THE FCA, ADVICE OF COUNSEL DEFENSE AND CMS COMMENTARY MEETS THE JURY

A recent court decision had highlighted two issues on the cutting edge of health care and False Claims Act ("FCA") law. Both address what happens in the transition from health care advice to health care litigation. The first is the application of the attorney client privilege and the advice of counsel defense. The second is the application of CMS advisory opinions beyond the regulatory sphere and in the courtroom.

ADVICE OF COUNSEL DEFENSE

In the extraordinarily complex environment of health care regulations, providers rely heavily upon the advice of counsel to comply with the Stark Law, the Anti-Kickback Statute and other statutes and regulations. If a provider hopes to rely upon that advice as a defense, though, it must:

- Waive the attorney-client privilege as to all communications with all counsel;
- Be completely forthright with counsel, providing all information at hand, not just the information that supports the desired goal;
- Tell counsel about opinions from other counsel and consultants; and
- Follow counsel's advice.

The more difficult question is what a provider should do when receiving contradictory or differing opinions from different counsel. The lesson from recent case law is stark - if the provider does not act on the most pessimistic advice, a jury can assume the advice was ignored "because (the provider) simply did not like what he had to say."

THE STARK LAW

The Stark Law prohibits referrals from physicians to facilities or entities in which they have a financial interest. An alleged Stark violation can be based upon employed physician's referrals to the employer hospital. Even when the doctors' compensation is based entirely upon their collections for their own personally performed professional services, those services may also generate facility fees to the hospital.The government's position in FCA cases is that physician compensation may actually be for the hospital's facility fees as well, thus violating the Stark Law.

CMS COMMENTARY AND JURIES

Providers and their counsel have long relied upon CMS commentary to determine what they can do within the limits of the Stark Law and other statutes and regulations. This is usually done within a very legalistic framework. Rarely, if ever, do practitioners consider the possibility that the commentary will be filtered through a lay-jury in the midst of a trial, rather than a government regulator in discussion with counsel. In a recent case, though, that very issue went to a jury and the jury rejected the application of the commentary. This suggests reliance upon compliance with CMS commentary may not be enough - the provider must also be able to demonstrate reasonable reliance to the satisfaction of a lay jury.

How must the health care industry adapt to this shifting paradigm?

First, it must consider how advice, even advice that tracks CMS's own guidance, will be contested by a prosecutor and interpreted by a jury. Even technically perfect compliance might not offer protection if "seems" or "feels" like a way around the law.

Second, even the process of getting advice must be undertaken with the knowledge that it might become evidence in a False Claims Act lawsuit. Practitioners must be aware of the rules of evidence and litigation risks as well as the Stark Law, applicable regulations and guidelines.

PRACTICAL TAKEAWAY

Courts are clearly conscious of the complex labyrinth of health care laws and regulations and are concerned about the collision at the intersection of advice and litigation. One judge described that intersection as:

An impenetrably complex set of laws and regulations that will result in a likely death sentence for a community hospital in an already medically underserved area.

After noting it was handcuffed by the statutes and a jury verdict, one court stated:

It is for Congress to consider whether changes to the Stark Law's reach are in order.

It is unlikely that Congress or the Department of Justice will take steps to reduce potential liability for Stark Law violations. Amendments to the FCA to encourage whistleblowers is a centerpiece to the ACA and a significant element in projected funding. Just this past week the HHS-OIG announced the creation of a litigation team focused upon recovering fines and penalties against providers, drugmakers and others suspected of violations that cause over-billing. The environment is getting more, rather than less, onerous, and courts' concerns are unlikely to change that.

In this environment, providers and their counsel must work ever harder to stay comfortably within the cozy confines of the envelope, rather than explore the edges of what might be permitted. They must do this with the knowledge that everything they do may end up litigated by hostile prosecutors in front of lay juries. This requires a deeper understanding, not just of the law but of the entire dynamic of a False Claims Act case, from the acts that lead to it, to how it is initiated, through how it is litigated.

Should you have any questions regarding the False Claims Act or defense against whistleblower actions, please contact:

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