

## HEALTH LAW UPDATE

September 30, 2010

### CMS POSTS STARK SELF-DISCLOSURE PROTOCOL

CMS has posted to its website the Voluntary Self-Referral Disclosure Protocol for violations of the Stark Law (SRDP) required under PPACA. The SRDP is similar to OIG's existing Self-Disclosure Protocol, which the OIG closed to Stark Law-only violations (i.e., those without a potential anti-kickback law violation) in March 2009. CMS states that the SRDP is to be used to resolve matters that a party believes are actual or potential violations of the Stark Law (not to determine whether a violation has occurred). Thus, disclosing parties should be prepared to resolve overpayment liabilities for the identified conduct. In this regard, submission of a disclosure under the SRDP suspends until settlement the new PPACA obligation to return potential overpayments within 60 days of identification.

The SRDP requires electronic submission and specifies the information necessary for the disclosure, including identifying information and a description of the nature of the matter being disclosed. The disclosing party must submit a complete legal analysis of the application of the Stark Law, including exceptions potentially applicable to the matter. A description of the circumstances under which the matter was discovered also is required, as well as information describing existing compliance measures and/or measures put in place to address the matter. Of note, CMS is requiring a full financial analysis at the time of submission, including the total amount actually or potentially due and owing. CMS also encourages parties to place estimated overpayment funds in interest-bearing escrow accounts to assure that adequate resources are set aside to repay amounts owed.

CMS will begin verification procedures upon receipt of the disclosure. To facilitate this process, the agency is requiring access to all financial statements and supporting documents without assertion of privileges, although CMS states that it will not request production of written communications subject to the attorney-client privilege.

Finally, CMS sets forth several factors that it will consider in reducing amounts owed, including (1) the nature and extent of the practice, (2) the timeliness of the self-disclosure, (3) cooperation in providing additional information, (4) litigation risk associated with the matter, and (5) the financial position of the disclosing party. Although PPACA grants CMS the authority to reduce amounts due and owing, the agency specifically states in the SRDP that it has no obligation to do so.

The SRDP provides a definitive avenue to address and resolve potential Stark Law violations. Suspension of the 60-day period to return overpayments offers an additional incentive to utilize the SRDP. Parties utilizing the SRDP should do so, however, only with full awareness of all components of the process.

For more information, please contact Donna S. Clark, [dclark@bakerlaw.com](mailto:dclark@bakerlaw.com) or 713.646.1302.

#### Editor

Policy Analyst

Kathleen P. Rubinstein, MPA  
[krubinstein@bakerlaw.com](mailto:krubinstein@bakerlaw.com)  
713.276.1650

#### National Co-Leaders

Thomas W. Kahle  
[tkahle@bakerlaw.com](mailto:tkahle@bakerlaw.com)  
513.929.3414

Christopher J. Swift  
[cswift@bakerlaw.com](mailto:cswift@bakerlaw.com)  
216.861.7461

#### Chicago

Tara Goff Kamradt  
[tkamradt@bakerlaw.com](mailto:tkamradt@bakerlaw.com)  
312.416.6222

#### Cleveland

Steven A. Eisenberg  
[seisenberg@bakerlaw.com](mailto:seisenberg@bakerlaw.com)  
216.861.7903

John S. Mulhollan  
[jmulhollan@bakerlaw.com](mailto:jmulhollan@bakerlaw.com)  
216.861.7484

Emily E. Williams  
[ewilliams@bakerlaw.com](mailto:ewilliams@bakerlaw.com)  
216.861.7373

Thomas S. Campanella  
[tcampanella@bakerlaw.com](mailto:tcampanella@bakerlaw.com)  
216.861.6551

Susan Whittaker Hughes  
[shughes@bakerlaw.com](mailto:shughes@bakerlaw.com)  
216.861.7841

#### Columbus

Richard W. Siehl  
[rsiehl@bakerlaw.com](mailto:rsiehl@bakerlaw.com)  
614.462.2639

Mark Hatcher  
[mhatcher@bakerlaw.com](mailto:mhatcher@bakerlaw.com)  
614.462.4765

Winnie Sim  
[wsim@bakerlaw.com](mailto:wsim@bakerlaw.com)  
614.462.4726

#### Costa Mesa

George Mooradian  
[gmooradian@bakerlaw.com](mailto:gmooradian@bakerlaw.com)  
714.966.8800

#### Denver

David Waller  
[dwaller@bakerlaw.com](mailto:dwaller@bakerlaw.com)  
303.764.4093

**Houston**

**Robert M. Wolin**  
rwolin@bakerlaw.com  
713.646.1327

**Susan Feigin Harris**  
sharris@bakerlaw.com  
713.646.1307

**Donna S. Clark**  
dclark@bakerlaw.com  
713.646.1302

**B. Scott McBride**  
smcbride@bakerlaw.com  
713.646.1390

**Krista M. Barnes**  
kbarnes@bakerlaw.com  
713.646.1352

**Sameer V. Mohan**  
smohan@bakerlaw.com  
713.646.1309

**Summer D. Swallow**  
sswallow@bakerlaw.com  
713.646.1306

**Ameena Ashfaq**  
aashfaq@bakerlaw.com  
713.646.1329

**Tiffany D. Reyes**  
tdreyes@bakerlaw.com  
713.646.1357

**Kati L. Freeman**  
kfreeman@bakerlaw.com  
713.646.1364

**Los Angeles**

**Neil Carrey**  
ncarrey@bakerlaw.com  
310.442.8835

**James D. Figura**  
jfigura@bakerlaw.com  
310.979.8462

**New York**

**John J. Carney**  
jcarney@bakerlaw.com  
212.589.4255

**Orlando**

**G. Thomas Ball**  
tball@bakerlaw.com  
407.649.4004

**Richard W. Siehl**  
rsiehl@bakerlaw.com  
407.649.4076

**Washington, DC**

**Terry Connerton**  
tconnerton@bakerlaw.com  
202.861.1613

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