

Medical Device Cases Show Increased Sunshine Act Scrutiny

By **Jaime Jones and Brenna Jenny** (June 11, 2021)

The U.S. Department of Justice recently announced its second False Claims Act settlement within the past half year resolving allegations that transfers of value not only violated the Anti-Kickback Statute, but also went unreported to the Centers for Medicare & Medicaid Services, in violation of the Sunshine Act.

Before this pair of settlements, neither the DOJ nor CMS had publicly announced any targeted efforts to enforce the Sunshine Act. Now, armed with new capabilities in data analytics, new leadership and a new mandate from Congress to root out Sunshine Act noncompliance, the DOJ and CMS have initiated a wave of enforcement in this space.

The Sunshine Act requires applicable manufacturers, among others, to submit annual reports to CMS disclosing payments and other transfers of value to covered recipients, which include certain types of health care providers and U.S. teaching hospitals.

CMS is authorized to impose civil monetary penalties, or CMPs, for inaccurate or late reporting, in an amount of up to \$117,664 for each transfer of value that an applicable manufacturer knowingly fails to report, up to a cap of \$1,176,638 per annual report.^[1] Lower CMPs are authorized for unknowing failures to report. The Sunshine Act defines "knowingly" through a cross-reference to the False Claims Act definition of the word.^[2]

CMPs under the Sunshine Act are "imposed and collected in the same manner" as the CMPs authorized by the Civil Monetary Penalties Law, which is enforced by the U.S. Department of Health and Human Services Office of Inspector General.^[3]

This process requires at least some level of coordination with the DOJ, because the secretary may initiate proceedings to impose CMPs "only as authorized by the Attorney General pursuant to procedures agreed upon by them."^[4]

When the government alleges that a manufacturer offered remuneration to a health care provider in violation of the AKS, the government may also be able to allege a corresponding violation of the Sunshine Act if the manufacturer has failed to report that transfer of value to CMS. As a result, the manufacturer is vulnerable to two forms of sanctions: an FCA action based on the alleged AKS violation and CMPs to address the Sunshine Act reporting violation.

Until recently, the DOJ had never incorporated Sunshine Act penalties into AKS cases, even where the allegations seemed to present a basis for supplemental CMPs. But within the past half year, the DOJ has done so twice.

First, in October 2020, the DOJ announced an FCA settlement with Medtronic PLC to resolve allegations that the company violated the AKS by paying for social events at a restaurant owned by a surgeon.^[5] For the first time, this FCA settlement also included a \$1.1 million CMP for a knowing failure to report those transfers of value to CMS in the company's annual Sunshine Act report.



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Last month, the DOJ announced a settlement resolving allegations that medical device company Medicrea International SA violated the AKS by paying for U.S.-based physicians to attend a single conference event in France.[6] In addition to the \$1 million Medicrea paid to resolve the AKS claims, Medicrea also paid an additional \$1 million CMP under the Sunshine Act.

Taken together, these cases highlight DOJ's increasing interest in pursuing AKS settlements — even on narrow, discrete violations involving a single physician or event — while also partnering with CMS to layer on supplemental Sunshine Act penalties at the upper range of permissible amounts for knowing failures to report.

This punitive approach to Sunshine Act reporting departs from CMS' historically collaborative and educational posture.

In the preamble to the agency's 2013 regulations implementing the Sunshine Act, CMS acknowledged that some commenters asked the agency to establish a process for sharing information reported under the Sunshine Act with DOJ and the HHS OIG.[7] CMS would not commit to doing so, explaining that "the purpose of this program is not to prosecute reporting entities, but to promote transparency."[8]

In March 2019, congressional leaders sent a letter to CMS demanding that "penalties for non-disclosure are implemented against bad actors who fail to report."^[9]

In a response two months later, CMS assured Capitol Hill that it had been "analyzing data trends that have emerged after multiple years of reporting."^[10] But rather than using these data analytics as a basis for enforcement actions, CMS reported that it had "conducted educational outreach and issued guidance" in response.^[11]

The DOJ appears to be working with CMS to implement an approach that now focuses less on education and more on penalties. Indeed, the DOJ's press release for the Medicrea settlement specifically characterized the resolution as responsive to the 2019 congressional request that CMS investigate Sunshine Act "non-compliance and pursue enforcement."^[12]

The DOJ may further influence Sunshine Act enforcement through the department's embrace of data analytics. At a qui tam conference earlier this year, the civil assistant chief for the Eastern District of Pennsylvania discussed how enforcement actions involving violations of the Sunshine Act are poised to increase, aided by data analytics.

Consistent with this warning, the Medicrea settlement was out of the Eastern District of Pennsylvania. These remarks are also in accord with other public acknowledgements by DOJ leadership that the department increasingly relies on sophisticated data analytics to identify targets for investigation.^[13]

CMS' Sunshine Act reporting data, when combined with broader Medicare billing data also owned by the agency, creates fertile ground for analysis by both the DOJ and CMS.

At the same time, new leadership at the U.S. Department of Health and Human Services gives reason to believe that HHS will become more interested in undertaking enforcement actions using its own authority, rather than relying on DOJ to vindicate its interests.

Recently confirmed HHS Secretary Xavier Becerra previously served as California's attorney general and in that role actively initiated health care enforcement actions. The health care

industry may soon witness not only more FCA settlements incorporating a Sunshine Act component, but also direct initiatives by CMS to root out noncompliance and impose CMPs.

CMS has the financial resources to expand this work. The Sunshine Act requires the Secretary to use funds collected through Sunshine Act CMPs to carry out the Sunshine Act reporting program.[14] With the CMPs collected in the Medtronic and Medicrea settlements, the agency now has \$2.1 million it can put toward new enforcement projects, and each new settlement can fund further activity.

To address this emerging area of government focus, companies should consider reviewing not only the accuracy of their Sunshine Act reports but also engaging in the type of data analytic work DOJ has acknowledged it is increasingly undertaking, and may already be engaging in, to identify potentially problematic relationships such as reported transfers of value that correlate with billing or prescribing patterns in CMS Medicare data.

While CMS may begin imposing CMPs separate and apart from FCA settlements, at least for now, the highest enforcement risk will be presented by cases that entail not just Sunshine Act reporting violations but also parallel AKS noncompliance.

Although CMS may be turning toward a more punitive approach to implementing the Sunshine Act, the agency still has a long history of collaboratively engaging with industry on reporting issues. Companies that identify historical errors in their reporting may wish to self-disclose to CMS and work on an administrative resolution.

As the Medtronic and Medicrea cases demonstrate, the government does not view mistakes that relate to a single event or health care provider as too small to pursue.

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[1] See 85 Fed. Reg. 2,869, 2,878–79 (Jan. 17, 2020).

[2] 42 U.S.C. §1320a-7h(e)(8).

[3] 42 U.S.C. §1320a-7h(b)(1)-(2).

[4] 42 U.S.C. §1320a-7a(c).

[5] Press Release, DOJ, Medtronic to Pay Over \$9.2 Million To Settle Allegations of Improper Payments to South Dakota Neurosurgeon (Oct. 29,

2020), <https://www.justice.gov/opa/pr/medtronic-pay-over-92-million-settle-allegations-improper-payments-south-dakota-neurosurgeon>.

[6] Press Release, DOJ, French Medical Device Manufacturer to Pay \$2 Million to Resolve Alleged Kickbacks to Physicians and Related Medicare Open Payments Program Violations [hereinafter Medicrea Press Release] (May 19, 2021), <https://www.justice.gov/usao-edpa/pr/french-medical-device-manufacturer-pay-2-million-resolve-alleged-kickbacks-physicians>.

[7] 78 Fed. Reg. 9,458, 9,508 (Feb. 8, 2013).

[8] Id.

[9] Letter from Senator Charles Grassley, Chairman of the Committee on Finance and Senator Ron Wyden, Ranking Member to Hon. Daniel Levinson and Hon. Seema Verma, available at [https://www.finance.senate.gov/imo/media/doc/2019-03-19%20CEG%20RW%20to%20HHS%20OIG%20and%20CMS%20\(Sunshine\).pdf](https://www.finance.senate.gov/imo/media/doc/2019-03-19%20CEG%20RW%20to%20HHS%20OIG%20and%20CMS%20(Sunshine).pdf).

[10] Letter from Administrator Seema Verma to Senator Charles Grassley, Chairman of the Committee on Finance (May 15, 2019), available at [https://www.finance.senate.gov/imo/media/doc/2019-05-15%20CMS%20to%20CEG%20\(Sunshine%20and%20PODs\).pdf](https://www.finance.senate.gov/imo/media/doc/2019-05-15%20CMS%20to%20CEG%20(Sunshine%20and%20PODs).pdf).

[11] Id.

[12] Medicrea Press Release, <https://www.justice.gov/usao-edpa/pr/french-medical-device-manufacturer-pay-2-million-resolve-alleged-kickbacks-physicians>.

[13] Press Release, DOJ, Acting Assistant Attorney General Brian M. Boynton Delivers Remarks at the Federal Bar Association Qui Tam Conference (Feb. 17, 2021), <https://www.justice.gov/opa/speech/acting-assistant-attorney-general-brian-m-boynton-delivers-remarks-federal-bar>.

[14] 42 U.S.C. §1320a-7h(b)(3); 42 C.F.R. §403.192(f).