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## What Hospitals and Physicians Should Know About CMS's Proposed Regulations for Disclosure and Reporting Requirements of Manufacturers and GPOs

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### Introduction

A new law enacted under the Patient Protection and Affordable Care Act of 2010 (“PPACA”),<sup>1</sup> requires manufacturers and group purchasing organizations (“GPOs”) to report and disclose payments made to teaching hospitals and physicians as well as ownership interests held in such entities by physicians or their immediate family members (the “Sunshine Act”).<sup>2</sup> This alert addresses certain aspects of the proposed rule issued by Center for Medicare and Medicaid Services (“CMS”) on December 19, 2011. CMS requests comments to be submitted by February 17, 2012.<sup>3</sup>

The Sunshine Act will have implications not only for the reporting entities, but also for the teaching hospitals and physicians who receive the payments (directly or indirectly) and for physicians and immediate family members (“IFMs”) who invest in or own interests in reporting entities. Even hospitals that are not teaching hospitals under the Sunshine Act will also potentially be impacted by the new law. For example, hospital employed physicians or department chairs may be listed on the CMS public website as receiving payments, consulting fees, royalties or other benefits from a reporting entity that were known or unknown to the hospital. Physicians will also want to know what information manufacturers and GPOs are publicly reporting about them under this new law and if and how they may correct any reported information.

While the Sunshine Act requires that the first disclosure be made on **March 31, 2013** in regard to the preceding **calendar year 2012**,<sup>4</sup> due to CMS’s delay in publishing regulations, CMS proposes to finalize the regulations during the early part of calendar year 2012 and only require information from the remaining part of 2012 to be reported by the March 31, 2013 submission date.<sup>5</sup>

<sup>1</sup> On March 23, 2010, President Obama signed into law the comprehensive health care overhaul known as the PPACA,” Pub. Law 111-148, as amended by the reconciliation bill (H.R. 4872) signed on March 30, 2010.

<sup>2</sup> The Sunshine Act is entitled the “Transparency Reports and Reporting of Physician Ownership or Investment Interests” and is found at Section 6002 of the PPACA. On May 17, 2010, K&L Gates LLP issued a client alert on the Sunshine Law under the PPACA. This alert can be located at: <http://www.klgates.com/health-care-reform-client-alert-series-new-disclosure-and-reporting-requirements-related-to-manufacturers-and-gpos-payments-to-teaching-hospitals-and-physicians-05-17-2010>.

<sup>3</sup> 42 CFR 78742 (December 19, 2011).

<sup>4</sup> See PPACA § 6002(a)(1).

<sup>5</sup> See 42 CFR at 78743.

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### Payments and Other Transfers of Value to Covered Recipients

The Sunshine Act requires applicable manufacturers to disclose payments and other transfers of value to teaching hospitals and physicians (other than a physician who is an employee of the manufacturer) (“covered recipients”).<sup>6</sup>

**Covered Recipients.** While the Sunshine Act defines “physician” and “employee,” there is no definition for “teaching hospitals.” CMS proposes to define a “teaching hospital” as any institution that received payments under any of the following statutory programs during the last calendar year for which such information is available: (1) IPPS Indirect Medical Education (§1886(d)(5)(B) of the Social Security Act); (2) Direct Graduate Medical Education (§1886(h) of the Social Security Act); or (3) Psychiatric Hospitals Indirect Medical Education (§1886(s) of the Social Security Act).<sup>7</sup> CMS proposes to publish a list of hospitals on an annual basis that receive medical education payments on its website.<sup>8</sup> Not surprisingly, CMS did not restrict teaching hospitals to academic medical centers.

**Form and Nature of Payments.** Both the *form of each payment* and the *nature of each payment* to a covered recipient must be reported. CMS provides some examples and further guidance on the reporting obligations.

**Food and Beverage.** For meals provided in group settings (e.g., a buffet), CMS proposes reporting the cost per covered recipient even if a particular individual did not consume the food. Hospitals and physician practices may want to put policies in place prohibiting sales representatives from providing any free items, such as food, in order to avoid having a physician’s name publically listed as a recipient of such items.

**Bona Fide Research.** For bona fide research activities, including clinical investigations, the reporting entities will need to report not only direct payments to covered recipients, but also indirect payments. For example, a “direct research” payment is provided directly to a physician or teaching hospital by an applicable manufacturer or a contract research organization (“CRO”)<sup>9</sup> or similar entity (e.g., site management organization).<sup>10</sup> An “indirect research payment” is one made by an applicable manufacturer or CRO (or similar entity) to a clinic, non-teaching hospital, or other research institution where such organization then pays the physician covered recipients serving as principal investigators.<sup>11</sup>

The research payments will be reported individually under the names of the physician covered recipients who served as the principal investigators, but must also include the name of the entity or individual that received the payment – for example, the non-teaching hospital. CMS proposes that for both direct and indirect payments, the total payment amount for the clinical research must be reported.<sup>12</sup>

**Exclusions from Payments or other Transfers of Value.** The Sunshine Act specifically excludes certain types of payments or other transfers of value from its reporting obligations.<sup>13</sup> CMS provides

<sup>6</sup> See PPACA § 6002(a)(1).

<sup>7</sup> See 42 CFR at 78745-78746.

<sup>8</sup> See 42 CFR at 78746.

<sup>9</sup> CRO as defined by 21 CFR 312.3(b).

<sup>10</sup> See 42 CFR at 78749.

<sup>11</sup> See *id.*

<sup>12</sup> See *id.*

<sup>13</sup> See PPACA § 6002(e)(10)(B).

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some guidance on certain categories of excluded items. For example, the Sunshine Act exempts from the reporting requirements payments or other transfers of value less than \$10, except if the total payments provided to a covered recipient during the year exceed \$100.<sup>14</sup> However, once the \$100 limit is passed, all payments must be reported (even those of less than \$10), necessitating extensive record keeping of all transfers of value.

### Ownership or Investment Interests

The Sunshine Act requires both manufacturers and GPOs to disclose ownership or investment interests held by physicians or their IFMs and any payments or other transfers of value to an owner/investor physician.<sup>15</sup>

In the proposed regulations, CMS adopts a broad view of what classifies an entity to be a GPO, including, not only traditional GPOs that negotiate contracts for their members but also entities that purchase any “covered drugs, devices, biologicals or medical supplies” (a “covered item”) for resale or distribution.<sup>16</sup> Fortunately, CMS proposes not to include in the definition of GPO an entity that buys covered items *solely for its own use*, for example, large practices or hospitals that purchase such covered items for their own use.<sup>17</sup> However, as proposed, it is not clear how CMS would treat health systems where all group purchasing is centralized at the parent/holding company level and then distributed to affiliated hospitals that are related but separate legal entities. Notably, CMS also indicates that it views *physician-owned distributors* (PODs) of covered items to be within the definition of GPO.<sup>18</sup>

Under the Sunshine Act, a covered item includes any drug, device, biological, or medical supply for which payment is available under Medicare, Medicaid or Children’s Health Insurance Program state plans (or waivers of such plans).<sup>19</sup> CMS is proposing to limit covered drugs or biologicals to those that require a prescription (eliminating “over-the-counter” items.) CMS is also proposing to limit covered devices (including medical supplies) to those that require premarket approval by or notification to the Federal Drug Administration (“FDA”).<sup>20</sup> However, CMS believes that the proposal to limit the definition of devices and medical supplies may be too narrow for GPOs given their business operations and is seeking comments on this limitation.<sup>21</sup>

### Report Submission and Correction

Pursuant to the Sunshine Act, reporting entities and covered recipient/owners will have 45 days to review the information submitted to CMS by manufacturers and GPOs. Under the proposed rule, CMS will permit covered recipients/owners to register with CMS in order to get notification of when the information is ready for review. If a dispute between the reporting entity and the covered recipient

<sup>14</sup> See PPACA § 6002(e)(10)(B)(i).

<sup>15</sup> See PPACA § 6002(a)(2).

<sup>16</sup> See 42 CFR at 78751-78752.

<sup>17</sup> See 42 CFR at 78752.

<sup>18</sup> See *id.*

<sup>19</sup> CMS is proposing that even in cases where the payment under a federal program is indirect, if it is being provided through a bundled or composite rate payment, it will be considered payment that is “available” under those programs (e.g., inpatient PPS, outpatient PPS, or ESRD PPS). See 42 CFR at 78744-78745.

<sup>20</sup> CMS notes that this will result in excluding many Class I devices and certain Class II devices which are exempt from premarket notification requirements (21 U.S.C. §360(l) or (m)). For example, CMS notes that tongue depressors and elastic bandages would be excluded. See 42 CFR at 78745.

<sup>21</sup> See 42 CFR at 78752.

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or owner/investor as to the reported information is not resolved by the parties at the end of the 45 day period, any entity involved may report the dispute and CMS will identify the information as “contested” and report both the original submission and any modified information. CMS is soliciting comments on how to notify covered recipients and physician owners/investors and how to publish contested data. After the expiration of the 45 day review period, CMS states that any errors or omissions must be reported immediately. CMS will publish the information for 2012 by September 30, 2013. For each year thereafter, CMS will publish the data for the preceding calendar year by June 30th.<sup>22</sup>

### Penalties

The Sunshine Act imposes civil money penalties (“CMPs”) for violations by applicable manufacturers or applicable GPOs. Failures to submit information in a timely, accurate and complete manner are subject to a CMP of at least \$1,000, but not more than \$10,000 for each payment/ownership or investment interest not reported in accordance with the Sunshine Act. The maximum CMP with respect to each annual submission is \$150,000. A “knowing” failure will be subject to a CMP of at least \$10,000, but no more than \$100,000 for each payment/ownership or investment interest not reported in accordance with the Sunshine Act. CMS proposes that a reporting entity will have the requisite knowledge/awareness if it has “actual knowledge, or acts in deliberate ignorance or reckless disregard of, the identity of the covered recipient.”<sup>23</sup> This standard mirrors the “knowledge” standard under the False Claims Act and other health care fraud and abuse laws. CMS also proposes to impute onto reporting entities any awareness of its agents.<sup>24</sup> The maximum CMP with respect to each annual submission for a knowing failure is \$1,000,000.<sup>25</sup>

Given the penalties associated with failure to comply with the Sunshine Act, manufacturers and GPOs will likely have a strong incentive to be overly inclusive on the information they are reporting, meaning teaching hospitals and physicians will want to be particularly vigilant in reviewing reported data.

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<sup>22</sup> See 42 CFR at 78753-78755.

<sup>23</sup> 42 CFR at 78751.

<sup>24</sup> See *id.*

<sup>25</sup> See 42 CFR 78757-78758; 78771.

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