# Quality fraud: What's that?

By Alice G. Gosfield, Esq.

*Every month,* DermWorld *covers legal issues in "Legally Speaking." This month's author is a health care attorney at Alice G. Gosfield and Associates, P.C.*

Many people believe that fraud and abuse pertain only to false claims, kickbacks, or Stark law violations. As value-based payment has begun to emerge as a driving force, a new range of potential frauds can occur. Payment based on metrics entails measurement which affects the amount of payment. Misstating the performance can be a problem. Quality reporting has expanded widely in the public programs, whether linked to payment or not. Some quality statements are made in claims either explicitly or implied — a subject the Supreme Court of the United Sates has addressed. Failure to do the right thing clinically or doing the wrong clinical thing can also create liability. Finally, medical necessity is no longer simply an overpayment issue. It can be a fraud issue as well.

## Bases for risk

Nineteen different types of providers (e.g., hospitals, home health agencies, ambulatory surgery centers, rural health clinics, and more) have conditions of participation to get paid by Medicare. These conditions include things like having organized medical staff, medical records, governing bodies, nursing staff, and other operational requirements. Physicians do not have such conditions, although they sign an agreement to be liable for overpayments when they participate in Medicare.

Quality reporting is a relatively recent phenomenon, now required by regulation for most facilities. Physicians and accountable care organizations (ACOs), by contrast, participate in the Merit-based Incentive Payment System (MIPS), which adjusts their payment up or down depending on their performance two years earlier. MIPS is a pay for performance program.

CMS has also implemented value-based purchasing programs for five different kinds of facilities. Under Stark and the anti-kickback safe harbors, CMS and the OIG have separately published regulations for compliant value-based arrangements and value-based enterprises. Stark is a physician-focused statute, applicable to Medicare and Medicaid only. The anti-kickback statute is far broader, applying to physicians and all other providers on the food chain of claim submission. The regulations allow multiple providers who remain independent to come together and share financially in the rewards for producing better value. The regulations confront different levels of financial risk, from no risk at all to full financial risk. They address definitions of value-based activities, value-based arrangements (VBAs), value-based enterprises (VBEs), value-based purposes, value-based participants, and target patient populations (TPP). Under Stark, failure to comply with the regulations is a violation of the law. Under anti-kickback, the regulations provide safe harbors where compliance assures no trouble with the government, but lack of compliance is not necessarily a violation but will be evaluated using prosecutorial discretion.

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## Potentially fraudulent quality failures

Against the background of those regulatory requirements, there are also other behaviors that can generate liability. "Clinical waste" has been defined as low-value spending for undesirable health care services. The three most relevant forms for this consideration are (1) failures of care delivery: poor execution or lack of widespread adoption of known best care processes; "doing the wrong thing" (errors and adverse events); not doing the right thing; (2) failure of care coordination: patients fall through the cracks of the fragmented health care system with lack of follow through; and (3) overtreatment, which is estimated to account for 2-8.4% of total health spending.

Under- and over-utilization and medical necessity represent another cadre of quality failures. The earliest concerns about over-utilization were hospital length of stay issues in 1972. While hospitals could be deemed to qualify for Medicare participation by virtue of their accreditation by the Joint Commission, the one activity that could not be deemed was utilization review, which they had to perform themselves. During the same timeframe, Congress inserted into the statute the ability to exclude health care professionals for providing services substantially in excess of a patient's needs or of a quality that was substandard. Of real significance and much under-appreciated is that medical necessity is inherent in all claims to Medicare and is attested to explicitly on the CMS 1500 form. This means that if a claim is submitted for unnecessary care, it not only entails an overpayment that must be returned, but also could be the basis for a determination of a false claim.

False quality reporting has been the issue in several court cases. In *U.S. ex rel Janssen v. Lawrence Memorial Hospital* the hospital allegedly falsified patients' arrival times in order to increase its Medicare reimbursement under a pay for reporting and pay for performance program. The hospital also separately submitted Data Accuracy and Completeness Acknowledgements on an annual basis, certifying that their data was in fact accurate and complete. The court granted the hospital its motion for summary judgment. The whistleblower had complained to the government about the hospital's falsifications and the government continued to pay. On appeal, the circuit court dismissed the Data Accuracy documents as boilerplate compliance forms and not dispositive of whether there had been falsification! By contrast, in *U.S. ex rel Prather v. Brookdale Senior Living Communities, Inc.*, the issues were whether the timing of physician signatures and whether they were obtained in face-to-face encounters could form the basis for a false claims allegation. The Sixth Circuit Court overturned dismissal. The government's continued payment was not dispositive, they said,

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since the signatures were specifically required to prevent fraud.

## The penalties

Medicare can terminate physician enrollment or participation for failing to disclose information or failing to provide access to information. There are two types of exclusions from the federal programs that may be imposed: mandatory exclusions, usually based on actions by another authority, such as a conviction under state law, but also including conviction of a crime relating to neglect or abuse of patients — not limited to the federal programs. Permissive exclusions may be imposed for at least one year where a physician:

> *has furnished or caused to be furnished items or services to patients (whether or not eligible for benefits under title XVIII or under a state health care program) substantially in excess of the needs of such patients or of a quality which fails to meet professionally recognized standards of health care.*

"Professional standards of care" are defined as *"Statewide or national standards of care, whether in writing or not, that professional peers of the individual or entity whose provision of care is an issue, recognize as applying to those peers practicing or providing care within a state."* More than 20 physicians have been excluded based on these quality-of-care provisions.

With respect to quality reporting risks, by making false statements or misrepresentation of material facts in any application, agreement, bid, or contract to participate or enroll as a health care professional under a federal health care program, such physician or supplier may be excluded. Further, a $100,000 civil money penalty per statement can be imposed on anyone who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim for payment for items and services furnished under a federal health care program."

## What to do

Most compliance plans should be amended to take into account the risks from quality fraud. Monitoring techniques and specific references to professional standards of care should be explicitly addressed. The government in its compliance program guidance says quality and patient safety should be included in compliance programs. They recommend monitoring Corporate Integrity Agreements (CIAs), especially those which are based on quality-of-care concerns. These are documents where the government requires the target physician to engage in concerted efforts which the government will monitor intrusively over five years. The CIAs are all publicly available.

All physician practices should standardize their care delivery to the science throughout the depth and breadth of operations including using clinical practice guidelines or some other explicit evidence-base, documented in the compliance plan and adhered to by all. Attention should be paid to documentation of medical necessity given its heightened significance in this context. The use of differing levels of clinicians and in the team approach to care ought to be explicitly confronted, as well. The context for assessing quality performance is changing rapidly. The heightened risk in the developing climate merits attention. **DW**