

HEALTH LAW

Update

NEWS FOR THE CLIENTS AND FRIENDS OF BASS, BERRY & SIMS PLC

To Self-Disclose or Not to Self-Disclose: *The Conundrum of the OIG's Self-Disclosure Protocol*

On April 15, 2008, the Office of Inspector General for the Department of Health and Human Services (the "OIG") released an Open Letter to Health Care Providers modifying certain requirements of the Provider Self-Disclosure Protocol (the "Self-Disclosure Protocol"). The OIG's stated purposes for the changes were to improve the disclosure process through good faith and prompt communication with providers and to increase the efficiency of investigations and settlements of self-disclosed violations of federal health care laws.

Less than a month after the OIG's April 15 Open Letter, the United States Department of Justice (the "DOJ") entered into a Settlement Agreement with Baptist Health South Florida, Inc. ("Baptist"). The DOJ, on behalf of the OIG, agreed to accept \$7,775,000 as a settlement amount after Baptist self-disclosed inadvertent violations of the federal physician self-referral law (the "Stark Law"). This *Health Law Update* considers the statements in the Self-Disclosure Protocol, including the changes contained in the April 15 Open Letter, in light of the real-world example of the Baptist settlement.

I. Overview of the Self-Disclosure Protocol, as Modified by the April 15 Open Letter

The Self-Disclosure Protocol is intended to facilitate the resolution of matters that potentially violate federal criminal and civil administrative laws. The OIG believes that providers, as participants in federal health care programs, have a legal and ethical duty to ensure the integrity of the federal health care programs. According to the OIG, providers must take measures to detect and prevent fraudulent activities and to voluntarily self-disclose evidence of potential fraud and abuse.¹ Prompt reporting will demonstrate the provider's good faith and willingness to cooperate with the OIG.²

In the event of a potential violation of law, the Self-Disclosure Protocol identifies certain basic information that should be disclosed in writing to the OIG, including contact information, organizational structure, all known information surrounding the potential violation, whether the provider is under investigation or inquiry, the findings of an internal investigation, action taken

¹ 63 Fed. Reg. 58400.

² 63 Fed. Reg. 58401.

in response to the potential violation, billing numbers, and a signed certification that the information is true "based on a good faith effort to bring the matter to the Government's attention for the purpose of resolving any potential liabilities to the Government."³ Importantly, the OIG is not bound by any findings made by the disclosing provider and there is no requirement for the OIG to resolve the matter in any particular manner.⁴

In the April 15 Open Letter, the OIG emphasized that providers who self-disclose must submit a complete and detailed description of the conduct being disclosed as well as a description of the provider's internal investigation (or a commitment of when it will be completed). The OIG also imposed the wholly new requirements that self-disclosing providers give an estimate of the damages to the federal health care programs and the methodology used to calculate that figure (or a commitment of when it will be completed) and a statement of the laws potentially violated. Further, the provider must be able to complete the investigation and damages assessment within three months after the OIG accepts the provider into the Self-Disclosure Protocol. The OIG reserved the right to remove providers from participation in the Self-Disclosure Protocol if they do not disclose in good faith and fail to respond to the OIG's request for additional information in a timely manner.⁵

For the healthcare community, a key takeaway from the April 15 Open Letter is that providers should do the "leg work" on the front end before self-disclosing to the OIG. At a recent teleconference sponsored by the American Health Lawyers Association ("AHLA"), an OIG representative informally indicated that failure to respond and failure to meet deadlines not only could result in removal of providers from the Self-Disclosure protocol but also could result in a subsequent full investigation and possible subpoena to other parties.⁶ Indeed, the threat of removal from the Self-Disclosure Protocol and the subsequent consequences, which could arguably make the self-disclosing provider worse off than it was before it began the process, were mentioned in the AHLA teleconference as some of the major changes introduced by the April 15 Open Letter. Other significant changes introduced by the April 15 Open Letter that were discussed in the teleconference include the timing and detail of the initial submission, as summarized above.

On a positive note, the April 15 Open Letter to providers states that the OIG will generally not require a Corporate Integrity Agreement or a Certificate of Compliance Agreement in connection with a self-disclosure. The OIG also reaffirmed its commitment from its April 24, 2006 Open Letter to settle self-disclosed violations for an amount near the lower end of the damages continuum using a multiplier of the value of the financial benefit conferred on the referring physician versus a penalty for every claim submitted.⁷

³ 63 Fed. Reg. 58401.

⁴ 63 Fed. Reg. 58401.

⁵ OIG Open Letter to Health Care Providers, April 15, 2008.

⁶ See "Open Letter to Providers – What You Need to Know Before Disclosing," AHLA-sponsored teleconference, June 10, 2008. Government officials such as the OIG representative participating on the call routinely indicate that their comments are not the official position of their agency; nonetheless, even informal comments can give some indication of the enforcement posture that an agency might take.

⁷ OIG Open Letter to Health Care Providers, April 15, 2008; OIG Open Letter to Health Care Providers, April 24, 2006.

Even though voluntary disclosure under the Self-Disclosure Protocol does not guarantee protection from civil, criminal, or administrative actions, such disclosure is a mitigating factor in determining the severity of the penalties and in the OIG's recommendations to prosecuting agencies.⁸ Self-reporting under the Self-Disclosure Protocol also offers providers the opportunity to minimize the potential cost and disruption of a full-scale audit and investigation by the federal government, to negotiate a fair monetary settlement and to avoid possible exclusion from the federal health care programs.

II. Baptist Settlement Agreement – Self-Disclosure Results in \$7,775,000 Settlement Payment

Baptist is a not-for-profit tax exempt health care system that owns and operates several hospitals in south Florida. On November 12, 2003, Baptist Hospital of Miami and South Miami Hospital entered into a two-year professional services agreement with Oncology Hematology Group of South Florida (the "Group") for the provision of physics and dosimetry services. During the two-year contract term, Baptist submitted claims to Medicare for reimbursement for services rendered to patients who were referred by the Group to each of these Baptist hospitals. In February 2006, after an internal compliance review, Baptist voluntarily self-disclosed to the OIG that its payments to the Group under the professional services agreement had inadvertently exceeded fair market value.

After more than two years of investigation and settlement negotiations, Baptist entered into a Settlement Agreement with the DOJ and the OIG in May of 2008. Although Baptist was not required to admit any wrongdoing or liability, the Settlement Agreement required Baptist to pay \$7,775,000 to the United States government to settle claims of health care fraud. In return, the federal government agreed to release Baptist from any civil or administrative monetary liability under the Federal False Claims Act, the Civil Monetary Penalties Law, the civil monetary penalty provisions of the Stark Law, and the Program Fraud Civil Remedies Act. The government also waived its right to seek permissive exclusion under the federal Anti-kickback Statute. However, the government reserved its right to pursue claims for criminal liability and to exclude Baptist from Medicare, Medicaid and other federal health care programs as mandated by federal statute.⁹

Consistent with the OIG's statements in the April 15 Open Letter, the DOJ and OIG did not require Baptist to enter into a Corporate Integrity Agreement or Certification of Compliance Agreement. So in this respect, the real-world example of the Baptist settlement conforms to what is stated in the April 15 Open Letter. Unfortunately, the Settlement Agreement does not indicate how the \$7,777,500 settlement amount was calculated, so it is not possible to ascertain whether any per claim penalties were factored into the settlement or whether the settlement figure simply represents lower end of the damages continuum using a multiplier of the value of the financial benefit conferred on the referring physicians. It is interesting that the letter issued by the Assistant Attorney General for the DOJ Civil Division makes no mention of any lenient treatment due to self-disclosure and does not use Baptist as an example for other providers to

⁸ The OIG has recovered nearly \$120 million for the Medicare Trust Fund through the Self-Disclosure Protocol since its inception in 1998. OIG Open Letter to Health Care Providers, April 15, 2008.

⁹ Settlement Agreement between Baptist, the DOJ and the OIG, dated May 12, 2008.

self-disclose. Rather, the letter states that the settlement with and recovery from Baptist underscores the federal government's commitment to "vigorously enforce" federal health care laws, including the Stark Law.¹⁰

III. How and When to Self-Disclose Must Be Decided Carefully and Thoughtfully

In deciding whether to voluntarily disclose a suspected violation of federal health care laws, providers should consider several possible consequences.

- (1) Admission will likely carry substantial civil penalties. Although the federal government's claim may be reduced from treble to double damages, the resulting civil penalties will likely be sizable.
- (2) Voluntary self-disclosure to one agency may not preclude a civil or criminal action from being initiated by another agency.
- (3) Voluntary disclosure may be used by private insurers as a basis for instituting a civil claim to the extent that they are damaged by the illegal conduct.
- (4) Voluntary disclosure of protected or confidential information may constitute a waiver of the attorney-client privilege and a waiver of the work-product doctrine for reports and other investigative materials furnished to the government. This information could become discoverable by a qui tam plaintiff.

These potential consequences must be carefully weighed against the benefits of self disclosure and the potential civil and administrative liability a provider may face, especially in light of the Baptist Settlement Agreement. If you have any questions about the Self-Disclosure Protocol or other matters discussed in this *Health Law Update*, please do not hesitate to contact any of the attorneys in our Healthcare Industry Practice Group listed below.

¹⁰ BNA News, Vol. 13, No. 93, May 14, 2008.

Bass, Berry & Sims Healthcare Attorneys

H. Stanford Adams, Jr.
(615) 742-7775
sadams@bassberry.com

Starr Brown
(615) 742-6530
sbrown@bassberry.com

Pooneh Ghiassi
(615) 742-7782
pghiassi@bassberry.com

Angela Humphreys
(615) 742-7852
ahumphreys@bassberry.com

Seth A. Killingbeck
(615) 742-7707
skillingbeck@bassberry.com

Claire F. Miley
(615) 742-7847
cmiley@bassberry.com

Shannon Pinkston
(615) 742-7727
spinkston@bassberry.com

Scott B. Shanker
(901) 543-5932
sshanker@bassberry.com

Krista L. Thornton
(615) 742-7734
kthornton@bassberry.com

H. Lee Barfield, II
(615) 742-6202
lbarfield@bassberry.com

Mary Beth Fortugno
(615) 742-7739
mfortugno@bassberry.com

Anna Grizzle
(615) 742-7732
agrizzle@bassberry.com

Clevonne M. Jacobs
(615) 742-7769
vjacobs@bassberry.com

David King
(615) 742-7890
dking@bassberry.com

T. Scott Noonan, Co-Chair
(615) 742-6273
snoonan@bassberry.com

Cynthia Y. Reisz
(615) 742-6283
creisz@bassberry.com

Catherine J.B. Sloan
(615) 742-7789
csloan@bassberry.com

Leigh Walton, Co-Chair
(615) 742-6201
lwalton@bassberry.com

Philip F. Berg
(615) 742-7908
pberg@bassberry.com

Valere B. Fulwider
(615) 742-7742
vfulwider@bassberry.com

Elisa E. Harris
(615) 742-6553
eharris@bassberry.com

J. James Jenkins, Jr.
(615) 742-6236
jjenkins@bassberry.com

Leslie Maclellan
(615) 742-7818
lmaclellan@bassberry.com

Brenda N. Phillips
(615) 742-6237
bnphillips@bassberry.com

Brian D. Roark
(615) 742-7753
broark@bassberry.com

Danielle M. Sloane
(615) 742-7763
dsloane@bassberry.com

Elizabeth S. Warren
(615) 742-7719
ewarren@bassberry.com

The materials contained herein have been abridged from the statutory sources and should not be construed or relied upon for legal advice. Readers are urged to consult legal counsel concerning particular situations and specific legal questions.

To ensure compliance with requirements imposed by the IRS, we inform you that this message is not intended to be used, and cannot be used, by the addressee or any other person for the purpose of avoiding penalties that may be imposed under the Internal Revenue Code.

315 Deaderick Street • Suite 2700 • Nashville, TN 37238-3001 • (615) 742-6200
The Tower at Peabody Place • 100 Peabody Place, Suite 900 • Memphis, TN 38103-3672 • (901) 543-5900
1700 Riverview Tower • 900 S. Gay Street • Knoxville, TN 37902 • (865) 521-6200