled to direct productivity credit for those orders, said Mr. Melvin.

The clarification applies to those two ancillary services only, not to radiology or laboratories, or other services typically offered in-house, he said.

CMS also lifted the prohibition on noncompete agreements. Under Stark II, practices could not impose noncompete agreements on physician recruits. Now, practices can bar competition for up to 2 years, but it's not clear how far geographically that noncompete can extend, said Mr. Melvin.

Practices have to "go back and look at everything," including how their physicians are being compensated and the arrangements the practice may have for equipment and leasing or services with hospitals or other DHS entities, he said.

"At the very least, they're going to want to do a review of the arrangements in place," to see if any of the exceptions being relied on will change with Stark III, added Ms. Nordeng.

The final Stark rule went into effect on Dec. 5, 2007. ■

CMS Unveils Electronic Health Records Incentive

BY JANE ANDERSON
Contributing Writer

Primary care doctors welcomed news of a federal project aimed at extending the use of electronic health records in small- to medium-size practices, but "The devil is in the details," said Dr. Steven E. Waldren, director of the Center for Health Information Technology at the American Academy of Family Physicians, in an interview. "What are going to be the real requirements for physician practices to participate and submit data?"

The demonstration project, sponsored by the Centers for Medicare and Medicaid Services, would be open to participation by up to 1,200 physician practices beginning next spring. Over a 5-year period, the project will provide financial incentives to physician groups using certified electronic health records (EHRs) to meet certain clinical quality measures.

Bonuses will be provided each year, based on a physician group's score on a standardized survey that assesses the specific EHR functions a group employs to support the delivery of care.

All participating practices would be required to use a certified EHR system to perform specific functions, such as clinical documentation and writing prescriptions. The system, which must be in place by the end of the second year of the 5-year demonstration, must also be approved by a certification body recognized by the Department of Health and Human Services.

The core incentive payment will be based on performance on the quality measures, with an enhanced bonus based on how well the EHR is integrated.

"This project will appropriately align incentives to reward doctors in small physician practices who use certified EHRs as tools to deliver higher-quality care," CMS's acting administrator Kerry Weems said in a statement.

Over the course of the demonstration project, CMS estimated that 3.6 million consumers will be affected directly as their primary care physicians adopt certified EHRs. CMS also is encouraging private insurers to offer similar incentives for adopting EHRs.

Dr. David Dale, president of the American College of Physicians, praised the demonstration project as "an encouraging step in the right direction," and said it was acknowledging that market forces alone will not be enough for physicians to afford new market systems.

"For physicians in small and medium-sized practices, the cost of an EHR system—not just the dollars spent on the hardware and software, but the time lost on training and conversion to a new system—makes implementing these systems a financial impossibility," Dr. Dale said in a statement.

AAFP's Dr. Waldren agreed that the biggest barriers to EHR implementation are the cost and the design of the physician payment system.

He added that CMS has not yet divulged the details of the project, including which EHR systems will be certified and whether physician practices must provide up-front funding for the EHR systems in order to join the demonstration.

"There's some great potential here to really move this forward—1,200 practices [are] a lot," Dr. Waldren said. "But we need to know what are going to be the requirements to participate." ■

Few Strong Studies Examine P4P Programs' Effect on Quality

BY JEFF EVANS
Senior Writer

WASHINGTON — The few studies that have examined the effectiveness of incentivized pay-for-performance programs have found a mix of moderate to no improvement in quality measures, Dr. Daniel B. Mark said at the annual meeting of the Heart Failure Society of America.

There are more than 100 incentive programs in the private U.S. health care sector under the control of employer groups or managed care organizations, but congressionally authorized programs by the Centers for Medicare and Medicaid Services get the most attention, said Dr. Mark, director of the Outcomes Research and Assessment Group at the Duke (University) Clinical Research Institute, Durham, N.C.

During the last 20 years, incentivized performance programs have shown that "what you measure generally improves and what gets measured is generally what's easiest to measure. But the ease of measurement does not necessarily define the importance of the measurement." Furthermore, little is known about whether these initiatives are cost effective for the health care system at large, Dr. Mark said, though he conceded that may be an oversimplification.

A systematic overview of 17 studies published between 1980-2005 on pay-for-performance programs found that 1 of 2 studies on system-level incentives had a positive result in which all performance measures improved. In nine studies of incentive programs aimed at the provider group level, seven had partially positive or fully positive results but had "quite small" effect sizes. Positive or partially-positive results were seen in five of six programs at the physician level (Ann. Int. Med. 2006;145:265-72).

Nine of the studies were randomized and controlled, but eight had a sample size of fewer than 100 physicians or groups; the other had fewer than 200 groups. "If these had been clinical trials, they would have all been considered extremely underpowered and preliminary," Dr. Mark said.

Programs in four studies created unintended consequences, including "gaming the baseline level of illness," avoiding sicker patients, and an improvement in documentation in immunization studies without any actual change in the number of immunizations given or effect on care. The studies did not include any information on the optimal duration of these programs or whether or not their effect persisted after the program was terminated. Only one study had a preliminary examination of the cost-effectiveness of a program.

Another study compared patients with acute non–ST-elevation myocardial infarction in 57 hospitals that participated in CMS' Hospital Quality Incentive Demonstration and 113 control hospitals to determine if a pay-for-performance strategy produced better quality of care. There was "very little evidence that there was any intervention effect," said Dr. Mark. Measures not incentivized by CMS also did not appear to change (JAMA 2007;297:2373-80).

In the United Kingdom, family practice physicians participated in a pay-for-performance program in 2004 that focused on 146 quality indicators for 10 chronic diseases as well as measures related to the organization of care and the patient's experience. The National Health Service substantially increased its deficit that year because the approximately $3.2 billion that was allocated for the project was eaten by greater than predicted success in achieving the quality indicators (83% achieved vs. an expected 75%). This led to an average increase in the physicians' pay of about $40,000 that year (N. Engl. J. Med. 2006;355:375-84).

Other investigators noted that in the 1998-2003 period prior to the NHS project all of the quality indicators had already been improving, "so it's not clear how much the program's achievements can actually be attributed to the program itself," he said (N. Engl. J. Med. 2007;357:181-90). And it is not clear what effect the program had on other conditions that were not a part of the incentive program. In any case, the U.K. government has significantly tightened up its requirements for earning extra money in the program in 2008, according to Dr. Mark.

Another study showed public reporting of quality measures alone could improve a set of quality indicators on heart failure and acute myocardial infarction by the same magnitude as a pay-for performance program that included public reporting (N. Engl. J. Med. 2007;356:486-96). ■