

Hall, Render, Killian, Heath & Lyman is a full service health law firm with offices in Indiana, Kentucky, Michigan and Wisconsin. Since the firm was founded by William S. Hall in 1967, Hall Render has focused its practice primarily in the area of health law and is now recognized as one of the nation's preeminent health law firms serving clients in multiple states. For more information about the firm please visit us at [www.hallrender.com](http://www.hallrender.com).

#### **Office Locations**

##### Indiana Offices

One American Square  
Suite 2000  
Indianapolis, IN 46282  
(317) 633-4884  
Contact: Brian C. Betner

8402 Harcourt Road  
Suite 820  
Indianapolis, IN 46260  
(317) 871-6222  
Contact: James R. Willey

##### Kentucky Office

614 West Main Street  
Suite 4000  
Louisville, KY 40202  
(502) 568-1890  
Contact: Rene R. Savarise

##### Michigan Offices

Columbia Center, Suite 315  
201 West Big Beaver Road  
Troy, MI 48084  
(248) 740-7505  
Contact: Kimberly J. Commins-  
Tzoumakas

2369 Woodlake Drive, Suite 280  
Okemos, MI 48864  
(517) 703-0921  
Contact: Brian F. Bauer

##### Wisconsin Office

111 East Kilbourn Avenue  
Suite 1300  
Milwaukee, WI 53202  
(414) 721-0442  
Contact: Scott W. Taebel

#### **Contact Us**

[hallrender@hallrender.com](mailto:hallrender@hallrender.com)

## **OIG Limits Access To Self-Disclosure Protocol In Open Letter To Providers**

On March 24, 2009, the Office of Inspector General ("OIG") of the Department of Health and Human Services released an Open Letter to Health Care Providers that narrows the Self-Disclosure Protocol ("SDP"). The Open Letter outlines how the OIG has decided to significantly limit the types of violations that are now accepted into the SDP.

In an about face from the OIG's encouraging position outlined in its April 24, 2006 Open Letter and effective immediately, the "OIG will no longer accept disclosure of a matter that involves only liability under the physician self-referral law in the absence of a colorable anti-kickback statute violation." The OIG will continue to accept providers "into the SDP when the disclosed conduct involves colorable violations of the anti-kickback statute, whether or not it also involves colorable violations of the physician self-referral law." This position is in stark contrast to the OIG's previous promotion to encourage providers to utilize the SDP for resolving civil monetary liability under the Physician Self-Referral Law ("Stark Law"). The OIG provides, however, that providers should not construe this narrowing of the SDP as the OIG's pull-back from its approach to enforcement of the Stark Law.

From both the Open Letter and other sources, this narrowing of the SDP likely stems from the OIG's desire to both prioritize resources and recognition of the difficulty in assessing penalties for seemingly technical violations of the Stark Law. At times, the OIG's settlement authority for civil monetary penalty ("CMP") damages can result in penalty amounts that seem disproportionate to the harm done to federal health care programs because of the "strict liability" nature of the Stark Law. In another important change, the OIG reveals that kickback-related submissions accepted into the SDP will require a minimum \$50,000 settlement amount in resolution. The OIG did clarify that it "will continue to analyze the facts and circumstances of each disclosure to determine the appropriate settlement amount consistent with our practice, stated in the 2006 Open Letter, of generally resolving the matter near the lower end of the damages continuum, i.e., a multiplier of the value of the financial benefit conferred."

In our experience the SDP has not been widely utilized among the provider community, and this new limitation may further undermine its application to many providers because Stark Law concerns often predominate their decision to self-disclose in the first place. Health care providers should carefully assess their now reduced options in dealing with matters that only involve possible Stark law violations to determine the best course of action, which may include determinations of Stark Law compliance, remediation, and overpayment refunds among others.

### **Important Take-aways:**

- The Self-Disclosure Protocol as a means for resolving civil monetary liability is now limited to violations of the federal anti-kickback statute as the primary basis for liability.
- The OIG will require a minimum settlement of \$50,000 for any submission accepted into the Self-Disclosure Protocol.
- Matters that involve Stark Law violations only should not be viewed as now having a lower enforcement priority.
- Possible Stark Law violations will continue to require careful analysis in order to determine the best resolution, which no longer includes self-disclosure as a means of minimizing liability if the possible violation is solely Stark Law related.

The Open Letter may be found at the following link:

<http://oig.hhs.gov/fraud/docs/openletters/OpenLetter3-24-09.pdf>

If you need additional information about this information please contact your regular Hall Render attorney or:

Scott W. Taebel at 414-721-0445 or [staebel@hallrender.com](mailto:staebel@hallrender.com)

Brian C. Betner at 317-977-1466 or [bbetner@hallrender.com](mailto:bbetner@hallrender.com)

*This publication is intended for general information purposes only and does not and is not intended to constitute legal advice. The reader must consult with legal counsel to determine how laws or decisions discussed herein apply to the reader's specific circumstances.*