

POLICY & PRACTICE

NQF Substance Abuse Standards

The National Quality Forum has issued a set of national, evidence-based consensus standards on identifying and treating substance abuse. The 11 practices were endorsed by 365 NQF member organizations, including health care providers, professional societies, purchasers, and federal agencies. Voluntary adoption of the standards would lead to improved patient outcomes, according to the NQF. The recommendations cover identification of substance use conditions, initiation and engagement in treatment, therapeutic interventions, and continuing care management. The guidelines can be purchased at the NQF Web site, www.qualityforum.org.

Settlement on Zyprexa Leaks

A former consultant to Eli Lilly & Co. has agreed to pay the drug maker \$100,000 to settle complaints that he leaked confidential information about Zyprexa (olanzapine) to a plaintiffs' attorney. Dr. David Egilman was an expert witness for the plaintiffs in Zyprexa product liability suits. Under the agreement, Dr. Egilman acknowledged that he had intentionally and illegally given attorney James Gottstein documents that had been made available by Lilly during discovery, and that "he knew that these materials painted an incomplete picture of the issues related to Zyprexa," according to a statement by Lilly. Mr. Gottstein shared the documents with the New York Times, which wrote a series of articles in December 2006 contending that Lilly had withheld information about side effects. Lilly said it would donate Dr. Egilman's settlement to the International Center for Clubhouse Development.

Court Date Set for Ayres

Psychiatrist Dr. William Ayres is set to go before a jury in San Mateo County, Calif., in March 2008 to face charges that he molested seven young male patients. In his Sept. 6 arraignment, Dr. Ayres pleaded not guilty. He has maintained his innocence since he was first arrested in April 2007 and charged with molesting at least five former patients. The arrest came after a 4-year investigation conducted by the San Mateo County Police Department. Dr. Ayres, who is 75, is a former president of the American Academy of Child and Adolescent Psychiatry.

Lawmakers OK Delay in Rx Rule

Coming down to the wire on a new federal mandate requiring the use of tamper-resistant prescription pads for all Medicaid prescriptions beginning Oct. 1, lawmakers in the House and the Senate passed legislation in late September that would delay the mandate's start until March 31, 2008. At press time, President Bush was expected to sign the legislation, although it was not clear whether he would sign it by Oct. 1, National Community Pharmacists Association spokesman John Norton told this newspaper. The tamper-proof prescription pad man-

date delay was bundled with extensions on several programs due to expire Sept. 30, including an abstinence education initiative that the Bush administration supports, Mr. Norton said. The original mandate, passed as part of war funding legislation earlier this year, requires all Medicaid prescription be written on "tamper resistant" paper to be eligible for federal reimbursement. Even though many states have similar requirements, pharmacists' organizations have maintained that most physicians do not currently use these types of pads, nor are supplies readily available.

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.

Task Force Looks at Physician Gifts

In New Jersey, which is sometimes called the nation's medicine cabinet, the state's attorney general is taking a closer look at the gift-giving practices of pharmaceutical and medical device companies. The Attorney General's Advisory Task Force on Physician Compensation, which met for the first time in September, is examining the potential impact of payments and gifts to physicians from the drug and device industry. The task force will also consider possible public disclosure of gifts, direct disclosure to patients, and limits on payments to physicians. Vermont, Maine, Minnesota, West Virginia, and the District of Columbia have passed laws requiring some form of reporting of payments made to physicians by pharmaceutical and medical device companies. In response to the formation of the task force, the Pharmaceutical Research and Manufacturers of America issued a statement citing PhRMA's 2002 Code on Interactions with Healthcare Professionals as an important safeguard. The code declares all forms of entertainment to be inappropriate and says that any gifts that are given to physicians should support medical practice and be valued at less than \$100. The New Jersey task force includes the state's Health and Senior Services Commissioner, members of the State Board of Medical Examiners, physicians, industry representatives, and consumer advocates.

—Alicia Ault

Self-Referral Rule Marks Return to Earlier Policy

BY ALICIA AULT
Associate Editor, Practice Trends

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 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

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

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 (such as chemotherapy or infusions) 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, he said.

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

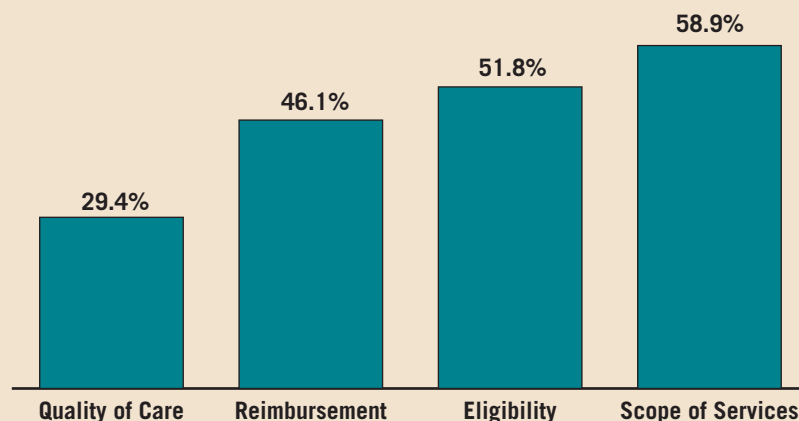
With the new rule, practices have to "go back and look at everything," including how their physicians are being compensated and the arrangements the practice may have for equipment and leasing or services with hospitals or other DHS entities, Mr. Melvin said.

"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 goes into effect on Dec. 5, 2007. ■

DATA WATCH

State Medicaid Programs Fall Short in All Categories



Note: Data calculated using the percentage of the mean score out of the total possible score. Source: 2000-2006 data, Public Citizen Health Research Group