On February 1st, 2013 the Centers for Medicare and Medicaid Services (CMS) released a final rule implementing the Physician Payment Sunshine Act (colloquially referred to as the “Sunshine Act”). Originally adopted as part of the Patient Protection and Affordable Care Act in March 2010, the Sunshine Act requires pharmaceutical companies and medical device manufacturers to report annually to CMS about transfers of value that they make to physicians and teaching hospitals. The information reported in these disclosures will then be compiled by CMS and posted in a publicly accessible database.

To help give you a better idea of how your practice will be affected by this final rule, we spoke with legal experts Mark Morrell and Susan Ziel from the firm Krieg Devault to shed light on common physician questions about the Sunshine Act.

Does the Sunshine Act require physicians to do anything?

Because physicians and teaching hospitals are defined as “covered recipients” under the final rule, the statute does not impose any specific requirement on them. Still, while action may not be required under the Final Rule, it is recommended for many physicians.

What information is reported to CMS?

Physicians and teaching hospitals should expect applicable manufacturers to report: the physician’s name, business address, medical specialty, license number, NPI number, and the form, amount, nature and date of the payment that were made. Similar information is required separately when a covered recipient has an ownership interest in a reporting organization. CMS will compile this information. Accordingly, physicians who are “covered recipients” should (i) anticipate requests for information from applicable manufacturers and GPOs, (ii) recognize that they will be listed on the CMS website; and (iii) evaluate whether further proactive steps can be taken to maintain compliance with state and federal law.

Will physicians have an opportunity to review (and potentially dispute) the information that is reported to CMS?

Yes, but the opportunity to review and dispute information is only permitted after that information is submitted to CMS. CMS considered a pre-submission review standard that would have required manufacturers and GPOs to provide physicians and teaching hospitals with an opportunity to review and dispute information prior its submission to CMS. Although the agency did not impose this requirement, it does recommend it as a way to ensure accurate reporting. Physicians who are covered recipients can request pre-submission review from the applicable manufacturer or GPO with whom they have a financial or investment relationship.
Physicians and teaching hospitals have a 45-day period after applicable manufacturers and GPOs submit data to CMS to review and dispute the information that will be published about them online. If a covered recipient disagrees with the information submitted, they can dispute it and – after the end of the 45-day period - Manufacturers and GPOs will have an additional 15 days to resolve any remaining disputes and submit updated, finalized information to CMS. If a dispute cannot be resolved during this period, the claim will be published as submitted and remain in dispute. Disputes resolved outside the stated time periods will not be reflected on the public website until the next update of the website.

Will the compensation received by physicians for conducting clinical trials programs be reported by pharmaceutical and device companies?

If a physician is compensated for a clinical trial as part of a contract involving a new product, manufacturers are still required to report it. However, the actual publication of these payments on the CMS website will be delayed until after the product receives the necessary FDA approvals or until four years after the payment was made (whichever is earlier). If the clinical trial involves a new application of an existing product, then the publication won’t be delayed.

What is the timeframe for collecting and disclosing information under the Sunshine Act?

The Final Rule sets forth several important dates. Applicable manufacturers and GPOs must begin to collect data on August 1, 2013. They must track data between August 1, 2013 and December 31, 2013 and report this data to CMS by March 31, 2014. Data will be submitted via an electronic system to be published by CMS at a later date.

Will physicians be subject to more fraud and abuse allegations as a result of the Final Rule?

The Final Rule does not impose any new fraud or abuse standards. Most importantly, being listed on the website does not demonstrate any wrongdoing or indicate any conflict of interest. Instead, the Final Rule exposes the details of compensation and investment arrangements to the public. In many states, these arrangements may not have been subject to public scrutiny previously. Others, (e.g., Vermont, Maine, California, Connecticut, Nevada, West Virginia, Massachusetts, and Minnesota) already have transparency laws in place. While the Sunshine Act preempts state laws if they are less restrictive it, parties will still need to comply with state law when it is more restrictive than the Sunshine Act.

We anticipate that the Sunshine Act will give many consumers, regulators, enforcement agencies and advocacy groups more information to use in fraud and abuse enforcement actions. In the event physicians are participating in arrangements that do not fall within an applicable Anti-Kickback Statute safe harbor or Stark exception, the potential for fraud and abuse claims increases when this information is publicly disclosed. Although physicians who are “covered recipients” under the Sunshine Act are not required to act, we advise physicians to review their compliance policies and protocols and evaluate whether further action is necessary to reduce the risk of not complying with applicable law.

What “takeaways” from the Sunshine Act can be implemented in my practice?

First, physician practices should make sure that their current organizational documents, employment agreements, compliance policies and conflict of interest disclosure procedures are up-to-date. Physicians, particularly those with outside activities that could be reported under the Final Rule, should be required to notify their physician practice so that the practice can proactively manage these new transparency requirements.

Second, physicians and teaching hospitals brought under the scope of the Sunshine Act should request the ability to conduct a pre-submission review from the manufacturers and GPOs with which they have financial arrangements. In the event that a pre-submission review is not made available, these covered recipients will need to take an active role in reviewing the information and disputing any inconsistencies.

Third, physicians and teaching hospitals should mark their calendars now to review the information reported to CMS. This data will be provided to CMS by March 31st annually, so physician practices should set aside time in April and May to review it. Maintaining accurate financial records is imperative to ensuring accuracy of the information made available to CMS.

Finally, it is important to remember that applicable manufacturers and GPOs face severe penalties if they do not comply with the Sunshine Act. Those that fail to report as required can fined up to $150,000 annually. This penalty can rise to $1,000,000 for those that intentionally fail to report. This means that the information will be disclosed, and covered recipients must anticipate the implications of the increased scrutiny that will accompany the disclosures.