



## Parting the Clouds - Some Thoughts on Why CMS Has Not Imposed Civil Monetary Penalties for Sunshine Act Violations

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*Although the Sunshine Act allows for the imposition of Civil Monetary Penalties, CMS has yet to bring a single action. This article reviews the rocky implementation of the Sunshine Act and explores possible reasons for the lack of enforcement actions.*

We are over two years into Sunshine Act (a/k/a “Open Payments”)<sup>2</sup> reporting and have not seen the Centers for Medicare and Medicaid Services (“CMS”), which administers the Sunshine Act, begin a single enforcement action. This is a bit surprising, given the fanfare surrounding the Sunshine Act’s inauguration, the ease with which penalties might be assessed, and the directive to fund CMS’s Sunshine Act program with penalties.<sup>3</sup> We can shed some light on this issue by looking at CMS’s rocky implementation of the Sunshine Act and its framework for resolving disputes over data accuracy.

### The Sunshine Act

The Sunshine Act establishes reporting requirements for two groups: applicable group purchasing orga-

nizations (“AGPOs”) and applicable manufacturers (“AMs”).<sup>4</sup>

AGPOs are domestically operated organizations that purchase, negotiate purchasing, or arrange for the purchasing of drugs, devices, biological or medical supplies available for reimbursement under Medicaid, Medicare or the Children’s Health Insurance Program.<sup>5</sup> Under the Sunshine Act, an AGPO must annually report to CMS ownership or investment interests a U.S.-licensed physician or that physician’s immediate family held in the AGPO during the previous year.<sup>6</sup>

AMs are domestically operated manufacturers of drugs, devices, biological or medical supplies available for reimbursement under Medicaid, Medicare or the Children’s Health Insurance Program.<sup>7</sup> They too must annually report to CMS ownership or investment interests a U.S.-licensed physician or that physician’s immediate family held in them during the previous year.<sup>8</sup> An AM must also report payments or other transfers of value it made indirectly or directly to a “covered recipient,” which is a U.S.-licensed physician or teaching hospital.<sup>9</sup>

### Why We Have Not Seen Enforcement Actions So Far

The Sunshine Act’s implementing regulation gives CMS some easily administered enforcement tools: broad audit authority and the ability to impose CMPs without showing a knowing violation of the law. Such broad authority could easily have translated into enforcement actions. Why have there been none?

## Sunshine Act Enforcement Tools

The Sunshine Act's implementation regulation grants CMS, the Department of Health and Human Services ("HHS"), HHS's Office of Inspector General ("OIG"), and those agencies' designees authority to audit AMs and AGPOs for Sunshine Act compliance at any time. To facilitate those audits and any ensuing enforcement, the Sunshine Act regulation requires AMs and AGPOs to maintain for five years "all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, and inspection of the [AM's] or [AGPO's] compliance" with the Sunshine Act.

CMS's enforcement arsenal also includes the authority to impose Civil Monetary Penalties ("CMPs") for failing to report data or reporting data late or inaccurately. The CMPs can range between \$1,000 and \$10,000 for each payment, transfer of value, or ownership or investment interest not reported timely, accurately, and completely, with an annual maximum of \$150,000. For each transaction an AM or AGPO knowingly reports late or inaccurately or knowingly does not report, the CMP range increases to between \$10,000 and \$100,000, subject to an annual cap of \$1,000,000. CMS may aggregate both sets of CMPs for a maximum yearly total of \$1,150,000

Early enforcement actions would have stymied CMS's efforts to create a regulatory scheme where AMs, AGPOs, and covered recipients resolve disputes between themselves. After each reporting period closes, covered recipients have 45 days to review information AMs and AGPOs reported about them and dispute what they believe is inaccurate.<sup>10</sup> AMs

and AGPOs have at least 15 days to investigate and adjudicate the disputes.<sup>11</sup> This 60-day window enables AMs, AGPOs, and covered recipients to communicate with each other about possible errors that typically can be worked out between the parties. Indeed, successful resolution of these disputes happens only with open lines of communication.

Beginning enforcement actions before AMs and AGPOs became comfortable using the dispute resolution process may have caused those companies to worry that accepting disputes would trigger investigations. Consequently, AMs and AGPOs may have become reticent to accept disputes. If AMs and AGPOs refused to work with covered recipients to resolve disputes, publicly available Sunshine Act data could have been riddled with so many disputes that the data would not been useful. Unusable data would have conflicted with CMS's mandate under the Sunshine Act: providing meaningful transparency into relationships between AMs, AGPOs, and covered recipients. As the administrator of the Sunshine Act, CMS may have been asked to take up the mantle of mediator. To do so would require an immense amount of staff and resources. It also would have put CMS exactly where it has said it does not want to be:

We maintain that we should not be actively engaged in mediating dispute resolutions. The relationship exists between the applicable manufacturer or applicable GPO, and the covered recipient or physician owner or investor, so these parties should be involved in the resolution of the dispute, not CMS. We believe that we are not the appropriate party to mediate the disputes.<sup>12</sup>

Refraining from enforcement activity during the first two Sunshine Act reporting cycles promoted cooperation among AGPOs, AMs, and covered recipients; in turn, CMS could claim that the data it published is more reliable.

Also, CMS's implementation of Sunshine Act reporting was not smooth. Data submission and

validation requirements were difficult, leading AMs and AGPOs to spend hours with CMS's technology support. Many AMs had great difficulty submitting and validating data.<sup>13</sup> (Those challenges led to CMS repeatedly extending the deadline for AMs and AGPOs to submit data.<sup>14</sup>) A program error concerning physician identification also led CMS to publish in full only a fraction of the records; approximately 40 percent were "deidentified," meaning that they did not identify who received the payment or other transfer of value.<sup>15</sup> Stakeholders across the board decried what they perceived to be a rush to meet a self-imposed and unnecessary deadline.<sup>16</sup> Those subject to an enforcement action may have pointed the finger back at CMS, arguing it would be unfair to subject them to penalties when CMS had such difficulty implementing Sunshine Act reporting. In so doing, they would have raised the profile of implementation challenges CMS may not have wanted brought any further into the light.

## What to Expect Next

We can expect CMS to begin enforcement actions soon. Sunshine Act reporting is no longer new: AMs, AGPOs, and covered recipients have two years of experience. Many successful dispute resolutions show that stakeholders are comfortable with the dispute resolution process, and resolutions will become easier with upcoming system enhancements.<sup>17</sup>

Furthermore, in its 2015 report to Congress on Sunshine Act reporting, CMS explained that it had already begun "an effort to increase submission compliance of specific entities that did not submit data."<sup>18</sup> Thus, AMs and AGPOs (which include physician-owned distributorships, another top target for government enforcement efforts) that have not reported Sunshine Act data can expect to be in CMS's enforcement crosshairs.

What can AMs and AGPOs do to get ready? We'll discuss that in next month's Life Science Compliance Update.

- 1 Mr. Moore's practice focuses on the pharmaceutical and medical device industries. A former state and federal prosecutor, he regularly counsels and represents clients regarding Sunshine Act, compliance, and healthcare fraud matters, such as those involving the Stark law, the Anti-Kickback Statute, and state and federal False Claims Acts. When providing these services, Mr. Moore draws on his experience being seconded to a multinational pharmaceutical company's legal department.
- 2 "The Sunshine Act" is an abbreviation of "Physician Payments Sunshine Act," this legislation's name when it was first introduced. Even though the legislation was later absorbed into and became section 6002 of the Patient Protection and Affordable Care Act, it continues to be commonly referred to as "the Sunshine Act." CMS uses "Open Payments," a name CMS created, to refer to its program implementing the Sunshine Act. Consistent with popular usage, this article uses "the Sunshine Act."
- 3 "Funds collected by the Secretary as a result of the imposition of a civil money penalty under this subsection shall be used to carry out this section." 42 U.S.C. § 1320a-7h(b)(3).
- 4 42 U.S.C. § 1320a-7h(a); 42 C.F.R. §§ 403.904, .906. These reporting requirements are subject to various exemptions in the Sunshine Act and its implementing regulation. See, e.g., 42 U.S.C. § 1320a-7h(e)(10)(B); 42 C.F.R. § 403.904(i).
- 5 42 U.S.C. § 1320a-7h(e)(1); 42 C.F.R. § 403.902.
- 6 42 U.S.C. § 1320a-7h(a)(2); 42 C.F.R. § 403.906.
- 7 42 U.S.C. § 1320a-7h(e)(2); 42 C.F.R. § 403.902.
- 8 42 U.S.C. § 1320a-7h(a)(2); 42 C.F.R. § 403.906.
- 9 42 U.S.C. § 1320a-7h(a)(1); 42 C.F.R. § 403.904(a).86  
42 C.F.R. § 403.908(g)(1)-(3).
- 10 42 C.F.R. § 403.908(g)(4).
- 11 78 Fed. Reg. at 9501.
- 12 Thomas Sullivan, Policy & Medicine, Physician Payments Sunshine Act: Issues To Watch For As You Submit Phase 2 Data, <http://www.policymed.com/2014/06/physician-payments-sunshine-act-issues-to-watch-for-as-you-submit-phase-2-data.html> (June 17, 2014); Thomas Sullivan, Policy & Medicine, Physician Payments Sunshine Act: With Just One Week Left for Data Submission, CMS Releases 27 New FAQs; Physician Access to Open Payments Begins "Mid-July," <http://www.policymed.com/2014/06/physician-payments-sunshine-act-with-just-one-week-left-for-data-submission-cms-releases-27-new-faqs.html> (June 23, 2014).
- 13 CMS, Data Submission and Attestation Period Close Soon (June 30, 2014), available at <http://policymed.typepad.com/files/cms-open-payments-email---penalty-delay.pdf>.

- 14 CMS, Press Release, CMS makes first wave of drug & device company payments to teaching hospitals and physicians public (Sept. 30, 2014), available at <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2014-Press-releases-items/2014-09-30.html>.
- 15 See, e.g., PhRMA, Letter to Shantanu Agrawal, M.D., June 13, 2014, available at [http://policymed.typepad.com/files/2014-6-13\\_letter-to-cms-re-phase-two\\_signed.pdf](http://policymed.typepad.com/files/2014-6-13_letter-to-cms-re-phase-two_signed.pdf).
- 16 Douglas Brown, Update on Open Payments (Oct. 29, 2015), available at [https://www.cms.gov/OpenPayments/Downloads/webinar-Data-Collection-Submittal-Changes-\[October-2015\].pdf](https://www.cms.gov/OpenPayments/Downloads/webinar-Data-Collection-Submittal-Changes-[October-2015].pdf).
- 17 CMS, Annual Report to Congress on the Open Payments Program for Fiscal Year 2014, at 18, available at <https://www.cms.gov/OpenPayments/Downloads/Open-Payments-April-2015-Report-to-Congress.pdf>.

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