

Physician

The Independent Medical Business Newspaper

Just in time for spring: Sunshine. On Feb. 1, 2013, the Centers for Medicare & Medicaid (CMS) issued the final rule on the "Sunshine Act." The Sunshine Act requires drug and device companies to report transfers of value to physicians and teaching hospitals. CMS issued its proposed regulations in December 2011. The final rule includes 35 pages of regulations, preceded by 251 pages of explanations, showing CMS's thoughtful analysis of the nearly 400 comments it received during the comment period. The final rule revises and clarifies a number of provisions.

We first wrote about the Sunshine Act's implications for Minnesota physicians in the November 2012 issue of *Minnesota Physician* ("Sunshine and scrutiny: managing compliance with ACA's Sunshine provisions from a provider perspective"). Here, we provide Minnesota physicians with updated guidance based on CMS's final rule. This article outlines the definitions, timeline, exclusions, rules on meals, and reporting categories set out in the final rule; and explains how the final rule affects Minnesota's existing partial gift ban and reporting requirements.

Final rule on the "Sunshine Act"

Be ready to comply

By David M. Aafedt, JD, and Christianna L. Finnern, JD

Definitions

The final rule clarifies certain definitions:

An "**applicable manufacturer**" (AM) is (1) an entity operating in the U.S. that is engaged in making or selling a covered product. Distributors that do not hold title to the covered product are not AMs. Or an AM is (2) an entity under common ownership with an entity in part (1), which assists in making or selling a covered product.

An "**applicable group purchasing organization**" (AGPO) is an entity operating in the U.S. that arranges for the purchase of a covered product.

"**Physician**" is defined as provided in the Social Security Act, which includes licensed doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and chiropractors. It excludes physicians who are employees of an AM and excludes residents.

"**Teaching hospitals**" are defined as those that receive

CMS funding for graduate medical education; CMS says it will publish, annually, the list of teaching hospitals.

Timeline

The final rule establishes a new timeline for the Sunshine reporting requirements. The start date for data collection is **Aug. 1, 2013**. Applicable manufacturers and applicable group purchasing organizations must track transfers of value to physicians or teaching hospitals. They must also track ownership or investment interests held by physicians or their immediate family members.

The data collected from Aug. 1–Dec. 31, 2013, must be submitted to the CMS's Open Payments website by **March 31, 2014**. Physicians will be able to register with Open Payments in 2014 to review the reported data before it is made public so that they can dispute and correct any mistakes. This data will be made publicly available on **Sept. 30, 2014**.

Exclusions from reporting

The final rule sets out clear exclusions from reporting. Key exclusions include transfers of value less than \$10, except where the annual total would exceed \$100. Small incidental items under \$10 (e.g., pens) given away at large conferences do not count toward the annual total.

Other exclusions are:

- Transfers of value because of existing personal relationships (e.g., where an AM employee gives a gift to her physician spouse)
- Educational materials that directly benefit patients (such as anatomical models, but not medical textbooks)
- Discounts and rebates
- In-kind items for providing charity care
- Product samples (including vouchers intended to defray patient costs)
- The loan of a medical device for a short-term trial period, not to exceed 90 days

In the final rule, CMS carefully explains what fits and does not fit within each of these exclusions. For example, physicians accepting items for charity care should be sure that the patients receiving this care truly cannot pay for it. If it would not be a hardship for a patient to pay for this medical care, then donated items

Resources and additional information

are considered transfers of value to the treating physician.

Rules on meals

The final rule also explains how meals must be reported. Often, an AM's sales representatives provide meals for an entire practice. If a physician partakes in the meal, it is considered a transfer of value and must be reported; however, the initial regulations were unclear on how the cost of the meal would be allocated.

According to the final rule, the total cost of the meal is to be divided by the total number of individuals who partake in the meal (including physicians and non-covered individuals such as nurses or staff). This number is the reportable transfer of value, but only for the physicians who actually partake in the meal. If a practice has three physicians and 10 nurses and the meal costs \$240, but only two physicians partake, the value is \$240 divided by 12, or \$20 per person. The AM must report transfers of value of \$20 each for those two physicians.

This rule allows physicians to avoid a reportable transfer of value by choosing not to partake in a meal supplied by an AM.

Reporting categories

The final rule also specifies exactly what must be reported. The AMs will be reporting the physician's full name, specialty, business address, National Provider Identifier (NPI) number, and the state professional license number. The reports must include the amount, form, date, and nature of the payment, and the name of the related covered product. If there is not a related covered product, AMs can report a related non-cov-

- CMS's final rule on the Sunshine Act: www.federalregister.gov/articles/2013/02/08/2013-02572/medicare-medicaid-childrens-health-insurance-programs-transparency-reports-and-reporting-of
- *Physician Payment Sunshine Act Final Rule: Definitions, Policy and Medicine*, Feb. 5, 2013: www.policymed.com/2013/02/physician-payment-sunshine-act-final-rule-definitions.html
- *Physician Payment Sunshine Act Final Rule: Quick Reference Guide, Policy and Medicine*, Feb. 13, 2013: www.policymed.com/2013/02/physician-payment-sunshine-act-final-rule-quick-referenceguide.html
- Minnesota Statute §151.461 ("Gifts to Practitioners Prohibited"): www.revisor.mn.gov/statutes/?id=151.461
- Minnesota Statute §151.47 ("Wholesale Drug Distributor Licensing Requirement"): www.revisor.mn.gov/statutes/?id=151.47
- CMS's National Physician Payment Transparency Program: Open Payments: www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html

ered product or "none."

Payments can be eligible for delayed publication if made pursuant to research on new drugs or devices in order to keep this research confidential while it first gets under way. If the payment was made to an entity other than the physician at the request of that physician, the name of this entity must be reported. Lastly, payments to physician owners or investors must be reported.

When AMs report the costs related to a physician's attendance at a medical conference, the AM cannot bundle these costs. This means that a physician who travels to a medical conference can incur many different transfers of value—and each will be specified in the publicly available reports. There will be separate lines for travel, meals, honoraria, and speaking fees if applicable. Though these transfers of value may be entirely appropriate, physicians should be aware that each of these costs will be reported as a separate payment and the applicable drug or device's name will be attached to each.

This means that if a physician flies business class, stays in a five-star hotel, eats at a Michelin-starred restaurant, and is paid a high hon-

orarium while attending a meeting about a particular stent, and then begins to use this particular stent, the physician should be aware that this invites scrutiny under the federal Anti-Kickback Statute (AKS). It remains illegal under AKS to pay physicians in order to influence their choice of a drug or device (42 U.S.C. §1320a-7b, "Criminal penalties for acts involving federal health care programs"). Prosecutors could easily interpret an \$800 flight, \$500 hotel, \$300 meal, and \$1,500 honorarium as influencing a surgeon's decision to use a new stent.

Effect on state partial gift ban and reporting requirements

Many Minnesota physicians already are familiar with some of the requirements of the Sunshine Act because of Minnesota's partial gift ban and reporting laws (Minn. Stat. §151.461 and §151.47, subd. 1(f) (2012)). Minnesota bans gifts worth more than \$50 annually to physicians (this applies to drug—not device—manufacturers and distributors) and requires these companies to report payments, honoraria, reimbursement, or other compensation to physicians totaling more than \$100. However, in

light of the CMS's final rule, the Minnesota Board of Pharmacy has announced that it will amend its disclosure requirements.

In a Jan. 8, 2013, letter, Board of Pharmacy Executive Director Cody Wiberg, noted that the "vast majority of data that is reported under Minnesota law is information covered by the Sunshine Act"; and, thus, the Board of Pharmacy has determined that it will "not require wholesalers and manufacturers to report

any data for calendar year 2012" (letter available at www.medispend.com/documents/MNRepealofReporting.pdf). Additionally, the Board of Pharmacy will ask the Minnesota State Legislature to repeal the state's reporting requirements in 2013. The board will not be asking for a change to Minnesota's partial gift ban.

This means that Minnesota physicians must check only the federal Open Payments website (see sidebar) to review reported transfers of value. Using Open Payments, Minnesota officials will be able to keep track of transfers of value from drug companies that would be disallowed under the partial gift ban. Physicians should be careful not to allow AMs to exceed the \$50 annual limit on gifts—and this includes meals. For physicians who interact only with drug companies, Sunshine is a new paradigm. All Minnesota physicians should evaluate what payments they are comfortable receiving as this data becomes public in a little over a year. ❑

David M. Aafedt, JD, and Christianna L. Finner, JD, are attorney shareholders at Winthrop & Weinstine, PA, Minneapolis.