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## Sunshine Act Begins to See Light of Day: CMS Issues Proposed Rule Implementing Physician-Payment Reporting Requirements

On December 14, 2011, the Centers for Medicare and Medicaid Services (CMS) released its long-awaited proposed rule to implement Section 6002 of the Affordable Care Act (ACA), commonly known as the Physician Payment Sunshine Act (Sunshine Act). While Section 6002 required the Secretary of Health and Human Services (Secretary) to publish regulatory guidance no later than October 1, 2011, CMS was unable to meet this deadline.<sup>1</sup> Congressional leaders recently increased pressure on CMS to release a proposed rule, and — just one day before a scheduled Senate Special Committee on Aging hearing on the Sunshine Act’s delayed implementation<sup>2</sup> — CMS obliged.

### Top Line Summary

- CMS proposes delaying the implementation of data collection requirements beyond the Sunshine Act’s mandated January 1, 2012 starting date, raising questions as to whether manufacturers and GPOs must collect information before the final regulations are issued.
- CMS would limit the scope of the rule by adopting, without expansion, key statutory definitions relating to categories and forms of reportable information.
- CMS proposes to allow physicians and teaching hospitals 45 days to confer with manufacturers and GPOs in order to resolve disputes over inaccurate or incorrect payment information. Failure to resolve a conflict will result in the publication of two competing accounts.
- CMS is accepting comments on the proposed rule until February 17, 2012, and intends to publish a final rule in 2012.

### Background of Federal Physician Payment Sunshine Act

The Sunshine Act requires the public reporting of payments, or other transfers of value, made to physicians and teaching hospitals by group purchasing organizations (GPOs) and manufacturers of covered drugs, devices, biologicals and medical supplies. CMS has said that “disclosure of [physician-industry] relationships will discourage the

<sup>1</sup> In March of this year, the Secretary gave CMS the lead on implementing the Sunshine Act. CMS then held a timely and well-attended Special Open Door Forum to solicit input from stakeholders. For more information on the implementation process, please see “Recent Developments in Implementation of Physician-Payment Sunshine Law,” Skadden, Arps, Slate, Meagher & Flom LLP, April 6, 2011 <http://www.skadden.com/Index.cfm?contentID=51&itemID=2390>

<sup>2</sup> “Parting the Clouds: Implementing the Physician Payments Sunshine Act,” U.S. Senate Special Committee on Aging, December 15, 2011, scheduled hearing, [http://aging.senate.gov/hearing\\_detail.cfm?id=335152&](http://aging.senate.gov/hearing_detail.cfm?id=335152&)

inappropriate influence on clinical decision-making that sometimes occurs while still allowing legitimate partnerships.”<sup>3</sup> The federal initiative differs from similar state-enacted sunshine laws in that it expands both the categories of information on which reporting is required and the forms of transfers of value subject to scrutiny. Failure to comply with the Sunshine Act’s requirements may result in aggregate civil monetary penalties of up to \$1,150,000 annually.

Although the Sunshine Act gave the Secretary discretionary authority to expand the categories and forms of transfers of value as to which reporting is required, CMS’s proposed rule largely adopts the statutory terms without expansion. Discussed below are certain notable aspects of the proposed rule.

### **CMS’s Proposed Delay Raises Questions Regarding Implementation Timeline**

In the preamble to its proposed rule, CMS states that due to the delay in publishing the proposed regulations “a final rule will not be published in time for manufacturers and GPOs to begin collecting the information required [by the Sunshine Act] on January 1, 2012, as indicated in the statute.” Accordingly, CMS proposes to relax the January 2012 start date by not requiring manufacturers and GPOs to collect payment data until after it publishes the final rule. While CMS’s statement appears to give manufacturers and GPOs welcome respite from Sunshine Act implementation, its effect is somewhat unclear, as the obligation to begin collecting data on January 1, 2012 is set forth in the statute itself.<sup>4</sup> As such, two questions exist for manufacturers and GPOs: (1) when should they begin to collect data, and (2) what impact does CMS’s proposed delay have on the Sunshine Act’s date-triggered preemption of state-disclosure laws?<sup>5</sup>

It is unlikely that either the Secretary or CMS will address these uncertainties before January 1, 2012. While manufacturers and GPOs ultimately may not be required to submit information gathered in the period between January 1, 2012 and CMS’s publication of final regulations, starting Sunshine compliance now could impart multiple benefits on entities that choose to do so. Manufacturers and GPOs, for example, can use the interim period to stress test new Sunshine Act policies, procedures and protocols. Perhaps more importantly, the timely collection of relevant data would provide fail-safe cover in the event CMS is challenged as exceeding its implementation authority. Manufacturers and GPOs not currently in a position to begin collecting payment data should endeavor to get necessary systems up and running before the final rule’s publication so that they too can take advantage of the apparent lead time granted by CMS.

CMS’s proposed delay of the Sunshine Act’s data collection requirements also creates ambiguity for manufacturers currently obligated under state or municipal law to report payments made to physicians and hospitals. Pursuant to the text of Section 6002, except in a few narrow circumstances, as of January 1, 2012, state and municipal payment-reporting laws are preempted by the Sunshine Act, and disclosures of payments made after this trigger date are to be made exclusively to the Secretary. In crafting the Sunshine Act’s state-law preemption provision, Congress presumably anticipated that

3 “Affordable Care Act Sunshine Rule Increases Transparency in Health Care,” CMS Press Release, December 14, 2011, [https://www.cms.gov/apps/media/press\\_releases.asp](https://www.cms.gov/apps/media/press_releases.asp)

4 Section 6002 of the ACA amended Social Security Act § 1128G to include the following: “On March 31, 2013, and on the 90<sup>th</sup> day of each calendar year beginning thereafter, any applicable manufacturer that provides a payment or other transfer of value to a covered recipient ... shall submit to the Secretary, in such electronic form as the Secretary shall require, the following information with respect to the preceding calendar year ...”

5 See ACA § 6002, “Relation to State Laws – In General: In the case of a payment or other transfer provided by an applicable manufacturer that is received by a covered recipient [] on or after January 1, 2012, [] the provisions of [the Sunshine Act] shall preempt any statute or regulation of a State or political subdivision of a State that requires an applicable manufacturer (as so defined) to disclosure or report, in any format, the type of information regarding such payment or other transfer of value.”

the federal law seamlessly would replace other provider payment-disclosure laws. In light of CMS's proposed delay, however, state disclosure laws are statutorily preempted as of January 1, 2012, while federal disclosure laws are unlikely to be in place until the latter half of 2012. It is unclear how the Secretary, CMS or the states will address this apparent gap period, but manufacturers should consider complying with state disclosure laws during periods not actively governed by the Sunshine Act's implementing regulations.

### Key Definitions Remain Unchanged

At its March 24, 2011 Special Open Door Forum, CMS elicited industry-stakeholder feedback on how to exercise its statutorily-vested authority to identify additional categories of required payment-related information. In response, manufacturers, GPOs and trade associations uniformly asked CMS to refrain from expanding the Sunshine Act's reach and instead focus on providing clear, insightful guidance on the statute's existing terms and provisions. CMS appears to have heard industry's pleas.

In particular, CMS's proposed rule adopts without modification the transfers of value categories identified in the Sunshine Act.<sup>6</sup> The proposed regulations also do not expand the statute's enumerated reportable "forms of payment" — requiring manufacturers and GPOs to classify payments or transfers of value as: (i) cash or cash equivalents, (ii) in-kind items or services or (iii) stock, a stock option, or any other ownership interest, dividend, profit or other return on investment — and assigns these terms their "dictionary definition."

Manufacturers and GPO stakeholders also requested that CMS provide guidance on how to account for payments that may fit more than "nature of payment" classification. CMS responded to that request by stating that: "If a payment or other transfer of value could reasonably be considered as falling within more than one category, the applicable manufacturers should select one category it deems to most accurately describe the nature of the payment."

### Payment-Data Dispute Resolution

CMS's proposed rule also implements the Sunshine Act's requirement that manufacturers, GPOs, physicians and teaching hospitals be given an opportunity to review and submit corrections to information submitted to the Secretary before it becomes public, by adopting the statutory minimum review period of 45 days. Under the proposed regulations, this period begins to run on the date of CMS's notification to the relevant entity that information is ready for review. CMS will make reported data available for review via a secure website where notified entities can review information reported specific to them. If the information is accurate, the manufacturer, GPO, physician or teaching hospital may electronically certify the data. If, however, the accuracy of reported data is disputed, CMS will, at a physician's or teaching hospital's request, furnish point of contact information for the reporting manufacturer or GPO. CMS's proposed rule requires the involved parties to resolve the dispute within the 45-day window and, upon resolution, notify CMS of the agreed-upon outcome. Where consensus is not reached and reported within the 45-day period, CMS publicly will report both the manufacturer's or GPO's version of the payment, as well as the physician's or teaching hospital's version of the payment.

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<sup>6</sup> The Sunshine Act identifies: "(I) consulting fees; (II) compensation for services other than consulting; (III) honoraria; (IV) gift; (V) entertainment; (VI) food; (VII) travel (including specified destinations); (VIII) education; (IX) research; (X) charitable contribution; (XI) royalty or license; (XII) current or prospective ownership or investment interest; (XIII) direct compensation for service as faculty or as a speaker for a medical education program; (XIV) grant; or (XV) any other nature of payment or other transfer of value as defined by the Secretary." ACA § 6002.

While many companies have expended significant resources on Sunshine Act compliance, and may feel as if they can see the proverbial light at the end of the tunnel, reporting necessary data should be just the beginning of a company's efforts. Prudent companies will use physician payment data as an essential component of their affirmative compliance monitoring programs, looking for compliance with internal and external rules, identifying potential compliance anomalies, and ensuring that physician-manufacturer relationships are lawful and appropriate. Financial relations with physicians continues to be a major risk area for pharmaceutical and medical device makers, and careful attention and analysis of payment data can substantially reduce a company's risk in this area.