

## OIG Regulatory Scrutiny: An Examination of Recent Cases

The surge in hospital-physician arrangements has coincided with increased OIG inspection and an overall heightened amount of regulatory scrutiny, both driven in part by healthcare reform. The Patient Protection and Affordable Care Act (ACA) establishes a new Self-Referral Disclosure Protocol (SRDP), which encourages hospitals to report actual or potential violations in an effort to avoid the disruption and cost of a full-scale Office of the Inspector General (OIG) investigation.<sup>1</sup> On September 23, 2010, the Centers for Medicare and Medicaid Services (CMS) released the SRDP, which set forth “a process to enable providers of services and suppliers to self-disclose actual or potential violations of the physician self-referral statute.”<sup>2</sup>

This new SRDP differs significantly from the OIG’s previously established self-referral protocol in that, among other provisions, it authorizes the Secretary to reduce the amount for all violations of the physician self-referral statute and allows providers and suppliers to disclose violations that only implicate the Stark Law.<sup>3</sup> Yet, while the SRDP gives CMS the authority to accept a settlement for less than the total amount of the overpayment, the SRDP does not require them to do so.<sup>4</sup> However, in mitigating the self-disclosure process and penalties for violations, the OIG may now increase efforts to investigate and prosecute more serious violations. In light of this trend, recent litigation concerning hospitals and physicians may provide insight into this new approach.

In June 2010, St. John’s Regional Medical Center (St. John’s) agreed to pay \$274,815 for alleged Stark and Anti-Kickback violations.<sup>5</sup> The OIG claimed that a wholly owned subsidiary of St. John’s entered into an improper financial relationship with a physician in violation of the Civil Monetary Penalties Act by: participating in a prohibited employment and rental agreement; allowing the contracted physician to become delinquent in his rent payments; and, compensating the physician for services without establishing a written agreement.<sup>6</sup> To avoid ongoing investigation, St. John’s self-reported this conduct to the OIG, which possibly resulted in assessment of a lesser penalty.<sup>7</sup>

In October 2010, another hospital self-reported Stark and Anti-Kickback violations to the OIG in an attempt to avoid higher fines and penalties. The OIG found that,

among other violations, Marion General Hospital entered into employment contracts and leases that were neither at Fair Market Value nor compliant with applicable laws.<sup>8</sup> These violations were apparently unintentional, as hospital president John Sanders said Marion General simply “*didn’t do the paperwork.*”<sup>9</sup> Consequently, the Ohio hospital was instructed to pay the government \$1,207,686 for this oversight.<sup>10</sup>

In a matter where the hospital did not self-report, a group of Chicago-based practices, United Shockwave Services, United Urology Centers, and United Prostate Centers (collectively known as “United”), settled with the OIG for a sum of \$7.3 million for various alleged violations of Stark and Anti-Kickback laws.<sup>11</sup> Among other claims, the OIG averred that United used its leverage in the metropolitan area to control referrals; threatened hospitals that it would refer patients to competitors unless the hospital agreed to contract with United; and, sold more of its shares to physicians who produced more referrals for the company.<sup>12</sup> According to the OIG, United conducted these violations across three states.<sup>13</sup>

In the coming years, heightened regulatory scrutiny will likely continue to coincide with increasing physician/hospital alignment, especially as the healthcare industry reacts to the ACA. The new SRDP may lead to more frequent, albeit less costly, penalties for Stark and Anti-Kickback violations. However, it remains to be seen whether hospitals and physicians will continue to be subject to high fines and other penalties for violating Stark and Anti-Kickback statutes, or if they will more stringently adhere to compliance rules and self-report when these rules are violated. Overall, the SRDP gives a new possibility to providers and suppliers who potentially violate the Stark Law, but also adds yet another layer to the increasingly complex regulatory healthcare landscape.

<sup>1</sup> “Patient Protection and Affordable Care Act” P.L. 111-148, 124 Stat. 772 (March 23, 2010).

<sup>2</sup> “CMS Voluntary Self-Referral Disclosure Protocol,” Centers for Medicare and Medicaid Services, [https://www.cms.gov/PhysicianSelfReferral/Downloads/6409\\_SRD\\_Protocol.pdf](https://www.cms.gov/PhysicianSelfReferral/Downloads/6409_SRD_Protocol.pdf), (Accessed 11/11/10).

<sup>3</sup> “CMS Voluntary Self-Referral Disclosure Protocol,” Centers for Medicare and Medicaid Services, [https://www.cms.gov/PhysicianSelfReferral/Downloads/6409\\_SRD\\_Protocol.pdf](https://www.cms.gov/PhysicianSelfReferral/Downloads/6409_SRD_Protocol.pdf), (Accessed 11/11/10).

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- <sup>4</sup> “CMS Voluntary Self-Referral Disclosure Protocol,” Centers for Medicare and Medicaid Services, [https://www.cms.gov/PhysicianSelfReferral/Downloads/6409\\_S\\_RDP\\_Protocol.pdf](https://www.cms.gov/PhysicianSelfReferral/Downloads/6409_S_RDP_Protocol.pdf), (Accessed 11/11/10).
- <sup>5</sup> “Kickback and Physician Self-Referral” U.S. Department of Health & Human Services Office of Inspector General, 2010, <http://oig.hhs.gov/fraud/enforcement/cmp/kickback.asp> (Accessed 10/20/10).
- <sup>6</sup> “Kickback and Physician Self-Referral” U.S. Department of Health & Human Services Office of Inspector General, 2010, <http://oig.hhs.gov/fraud/enforcement/cmp/kickback.asp> (Accessed 10/20/10).
- <sup>7</sup> “Kickback and Physician Self-Referral” U.S. Department of Health & Human Services Office of Inspector General, 2010, <http://oig.hhs.gov/fraud/enforcement/cmp/kickback.asp> (Accessed 10/20/10).
- <sup>8</sup> “Marion General Hospital Admits Violations, Agrees to \$1.2M Fine” By John Jarvis, Marion Star, <http://www.marionstar.com/article/20101015/NEWS01/10150315/MGH-self-reports-violations-pays-fine> (Accessed 10/20/10).
- <sup>9</sup> “Marion General Hospital Admits Violations, Agrees to \$1.2M Fine” By John Jarvis, Marion Star, <http://www.marionstar.com/article/20101015/NEWS01/10150315/MGH-self-reports-violations-pays-fine> (Accessed 10/20/10).
- <sup>10</sup> “Marion General Hospital Admits Violations, Agrees to \$1.2M Fine” By John Jarvis, Marion Star, <http://www.marionstar.com/article/20101015/NEWS01/10150315/MGH-self-reports-violations-pays-fine> (Accessed 10/20/10).
- <sup>11</sup> “OIG Enters Into \$7.3 Million Civil Monetary Penalty Settlement with Physician-Owned Enterprise” Press Release, U.S. Department of Health & Human Services Office of Inspector General, July 8, 2010, p.1.
- <sup>12</sup> “Kickback and Physician Self-Referral” U.S. Department of Health & Human Services Office of Inspector General, 2010, <http://oig.hhs.gov/fraud/enforcement/cmp/kickback.asp> (Accessed 10/20/10).
- <sup>13</sup> “OIG Enters Into \$7.3 Million Civil Monetary Penalty Settlement with Physician-Owned Enterprise” Press Release, U.S. Department of Health & Human Services Office of Inspector General, July 8, 2010, p.1.



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