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Proposed CMS Rules Present a New Threat to Habitual Health Care Fraud Offenders

BY R. SCOTT OSWALD AND DAVID L. SCHER

The Federal Bureau of Investigation estimates that health-care fraud costs our nation $80 billion annually, and every year we hear about pharmaceutical makers and health-care providers settling allegations of fraud for hundreds of millions of dollars.[1]

In the last few years, we have also seen settlements exceeding $1 billion, including an eye opening $3 billion settlement with GlaxoSmithKline (GSK) in July 2012(16 HFRA 509, 7/11/12). Many companies are repeat offenders, settling multimillion dollar claims year after year. Indeed, GSK paid $750 million in 2010 to settle criminal and civil claims relating to the manufacture and sale of adulterated drugs. Other repeat offenders include giants Pfizer, Inc. and Novartis Pharmaceuticals, Corp.

For many organizations, fraud settlements with the government seem like a cost of doing business, and the government is taking notice.

On April 29, the Centers for Medicare & Medicaid Services announced proposed rules intended to combat repeat offenders and encourage individuals with information about wrong doing to come forward. Under the new rules, the CMS proposed to expand its authority to deny or revoke a provider's or supplier's enrollment in Medicare based on a pattern or practice of submitting claims for services that fail to meet Medicare requirements or any felony conviction.

The CMS is also seeking significant changes to the existing Incentive Rewards Program (IWP) by increasing the maximum reward for whistleblowers from $1,000 to $9.9 million. The agency received 120 comments during the comment period, which closed on June 28, and it should be well on its way to preparing the final rule.

I. Revocation for a Pattern or Practice of Billing for Services That Do Not Meet Medicare Standards

Under the existing language of 42 C.F.R. § 424.535(a)(8), CMS may revoke a provider's or supplier's Medicare billing privileges if the provider or supplier submits a claim or claims for services that could not have been furnished to a specific individual on the date of service.

Those instances include, but are not limited to, situations where the beneficiary is deceased, the directing physician or beneficiary is not in the state or country when services were furnished, or when the equipment necessary for testing is not present where the testing is said to have occurred.

The CMS proposed to add a new paragraph allowing revocation when ''CMS determines that the provider or supplier has a pattern or practice of submitting claims for services that fail to meet Medicare requirements,'' but the revision does not define what constitutes a ''pattern or practice.''

[1] Health Care Fraud, http://www.fbi.gov/about-us/investigate/white_collar/health-care-fraud (last visited Sept. 1, 2013).

Oswald is managing principal and Scher is principal at the Washington-based law firm The Employment Law Group PC. The authors can be reached via the law firm's website at http://www.employmentlawgroup.net/.

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The CMS stated that it proposed the addition because the existing regulations address individual claims and not overall billing patterns. The proposed rule also appears to be calculated to address so called ''worthless services'' claims. Under the ''worthless services'' theory, developed through litigation under the False Claims Act, a provider may be liable to the government if it renders services that are not medically necessary or which are so far afield from the standards of care that they are ''worthless.''

Comments to this proposed change show concern for the proposed rule's ambiguity as well as a lack of due process. For example, the American Podiatric Medical Association (APMA) asked that ''CMS provide additional detailed information, including examples, about the process of identifying and quantifying a pattern or practice, as well as the actual revocation process of Medicare billing privileges.'' The APMA also suggested that CMS implement a ''reckless disregard'' or ''knew or should have known'' standard.

Other comments expressed significant concern about the lack of due process and the possibility of inconsistent enforcement. The Emergency Department Practice Management Association (EDPMA) and American College of Osteopathic Emergency Physicians (ACOEP) submitted joint comments stating ''we cannot support the proposed provision unless appropriate procedural safeguards are put in place to ensure due process and prevent arbitrary and capricious enforcement.''

The government's request for comments states that CMS would take into account factors such as:

- the percentage of submitted claims that were denied;
- the total number of claims that were denied;
- the reason(s) for the claim denials;
- whether the provider or supplier has any history of ''final adverse actions'' (as that term is defined under § 424.502);
- the length of time over which the pattern has continued; and
- how long the provider or supplier has been enrolled in Medicare.

However, those considerations are missing from the proposed rule, leaving the door open for unprecedented efforts to revoke providers' and suppliers' credentials.

II. Denial or Revocation for Felony Conviction

At present under 42 C.F.R. § 424.535 (a)(3), CMS may:

> [D]eny or revoke a provider or supplier's Medicare billing privileges if the provider or supplier—or any owner of the provider or supplier—has, within the 10 years preceding enrollment or revalidation of enrollment, been convicted of a federal or state felony offense that CMS has determined to be detrimental to the best interests of the Medicare program and its beneficiaries.

Section 424.535 (a)(3)(i) contains a specific list of felonies, including murder, rape, assault, extortion, insurance fraud, and any felony that placed the Medicare program or its beneficiaries at immediate risk, such as criminal neglect. For CMS to be able to act, the individual must be convicted or have entered into a pretrial diversion.

CMS proposed to eliminate the enumerated list of offenses, thereby enlarging its authority to deny or revoke a provider's or supplier's enrollment in Medicare based on any felony conviction at its discretion. The CMS also proposed to include the conviction of a ''managing employee.''

As justification, CMS remarked in its summary of the proposed rule that, ''We have found numerous instances in which a particular managing employee of a provider or supplier has as much, if not more, control of and involvement with the entity as does the owner.''

While the proposed changes to section 424.535 did not draw as many comments or criticisms, they, too, contain ambiguity of which providers and suppliers should be aware. The variety of crimes that are considered felonies varies greatly from state to state.

Acts that are treated inconsistently among states include possession of marijuana, possession of different types of firearms, and larceny of varying amounts. What may not be a crime in one state could be a misdemeanor or felony in another, and employers with locations in multiple states should develop policies that take into consideration the varying definitions.

III. Expansion of Incentive Rewards Program

The government's traditional tool for combatting Medicare fraud is the False Claims Act (FCA), 31 U.S.C. §§ 3729 – 3733. The FCA provides that anyone who knowingly submits a false claim for payment to the government may be liable for three times the government's damages plus a penalty of up to $11,000 per occurrence. The law dates to 1863 and was enacted to address concerns of fraud committed against the Union Army.

The FCA contains a *qui tam* provision that permits an individual with knowledge of fraud committed against the government to sue on its behalf. Most whistleblowers are current or former employees, and they take a great risk in coming forward. To encourage individuals to come forward and expose fraud on the government, the FCA awards whistleblowers up to 30 percent of the government's recovery, plus attorneys' fees and costs.

Complementing the FCA is a little known program called the Medicare Incentive Reward Program (IRP). The IRP, located at 42 C.F.R. § 420.405, ''pays a monetary reward for information that leads to the recovery of at least $100 of Medicare funds from individuals and entities that are engaging in, or have engaged in, acts or omissions that constitute grounds for the imposition of a sanction.''

Individuals providing information must be the original source, and the reward, payable at the discretion of CMS, is capped at $1,000. In contrast to the FCA, the IRP is intended to motivate Medicare beneficiaries to scrutinize their statements and to report suspicious activity.

The 15-year-old program has seen limited success, with only 18 rewards paid, totaling less than $16,000, and recoveries of less than $3.5 million. By comparison, between 2009 and the end of FY2012, the Department of Justice recovered over $9.5 billion in federal healthcare dollars under the FCA. FCA recoveries have no doubt contributed to Medicare's growing life expectancy.

To further combat fraud and abuse, the government is revamping the IRP and seeks to increase the poten-

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tial reward to 10 percent of the first $66 million recovered (a maximum of $9.9 million). The proposed revisions are laid out at 78 Fed. Reg. 25013 (Apr. 29, 2013).

IV. Conclusion

The government has realized the grave cost of widespread fraud within our medical system. Indeed, on May 31, Health and Human Services Secretary Kathleen Sebelius participated in a news conference discussing the 2012 Medicare Trustees' Report, which revealed a projected two-year increase in the life expectance of the Medicare Trust Fund, from 2024 to 2026. During the conference, Sebelius attributed the increase in part to the government's crack down on fraud and abuse.

The regulations proposed by CMS seek to empower the government to better prevent and detect fraud and to crack down on repeat offenders by keeping them of out medicine. The changes pose a new threat to organizations that view fraud settlements with the government as a cost of doing business and appear to signal that the government is looking for long-term solutions to health-care fraud.

Providers and suppliers should be aware of the government's focus on repeat offenders and its efforts to expand the tools available to combat fraudulent and wasteful claims. Providers should be proactive in addressing recurring problems and in addressing internal compliance concerns.