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COMMENTARY

Overreach of False Claims Act Harms the Health Care Industry

The Department of Justice ("DOJ") recently issued an interim rule that nearly doubles civil penalties for hospitals and health care entities that violate the False Claims Act ("FCA"). The rule increases the penalty range for FCA violations from $5,500–$11,000 per violation to $10,781–$21,563. And those penalties are *in addition to* treble damages for the amount of the claims alleged to be false.

Real health care fraud exists in the United States: billing for medically unnecessary procedures or for procedures never performed in the first place, charging for products that patients don't need, or intentionally overbilling services. But these are not the kinds of frauds driving the majority of civil health care cases brought by "whistleblowers" and sometimes government regulators. Rather than bringing real fraud cases, whistleblowers' counsel troll for those inside health care organizations who can bring actions that are increasingly about alleged failures to comply with the complexities of the Stark Law and Anti-Kickback statute ("AKS"). Why? Whistleblowers and their counsel can receive up to 30 percent of any recovery.

Whistleblowers' counsel and the government regulators have been quite successful: in FY2015, the DOJ collected more than $3.5 billion in civil FCA penalties, $598 million of which went to whistleblowers and their lawyers. A majority of that money was collected from health care entities in cases initiated by whistleblowers.

Hospitals and other providers, pharmaceutical companies, and medical device companies are most often hit with these enormous penalties. Take the 2014 settlement between the DOJ and Halifax Hospital in Daytona, Florida. In an FCA case brought by an employee and pursued by the DOJ, this community hospital paid $85 million for allegedly submitting false claims to Medicare. But Halifax wasn't penalized for failing to provide services or for providing medically unnecessary services. Instead, Halifax was hit with an $85 million settlement for miscalculating oncologists' bonuses. The bonus structure allegedly violated regulations under the Stark Law. Even though patients likely received lifesaving services and the doctors provided critical care, Halifax paid out millions to government regulators and whistleblowers' counsel—money that could have been used for improving the physical plant or services of the hospital.

The naive would think these entities wouldn't pay the settlements if they were not liable. But health care entities often choose to settle these cases, even though many would likely win if they went to trial. Paying millions of dollars to private lawyers, their clients, and government regulators is harmful to these cash-strapped entities, but the risks of losing in court—even if a

small risk—can be devastating. Damages assessed at trial (because of the way they are currently calculated) can drive hospitals and corporations into bankruptcy, but the bigger risk is losing the ability to bill to federal health care programs, like Medicare and Medicaid. Settling, while costly, means that the entities can continue to participate in these programs—and keep their doors open to patients.

The overreach of the FCA is bad policy. But there are fixes.

First, a conviction of violating the AKS should be necessary before it can be used in a civil case as a predicate for an FCA case. The AKS is a criminal law that requires proof beyond a reasonable doubt that health care entities made payments or provided goods or services to get business—a much higher and more difficult standard than what is needed to prove a violation of the FCA. If criminal AKS violations are going to be grounds for FCA actions, those actions should have to be proven beyond a reasonable doubt.

Second, in Stark- and AKS-based FCA cases, damages should be calculated according to the government's actual loss, not the gross payment that the government made to the health care provider or entity. The government already received value from the hospital or service provider, and it would have incurred the same cost for the patient's treatment at a different hospital. The trebled damages should be calculated based on the *actual* loss, if any, to the government.

Third, the FCA currently requires that violations be merely reckless. Instead, the FCA should be amended to require proof of willful violations before these huge damages can be awarded. The health care regulations are voluminous and complex. Today, honest mistakes and misunderstandings are characterized as reckless to get at the FCA penalties. Such entity-busting damages should not be available if the defendant did not willfully violate the law—that is, with knowledge that the conduct was wrong.

Finally, the threat of debarment from federal health care programs without a criminal conviction or a specific finding by a court that the conduct at issue requires exclusion must be removed. This threat coerces health care entities into settlements that draw millions of dollars away from patient care and into the pockets of whistleblowers' attorneys.

These proposed amendments to the FCA and exclusion requirements will not be easy to achieve. They require Congress to amend the relevant statutes and will be met by strong opposition from the lawyers who profit from these programs, and also likely from HHS and DoJ. Indeed, over the past decade, those groups have succeeded in expanding FCA liability through several statutory amendments. Nonetheless, the health care industry, through its many advocacy groups, along with other industries that are involved in government procurement, should start the process and open a dialog with the relevant congressional committees. Otherwise, the industry will face increasing leverage to pay large sums of money for conduct not deserving of such penalties.

The FCA playing field should be leveled.

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