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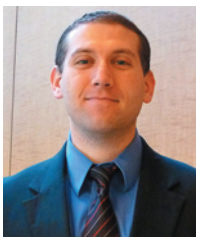
Opening the Shades: Will Teaching Hospitals Need to Apply Sunscreen to Avoid Being Burned by the Sunshine Act?



By Abraham Gitterman

I. Introduction

In response to heightened legal and public scrutiny surrounding physician–industry relationships and collaboration, Congress included the Physician Payments Sunshine Act (''Sunshine Act'') in the Patient Protection and Affordable Care Act (''ACA'').[1] Under the final regulations promulgated by the Centers for Medicare & Medicaid Services (''CMS'') (the ''Final Rule''), applicable manufacturers (''AMs'')[2] of drugs, devices, biologicals, or medical supplies covered under Medicare, Medicaid or Children's Health Insurance Plan (''CHIP''), must report annually to CMS, in an electronic format, certain payments or other transfers of value to ''covered recipients,'' defined as physicians and teaching hospitals.[3]

Data collection for applicable manufacturers and GPOs began on Aug. 1, 2013, and such entities must report the partial 2013 year data to CMS by March 31, 2014.[4] CMS will aggregate all payments and expects to publish the data on a searchable website by Sept. 31, 2014. AMs that fail to comply with the reporting requirements may be subject to civil monetary penalties.

Under the Final Rule, teaching hospitals are defined as any hospital receiving Medicare payments for direct graduate medical education (''GME'') or Indirect Medical Education (''IME'') payments,[5] which may include many academic medical centers (''AMCs'') and medical schools.[6]

[1] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6002, 124 Stat. 119, amended by Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029. Now referred to as ''Open Payments,'' *available at* http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html.

[2] Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting the Physician Ownership or Investment Interests. 78 Fed. Reg. 9458, 9518 (Feb. 8, 2013).

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[3] This article does not address the group purchasing organization (GPO) provisions of the Sunshine Act. For a full analysis of the final regulations promulgated by CMS, *see* Abraham Gitterman, *What is the Best Way for Manufacturers and Physicians to Apply Sunscreen to Avoid Being Burned by the Final Sunshine Act Regulations?* FDLI Policy Forum, Vol. 1, Iss. 4 (Feb. 2013).

[4] Reports by applicable manufacturers for subsequent calendar years are due on the 90th day of each calendar year thereafter. 78 Fed. Reg. 9496.

[5] Payments to non-healthcare departments at universities affiliated with a teaching hospital, are not reportable, except if meant as a pass through. 78 Fed. Reg. at 9468. Payments to a veterinary school associated with hospitals are also excluded.

[6] CMS will publish a ''final'' list of teaching hospitals once annually, which is made available 90 days before the reporting year and includes tax identification numbers. CMS, Teaching Hospitals, *available at* http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Teaching-Hospitals.html. Reporting is not required for payments made to an unlisted hospital during

While the Sunshine Act does not impose requirements or penalties directly on teaching hospitals or require such entities to track, collect or report data, the increased transparency that the Sunshine Act brings to the relationships teaching hospitals and their physicians may have with industry exposes them to unprecedented scrutiny.

Specifically, the publication of payment data may damage a teaching hospital's public reputation or subject it to investigation by various government agencies and prosecutors at both the state and Federal level.

Teaching hospitals should take affirmative steps to protect themselves from unwarranted scrutiny from the public and government officials, as well as decreased patient trust. For example, teaching hospitals may want to create and implement internal policies and procedures to support compliance in relationships with industry, ensure that employees and physicians follow those internal policies and procedures through adequate oversight, and work closely with AMs to ensure that payment data is neither misleading nor inaccurate.

Teaching hospitals should also implement policies and procedures for handling any communication with patients, payors, relevant third parties (e.g., vendors or suppliers), the media, and government officials about Sunshine Act data.

This article describes the Sunshine Act reporting requirements that should be most relevant to teaching hospitals, the potential ramifications that teaching hospitals could face given this new transparency, and how teaching hospitals can make internal changes that will allow them to continue to collaborate with industry in a compliant manner.

II. Public Disclosure of Teaching Hospital Payments Under the Sunshine Act

Many teaching hospitals already have in place internal policies and procedures governing the types of interactions and relationships that are reportable by AMs under the Sunshine Act.

Those policies, often referred to as ''conflict of interest'' policies, typically address: (1) industry-supported research activities; (2) consulting contracts, meals and gifts; (3) activities that may occur on- or off-campus, such as industry-supported (i) education and training; (ii) scholarships and trainee funds; (iii) continuing education (CE); and (iv) speaking;[7] (4) disclosure of financial interests to patients and the public; and (5) drug or supply samples or medical device loans.[8]

Many teaching hospitals also have policies and procedures governing industry interactions with members of purchasing and formulary committees, and access of industry sales personnel (''sales reps'') to teaching hospital personnel.

Given that AMs will be reporting payments related to these and other interactions, teaching hospitals should pay close attention to these relationships to ensure compliance with internal hospital policies and federal and state laws to prevent any investigations or public scrutiny and avoid jeopardizing the hospital's reputation.

A. Research

Many teaching hospitals and their physicians collaborate with industry on clinical research. The Sunshine Act requires AMs to report research-related[9] payments to teaching hospitals or their physicians for preclinical research,[10] FDA Phases I-IV research, investigator-initiated investigations, new generic drug research, and medical device research for products cleared under the 510(k) process.[11]

However, rather than publish such payments annually, the Sunshine Act allows AMs to delay publication for up to four years after the date of payment if certain requirements are met.[12] Under the Final Rule, AMs must report the ''total amount of the research payment, including all research-related costs for activities outlined in a written agreement, research protocol, or both.''[13]

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that reporting year. CMS FAQ 9144. CMS also noted in an FAQ that if there are ''minor discrepancies'' in the hospital name and/or address, AMs should use the information on the teaching hospital list provided by CMS.

[7] Including compensation to physicians for travel, lodging or attendance at such activities.

[8] Many of these policies are evaluated annually by the American Medical Students Association's (AMSA) ''PharmFree Scorecard,'' *available at* http://www.amsascorecard.org/ [hereinafter AMSA Scorecard]. The Scorecard is funded through the Consumer and Prescriber Education grant program through the Oregon Department of Justice, which resulted from the Neurontin settlement in 2004. Medical schools, many of which are teaching hospitals, voluntarily submit these policies to AMSA, which then uses a methodology, developed jointly by AMSA and the Pew Prescription Project, to grade these policies as ''model,'' ''good,'' or ''absent or unlikely to have substantial effect on behavior.''

[9] CMS adopted the same definition used in the Public Health Service Act in 42 CFR § 50.603, which defines research as ''a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social sciences research.'' 78 Fed. Reg. at 9482.

[10] Defined as ''laboratory and animal research that is carried out prior to beginning any studies in humans.'' *Id*.

[11] Individuals or entities that have no FDA-approved products that are reimbursable by CMS, but may be making otherwise reportable research payments are not required to report payments. Rather, payment reporting obligations begin, or the entity becomes an AM ''180 days following a product becoming 'covered.' '' Material transfers (e.g., provision of a protein) to a researcher for discovery collaboration do not need to be reported when not part of a commercial or marketing plan and precede the development of a new product because such transferred material does not have an independent value at such an early stage of the research process. *Id*. at 9482-83

[12] CMS may delay publication for payments related to: (1) research on, or development of, a new drug, device, biological, or medical supply, or a new application of an existing drug, device, biological, or medical supply; or (2) clinical investigations regarding a new drug, device, biological, or medical supply. Research payments in connection with research related to new applications of existing products, however, will not be subject to delayed publication unless the research activities that resulted in the payment were not within the scope of a ''clinical investigation.'' *Id*. at 9505. For the research payment to qualify for delay, it must be subject to a written agreement or contract or a research protocol. This includes an unbroken chain of agreements that link an AM with a CR constitutes a research agreement. For example, an agreement between an AM and a contract research organizations (CRO), between a CRO and a site management organization (SMO), and then between an SMO and a teaching hospital would be considered a continuous chain of agreements constituting a research agreement. *Id*. at 9482.

[13] 42 CFR § 403.904(f)(ii).

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CMS explained that the total amount of research payment includes ''costs associated with patient care such as diagnostics, exams, laboratory expenses, time spent by healthcare professionals treating the patient and managing the study, and the provision of study products or other in-kind items.''[14] Additionally, CMS stated that AMs are ''not required to assign a specific value to clinical study drugs that are provided to principal investigators,'' but rather report that value in the ''total amount of research payment.''[15]

The Final Rule also clarifies that the total amount of the research payment should not include any payments for activities, which are separate or segregable from the written agreement or are paid through a method different from that of the research.[16] Thus, payments made directly to a physician for serving on a study steering or data monitoring committee that are not part of the larger research payment should be reported separately.[17]

Conversely, payments for medical research writing and/or publication would be included in the research payment if the activity was included in the written agreement and paid as part of the research payment. CMS also explained that meals and travel associated with research should be reported separately, ''unless included in the written agreement or research protocol and paid for through the large research contract.''[18]

Research payments may implicate related regulatory obligations that teaching hospitals may have, such as financial disclosure statements that may be required by the Food and Drug Administration (''FDA'') and the National Institutes of Health (''NIH''). Teaching hospitals should be wary about possible discrepancies between these overlapping reporting obligations, as they could lead to significant consequences. For example, FDA regulations require AMs who submit a marketing application (e.g., new drug application or NDA), to submit certain information about the compensation to, and financial interests and arrangements of, any clinical investigator[19] conducting clinical studies covered by the regulation.[20]

Discrepancies between Sunshine Act reporting and FDA financial disclosure forms could cause the agency to refuse filing a marketing application and lead to scrutiny of the principal investigator(s) and the institution where the research was conducted.[21]

NIH regulations require institutions—such as teaching hospitals—applying for Public Health Service (PHS) grants to obtain financial disclosure statements from investigators who plan to participate in the research and must manage, reduce, or eliminate significant financial interests that could be affected by the research.[22] Such institutions must also report the existence of conflicting financial interests to the government agency that awards the grant and assure the agency that the interest has been managed, reduced, or eliminated.[23]

Discrepancies between Sunshine Act and NIH reporting could cause NIH to restrict or prohibit future funds from going to a teaching hospital or ask a teaching hospital to return awarded funds.

There are several examples of when prominent teaching hospitals have come under public scrutiny for failing to make proper disclosures to NIH. For example, in 2008, the Senate Finance Committee, under the direction of Sen. Charles E. Grassley (R-Iowa)—co-author of the Sunshine Act—investigated the financial relationships that researchers in academic medical institutions had with manufacturers.

The investigations uncovered several physician-researchers at prominent teaching hospitals such as Harvard,[24] Stanford,[25] and Brown,[26] who had accepted funding from both the NIH and various manufacturers, but failed to fully or properly disclose the extent of their financial ties to their respective institutions, and the in-

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[14] 78 Fed. Reg. at 9484.

[15] CMS FAQ 9118.

[16] 78 Fed. Reg. at 9484.

[17] *Id*.

[18] *Id*.

[19] Means any listed or identified investigator or subinvestigator who is directly involved in the treatment or evaluation of research subjects. The term also includes the spouse and each dependent child of the investigator or subinvestigator. (21 CFR § 54.2(d)).

[20] *See generally* 21 CFR § 54.1.

[21] If FDA determines that the financial interests of any clinical investigator raise a serious question about the integrity of the data, FDA may: (1) initiate an audit of the investigation data derived from the investigator in question; (2) request that the applicant submit further analyses of data; (3) request that the applicant conduct additional independent studies to confirm the results of the questioned study; and (4) refuse to treat the study as providing data that can be the basis for an FDA action. 21 CFR § 54.5(c). *See also* FDA Guidance for Clinical Investigators, Industry, and FDA Staff: Financial Disclosure by Clinical Investigators (Feb. 2013).

[22] Responsibility of Applicants for Promoting Objectivity In Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors, Final Rule, 76 Fed. Reg. 53256, 53289 (Aug. 25, 2011).

[23] *Id*. Teaching hospitals and/or their physicians will need to closely track when payments to a physician exceed $5,000—the threshold for a significant financial interest. Additionally, institutions and researchers will need to resolve the differences between NIH and Sunshine regulations regarding the reporting of any reimbursed or sponsored travel related to investigators' institutional responsibilities.

[24] For example, congressional investigators found that three child psychiatrists from Harvard University who were awarded federal research grants received several hundred thousand dollars in consulting fees from manufacturers, which they failed to report to Harvard. Gardiner Harris, *Researchers Fail to Reveal Full Drug Pay*, New York Times, (Jun. 8, 2008). Dr. Joseph Biederman, a renowned child psychiatrist at Harvard Medical School, and a colleague, Dr. Timothy E. Wilens, had reported to university officials earning several hundred thousand dollars each in consulting fees from drug makers from 2000 to 2007, when in fact they had earned at least $1.6 million each. Another Harvard colleague, Dr. Thomas Spencer, reported earning at least $1 million from drugmakers after Grassley pressed him for the information. The federal grants received by Drs. Biederman and Wilens were administered by Massachusetts General Hospital, which in 2005 won $287 million in such grants.

[25] Alan Schatzberg, who was president-elect of the American Psychiatric Association, owned about $6 million in stock in Corcept Therapeutics, which was studying the development of mifepristone for treating psychotic depression. He is also a co-patent holder for the drug and he received an NIH grant to oversee the research. *See* Ed Silverman, *Stanford's Schatzberg Defends His Record*, Pharmalot (Sept. 8, 2008).

[26] Brown University's Martin Keller. Keller, a psychiatrist at Brown University, was a controversial figure for his role in studying Glaxo's Paxil antidepressant. *See* Ed Silverman, *Grassley Targets Brown's Keller Over Grants*, Pharmalot (Jul. 14, 2008).

stitutions failed to monitor them for conflicts.[27] In another case involving Emory University, NIH froze the grant funding for a physician for failed NIH disclosures. In another case, NIH and Stanford shifted the physician off the NIH grant. NIH stated that it would take ''all appropriate action to ensure compliance'' with conflict of interest requirements.[28]

The Department of Health and Human Services Office of Inspector General (HHS OIG) may also initiate an investigation on behalf of NIH if any fraud, waste or abuse related to NIH grants or grant funds is reported or suspected.[29] The OIG has previously expressed concern in a public report that institutions are not adequately implementing conflict of interest reporting and disclosure requirements.[30]

Given these interconnected reporting requirements, and the fact that government agencies can easily share this data, teaching hospitals should take steps to ensure that this data is reported consistently and accurately. For example, teaching hospitals should educate and train their staff and physicians on the various reporting requirements for CMS, FDA, and NIH to ensure compliance and consistency.

AMs and teaching hospitals should also ensure that the disposition of any equipment or supplies provided through research agreements is appropriately addressed once the research is complete. For example, an AM may be able to sell study equipment such as refrigerators or freezers to teaching hospitals or physicians at fair market value after a study is complete.

Otherwise, the AM will need to take back such equipment or supplies because failure to do so may be considered a reportable payment or transfer of value separate and apart from the original research grant.

B. Interactions With Industry

Under the Sunshine Act, AMs must report payments or transfers of value to physicians for consulting, meals, travel, gifts, education, and other interactions or activities. If a payment or transfer of value for an activity is associated with multiple categories, ''each segregable payment [must] be reported separately in the appropriate category.''[31] Thus, AMs cannot ''lump sum payments or other transfers of value,'' but instead must ''break out the distinct parts of the payment that fall into multiple categories for both form of payment and nature of payment.''[32]

As noted above, many teaching hospitals currently have policies addressing these interactions. Oversight and compliance with such policies will be crucial for teaching hospitals to reduce the risk of being investigated or harming their public reputation. Further, noncompliance with internal hospital policies—particularly those mandated by federal agencies or recommended by professional medical associations, or other academic or medical groups (e.g., the AAMC, IOM, AMA, etc.)—may also be an indication to government agencies and officials of widespread misconduct, which may enhance penalties, fines and regulatory actions taken, particularly if they relate to patient safety.

1. Consulting, Meals and Gifts

Teaching hospitals have internal policies that may prohibit or limit industry interactions with physicians for consulting, meals and gifts. For example, some teaching hospitals: (1) require prior institutional review or approval of consulting relationships; (2) prohibit all gifts and on-site meals funded by industry, regardless of the nature or value;[33]and (3) prohibit payments above $50 per year, or prohibit gifts but allow meals. Additionally, teaching hospitals may ban sales representatives from the premises,[34] or impose ''significant limitations'' on sales reps.[35] In the past, AMs may have provided meals and gifts to covered recipients through sales representatives (''sales reps''), promotional meetings, or other activities.[36]

The Sunshine Act requires the reporting of payments to teaching hospital physicians for consulting fees, meals, and gifts.[37] Thus, AMs may report certain payments to teaching hospitals and/or their physicians that are prohibited or limited under internal policies. Such reporting may suggest that internal policies are not being followed and could jeopardize patient trust and increase the risk of investigation by federal or state authorities under health care fraud and abuse laws.

2. Education, Training, Speaking, and Continuing Education

Many teaching hospitals have internal policies governing whether their physicians may participate in edu-

[27] Investigations also revealed similar discrepancies at the University of Texas, University of Cincinnati, and Emory University. For a more in-depth discussion of these issues, *see* Abraham Gitterman, *Proposed FDA Guidance on Financial Disclosure and the Physician Payment Sunshine Regulations–Divergent Paths and Duplicated Efforts*, Policy & Medicine (May 17, 2013) *available at* http://www.policymed.com/2013/05/proposed-fda-guidance-on-financial-disclosure-and-the-physician-payment-sunshine-regulations-diverge.html.

[28] Gardiner Harris, *Top Psychiatrist Didn't Report Drug Makers' Pay*, New York Times (Oct. 3, 2008).

[29] 2.3.10. http://grants.nih.gov/grants/policy/nihgps_2013/nihgps_ch2.htm#disposition_of_appls

[30] https://oig.hhs.gov/oei/reports/oei-03-09-00480.pdf

[31] 78 Fed. Reg. 9475-76. For example, if a physician received meals and travel in association with a consulting fee, the AM must report ''three separate line items,'' with three separate payment amounts: one for consulting fees, one for meals and one for travel.''

[32] *Id*. at 9476.

[33] *See* AMSA Scorecard. 93 institutions in 2013 had such policies, increasing from 81 in 2011-2, 66 in 2010, 44 in 2009 and 19 in 2008.

[34] *Id*. University of South Dakota Sanford School of Medicine, Florida State University College of Medicine, and the Commonwealth Medical College have such policies. The two former schools, however, state that their policies apply only to a small subset of areas where there students train. Stony Brook University School of Medicine also received a perfect score in this category, but permits sales reps to interact with patients only in non-patient care areas and not anywhere near sites of medical education. *Id*.

[35] *Id*. 90 percent of schools (133) had such policies in 2013. For example, some teaching hospitals require meetings in only non-patient care areas or meetings only by appointment or invitation and some teaching hospitals require sales reps to where a vendor badge.

[36] Industry codes adopted by many AMs, however, prohibit gifts and provide detailed guidance about appropriate interactions with physicians and teaching hospitals. *See e.g.,* PhRMA Code on Interactions with Health Care Professionals, AdvaMed Code of Ethics.

[37] A general category intended to include payments or transfers of value that do ''not fit into another category.'' 78 Fed. Reg. 9480.

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cation or training supported by AMs, either as a speaker or attendee. For example, some teaching hospitals ban their faculty from speaking on behalf of AMs, such as participation on ''speakers bureaus.''[38] Other hospitals severely restrict participation in speaker bureaus by restricting long-term speaking agreements or preventing industry's role in determining presentation content.[39] Teaching hospitals also regulate industry support of on-site[40] and off-site education.[41] For example, some teaching hospitals prohibit personnel from accepting payment, gifts or financial support from industry to attend lectures and meetings.[42]

Some teaching hospitals make exceptions for modest meals if part of a larger program, and some allow physicians to accept travel support if it is subject to institutional approval or industry is prevented from selecting (''earmarking'') the recipients.[43] In addition, some teaching hospitals prohibit AMs from providing direct financial support for educational activities, including continuing education (CE), directly or through a subsidiary agency.[44] Some teaching hospitals, however, allow AMs to contribute unrestricted funds to a central fund or oversight body at the hospital (e.g., CE department), which, in turn, would pool and disburse funds for programs.

Payments or transfers of value to the hospital or physician for educational and training activities, including CE, may be reportable under the Sunshine Act,[45] and may be categorized in several nature of payment categories, including (1) honoraria; (2) education; (3) grant; (4) compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a CE program; (5) compensation for serving as faculty or as a speaker for an unaccredited and non-certified CE program; and (6) compensation for serving as faculty or as a speaker for an accredited or certified CE program. The Final Rule, however, excludes almost all payments or transfers of value to teaching hospitals or physicians for accredited CE programs if three conditions are met.[46]

Nevertheless, AMs may report certain payments to teaching hospitals and/or their physicians for education and training that are prohibited or limited under these internal policies. Such reporting may suggest that internal policies are not being followed and could jeopardize patient trust and increase the risk of investigation by federal or state authorities under health care fraud and abuse laws.

3. Samples, Loans, Warranties, Repairs

Certain teaching hospitals prohibit industry samples from their institutions except under certain narrow circumstances.[47] The Final Rule, however, exempts from reporting ''product samples'' ''intended for patient use'' that are not intended to be sold, including ''any drug, device, biological, or medical supply.'' [48] The Final Rule also excludes from reporting the loan of a covered device or the provision of a limited quantity of medical supplies for a ''short-term trial period'' not to exceed 90 days or a quantity of 90 days of average daily use to permit evaluation of the device or medical supply by a physician.[49]

CMS expanded the loan exclusion to include covered devices ''under development'' including ''a supply of disposable or single use devices (including medical supplies) intended to last for no more than 90 days.''[50] CMS clarified that once a short-term loan exceeds the

[38] The AMSA Scorecard identified 18 schools with such bans in 2013, including: Harvard Medical School, NYU School of Medicine, Duke Univ. School of Medicine, Columbia Univ. College of Physicians and Surgeons, Univ. of Arkansas School of Medicine, Univ. of Maryland School of Medicine, Georgia Health Sciences Univ., Univ. of South Carolina School of Medicine, Univ. of Hawaii John A Burns School of Medicine, Creighton Univ. School of Medicine, Wake Forest Univ. School of Medicine, Univ. of Massachusetts Medical School, Emory Univ. School of Medicine, Stanford Univ. School of Medicine, Albert Einstein College of Medicine, Univ. of Alabama Birmingham, Univ. of Florida and Jefferson Medical College.

[39] *Id*. (citing 26 schools in 2013). To gain a perfect score, a medical school must prevent speaking relationships from functioning as *de facto* gifts or marketing. Other ''effective policies contain elements such as limits on compensation and reimbursement and a requirement to ensure the scientific integrity of information presented.'' Other schools permit and regulate industry-funded speaking but with less stringent limits on longevity, content or compensation. *Id*.

[40] On-site education means within the medical school or hospital campus.

[41] Off-site education is at outside facilities, including professional conferences

[42] AMSA Scorecard, citing 102 schools with such policies in 2013, increasing from 88 in 2011-12.

[43] *Id*. Approximately 80 percent of medical schools in 2013 had policies that either prevent industry from earmarking or awarding funds to support the training of particular individuals (recipients must be chosen by the school or department), or mandate institutional review of the giving of funds. Such policies do not preclude grants that fund a specific research project.

[44] *Id*. 28 schools in 2013 had such policies, increasing from 20 in 2011-12. In 2008, only 5 schools had perfect policies in this category.

[45] To the extent that payments for these activities are made to ''medical residents,'' such payments are not reportable, unless meant as ''pass through'' payments. 78 Fed. Reg. 9467. However, payments to fellows are reportable. *See* CMS FAQ 8372.

[46] 42 CFR § 403.904(g). For a detailed explanation of the CME rules, *see* CME Coalition, Continuing Medical Education (CME) Programs: Compliance Guide for Sunshine Rule (Jul. 25, 2013), *available at* http://cmecoalition.org/SunshineActGuidelines.pdf and CME Colaition's FAQs Supplement to the Guide (Sept. 25, 2013, *available at* http://www.cmecoalition.org/sites/cmecoalition.org/files/resources/CME%20Compliance%20Guide%20Supplimental%20FAQs_0.pdf. Mr. Gitterman drafted the Compliance Guide and FAQs while he was employed at Rockpointe, Inc. *See also* Abraham Gitterman, Thomas Sullivan, Andrew Rosenberg, ''The Implications of the Physician Payments Sunshine Act for CME Providers,'' MeetingsNet (Dec. 16, 2013), *available at* http://meetingsnet.com/cme-regs/implications-physician-payments-sunshine-act-cme-providers?page=1.

[47] AMSA Scorecard, citing 42 schools with such policies in 2012, increasing from 31 in 2011, and just 20 in 2009. For example, some schools may permit samples with the approval of the Pharmacy and Therapeutics (P&T) committee or may incorporate samples into a larger program designed to ensure the availability of brand-name and generic medications to under-insured patients. In both cases, institutions must prevent sales reps from giving samples directly to physicians.

[48] 42 C.F.R. § 403.904(i)(3); 78 Fed. Reg. 9487. For example, CMS explained that ''single use or disposable devices, demonstration devices or evaluation equipment'' are excluded from reporting as samples as long as they ''are intended for use by patients.''

[49] *Id*. at 9487. 42 C.F.R. § 403.904(i)(5).

[50] *Id*.

90-day exclusion period, ''regardless of whether the days were consecutive,'' the AM must begin reporting the value of the loan from the 91st day.[51] The short-term loan exclusion applies on a ''per-covered recipient basis.''[52]

The Sunshine Act also excludes from reporting items or services provided under a contractual warranty (including service or maintenance agreements),[53] such as repairs, services or additional training.[54] CMS finalized that ''as long as the contractual warranty specified in the terms prior to expiration and the terms do not change, then the exclusions may extend to items and services provided outside the expiration period.''[55]

Although AMs do not have to report samples, loans, or related services as noted above, teaching hospitals and their staff should closely monitor these arrangements to ensure compliance with the Final Rule. Otherwise, payments or value may be attributed to the teaching hospital or physician, which may suggest that internal policies are not being followed and could jeopardize patient trust and increase the risk of investigation by federal or state authorities under health care fraud and abuse laws.

C. Disclosure, Informed Consent and Consumer Protection

Although some teaching hospitals already require personnel to disclose past and present financial ties with industry (e.g., consulting) on a publicly available website and/or disclose these relationships to patients when such a relationship might represent an apparent conflict of interest,[56] patients and other consumers will have even greater access to information about such relationships under the Sunshine Act.

Teaching hospitals also have policies regarding hospital Pharmacy and Therapeutics (P&T) Committees that make or influence purchasing decisions, as well as senior officials, deans and department chairs at hospitals that may influence utilization of products or services.[57] For example, some teaching hospitals have policies that require P&T committee members to disclose their financial relationships and to exclude from the committee physicians that have financial ties to manufacturers.[58]

These internal policies coupled with the Sunshine Act may raise new physician and institutional liability issues under state informed consent and consumer protection laws for inadequate disclosure of financial relationships.

For example, Oregon's Department of Justice announced the settlement of a civil case in August 2013, involving two doctors who failed to disclose to patients that they received payments from a Biotronik, a medical device manufacturer, for training on various devices including pacemakers, defibrillators and related devices.[59] As part of the settlement agreements, the physicians must provide on their websites a hyperlink to Open Payments, which will include the information reported to CMS by Biotronik.

Lack of disclosure could also result in medical malpractice litigation, actions by state licensure boards, or internal decisions regarding credentialing or privileges. In addition, OIG ''does not believe that disclosure to a patient of the physician's financial interest . . . is sufficient to address [fraud and abuse] concerns'' in the context of physician owned distributors.[60] In other words, federal agencies may be concerned that financial relationships, regardless of whether they are disclosed to a patient, could affect the kind or quality of care patients receive, which could lead to scrutiny (e.g., medically unnecessary services).

Federal and state prosecutors, as well as government payers, may also target payments made to teaching hospital physicians that are on P&T committees or formularies as evidence of kickbacks or other improper influence. In fact, OIG recently addressed its concern that P&T committees ''have limited oversight of committee members' conflicts of interest.''[61]

III. Recommendations for Teaching Hospitals

By taking certain steps described below, teaching hospitals and AMs should be in a better position to ensure that payments and relationships are reported accurately and consistently and that they do not invite unwarranted scrutiny from the public or government officials.

These suggestions are offered to ensure that teaching hospitals continue to collaborate with manufacturers to

[51] *Id*.

[52] CMS FAQ 8958. Thus, if a ''manufacturer loans a medical device (whether the same device or not) to different teaching hospital recipients, each for a period of 90 days or less, each loan would be eligible for the exclusion.'' *Id*. If a covered recipient purchases the device within the 90 days, AMss do not need to report the value of the loan.

[53] 42 C.F.R. § 403.904(i)(6).

[54] CMS FAQ 8960.

[55] 78 Fed. Reg. 9488. In addition, CMS finalized that ''items or services provided under a contractual service or maintenance agreement'' are also subject to the contractual warranty exclusion because they are ''so similar to warranty agreements.'' *Id*. Similarly, CMS finalized that ''replacement products in the case of a product recall'' are also included in this exclusion category. *Id*.

[56] AMSA Scorecard, noting that 41 schools (26 percent) had a model or ''perfect'' policy in terms of disclosure in 2013, increasing from 29 in 2011-12.

[57] Tracy E. Miller, *The Payment Sunshine Act: Assessing the Compliance Risks for Healthcare Providers*, AHLA Connections (Aug. 2011).

[58] AMSA Scorecard, noting that more than 50 percent (83) of institutions had such policies in 2013. Exclusion may be specific to participation in particular decisions for which the staff member has a conflict of interest. AMSA clarified that this standard is not intended to prohibit indirect financial interests, such as investments in mutual funds that may own pharmaceutical company shares. This policy also does not prevent expert clinicians from advising a committee, provided that potential conflicts are disclosed.

[59] Nick Budnick, *Groundbreaking Oregon DOJ cases target doctors' failure to inform patients about device payments*, The Oregonian (Aug. 6, 2013) *available at* http://www.oregonlive.com/health/index.ssf/2013/08/groundbreaking_oregon_doj_case.html.

[60] Thomas Sullivan, *OIG Special Fraud Alert–Physician Owned Distributors*, Policy & Medicine (Apr. 2, 2013), *available at* http://www.policymed.com/2013/04/oig-special-fraud-alert-physician-owned-distributors.html.

[61] HHS-OIG, *Gaps in Oversight of Conflicts of Interest in Medicare Prescription Drug Decisions* (Mar. 2013), *available at* https://oig.hhs.gov/oei/reports/oei-05-10-00450.pdf.

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discover and develop new treatments, improve patient care and outcomes, and enhance physician training and education. In fact, CMS reiterated in the final rule that ''financial relationships alone do not signify and inappropriate relationship'' and ''collaboration among physicians, teaching hospitals, and industry contributes to the design and delivery of life-saving drugs and devices.''[62]

First, teaching hospitals should update internal policies or procedures to account for Sunshine Act reporting. Although not required by the Sunshine Act, hospitals should designate an official (e.g., compliance officer) to register with Open Payments to review all payments attributed to the hospital, and if necessary, to initiate any disputes.[63] Open Payments is the CMS Website where the agency will eventually post payments, where AMs will register and submit payment data, and where physicians, teaching hospitals, and related stakeholders will register and get other information. Teaching hospitals may also want to encourage physicians affiliated with the hospital, particularly those engaged in research, to register with Open Payments and direct such physicians to the online resources CMS has created. If resources permit, teaching hospitals could offer assistance or training for physicians or staff who have questions, concerns or disputes regarding the reporting. Such training should address the 45-day review period that physician and teaching hospitals have to dispute and correct payment data.[64] By reviewing data and correcting disputes, the data that is reported should be more accurate and line up more consistently with FDA and/or NIH data, where applicable. AMs may want to consider providing periodic updates of payment data that they may have on teaching hospitals and/or their affiliated physicians, which may help prevent these disputes and avoid any surprises. Otherwise, inaccurate payments may be attributed to the hospital and/or physician, which could result the appearance of impropriety, or inquiries from other federal agencies.

Second, teaching hospitals will need to work closely with AMs to ensure proper reporting under the special research rules. Teaching hospitals should explain to physicians the nuances of the special research reporting rules because of the frequent interactions manufacturers (particularly of medical devices) must have with physicians to develop products. AMs will not always be able to capture in a written agreement or research protocol each interaction necessary for the research and development of a product before, during and after FDA approval or clearance. As a result, meals, travel, education, consulting, honoraria or training associated with research may become ''separate or segregable'' activities not eligible for delayed publication, even though they are associated with research. Teaching hospitals can explain these nuances to physician-researchers to avoid any potential disputes or concerns about published payments they may have expected to be delayed. Hospitals should also remind physicians that research payments must be reported even if the physician conducting research or engaging in other reportable activities does not regularly treat patients.[65] Research payments will also be reported and made public even if the product being studied does not eventually receive FDA approval or clearance.[66]

Third, AMs should ensure that consulting agreements: (1) are in writing and for fair market value (''FMV''); (2) are ''in response to a legitimate need by'' the AM; and (3) have a connection between ''the competence of the [physician] paid and the purpose of the arrangement.''[67] While it is unclear at this point how CMS or OIG will conduct audits of Sunshine Act reports, if either agency audit an AM and find evidence of agreements that do not meet these requirements, the AM and/or teaching hospital could be subject to further investigation under the Anti-Kickback Statute or False Claims Act, and related state laws. AMs should also be aware that some teaching hospitals have policies and procedures that require prior institutional review or approval of consulting relationships.[68] Non-compliance with these internal policies may result in the teaching hospital later terminating the contract and/or a reprimand of the consulting physician that could delay or interrupt services the AM may need from that physician. Teaching hospitals should also remind physicians that AMs may attribute multiple payments to them for one consulting agreement (e.g., meals, travel, fees), which could suggest that the physician is exceeding the amount of time permitted for outside activities or jeopardizing his or her roles and responsibilities at the hospital, even though the payments may be affiliated with only one interaction.

Additionally, teaching hospitals should monitor compliance with current internal policies controlling physician interactions with industry (e.g., meals, education, etc.) to avoid negative inferences that government agencies or prosecutors may impute for non-compliance. For example, if an AM reports meals to physicians at a teaching hospital that prohibits such meals, government agencies or prosecutors may suspect kickbacks or improper financial arrangements with those individuals, and potentially to other physicians or the hospital itself due to the hospital's non-compliance with their own internal policies. To avoid these risks, AMs should check with teaching hospitals about whether meals or engaging physicians as speakers is prohibited and under what circumstances. Several AMs have identified high-risk payment category areas (e.g. speaking, meals), and implement monthly or quarterly audits of physician payments to avoid potentially suspect payment amounts or trends when CMS makes the payment data public.[69] For example, AMs

[62] 78 Fed. Reg. 9459.

[63] 78 Fed. Reg. 9501-03; 42 C.F.R. § 403.908(g).

[64] 42 C.F.R. § 403.908(g). Physicians and teaching hospitals that register with CMS voluntarily will be able to sign into Open Payments securely, review only their data, and initiate a dispute if necessary, which allows an additional 15 days to resolve the dispute. CMS, however, will not be involved in resolving the dispute. Only data changes initiated during the 45-day review and correction period and resolved by the end of the 15-day period will be captured in the initial publication of the current reporting year of data on the public website. If the dispute is not resolved in this period, CMS will publish the payment with the notation ''disputed.''

[65] 78 Fed. Reg. at 9483.

[66] *Id*. at 9505.

[67] 78 Fed. Reg. 9480.

[68] AMSA Scorecard, noting that 71 medical schools in 2013 already require this kind of prior review.

[69] Meenakshi Datta, *Beyond Sunshine: Looking Ahead to Fraud and Abuse Risks Raised by Transparency Reports*, Presentation at Disclosure Summit (Feb. 20, 2013).

may want to set annual limits on the amount of compensation a physician may receive (e.g., $50,000); however, such policies should be tailored to account for large payments that may be attributed for research grants or other outside income (e.g., patents, royalties, licenses, etc.).

Fourth, teaching hospitals will need to work closely with manufacturers to: (1) differentiate between samples and short-term loans; and (2) communicate the timing of any loans and purchasing of loaned devices to ensure proper. Hospital compliance officers may want to set reminders or schedule pick-up dates far in advance to avoid any loans exceeding 90-days. Otherwise, AMs would have to report the value of the loan after the exempt period (e.g., day 91 and on), which the hospital may not be prepared to confirm prior to CMS publication or which could be inconsistent with or violate internal hospital policies. Physicians should also be reminded that while samples are exempt under the Sunshine Act, they are reportable under Section 6004 of the ACA, and must comply with numerous other state and federal laws.

Fifth, teaching hospitals should evaluate the impact on patients of the increased transparency Sunshine will bring. For example, a teaching hospital could post signs in patient areas of the hospital, similar to required HIPAA notices, informing patients that the hospital and/or some of its physicians may receive certain payments from AMs (e.g., education, grants, etc.). The notice could give patients the Open Payments website information and could provide brief instructions on how to use the website. Some physician practices are already including such information on patient-sign in sheets or other patient forms. The hospital or physician staff could also refer patients to a new initiative, ''Partners for a Healthy Dialogues,'' which provides helpful information to patients about interactions AMs may have with physicians and teaching hospitals, including videos and charts.[70] Teaching hospitals may also want to consider offering additional training or CE regarding informed consent and disclosure.

Sixth, teaching hospitals may need to create greater flexibility in their on-site educational policies, particularly for medical device manufacturers who frequently need access to patient and treatment areas to conduct FDA-mandated training on their devices and or updates, changes or modifications to such devices. Alternatively, such hospitals may need to adjust their off-site educational policies to ensure that physicians have access to this critical training and education that will enhance patient safety and improve the effectiveness of the device. Similarly, teaching hospitals should allow flexibility for on- and off-site educational programs that may be necessary under FDA required Risk Evaluation and Mitigation Strategies (REMS) or that focus on safety updates and/or labeling changes.

Regardless of what approach is taken, teaching hospitals should ensure that physicians do not violate or undermine internal policies where they exist, by engaging in educational activities that result in having their name and payments publicly reported.[71] Given that CMS practically excluded from reporting all payments and transfers of value associated with certain accredited CE programs, teaching hospitals should allow physicians to attend any on- or off-site programs that meet the three conditions outlined by CMS in the final rule.[72]

Additionally, AMs and teaching hospitals should consult guidance promulgated by CE stakeholders regarding the commercial support of CE programs. Moreover, given how rapid scientific and medical literature changes, and the lack of time physicians have to stay up-to-date on the latest product developments and breakthroughs and clinical data, teaching hospitals should also permit physician attendance at unaccredited educational programs as well. While payments for education or meals may be attributed to physicians for attendance at such programs under the Sunshine Act, their educational nature will often outweigh any potential negative perceptions.

Lastly, although not discussed in-depth here, teaching hospitals should implement policies and procedures to determine whether any ''indirect payments'' are reportable, such as grants that an AM may have provided to a charity or professional medical association, which subsequently provides funds, in whole or in part, to the teaching hospital and/or its physicians.[73]

IV. Conclusion

While the Sunshine Act does not impose penalties on teaching hospitals, the various relationships and interactions hospitals and their affiliated physicians have with industry require a renewed focus on internal policies and procedures to ensure that this collaboration and innovation continues. The increased transparency from Open Payments in 2014, along with greater public scrutiny of teaching hospital conflict of interest poli-

[70] *See* http://www.healthydialogues.org/patients/.

[71] *See e.g.*, ''ProPublica Intimidates Denver Area Hospitals and Medical Schools,'' Policy & Medicine (Jan. 31, 2011), *available at* http://www.policymed.com/2011/01/propublica-intimidates-denver-area-hospitals-and-medical-schools.html.

[72] CMS provided such exclusions by recognizing that accrediting and certifying bodies and industry standards for commercial support ''create important and necessary safeguards prohibiting the involvement of the sponsor in the educational content.'' 78 Fed. Reg. at 9492.

[73] CMS defined an indirect payment as a payment or transfer of value made to a physician or teaching hospital through a third party, where the AM ''requires, instructs, directs or otherwise causes'' the third party to provide payment or transfer of value, in whole or in part, to a physician or teaching hospital. *Id*. at 9522. In other words, ''indirect payments . . . are made to an entity or individual (that is, a third party) to be passed through to a'' physician or teaching hospital. *Id*. at 9470. The final rule excludes from reporting indirect payments where the AM is ''unaware of the identity'' of the physician or teaching hospital ''during the reporting year or by the end of the second quarter of the following year.'' 78 Fed. Reg. 9525; 42 CFR § 403.904(i)(1). For example, CMS would not require reporting of any payments or transfers of value to nurses who attended a manufacturer supported CE event because reporting is only required for physicians. However, if an AM supports nurses to attend the CE program with the purpose of educating the physician upon their return, CMS may consider this a reportable ''indirect payment'' to that physician because the payment or transfer of value to the nurses ''passed through to a physician.'' *Id*. at 9467. Likewise, if an AM required, instructed, directed or otherwise caused a teaching hospital's foundation to provide a donation, in whole or in part, to the teaching hospital, this payment would be a reportable indirect payment. CMS FAQ 9142. The payment would also be reportable if an AM made a payment or transfer of value to a teaching hospital's foundation at the request of or designated on behalf of the teaching hospital.

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cies,[74] demonstrates that a number of interested stakeholders will be closely watching many hospital interactions. Moreover, AMs may need to adjust interactions with teaching hospitals in particular regions that have strong policies regarding industry interactions, such as California, Massachusetts, Texas, Florida, Pennsylvania and Maryland.

Teaching hospitals should begin reviewing policies regarding interactions with industry, particularly in high-risk areas that may be unique to the hospital or where a history of non-compliance or inexperience exists. Similarly, AMs may want to review and train applicable employees about internal policies that particular teaching hospitals may maintain, to the extent they are not already doing so, to ensure that company activities are proper at such institutions.

Activities conducted by AMs and their agents or employees that violate internal teaching hospital policies may suggest to the government evidence of wrongful intent. Monitoring these activities to ensure compliance with applicable internal policies and laws will be critical to avoid unwarranted investigations or damaged reputation.

More importantly, teaching hospitals and applicable manufacturers that work together to ensure compliance with the Sunshine Act will allow these tremendously beneficial relationships and collaborations to continue saving lives and improving the care patients receive.

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Gitterman is admitted only in Pennsylvania and New Jersey. He is practicing law in the District of Columbia during the pendency of his application for admission to the D.C. Bar and under the supervision of lawyers of the firm who are members in good standing of the D.C. Bar. The content of this article is intended for informational purposes only. It is not intended to solicit business or to provide legal advice. Laws differ by jurisdiction, and the information on this Web site may not apply to every reader. You should not take, or refrain from taking, any legal action based upon the information contained in this article without first seeking professional counsel. Your use of this article does not create an attorney-client relationship between you and Arnold & Porter LLP.

[74] AMSA Survey to Review Policies at U.S. Teaching Hospitals (Apr. 9, 2013), *available at* http://www.amsa.org/AMSA/Homepage/About/News/040913.aspx (noting that the 2014 Scorecard will cover over 400 teaching hospitals). The new Scorecard will also expand review of ''samples'' and P&T committees specific to teaching hospitals.