

Stark II Final Regulations – Phase I **10 THINGS YOU SHOULD KNOW**

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Wait no more...the Stark II regulations are now final. In the same amount of time that it would take for a high school graduate to become a board certified surgeon, it has taken HCFA to tell us what the original Stark law really means – things like what health care services Congress actually intended to cover under Stark! After more than a decade of debate, and thousands of public comments, the Stark law finally has some meat on its bones, ready for all to digest.

The new regulations are a “good news, bad news” kind of affair. The good news is that HCFA listened to many of the criticisms levied at the proposed Stark II regulations and has taken a more realistic approach to regulating self-referrals by physicians. And the bad news? The regulations are now final and many uncertainties from the proposed regulations have been clarified. Physicians can no longer seek comfort in the idea that “the regulations are only proposed and the government won’t enforce the Stark law until they’re finalized”.

The Stark II regulations prohibit self-referrals by physicians for certain “designated health services” (DHS), including lab, radiology, DME, physical and occupational therapy, ultrasound, and a host of other services and procedures, unless certain statutory exceptions are met. The exceptions are probably the most important part of the regulations, for it is the exceptions that allow many physician practices to legally furnish these designated health services.

services that are invasive procedures that require the insertion of a needle, catheter, tube or probe (e.g., cardiac catheterization and endoscopies, except where they are inpatient or outpatient hospital services). In addition, certain preventive health services such as screening mammographies and bone density studies have been excluded.

4. The regulations offer specific examples of compensation arrangements that will be considered legal. A physician may be paid a productivity bonus based on his or her own personal productivity, including the services of NPs and PAs that are billed “incident to” the physician’s services. A group practice may distribute DHS revenues any way it deems fit if the DHS revenues do not exceed 5% of the group’s revenues, and the physician does not receive more than 5% of total compensation from the DHS revenues.

5. The Stark regulations allow separate group practices or physicians to share DHS facilities (e.g., lab, x-ray, MRI) if the physicians work in the same building, provided the supervision and billing requirements of the regulations are met. However, part-time sharing arrangements in another building (e.g., an MRI that is “block” leased to a group 2 days per week) will not be permitted.

6. Stark requires that compensation arrangements between DHS entities and physicians be “set in advance”. The regulations settle the issue of whether per use (“click” fees) or percentage compensation arrangements are acceptable. The former are generally okay, but most percentage compensation arrangements are prohibited unless the percentage is based on a single fee schedule.

7. In a significant departure from

the proposed regulations, group practices that have multiple locations (“group practices without walls”) can treat them as separate cost or profit centers for compensation purposes so long as the group practice is operated as a unified business with a central governing body, centralized billing and accounting, and centralized utilization review. The group may divide profits based on the performance of each satellite office that has 5 or more physicians practicing there.

8. Many group practices have been able to continue to furnish designated health services because of the “in-office ancillary services” exception under Stark. When ancillary services are furnished by mid-level providers or technicians, Stark requires that those persons be *directly supervised* by the physician. The proposed regulations defined direct supervision as requiring the physician to be present in the office suite. The final regulations require the same level of supervision that is required for Medicare coverage and billing purposes. In addition, independent contractors can furnish the necessary supervision, but they must reassign to the group practice the right to bill Medicare.

9. For indirect compensation arrangements, the entity billing for designated health services must have knowledge of the prohibited financial relationship with the referring physician.

10. Most importantly, the new regulations reinforce the government’s position that a violation of the Stark law may trigger liability under the federal False Claims Act. While liability for a violation of Stark only involves refunding of payments, the False Claims Act contains draconian remedies that can bankrupt a physician or group practice.