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News

Provider Regulation

Growing Availability of Quality Data May Spur New Type of Enforcement Actions, AHLA Told

LAS VEGAS--Enforcement actions targeting institutions' failure to provide adequate care, whether civil or criminal, are increasingly being built on the greater amount of quality-of-care data and information culled from a growing array of sources, according to a Feb. 6 presentation to a gathering of health care attorneys.

James G. Sheehan, associate U.S. attorney for the Eastern District of Pennsylvania, said his office is continuing its focus on ensuring that health care providers receiving federal health care dollars give patients high quality care, as they adjust to the "Medicare revolution" that is changing the federal reimbursement system from one based on payment for procedures performed to one based on outcomes.

As this revolution moves ahead, he said, new enforcement cases targeting lapses in delivery of quality care will be developed from data-mining activities conducted by a range of regulatory and oversight entities, as well from information from regulators, whistleblowers, media, and others. Discrepancies in the information from multiple sources on one provider or facility may serve as the "red flag" that gets prosecutors' attention, he said.

"We are reviewing assorted sources of quality information on your facility to see what it says and if it is consistent. You should be doing the same," he said. The fact that the data may be flawed or missing will not itself give rise to a claim of fraud or false statement, he added, but it does bring attention to and raises concerns about the facility.

"We are certainly going to look further at institutions where the data just doesn't make sense," he said. Sheehan made his remarks at the American Health Lawyers Association Hospitals and Health Systems Law Institute.

Egregious Cases

Sheehan, who said he was not speaking in an official capacity, said his office will continue to focus criminal investigations only on the most egregious failure of care cases and that the general approach is to give voluntary compliance efforts a chance to work. He noted that his office has received complaints from some whistleblowers who were asked whether they had attempted to avail themselves of internal remedies. That should be done first, but if voluntary compliance and corrective action efforts do not solve the problem, his office is prepared to act, he said.

Sheehan said his office would continue to ask the same underlying questions to determine whether prosecution is appropriate:

- Was there a systemic failure by the institution's management and the board to address quality issues?
- Did the institution make false reports about quality or fail to file mandated reports?
- Has the institution profited from ignoring poor quality or ignoring providers of poor quality?
- Have patients been harmed by poor quality care or been given false information about it?

Sheehan noted that some of the sources of data that will be considered in initiating or pursuing such an investigation include information from the reporting hospital quality data for annual payment update (RHQDAPU), information from the Joint Commission on Accreditation of Healthcare Organizations, state reporting, mandated reporting of errors and near misses, mandated apologies required under some state laws, quality improvement organizations, pay-for-performance contracts in the private sector, and whistleblowers.

With respect to this last group, Sheehan noted provisions of the Patient Safety and Quality Improvement Act of 2005 that gave quality-of-care whistleblowers most of the same protections afforded whistleblowers under the False Claims Act. "I expect an increase in the number of mixed cases in which whistleblowers allege both quality lapses and false claims in one action," he said.

Compliance Programs

The wider threat of enforcement actions against providers makes the development of programs designed to assess and maintain compliance in the quality of care arena paramount, Sheehan said. Cheryl Wagonhurst, who made the presentation with Sheehan, agreed.

Wagonhurst emphasized the need for a commitment to quality care and outcomes to become completely integrated into an institution's compliance program. "It is not a question of *if* but *when* quality of care issues will arise" in an enforcement context. "If not Jim, then it will be CMS, based on

the increasing amount of data at their disposal, who will be knocking at your door," she added.

Wagonhurst stressed the need to create a mechanism to audit current the existing compliance regime to assess quality assurance, utilization review, peer review, and training of the medical staff and the institution's board members. It is this process that leads to discovery of breakdowns in the system that can cause quality of care problems, she said.

The compliance program built on this assessment must ensure that all data, reports, hotline calls, and other feedback is integrated and assessed by the compliance team with the support of senior management and the board, she added. "Medical staffs and boards need to know this stuff," she concluded.

Wagonhurst is a former compliance counsel with Tenet Healthcare and now is with Foley and Lardner in Los Angeles.

More infirmation about the meeting is available at http://www.healthlawyers.org/Content/ContentGroups/Programs3/2007/Br-LTC07.pdf.

By Peyton M. Sturges
