Shining Light on the Sunshine Act

INTRODUCTION

Section 6002 of the Patient Protection and Affordable Care Act, also known as the Sunshine Act, requires that manufacturers report payments or other transfers of value made to physicians and teaching hospitals [1,2]. The tracking of such payments goes into effect on August 1, 2013, and the new rules could affect radiologists. In this column, I pose and answer several questions regarding the Sunshine Act.

WHO DOES THE REPORTING?

Physicians are not required to report payments or transfers of value made to them. Rather, manufacturers that operate in the United States and produce at least 1 “covered product,” such as a drug, medical device, medical supply, or biologic agent, must participate and report to CMS. Group purchasing organizations in the United States that purchase, arrange for, or negotiate the purchase of covered items must also report. Covered products are items for which payment is made under Medicare, Medicaid, or the Children’s Health Insurance Program, either separately through a fee schedule, such as the Medicare Physician Fee Schedule, or as part of a bundled payment, such as inpatient diagnosis-related groups. Thus, many of the products used in radiology, such as imaging equipment, contrast agents, PACS and IT equipment, and interventional devices, are covered. The complete time frame for the Sunshine Act is summarized in Table 1.

ON WHOM ARE THE DATA COLLECTED?

The Sunshine Act covers 3 categories for reporting purposes: physicians, teaching hospitals, and physician owners or investors (and their family members). All physicians are covered, whether they are Medicare or Medicaid enrolled or not, but the act excludes residents and also physicians who are employees of the applicable manufacturers. All teaching hospitals that receive payments under Medicare, such as for direct graduate medical education, are covered by the act. A complete listing of these teaching hospitals can be found on CMS’s website [3].

WHAT ARE TRANSFERS OF VALUE?

The Sunshine Act covers a number of transfers of value, including consulting fees, honoraria, gifts, entertainment, food and beverages, education, research, travel and lodging, and grants, among others.

CMS also requires the reporting of indirect payments made by a manufacturer to a physician or teaching hospital through an intermediary, such as a specialty society, when the manufacturer requires or directs that the intermediary provide the payment to a specific physician or teaching hospital. In this scenario, the physician who subsequently receives the payment is reportable.

Regarding physician owners or investors (and their family members), reporting includes owners of stock, stock options, partnership shares, and limited liability company memberships, together with loans, bonds, or other financial instruments that are secured with an entity’s property.

Excluded from reporting is anything valued less than $10, unless the aggregate amount during a calendar year exceeds $100. Also excluded from reporting are educational materials for patient use, the loan of a medical device for a short-term trial period (not to exceed 90 days), items under contractual warranty, and transfers when the physician is a patient.

HOW MAY RADIOLOGISTS REVIEW AND DISPUTE THE DATA?

Radiologists and teaching hospitals must register with CMS to review submitted data before CMS makes the data public. CMS does not require manufacturers to provide ongoing notice to physicians regarding payments they intend to report. If the data are found to be inaccurate, radiologists have 45 days to dispute the reported information, and manufacturers are required to work with the disputing physician or teaching hospital to correct the disputed data. If the dispute is not resolved, the data are still made public but shown as “under dispute.” From days 46 to 60, disputes may still be initiated and completed, but subsequent corrections may not be reflected in the public data. CMS has made it clear that it will not mediate disputes.

WHAT ABOUT CONTINUING MEDICAL EDUCATION?

The Sunshine Act distinguishes between accredited and unaccredited continuing medical education (CME) to determine if CME-related payments to physicians are reportable or not. Payments made to subsidize the costs of attendees at continuing education programs are not reported. Payments for faculty members or speakers at CME events are also not reportable, as long as all of the following 3 criteria are met: (1) the program meets the accreditation or certification requirements and standards of the ACCME, American Osteopathic Association, the AMA, the American Academy of Family Physicians, or the American Dental Association’s Continuing Education Recognition Program; (2) the manufacturer does not select the covered recipient speaker, nor does the manufacturer provide the CME vendor with a distinct identifiable set of individuals to be considered as speakers; and (3) the manufac-
turer does not directly pay the covered recipient speaker.

Vendor support for accredited radiology CME should not be dramatically affected as long as vendor contributions are allocated for general educational activities and not designated for specific speakers. This allows the funds to subsidize the course fees of the attendees and does not require reporting.

**WHAT ABOUT PROVIDING FOOD TO A RADIOLOGY DEPARTMENT OR AT A CME EVENT?**

Meals provided by manufacturers in a group setting, such as lunch in a radiology department, are reportable on a per-person basis. For instance, if a device sales representative provides lunch to a radiology department at a cost of $200, and 8 technologists and 2 physicians partake of the food, the per-person cost is $20. The meal would be reported on the basis of the per-person cost for only the 2 physicians who attended at $20 per physician.

During CME conferences, manufacturers are not required to report food and beverages provided in settings in which it would be difficult to establish the identities of people partaking in the food, such as a large buffet meal, snacks, or coffee made available to all conference attendees.

**WHAT ABOUT RESEARCH PAYMENTS?**

CMS defines research using the same definition as the Public Health Service Act, whereby research must be subject to a research protocol or a written agreement or contract [4]. This includes research agreements between a manufacturer and a contract research organization such as a core imaging laboratory. Manufacturers are required to report the total amount of the research payment included in a research protocol or agreement provided to a teaching hospital or physician. Additionally, the manufacturer must report the names of physician principal investigators covered in the research study. Transfers of value separate from the research agreement are separately reportable. For preclinical research, such as animal or laboratory research, manufacturers must report only the names of the research institution and the principal investigator(s) and the total amount of the payment. If they meet certain criteria, manufacturers may delay the publication of payments related to research for up to 4 years or until the covered product under investigation receives FDA approval.

**CONCLUSIONS**

The Sunshine Act seeks to bring greater transparency to the relationships between industry and physicians while maintaining the balance between the positive contributions to innovation, education, and research and the negatives associated with conflicts of interest. It remains to be seen what, if any, unexpected downstream consequences could be felt by the radiology community. For instance, will vendor support of specialty society CME become harder to find? Will research funding from industry be affected? Will the local representatives with whom we have built relationships become less visible in our departments? By understanding the rules of the Sunshine Act, radiologists can speak confidently with industry to ensure that neither side reacts in a way that could lessen the many beneficial aspects of collaboration between industry and radiology.

### REFERENCES


**Table 1. Important dates**

<table>
<thead>
<tr>
<th>Date and Event</th>
<th>Activity</th>
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<tbody>
<tr>
<td>August 1 to December 31, 2013</td>
<td>Manufacturers are required to begin collecting and tracking information.</td>
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<tr>
<td>Early 2014</td>
<td>Physician registration for the 2013 cycle starts.</td>
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<tr>
<td>March 31, 2014</td>
<td>Manufacturers will report the data for 2013 to CMS.</td>
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<tr>
<td>August 2014</td>
<td>CMS must make consolidated reports available for the 2013 abbreviated reporting period.</td>
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<tr>
<td>September 30, 2014</td>
<td>CMS will release most of the data on a public website.</td>
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<tr>
<td>June 30, 2015</td>
<td>CMS to publish 12 months of data from the 2014 program cycle.</td>
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