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HEALTH CARE
UPDATE

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Andrew's health care practice is focused in the areas of compliance, regulation, transactions and non-profit governance. Andrew regularly advises health care providers on a variety of regulatory and transactional issues, including the Patient Protection and Affordable Care Act of 2010 and related regulations, the Anti-Kickback Statute, the Physician Self- Referral (Stark) law, EMTALA, licensing of physicians and of health care facilities, physician recruitment, and HIPAA and state privacy laws. Andrew has particular expertise and experience appearing before the New Hampshire Health Services Planning and Review Board in certificate of need proceedings.

TRANSPARENCY REPORTS REQUIRED BY THE "PHYSICIAN PAYMENT SUNSHINE ACT" - PROPOSED RULES OFFER GUIDANCE FOR "APPLICABLE MANUFACTURERS" AND "COVERED RECIPIENTS"

INTRODUCTION

Buried deep in the Patient Protection and Affordable Care Act (as amended by the Health Care and Education Affordability and Reconciliation Act of 2010 - collectively, "ACA") are new "transparency" requirements applicable to certain health care providers, suppliers of medical devices, and pharmaceutical companies. "Transparency" is not a mere buzzword. This law, titled "Transparency Reports and Reporting of Physician Ownership or Investment Interests" ("Sunshine Act"), carries weight because it mandates that the general public have access to new "transparency reports" detailing financial relationships among physicians, teaching hospitals, and manufacturers of drugs or medical devices. In December, the Center for Medicare and Medicaid Services ("CMS") issued proposed rules that provide initial guidance for device and pharmaceutical manufacturers ("applicable manufacturers") who must report. [1] The proposed rules also serve as a means of informing physicians and teaching hospitals ("covered recipients") what to expect in terms of how certain financial relationships will soon become readily available to the public.

THE "SUNSHINE ACT," SECTION 6002 OF THE ACA

A significant aspect of the ACA is to encourage collaboration among physicians, teaching hospitals, and industry manufacturers to improve efficiencies and innovation in the health care system. At the same time, policy makers have long recognized that payments from manufacturers to physicians and teaching hospitals can introduce conflicts of interest "that may influence research, education, and clinical decision-making in ways that compromise clinical integrity and patient care, and lead to increased program [health care] costs." [2]

Understanding the extent and nature of financial relationships among physicians, teaching hospitals, and manufacturers may lead to greater transparency in the system, and also may allow patients to make more informed decisions in choosing doctors, hospitals, and treatment plans. In an effort, therefore, to provide greater information to the public of the financial relationships that physicians and teaching hospitals have with durable medical equipment suppliers, manufacturers, and the pharmaceutical industry, Congress included within the ACA the Sunshine Act. [3]

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[1] 76 Federal Register ("Fed. Reg.") 78742, December 19, 2011/Proposed Rules.
[2] 76 Fed. Reg. 78764.
[3] Section 6002 of the ACA; 42 U.S.C. §1320a-7h.

The Sunshine Act requires a manufacturer of a covered drug, device, biologic, or medical supply (an "applicable manufacturer") to report annually to CMS "payments or other transfers of value" to a physician or teaching hospital (a "covered recipient"). This statute also requires such manufacturers and applicable Group Purchasing Organizations ("GPOs") to report information regarding an ownership or investment interest held by a physician (or a physician's immediate family member) in these entities.

Payments and Other Transfers of Value

The Sunshine Act details those payments or other transfers of value as:

- Consulting fees;
- Compensation for services other than consulting;
- Honoraria;
- Gift;
- Entertainment;
- Food;
- Travel (including the specified destination);
- Education;
- Research;
- Charitable contribution;
- Royalty or license;
- Current or prospective ownership or investment interest;
- Direct compensation for serving as faculty or as a speaker for medical education programs;
- Grant; or
- Any other nature of the payment or other transfer of value. [4]

What Must Be Reported for "Payments or Other Transfers of Value"

Beginning March 31, 2013, and by the 90th day of each calendar year thereafter, any "applicable manufacturer" that provides a payment or other transfer of value to a "covered recipient" must submit to CMS, via electronic format, information regarding any payments or transfers of value provided in the preceding calendar year. An applicable manufacturer must deliver to CMS the following information:

- The name of the covered recipient;
- The business address of the covered recipient;
- The National Provider Identifier of the covered recipient;
- The amount of the payment or other transfer of value and the date on which it was provided;
- A description of the form of the payment or other transfer of value (for example, cash or cash equivalent, "in-kind items or services," stock or other ownership interests, or any other form of payment or other transfer of value); and
- A description of the nature of the payment or other transfer of value, such as a consulting fee, honoraria, gift, entertainment, food, travel, or education.

The statute broadly defines "physician" to include dentists, podiatrists, optometrists, and chiropractors. The definition does not include nurses, nurse practitioners, or physician assistants.

Physician Ownership in Applicable Manufacturer or Group Purchasing Organization

Under the same timeline as payments or transfers of value, applicable manufacturers or applicable GPOs must submit to CMS certain information concerning any ownership or investment interest held by a physician (or a physician's immediate family member) in the applicable manufacturer or GPO during the preceding calendar year. [5] In addition to the preceding items for payments or transfers of value, this information includes:

- The amount invested by each physician who holds an ownership or investment interest;
- The value in terms of each ownership or investment interest; and
- Any payment or other transfer of value provided to a physician who holds an ownership or investment interest.

[4] 42 U.S.C. §1320a-7h(a)(1)(A)(vi).

[5] 42 U.S.C. §1320a-7h(a)(2).

Exclusions from "Payments or Other Transfers of Value"
The Sunshine Act also provides a list of items not considered payments or other transfers of value and which therefore are excluded from reporting. [6] The statute offers applicable manufacturers and covered recipients some leeway by excluding the following items and services:

- A transfer of anything, the value of which is less than $10, unless the aggregate amount exceeds $100 in any calendar year. These amounts are adjusted by the percentage increase in the consumer price index.
- Product samples that are not intended to be sold and are intended for patient use.
- "Educational materials" that directly benefit patients.
- The loan of a covered device for a short-term trial period, not to exceed 90 days.
- Items or services provided under a contractual warranty, including the replacement of a covered device where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.
- A transfer of anything of value to a covered recipient when the covered recipient is a patient.
- Discounts (including rebates).
- In-kind items used for the provision of charity care.
- Dividends or other profit distribution from a publicly traded security or mutual fund.
- For those applicable manufacturers who offer self-insured plans, a payment for the provision of healthcare to employees under the plan.
- The transfer of anything of value to a licensed non-medical professional, provided that the transfer is payment solely for the services of such licensed non-medical professional.
- A transfer of anything of value to a physician if the transfer is payment solely for the services of the physician with respect to a civil or criminal action or administrative proceeding.

Penalties under the Law
The Sunshine Act prescribes penalties for failure to report. Any applicable manufacturer or applicable GPO that fails to submit the information required is subject to a civil monetary penalty ("CMP") of not less than $1,000 but not more than $10,000 for each payment or other transfer of value, ownership interest, or investment interest not reported. [7]

The total amount of CMP imposed on an applicable manufacturer will not exceed $150,000 in any calendar year. If, however, an applicable manufacturer knowingly fails to report, then the CMP impact will be between $10,000 and $100,000 for each payment or other transfer made.

Preemption of State Law
The statute specifically preempts any state law that requires an applicable manufacturer to disclose or report to the state any payment or other transfer of value. To the extent, however, that a particular state law requires additional information, that information should be provided to the state.

THE PROPOSED RULES ON TRANSPARENCY REPORTS

Originally, CMS was to have the proposed rules issued in October of 2011, but the rules appeared in mid-December. CMS's preamble to the proposed rules and the initial draft offer a means of discerning what the rules ultimately will require.

As with the administrative rule process in general, the proposed rules clarify certain issues, but CMS has requested comments from interested parties. As a result, the proposed rules may be amended significantly, although many of their provisions are likely to remain.

What the Proposed Rules Clarify
Certain provisions in the preamble to the proposed rules clarify the Sunshine Act and the manner in which CMS will administer it.

[6] 42 U.S.C. §1320a-7h(e)(10)(B).

[7] 42 U.S.C. §1320a-7h(b). The Sunshine Act has been codified as a component of the Federal Fraud and Abuse Laws. See, e.g., the Federal Anti-Kickback Statute, 42 U.S.C. §1320a-7.

- The rules require separate reporting by applicable manufacturers who have made payments or other transfers of value to a covered recipient, and for those physicians who have an ownership or investment interest in that applicable manufacturer.
- The definition of a covered drug, device, or pharmaceutical product includes any drug or device "available" under Medicare, Medicaid, or CHIP. [8] In the preamble to the proposed rules, CMS has stated that drugs, devices, biologicals, or medical supplies included in a composite payment rate, as well as those reimbursed separately, are considered to be "covered." Thus, a "covered drug, device, biological, or medical supply" includes an item available both as part of a fee schedule payment and as part of a composite payment rate.
- With respect to a device or medical supply, CMS has proposed to limit the definition to those that, by law, require pre-market approval by the Food and Drug Administration.
- The definition of "covered drugs" does not include over-the-counter drugs.
- CMS also has clarified that payments or other transfers of value can include payments provided to a physician through a physician group practice. [9]
- For reporting on the nature of a payment or other transfer of value, CMS's proposed rules require that the categories describing the nature of the payment or other transfer of value are mutually exclusive. [10] Therefore, an applicable manufacturer must categorize each payment or other transfer of value, or "separable part of that payment or transfer of value," in one of the categories listed, using the designation that best describes the nature of the payment or other transfer of value. If a payment or other transfer of value can reasonably be considered to fall within more than one category, an applicable manufacturer should select the category that it deems most accurately describes the nature of the payment or transfer of value. [11]
- CMS has proposed a special rule for research payments. This requires applicable manufacturers to designate each research payment or transfer of value as either "direct research" or "indirect research." Direct research is a payment provided to a covered recipient directly by the applicable manufacturer or through a contract research organization. Indirect research is a payment provided by an applicable manufacturer to a clinic, hospital, or other institution conducting the research when that clinic or hospital, in turn, pays the physician covered recipient serving as the principal investigator. For all payments designated as research, whether direct or indirect, CMS has proposed that applicable manufacturers provide a written agreement and research protocol governing the research.
- With regard to indirect research, the applicable manufacturer must provide in its transparency report the total amount paid to the clinic or hospital conducting the research and, as well, report the name and National Provider Identification of each principal investigator. [12]
- If payment is made for direct research to a teaching hospital, the payment to the teaching hospital must be reported as direct research under the name of the teaching hospital and indirect research under the name and NPI (if applicable) of the physician covered recipient serving as principal investigator.

Jurisdictional Clarification

CMS has proposed that applicable manufacturers will be deemed required to report regardless of where the covered drug, device, or medical supply is actually produced or where the entity is actually

[8] Children's Health Insurance Program.

[9] 76 Fed. Reg. 78746.

[10] 76 Fed. Reg. 78768.

[11] The categories are: (1) Consulting Fee, (2) Compensation for Services Other than Consulting, (3) Gift, (4) Entertainment, (5) Food and Beverage, (6) Travel and Lodging, (7) Education, (8) Research, (9) Charitable Contribution, (10) Royalty or License, (11) Current Ownership or Investment Interest, (12) Direct Compensation for Serving as Faculty or Speaker for a Medical Education Program, (13) Grant, (14) Other.

[12] 76 Fed. Reg. 78769.

located or incorporated, as long as "only one" covered drug, device, or medical supply is in the United States.

Public Viewing of Payment and Ownership Information
The preamble notes that the Sunshine Act requires CMS to produce on a publicly available Web site the data reported by applicable manufacturers and applicable GPOs for calendar year 2012 by September 30, 2013. [13] CMS must publish the data for subsequent calendar years by June 30th. Under the statute, the public Web site must be searchable, understandable, downloadable, and easily aggregated on various levels. [14] Particular information on payments and other transfers of value will be included on the public Web site - all "in a format that is searchable, downloadable, understandable and able to be aggregated." [15] Such information includes:

- Applicable manufacturer's name;
- Covered recipient's name, specialty (for a physician only), and business address;
- Amount of payment or other transfer of value;
- Date of payment;
- Form of payment or other transfer of value;
- Nature of payment or other transfer of value;
- Name of the covered drug, device, biological, or medical supply, when applicable; and
- If the covered recipient has not received the payment directly, the name of the entity that has received the payment or other transfer of value.

With regard to physician ownership and investment interests, the following would be included on a public Web site that again must adhere to a format that is searchable, downloadable, understandable, and able to be aggregated:

- Whether the ownership or investment interest is held by the physician or an immediate family member of the physician;
- Dollar amount invested;
- Value in terms of each ownership or investment interest; and
- Any payment or other transfer of value provided to the physician owner, including the amount of payment or other transfer of value, date of payment or other transfer of value, form, nature of payment or other transfer of value, and the name of the covered drug, device, biological, or medical supply.

CMS has proposed that its publicly available Web site will include information on any enforcement activities under the Sunshine Act concerning the applicable manufacturer or covered recipient. CMS has asked for additional comment regarding the format for how this information should be displayed to the public.

Delayed Publication for Payments Made Pursuant to Product Research or Development Agreements in Clinical Investigations
CMS has noted that the Sunshine Act provides for delayed publication of payments or other transfers of value made pursuant to ongoing product research or development agreements or clinical investigations. [16] Delayed information about payments or other transfers of value must be made publicly available after the earlier of either (1) the approval or licensure of a covered drug or device, or (2) four calendar years after the date of initial payment. CMS has proposed that applicable manufacturers should indicate on their submitted reports whether a payment or other transfer of value should be granted a delay in publication. CMS also has proposed that following FDA approval or licensure, applicable manufacturers must indicate in their next annual submission that the payment should no longer be granted a delay and should be published. CMS has stated that payments or other transfers of value granted delayed publication are limited to relationships for bona fide research or investigation activities, which, if made public, would damage the manufacturer's competitive interests. [17] In order

[13] 42 U.S.C. §1320a-7h(c)(1)(c).
[14] Ibid.
[15] 76 Fed. Reg. 78755.
[16] 76 Fed. Reg. 78756.
[17] 76 Fed. Reg. 78756.

to ensure that any delay of publication is for bona fide research, CMS has proposed that it be sent a written statement or contract as well as a written research protocol.

Process for Covered Recipients and Applicable Manufacturers to Review Information and Correct Errors Prior to Public Posting

CMS has proposed a process by which both applicable manufacturers and covered recipients will have the opportunity to review and submit corrections to the information submitted by applicable manufacturers. The period for review will be 45 days. CMS plans to notify those applicable manufacturers, GPOs, and covered recipients when the reported information is ready for review, at which point entities may log into a secure Web site where they will be able to view the information reported. Upon review, and if the information is accurate, the applicable manufacturer then will electronically certify that the information reported is accurate. If there is any dispute after a covered recipient has reviewed the information, CMS will provide the point-of-contact information for the applicable manufacturer or GPO. The covered recipient or a physician owner/investor must on its own directly contact the applicable manufacturer to attempt to resolve any dispute concerning the reported payment or data provided to CMS. If the dispute is not resolved by the end of the 45-day review period, CMS then will publicly report the data provided by the applicable manufacturer as well as any information received from the covered recipient. [18] It is clear, therefore, that physicians and teaching hospitals will need to be active participants in the reporting process.

CONCLUSION

Section 6002 (42 U.S.C. 1320a-7h) of the ACA requires applicable manufacturers to report on an annual basis to CMS certain payments or transfers of value provided to physicians or teaching hospitals. The proposed rules require active participation not only of applicable manufacturers, but of physicians and teaching hospitals. Indeed, CMS has estimated that approximately 1,150 applicable manufacturers and 420 applicable GPOs will submit reports. In addition, CMS has calculated that roughly 1,100 teaching hospitals and 700,000 physicians will meet the definition of covered recipient and will need to review the data submitted during the 45-day review period. Whether this effort at transparency will assist in the dissolution of payments made for nefarious reasons and reward genuine collaborative relationships remains unanswered.

If you or your organization would like to offer comments to CMS regarding the proposed rules on "transparency reports," please contact the author.

[18] 76 Fed. Reg. 78770; Proposed Section 403.908(g).

If you have any additional questions regarding this Update or have any other Health Care Law needs, please contact any member of the Health Care Law Group.

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