

## The Sunshine Act and Health Care Transparency

In response to consumer complaints that industry compensation paid to physicians, estimated at \$20 to \$57 billion each year,<sup>1</sup> may influence their choice of prescription drugs or treatment plans, the Affordable Care Act of 2010 (ACA) requires healthcare industry payments made to physicians to be publicly disclosed under the Physicians Payments Sunshine Act,<sup>2</sup> which was finalized this month by the Centers for Medicare and Medicaid Services (CMS). While the intent of the Sunshine Act is to deter industry influence on medical treatment, some physicians are concerned that the provisions will unfairly taint legitimate work they do for the healthcare industry.<sup>3</sup>

CMS has stated that “...disclosure of [physician-industry] relationships will discourage the inappropriate influence on clinical decision-making that sometimes occurs while still allowing legitimate partnerships,”<sup>4</sup> e.g., clinical trial research. However, physicians acknowledge that even legitimate relationships are subject to undue influence as industry sway in medical research ultimately affects the practice of medicine based on research outcomes.<sup>5</sup> Many states have already responded to consumer concerns by requiring disclosures of gifts in hopes that physicians receiving benefits from the healthcare industry will not be incentivized to prescribe more expensive products.

The Sunshine Act requires manufacturers of drugs, devices, biological and medical supplies covered by Medicare, Medicaid, or the Children’s Health Insurance Program to report to CMS those payments or other “transfers of value” they make to physicians or teaching hospitals.<sup>6</sup> Transfers of value can include consulting fees, food, travel, education, research, or direct compensation for speaking at a medical continuing education (CME) program. The Sunshine Act also requires group purchasing organizations to disclose to CMS physician ownership or investment interests. These violations of the Sunshine Act will be subject to civil monetary penalties not to exceed \$150,000 annually for failure to report, and \$1,000,000 annually for knowingly failing to report.<sup>7</sup>

These provisions prompted more than 300 comments from stakeholders during the 2012 notice and comment period.<sup>8</sup> Of particular concern were mandatory disclosures of payments made, directly or indirectly, to physicians speaking at CME programs. However, the final provisions of the Sunshine Act do not mandate

company reporting for payments made to speakers at accredited CME events if the companies do not select the speakers, or if they do not pay them directly.<sup>9</sup> Also of concern were the lengthy delays in implementation, prompting several prominent academic physicians to appeal to the White House, urging prompt passage of the Sunshine Act.<sup>10</sup> The letter cited various research, including a recent survey published in the *Journal of the American Medical Association* suggesting that more than a third of physicians “sometimes or often” prescribe brand-name drugs in place of generics despite patient requests, and physicians are more likely to do so if they receive food, beverages or drug samples from pharmaceutical manufacturers.<sup>11</sup>

The Sunshine Act becomes effective 60 days after the February 8, 2013 publication of the Final Rule. Applicable manufacturers and group purchasing organizations must collect data, beginning on August 1, 2013, and report the requisite payment to CMS by March 31, 2014. With certain industry compensation information being made public, obtaining a certified opinion of value that the compensation paid to the physician for services actually rendered is at fair market value (FMV) and is commercially reasonable will likely become increasingly important going forward.

- 1 “Ain’t No Sunshine Yet for Docs,” Jenny Gold, Kaiser Health News, May 7, 2012, <http://capsules.kaiserhealthnews.org/index.php/2012/05/aint-no-sunshine-yet-for-docs/> (Accessed 2/19/2013).
- 2 “Patient Protection and Affordable Care Act” Pub. Law 111-148, 124 STAT 689 (March 23, 2010).
- 3 “New Health Law Will Require Industry to Disclose Payments to Physicians,” Arlene Weintraub, Kaiser Health News, April 26, 2012, <http://www.kaiserhealthnews.org/stories/2010/april/26/physician-payment-disclosures.aspx> (Accessed 2/19/2013).
- 4 “Affordable Care Act Sunshine Rule Increases Transparency in Health Care,” CMS Press Release, December 14, 2011, <https://www.cms.gov/apps/media/press/release.asp?Counter=4220&intNumPerPage=10&checkDate=&checkKey=2&srchType=2&numDays=0&srchOpt=0&srchData=transparency&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=1&pYear=1&year=2011&desc=&cboOrder=date> (Accessed 2/19/2013).
- 5 “What the Sunshine Act Means for Health Care Transparency,” Alice Dreger, The Atlantic, February 6, 2013, <http://www.theatlantic.com/health/archive/2013/02/what-the-sunshine-act-means-for-health-care-transparency/272926/> (Accessed 2/19/2013).
- 6 CMS, “Affordable Care Act Sunshine Rule Increases Transparency in Health Care,” December 14, 2011.
- 7 *Ibid.*

- 8 Gold, May 7, 2012.
- 9 “Medicare, Medicaid, Children’s Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests,” Centers for Medicare & Medicaid, Federal Register Vol. 78, No. 27, February 8, 2013, p. 9461.
- 10 Letter from Marcia Angell, Editor-in-Chief, New England Journal of Medicine to the White House, January 13, 2013, <http://freepdfhosting.com/fe8035359b.pdf> (Accessed 2/19/2013).
- 11 “Physician Acquiescence to Patient Demands for Brand-Name Drugs: Results of a National Survey for Physicians,” Journal of the American Medical Association Internal Medicine, Vol. 173, No. 3, p. 237-239, <http://archinte.jamanetwork.com/article.aspx?articleid=1555818> (Accessed 2/24/13)



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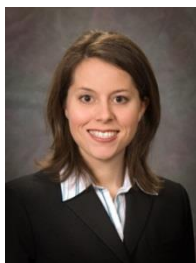
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