Self-Referral Rule Heralds A Return to Earlier Policy

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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 September 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 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," he 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.

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 under the Stark law) urged CMS to revert to the old policy.

CMS 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 or who prescribe physical therapy, occupational therapy, and speech-language pathology, are entitled to get 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.

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.

With the new rule, practices will have to review all their arrangements, from physician compensation to leasing or services agreements, to see if any of the exceptions they relied on will change with Stark III, added Ms. Nordeng. The final Stark rule goes into effect on December 5, 2007. ■

UnitedHealthcare Agrees to $20 Million Settlement in Claims Processing Case

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 settlement.

The company has also agreed to a 3-year process improvement plan that will run through the end of 2010. 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, one of the lead parties 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.

The District of Columbia and the following states signed on to the agreement: Alabama, Alaska, Arkansas, California, Connecticut, Florida, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Michigan, Minnesota, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Utah, Vermont, Virginia, West Virginia, and Wyoming.

—Mary Ellen Schneider

POLICY & PRACTICE

WHI Results Still Confusing

Just 18% of physicians said they have "no confusion at all" about the results of the Women's Health Initiative study, according to an online survey of more than 400 physicians conducted on behalf of The Hormone Foundation. In addition, only 15% said they believe patients accurately understand the risks of hormone therapy. The results "underscore the importance of physicians' role in educating patients and [the public] on menopause management," said foundation director Paula Correa. The survey, sponsored by Novogyne Pharmaceuticals, also found that 74% of physicians still consider hormone therapy as a first-line treatment for menopause symptoms. Novogyne manufactures the hormone therapy patches, Vivelle-Dot, Vivelle, and CombiPatch.

Aventis Settles Pricing Fraud Case

Drugmaker Sanofi-Aventis has agreed to pay more than $190 million to settle allegations of fraudulent drug pricing and marketing against Aventis Pharmaceuticals, one of its predecessor companies. According to the U.S. Department of Justice, Aventis used the difference between the inflated prices that were used to set reimbursement rates and the actual prices charged to customers to market the antiemetic, Anzemet. In doing so, it caused fraudulent claims to be submitted to Medicare and other federal health care programs. The case arose after Ven-A-Care of the Florida Keys Inc. filed a False Claims Act suit, which allows a private person to file a whistle-blower suit on behalf of government. To continue working with federal programs, Sanofi-Aventis agreed to report accurate prices. Almost $180 million of the settlement will go to the federal government and the balance, to states and the District of Columbia. The whistle blowers will receive about $32 million.

Insurance Premium Increase Slows

Employer-sponsored health insurance premiums rose on average 6.1% in 2007, reflecting a continuing slowdown in premium increases. The 2007 premium increase is the smallest hike since 1999, according to an employer survey by the Kaiser Family Foundation and the Health Research and Educational Trust. But experts say the slowdown is likely temporary and isn't providing relief to individuals or employers. In fact, the 6.1% increase is higher than the average increase in wages (3.7%) and in the overall inflation rate (2.6%). In 2007, the average premium for family coverage in the United States is $12,106 with workers paying about $3,281 for their share of the policy. The market continues to be dominated by preferred provider organizations, which insure about 57% of covered workers; consumer-driven plans account for only about 5%. For details, visit www.kff.org/insurance/7672.

Rise in Adverse Drug Event Reports

The number of serious and fatal adverse drug events (ADEs) reported to the Food and Drug Administration more than doubled between 1998 and 2005, according to a report in the Sept. 10 issue of Archives of Internal Medicine. The agency defines a serious adverse event as an event resulting in death, a birth defect, disability, hospitalization, or that requires intervention. During the 8-year period, 467,809 serious events met the inclusion criteria. The number of reported serious ADEs increased from 34,966 in 1998 to 89,842 in 2005, a 2.6-fold increase; the number of reported deaths during that time increased 2.7-fold, from 5,519 to 15,107. The increase was largely a result of expedited reports from manufacturers of serious events not included on the label. Contrary to expectation, drugs related to safety withdrawals accounted for a "modest share" of reported events and declined over time. Of the 15 drugs most frequently cited in fatal events, there was a "disproportionate contribution of pain medications [7] and drugs that modify the immune system [4]." Drugs named in serious ADEs spanned a variety of classes, but within that group, events tied to 13 new biotechnology products increased almost 16-fold, from 580 in 1998 to 9,181 in 2005.

Bill Seeks MD Gift Disclosure

Legislation in the Senate would require quarterly disclosure of gifts, honoraria, travel, and other payments to physicians by pharmaceutical, medical device, and biotechnology manufacturers. S. 2029 was introduced by Sen. Chuck Grassley (R-Iowa) and Sen. Herb Kohl (D-Wisc.) and would apply to manufacturers with more than $100 million in gross revenues. The U.S. Health and Human Services Department would be required to make the disclosure data available on the Internet. Penalties would range from $10,000 to $100,000 per violation. Ken Johnson, senior vice president of the Pharmaceutical Research and Manufacturers of America, said in a statement that his group had not yet reviewed the bill but that contact with physicians is essential for education purposes. The group's guidelines suggest gifts to physicians should not exceed $100. The American Medical Association had also not yet read the proposal, but in testimony earlier this year, noted that it has extensive guidelines on accepting anything from industry.

Mass. Considers Retail Clinic Rules

Massachusetts' Public Health Council is considering rules that would limit the scope of retail medical clinics in the state. The proposal is in response to a request by CVS Corp. to open 20-30 of its MinuteClinics in the Boston area beginning this fall. Under the proposal, applicants would need to: state what services they intend to provide; develop policies that limit the number of times each patient could receive care there; and refer patients without a primary care physician to one in the area who is accepting new patients.

—Renée Matthews