Compliance measures needed by healthcare providers to prevent violations of healthcare billing and compliance with the Affordable Care Act.

By Brian Dickerson, Roetzel, Washinton DC and Jon May, Roetzel, Fort Lauderdale

The Centers for Medicare and Medicaid Services (CMS), the agency responsible for managing the billing of federal health care programs, has drawn criticism from many for what some politicians are calling an abysmal job of maintaining a healthcare system which reduces fraud. While CMS attempts to discover how to investigate fraud, the Department of Justice (DOJ) is not waiting and has committed itself to investigate and prosecute alleged fraudulent schemes, targeting fraud in overpayments to hospitals and other medical providers, such as physician practice groups. The DOJ has targeted large healthcare providers to small health care practice groups throughout the country including in northern Ohio.

On January 4, 2013, the United States Department of Justice intervened for purposes of effectuating the settlement of a qui tam action (filed under the federal False Claims Act or "FCA") against a non-profit community hospital system, an independent physician group and two physicians that practiced in Northern Ohio. The suit was originally filed by a former manager of the hospital's catheterization and electrophysiology laboratory. The complaint alleged that over a five year period the hospital and the physician group performed unnecessary cardiac procedures to Medicare patients. Specifically, the United States alleged that the hospital and the physician group over-prescribed angioplasty procedures, and improperly "unbundled" angioplasty and angiogram services, leading to the routine scheduling of "serial" angioplasties. The Medical Providers were also accused of performing angioplasty and stent services on individuals whose blood vessels were not sufficiently occluded to require such procedures.

The hospital and the physician group agreed to pay the United States approximately $4.4 million to settle the allegations that they submitted false claims to Medicare. As a result of the settlement, the whistleblower, will receive approximately $660,000 of the government's recovery.

The word is out that the Department of Justice intends to focus its attention on hospital systems and other medical providers like physician practice groups, and the industry will be surprised by the number of whistleblower suits presently filed and awaiting a decision by the DOJ to intervene. Moreover, the industry is no longer looking at threats from low-level employees who are only aware of what they see in their small part of the company. As the above complaint reflects, managers, persons with a broader picture of the scope of wrongdoing and access to emails and other kinds of incriminating evidence, are more than willing to cooperate and are incentivized to make such claims.

Most FCA actions are settled before the complaint is unsealed. And in many instances, the settlement is for twice the amount of the overpayment. However, by statute, the government is entitled to recover treble damages plus a civil penalty of from $5,500 to $11,000 for each false claim submitted — an amount that could easily bankrupt a business.

Over the last four years, the United States has recovered over $13 billion dollars from fraudulent billing in Medicare. Because all stakeholders in the coming debate are going to be looking for ways to save money, more and more pressure will be placed on the DOJ to employ all the tools at its disposal, from civil actions under the False Claims Act to criminal prosecutions, in order to put an end to what the government believes is endemic fraud within the medical industry.

To assist healthcare companies in preventing the whistleblower cases and government action, each healthcare provider should implement an effective compliance program, which is designed to prevent fraudulent billing, illegal kickbacks, and activities which subject a provider to healthcare fraud and the False Claims Act. When DOJ is pursuing a civil healthcare fraud case, as with the False Claims Act, or when it believes that fraud is criminal, the United States Attorneys prosecuting the case, must follow the *U.S. Attorney Handbook* and Tile 9, "Principles of Federal Prosecution of Business Organizations". Within this title, 9-28-800 sets the parameters which must be contained within a compliance program for the U.S. Attorneys to evaluate when a company has a compliance program and how the DOJ should analyze the compliance program to determine if it is effective and implemented properly. If the DOJ determines the compliance program has all of the necessary parameters as set forth in 9-28-800 and the act that is being investigated was not intentional or committed with reckless disregard (healthcare provider knew illegal billing or kickback was occurring and just ignored it or covered it up) then the healthcare provider can avoid substantial treble damages and criminal implications.

The parameters set forth within the *U.S. Attorney Manual* will have to be the cornerstone of any compliance programs of hospital administration and will become a necessary component of any medical practice that receives money from a federal government health program such as Medicare. Pursuant to the Patient Protection and Affordable Care Act (PPACA), the Secretary of Health and Human Services and the Office of the Inspector General are directed to establish core guidelines for such compliance programs for healthcare providers. Although Congress has mandated that these guidelines take into consideration the size of the practice being regulated, no one knows how complicated or expansive these regulations will be, once put in practice. Thus far the only compliance regime that has been mandated under the law applies to skilled nursing facilities and nursing homes. Although HHS has not yet issued regulations these providers, the statute requires these facilities to have an effective compliance program in place by March 23, 2013 and contain the core principles needed to create and implement such programs.

Section 6102 of the PPACA defines a "compliance and ethics program" as a program "reasonably designed, implemented, and enforced so that it generally will be effective in preventing and detecting criminal, civil, and administrative violations . . . and in promoting quality of care." To that end, a compliance program must include the following elements:

- The establishment of compliance standards and procedures reasonably capable of reducing the likelihood of violations and promoting quality of care;
- The assignment of specific high-level individuals with overall responsibility to oversee compliance, and with sufficient resources and authority to enforce the compliance standards;
- The use of due care to avoid delegating substantial discretionary authority to individuals known to have a propensity to engage in violations;
- The effective communication of compliance standards and procedures to all employees;
- The establishment of monitoring and auditing systems designed to detect violations and, in addition to this, a mechanism through which employees can report violations without fear of retribution;
- The consistent enforcement of compliance standards through appropriate disciplinary actions;
- The establishment of a procedure for responding appropriately to any violation that has been detected and for preventing further similar violations; and
- The periodic reassessment of the compliance program to identify changes necessary to reflect changes within the organization.

Obviously a different set of principles will have to be developed for small medical practices that do not have the infrastructure found in large institutions that have full-time staff devoted to ensuring compliance with every government regulation from Stark III to HIPAA. But it is clear that at a minimum medical practices, no matter how small, are going to be held accountable for having procedures in place to educate each employee on the laws proscribing fraud and abuse and a means to alert the owners of the practice to any unlawful conduct. Even in the absence of any fraud, failure to have an effective compliance program will lead to exclusion from Medicare.

It is important for Ohio healthcare providers to implement an effective and proper compliance program and examine its business operations to ensure that the provider and its employees, agents and third party contractors are in compliance with federal and state billing practices. Otherwise, it could be the employee or former employee of any provider in Northern Ohio reporting the provider to the United States Attorney's office as a whistleblower and recovering part of the settlement obtained from the provider by the United States Department of Justice. So surely, the best message is to take preventative measures to insure your healthcare business is in compliance with applicable laws. ■

1. False Claims Act, 31 U.S.C. §§3729-33 (the "FCA" or the "Act").
2. §3729(a)(1).
3. *See* Press Release, Office of Pub. Affairs, U.S. Dept. of Justice, Acting Associate Attorney General Tony West Speaks at Pen and Pad Briefing Announcing Record Civil FY 2012 Recoveries (Dec. 4, 2012), http://www.justice.gov/iso/opa/asg/speeches/2012/asg-speech-1212041.html.
4. Sec. 6401(a)(7), Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §2702, 124 Stat. 119, 318-319 (2010).