The Law Offices of
Jason M. Healy PLLC

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OIG Invites Suggestions to Improve the Provider Self-Disclosure Protocol

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Almost every health care provider at some time will face this situation: previous conduct or billings related to Medicare services appear to have been out of compliance with Medicare program laws, rules, or policies. In evaluating options for disclosing such actions to Medicare, health care providers understandably look for an established process to resolve the matter. The Department of Health & Human Services (HHS) Office of Inspector General (OIG) recognized the need for an established disclosure process almost 14 years ago and developed the Provider Self-Disclosure Protocol. The Self-Disclosure Protocol was designed to facilitate cooperation between the Federal government and health care providers by establishing a process for providers to disclose and resolve potential violations of health care program laws. However, in general, the OIG has failed to make the program attractive enough to convince providers that the benefits of participation outweigh the risks of inviting OIG enforcement. As a result, the Self-Disclosure Protocol has been only mildly successful. The OIG is now looking for ways to improve the Self-Disclosure Protocol. On June 18, 2012, the OIG announced that it will update the Provider Self-Disclosure Protocol and solicited input from the public.[1] This announcement is significant because it marks the first time that the OIG has explicitly solicited public comments regarding the Self-Disclosure Protocol. The OIG's call for comments presents an excellent opportunity for health care providers to request the kinds of improvements to the Self-Disclosure Protocol that would make participation more attractive.

Public comments on the proposed update to the Self-Disclosure Protocol must be submitted to the OIG by **August 17, 2012**. Please let us know if you would like assistance preparing a comment letter.

Background. The OIG first published its Provider Self-Disclosure Protocol in October 1998.[2] It was established to "provide guidance to health care providers that decide voluntarily to disclose irregularities in their dealings with the Federal health care programs."[3] Specifically, the Self-Disclosure Protocol offered disclosure submission, internal investigation, and self-assessment guidelines to health care providers for potential fraud involving the Federal health care programs. Providers were told how to investigate conduct, quantify damages, and report the conduct to the OIG in order to resolve the provider's liability exposure under the OIG's civil money penalty (CMP) authorities. To date, the OIG

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attributes over 800 self-disclosures to the Self-Disclosure Protocol, netting a combined recovery of more than $280 million.[4] However, this amount pales in comparison to the nearly $4.1 billion recovered by the Health Care Fraud and Abuse program in 2011 alone.[5]

The OIG issued additional guidance about the Self-Disclosure Protocol in Open Letters to Health Care Providers in 2000,[6] 2001,[7] 2006,[8] 2008[9] and 2009.[10] Yet, providers were not asked to publicly comment on this guidance and, as a result, the Open Letters often failed to adequately address providers' concerns. For example, the Open Letters from 2000 and 2001 addressed the OIG's exercise of its permissive exclusion authority and the use of corporate integrity agreements (CIAs), but they failed to provide any degree of certainty as to when these enforcement options would *not* be exercised.[11]

In its 2006 Open Letter, the OIG discussed how providers who self-disclose are less likely to get a CIA, or may get the OIG's less demanding version of a CIA (called a Certification of Compliance Agreement (CCA)) but offered no guarantee.[12] In the same Open Letter, the OIG expanded the Self-Disclosure Protocol to physician self-referral ("Stark") law and anti-kickback statute violations. The OIG stated that it would "generally settle" these Self-Disclosure Protocol "matters for an amount near the lower end" of the damages scale and waive its exclusion authority for providers that demonstrated "the requisite level of trustworthiness." Such statements at first appear to provide assurance, but they contain enough ambiguity and hedging to result in little certainty. Adding to the level of uncertainty was the OIG's warning that its "agreement to resolve an SDP matter is not binding upon [the Department of Justice]," which has authority to prosecute False Claims Act violations, among other things.

The 2008 Open Letter increased the amount of information required in the initial submission, but confirmed earlier statements that "mere billing errors or overpayments" should be referred to Medicare payment contractors instead of the OIG.[13] In its most recent Open Letter, the OIG limited the scope of the Self-Disclosure Protocol for anti-kickback violations by establishing a $50,000 minimum settlement amount (the highest penalty per kickback) and excluding acceptance of Stark violations that lack an anti-kickback element.[14] Arguably, the OIG's Open Letters have made only modest improvements to the Self-Disclosure Protocol. By taking great care not to give up too much enforcement authority, the OIG has designed a program where providers still are not sufficiently incentivized to participate and are offered little to no guarantees. To remedy the situation, the OIG is now turning directly to the health care provider community for comments, recommendations and suggestions.

Potential Benefits of Self-Disclosure. The most significant potential benefit of utilizing the Self-Disclosure Protocol is that a provider may effectively eliminate its civil penalty exposure and threat of Medicare program exclusion. This possible advantage is a consequence of prosecutors looking favorably upon providers that have self-reported and cooperated accordingly.[15] Similarly, self-disclosure may lead to a

reduction in civil monetary penalties imposed under the Stark law and anti-kickback statute, which carry separate fines. For example, while an anti-kickback violation may subject an offender to a $50,000 penalty for each illegal act and up to three times the amount of remuneration as damages,[16] the OIG has communicated a commitment to minimizing the monetary penalty.[17] However, the availability of these benefits ultimately remains at the discretion of the OIG and does not extend to other government agencies, such as the Department of Justice. With no guaranty of more favorable treatment under the Self-Disclosure Protocol, providers must seriously consider the corresponding risks associated with self-disclosure.

Potential Risks of Self-Disclosure. Because of the potential criminal and civil liability in cases of Medicare fraud, self-disclosure involves certain risks for providers. From a financial perspective, the Self-Disclosure Protocol requires providers to make necessary repayments as well as finance costly pre- and post-disclosure investigations. In the case of actual fraud, self-disclosure inevitably brings such wrongdoing to the attention of the government and the general public, and subjects the provider to potential criminal liability as well as a variety of ongoing compliance and reporting obligations. While the disclosure of fraud may generate adverse publicity and seriously damage a provider's business reputation, the revelation may also provide a roadmap for prosecution in subsequent litigation. The legal impact of self-disclosure can be even more significant if the disclosure is construed as, or leads to, a waiver of protections afforded by attorney client privilege and the work product doctrine.

Criticisms of the Existing Self-Disclosure Protocol. Given the high stakes of self-disclosure, the OIG's Self-Disclosure Protocol should be straightforward, instructive, and predictable. However, in practice, providers often find the Self-Disclosure Protocol difficult to navigate, even struggling to identify overpayments and differentiate between those that represent fraud and those that are a product of innocent mistake. The agency has taken steps recently to clarify its rules on overpayment determinations and reporting, but questions remain. (Please see our recent Legal Alert entitled "CMS Proposed Rule on Overpayment Reporting and Repayment."[18]) Additionally, where an overpayment determination is made, providers must determine not only how much information to disclose, but whether disclosure should be made to the OIG, DOJ, or the relevant Medicare payment contractor.[19] In light of these difficulties, providers often criticize the Self-Disclosure Protocol as unfairly punitive, arguing that the certainty of punishment and the uncertainty of reduced penalties discourage providers from participating.

Providers' Opportunity for Comment. The OIG's solicitation of public comments on the Self-Disclosure Protocol provides an excellent opportunity for providers to seek changes that make it easier to navigate the process and guaranty, or at least improve the odds of, favorable treatment for self-disclosure. As it stands, the potential benefits of the Self-Disclosure Protocol are outweighed by the certain risks, and many

health care providers remain dubious. To improve the Self-Disclosure Protocol and add real clarity, the OIG should:

- Guarantee a reduction in monetary penalties;
- Guarantee that the OIG will not exercise its permissive exclusion authority; and
- Adopt a settlement process, like the alternative dispute resolution (ADR) programs used by courts, that involves other government agencies to foreclose the possibility of criminal prosecution.

Whether a provider has experience with the Self-Disclosure Protocol or not, it should consider submitting comments, recommendations and suggestions to the OIG with the aim of securing a better option to consider in the future, if circumstances warrant.

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[1] Solicitation of Information and Recommendations for Revising OIG's Provider Self-Disclosure Protocol, 77 Fed. Reg. 36281 (June 18, 2012). In a related release, on June 15, 2012, CMS issued a transmittal announcing that the OIG is updating the self-audit compliance guidelines on its website. *See* Medicare Program Integrity Manual, 100-08, Trans. No. 425, June 15, 2012—Provider Self Audits. Although the self-audit compliance guidelines are separate and distinct from the OIG Self-Disclosure Protocol, providers may find it useful to consult the self-audit guidelines when considering the Self-Disclosure Protocol.

[2] Publication of the OIG's Provider Self-Disclosure Protocol, 63 Fed. Reg. 58399 (Oct. 30, 1998).

[3] 63 Fed. Reg. 58400-02.

[4] 77 Fed. Reg. 36281.

[5] The Department of Health and Human Services and the Department of Justice Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2011, 1 (Feb. 2012).

[6] OIG, *An Open Letter to Health Care Providers*, dated March 9, 2000.

[7] OIG, *An Open Letter to Health Care Providers*, dated November 20, 2001.

[8] OIG, *An Open Letter to Health Care Providers*, dated April 24, 2006.

[9] OIG, *An Open Letter to Health Care Providers*, dated April 15, 2008.

[10] OIG, *An Open Letter to Health Care Providers*, dated March 24, 2009.

[11] *See Open Letter*, 2001*; Open Letter*, 2000.

[12] *Open Letter*, 2006.

[13] 77 Fed. Reg. 36281, *citing Open Letter*, 2008.

[14] *Open Letter*, 2009.

[15] It is important to note that there is no guarantee of favorable treatment with regard to criminal exposure. Throughout its guidance the OIG has stressed that criminal proceedings are independent from OIG Self-Disclosure Protocol procedures, stressing "that OIG's agreement to resolve [a Self-Disclosure Protocol] matter is not binding upon [the Department of Justice]." *Open Letter*, 2006.

[16] 42 U.S.C. § 1320a-7a(a).

[17] *See Open Letter*, 2006 ("Subject to the facts and circumstances of the case, OIG will generally settle SDP [Self-Disclosure Protocol] matters for an amount near the lower end of [the damages] continuum").

[18] http://healylawdc.com/images/LTACH_Legal_Alert_-_Overpayment_Reporting_Repayment_-_Feb_2012.pdf.

[19] *Id.*; *see Open Letter*, 2008 (instructing that "mere billing errors or overpayments" should be reported to fiscal intermediaries rather than OIG).

About Us

The Law Offices of Jason M. Healy PLLC is a Washington, D.C. based law firm serving national and local clients. We focus primarily on legal issues affecting health care providers and welfare benefit plans. We help health care providers and their trade associations understand Medicare and Medicaid laws and regulations, and address compliance matters. We also represent health care providers in reimbursement audits, appeals, litigation, and transactions. We help sponsors of welfare benefit plans understand and comply with federal and state laws and prepare plan documents. Located in Washington, DC, just minutes from the Department of Health and Human Services, Congressional offices, and the White House, we are well positioned to provide legal support for advocacy efforts. Our Principal, Jason M. Healy, is a health care lawyer with over 14 years of experience with the array of legal issues facing health care providers.

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We're Growing!
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We recently expanded our legal team to better serve our health care and employee benefits clients. We welcome you to view complete profiles on our lawyers at our web site (www.healylawdc.com). Please contact us by email (jhealy@healylawdc.com) or phone (202-706-7926) if we can be of any assistance.

Jason M. Healy Principal **|** Jason has represented hospitals, skilled nursing facilities, home health agencies, hospices, institutional pharmacies, medical device manufacturers, durable medical equipment suppliers, health care trade associations and medical educators over the past 14 years. His practice encompasses a wide range of regulatory, litigation, legislative, corporate and contractual matters for health care clients. Jason concentrates in counseling long term acute care hospital (LTCH) and other hospital providers on legislative, regulatory, reimbursement, compliance, development and other issues. He routinely represents providers in Medicare and Medicaid reimbursement appeals, coverage appeals, enrollment appeals, and termination appeals. He has significant experience and success with large group cases, complex reimbursement, statistical sampling, and medical necessity cases. Jason has defended health care clients in government enforcement actions, including audits, investigations, *qui tam* False Claims Act cases, and other administrative and litigation matters. In addition, Jason has helped providers develop compliance programs and appropriately respond to compliance issues. Jason also advises clients on how to properly structure transactions and other business activities to comply with health care fraud and abuse laws, such as the Anti-Kickback Statute and the Physician Self-Referral ("Stark") Law. He has developed model legislation and advocated for client interests in advocacy with federal policymakers.

Amy D. Healy Counsel **|** Amy has practiced in the field of employee benefits and health insurance for more than 10 years. She has significant experience advising employers and other benefit plan professionals on welfare benefit plan matters. Her experience includes both welfare plans and tax-qualified retirement plans governed by the Employee Retirement Income Security Act (ERISA) and the Internal Revenue Code. She also has experience with federal and state health insurance matters, including Medicare Secondary Payer (MSP) rules, Medicare Advantage (MA) plans, and high-risk pools. Amy has advised clients on compliance with the Affordable Care Act (ACA) health reform law. Amy has extensive experience with Section 125 cafeteria plans, self-funded medical plans including active and retiree medical plans, health reimbursement arrangements, health savings account plans, dental plans, vision plans, and "wrap plans" that supplement the insurance certificates of coverage for fully-insured arrangements. Amy also advises plan sponsors on compliance issues under COBRA and HIPAA, including HIPAA privacy and security compliance.

Chiarra-May E. Stratton Associate **|** Chiarra has represented hospital systems, physician group practices, home health agencies, hospices, regional and national pharmacies, physician groups, and long-term care facilities, as well as non-profit corporations and charities over the past 10 years. Her practice has focused on a wide-range of regulatory and transactional issues affecting health care entities, including HIPAA compliance, EMTALA, patient safety, medical staff issues including disciplinary and peer review-related matters, changes of ownership, licensure, and ensuring compliance with federal and state health care fraud and abuse laws. Chiarra has also counseled non-profit entities regarding federal tax-exempt issues, including obtaining and maintaining federal tax-exempt recognition and preparing organizing and governance documents and policies. Prior to joining the firm, Chiarra worked with a state disease management program to develop outcomes measures and program strategies in an effort to improve clinical care and outcomes for chronic condition treatment programs in the state of Indiana.

Brittany M. Barron Associate **|** Brittany's government experience includes positions at the U.S. Department of Health & Human Services (HHS) Office of General Counsel, Centers for Medicare and Medicaid Services (CMS) Division, and the Departmental Appeals Board (DAB), Medicare Operations Division. At HHS Office of General Counsel, Brittany prepared memoranda analyzing legal questions and recommending agency policies. At the DAB, Brittany analyzed decisions and dismissals by Administrative Law Judges, assessed provider compliance with regulations and statutory deadlines, and drafted administrative final actions for Medicare appeals. Prior to joining the firm, Brittany was Regulatory Counsel at the Food and Drug Administration (FDA) in its Center for Tobacco Products, Office of Compliance and Enforcement, where she advised stakeholders on compliance and enforcement issues under controlling statutes for tobacco products. She also resolved a broad range of issues concerning application of the agency's enabling legislation, pertinent regulations, and legislation affecting operations.

Reuben J. Oswald Law Clerk **|** Reuben has experience with health care regulatory issues, administrative appeals, litigation, and transactions. This includes Medicare and Medicaid appeal representation through a legal services clinic in the District of Columbia. He previously held positions working for a renewable energy organization on energy policy and corporate securities laws, as well as a non-profit organization on federal and state tax issues.