Incentives Aren't Improving Care, Expert Says

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, which, in some instances, have led to unintended consequences, Dr. Daniel B. Mark said at the annual meeting of the Heart Failure Society of America.

There are more than 100 reward or incentive programs that have started in the private U.S. health care sector under the control of employer groups or managed care organizations, according to Dr. Mark, but congressionally authorized programs by the Centers for Medicare and Medicaid Services have received the most attention, he said.

It is important to examine the evidence base that pay-for-performance programs actually improve quality because "people are making this association," 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, very little, if anything, is known about whether these initiatives are cost effective for the health care system at large, Dr. Mark said, although he noted that that may be an oversimplification of the outcomes of such programs.

A systematic overview of 17 studies published during 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 of these had a sample size of fewer than 100 physicians or groups; the other study 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 appeared to have 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 that did not participate in the program to determine if a pay-for-performance strategy produced better quality of care. There was "very little evidence that there was any intervention effect," according to Dr. Mark. Measures that were 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 that 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). ■

Final Self-Referral Rule Marks a Return To Earlier 'Standing in the Shoes' Policy

BY ALICIA AULT
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In issuing the third phase of the final regulations implementing the physician self-referral rule, also known as the Stark law, the Center for Medicare and Medicaid Services has returned to a stance it held in the first phase.

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

Under the new 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, according to several attorneys.

This reversion back to the initial Stark policy 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. As a result, "the application of exceptions will be different going forward," Mr. Melvin said in an interview.

That means that most physicians who have 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. Ms. Nordeng agreed that the return to the "stand in the shoes" view was the most significant component of Stark III.

Under Stark II—an interim policy that began in 2004—physicians were considered to be individuals, outside of their practices. Exceptions to the law were evaluated using an indirect compensation analysis, which ended up being onerous and was the subject of many complaints to CMS. In comments on Stark II, physician groups, hospitals, and other facilities (called designated health services, or DHS entities) urged CMS to revert to the old policy.

With the final rule, most physicians who have referral arrangements will have 'a lot of contracts that will have to be looked at and possibly revised.'

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

In the Stark III rule, CMS wrote that 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.

The regulations clarify that physicians who administer pharmaceuticals under Medicare Part B are entitled to get direct productivity credit for those orders. The clarification applies to those two ancillary services only, not to radiology or laboratories, or other services typically offered in-house, said Mr. Melvin.

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, Mr. Melvin added.

With the new rule, 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.

The final Stark rule goes into effect on December 5, 2007. ■

UnitedHealthcare Agrees to $20 Million Claims Settlement

The insurance giant UnitedHealthcare could pay up to $20 million to state regulators as part of an agreement to settle allegations that the company violated state laws in its claims processing.

Under the settlement, UnitedHealthcare has agreed to pay about $12.2 million up front to 36 states and the District of Columbia. The payout could grow to $20 million if other states join the suit.

UnitedHealthcare has also agreed to a 3-year process improvement plan. The company will be required to self-report data quarterly and annually on how it performs on a set of national performance standards. These benchmarks will focus on claims accuracy and timeliness, appeals review, and consumer complaint handling. A lack of compliance with the benchmarks could result in additional financial penalties, according to the National Association of Insurance Commissioners.

The settlement follows a multistate investigation that found errors in claims processing such as not applying correct fee schedules and deductibles. There were also frequent violations of prompt payment rules, according to the New York State Insurance Department, a lead party in the settlement.

The settlement was praised by the National Association of Insurance Commissioners and the states involved. UnitedHealthcare also praised the settlement as evidence of how the industry can work with state regulators. "This new, forward-thinking approach focuses the regulatory process for the states and our company on a practical set of uniform performance standards, while providing clearer and more meaningful means of assessing how well we are serving customers," Kenneth A. Burdick, CEO of UnitedHealthcare, said in a statement.

—Mary Ellen Schneider