

# Understanding the Affordable Care Act Bit by Bit: Will Transparency and Sunshine Shrink Costs?



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As of August 1, 2013, the Sunshine Act mandates that any transaction between a physician (or teaching hospital) and the pharmaceutical or device industries more than \$10 in value must be publicly disclosed. Physician and industry leaders have sounded alarms about the impact of this extreme level of transparency; physicians are nervous, for they fear information published online will tarnish their reputations, and industry representatives are arguing that these financial arrangements with doctors have created “significant clinical innovations,”<sup>1</sup> so they should not be jeopardized. Furthermore, industry representatives say disclosures may result in the unfair revelation of trade secrets.<sup>2</sup>

Despite the level of surprise expressed on both sides of this initiative, the Sunshine Act is consistent with decades of documented scrutiny as well as concern about ties between the medical and manufacturing communities. Also — as is frequently true with the ACA — most physicians are not yet aware of the details of this component of the law.

## Historical context

Transparency has been an important concept in public and private affairs in this country since its inception, and it has evolved through the decades from the 1966 Freedom of Information Act<sup>3</sup> to the dominance of the Internet.

Similarly, the principle of transparency in medicine has a long history and predates the ACA. In 1974, the National Research Act<sup>4</sup> led to the development of Institutional Review Boards to oversee the conduct of human experimentation and research. The Omnibus Budget Reconciliation Act of 1989 (commonly known as “Stark”) is, at its core, a statutory requirement for transparency regarding a physician’s conflicts of interest.

In its pivotal, 2001 report entitled “Crossing the Quality Chasm,” the Institute of Medicine established 10 new rules to redesign and improve care, of which “the need for transparency” ranked seventh.<sup>5</sup>

The Patient Safety and Quality Improvement Act of 2005<sup>6</sup> sought to create a centralized data bank of medical errors and near misses for purposes of research, quality improvement and systems analysis. So examples of transparency requirements are numerous and span the history of American medicine.

As demonstrated by these examples, most transparency initiatives to date have sought to improve the quality of care that patients receive. There has always been a concern that a patient’s treatment should be exclusively controlled by their particular medical condition and never influenced by financial considerations (such as a physician’s ownership in a CT scan, as regulated by Stark), gifts or other monetary incentives (such as kickbacks from manufacturers, as prohibited under the anti-kickback statute<sup>7</sup>) or business decisions (such as a physician’s medical decision-making being subject to an employer’s bookkeeping at the expense of patient care, as precluded by the traditional corporate practice of medicine state laws). The argument for transparency leading to quality improvement is a strong one.

However, our focus here is on transparency as an avenue to decrease the cost of health care, because the prevailing belief is that the loyalty between and preferences among health care providers and suppliers, created through gifts and incentives, often come at the expense of higher medical treatment prices.

## Gifts and financial exchanges

Any discussion of physician/industry interactions must start with an acknowledgment that there are a wide range of potential dealings, ranging from the criminal to the worthy. Financial interactions between physicians and representatives from the pharmaceutical and medical device industries have always been scrutinized when they rise to the level of kickbacks.



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Health law is replete with cases of criminal liability for sham consulting contracts,<sup>8</sup> kickbacks for marketing publications masquerading as scientific research,<sup>9</sup> and prescription fraud.<sup>10</sup> On the other extreme, industry support of research into new drugs and treatment regimens — while not without some controversy<sup>11,12</sup> — can, as the IOM’s 2001 report wrote, “benefit society, most notably by promoting the discovery and development of new medications and medical devices that improve individual and public health.”<sup>13</sup>

The majority of relationships between physicians and the pharmaceutical and manufacturing industries lie in between these two extremes. Research conducted in 2004 found that 94 percent of physicians reported some type of relationship with pharmaceutical companies, with acceptance of free lunches for the office and/or drug samples being the most common form of gifts;

financial support for educational programs or professional meetings was also reported by 35 percent of physicians surveyed.<sup>14</sup>

Concern about the ubiquitous nature of industry involvement in the day-to-day operations of physician practices led a number of states to prohibit these activities or require any financial transfers to be reported publicly, with exceptions for nominal gifts defined by those state laws (ranging from \$25 to \$100).<sup>15</sup>

The ACA pre-empts these state laws so that entities that fall under the Sunshine Act will only have to comply with a single set of reporting requirements.<sup>16</sup>

Independent of state law, most academic institutions across the country have restricted gifts and other ties to industry, which is consistent with a 2008 report issued by the American Association of Medical Colleges (AAMC) calling on academia to “prohibit or severely

restrict physicians and trainees from accepting travel funds, free food, and other gifts and services from drug and medical device companies.”<sup>17</sup> The Accreditation Commission on Continuing Medical Education (ACCME)<sup>18</sup> and the Licensing Commission for Medical Education (LCME)<sup>19</sup> have similar restrictions.

In 2007, the IOM appointed the Committee on Conflict of Interest in Medical Research, Education, and Practice to examine conflicts of interest in medicine.<sup>13</sup> In the press release that followed, a committee representative stated, “It is time to end a number of long-accepted practices that create unacceptable conflicts of interest, threaten the integrity of the medical profession, and erode public trust while providing no meaningful benefits to patients or society.”<sup>20</sup>

The IOM addressed the issue again in 2009, recommending, “All medical institutions, including academic medical centers, professional

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societies, patient advocacy groups and medical journals, establish conflict-of-interest policies that require disclosure and management of individual and institutional financial ties to industry.”<sup>11</sup>

The industry responded to these public and professional anxieties about undue influence of financial interactions when the Pharmaceutical Research and Manufacturers of America (PhRMA) updated its “Code on Interactions with Healthcare Professionals” in 2008: Concerned that pharmaceutical companies’ interactions with health care professionals not be perceived as inappropriate by patients or the public at large... the code is based on the principle that a health care professional’s care of patients should be based, and should be perceived as being based, solely on each patient’s medical needs and the health care professional’s medical knowledge and experience.<sup>21</sup> The code established a voluntary reporting mechanism where PhRMA members could report transfers of value to physicians and medical institutions.

Despite all of these attempts to rein in potential conflicts of interest, or even the appearance of conflicts, money has continued to flow.<sup>11</sup> Pharmaceutical and device manufacturers are in the business of sales, and interpersonal involvement with doctors has proven to be very effective for the industry.<sup>11</sup>

The extent of these programs is evident through research conducted and published by ProPublica, the independent, nonprofit newsroom

that produces investigative journalism in the public interest.<sup>22</sup>

In 2010, ProPublica released details about physicians who were paid by pharmaceutical companies to speak, research, and promote their products.<sup>23</sup> Its web page titled, “Dollars for Docs — How Industry Dollars Reach Your Doctors,” is a searchable index of \$2.1 billion in disclosed payments voluntarily reported by 15 companies under the 2008 PhRMA Code.<sup>24</sup>

At the time of this writing, ProPublica features data obtained through a Freedom of Information Act request for records relating to Medicare Part D prescriptions, which demonstrates that “hundreds of physicians across the country were prescribing large numbers of dangerous, inappropriate or unnecessary drugs” allegedly because of industry influences.<sup>25</sup>

A survey published in the *Archives of Internal Medicine* in 2010 found, “Physicians with industry relationships said they were more likely to prescribe a brand-name drug when a generic was available.”<sup>26</sup>

As a corollary from the device manufacturing industry, makers of artificial hips and knees paid \$310 million to resolve allegations that they purchased surgeon loyalty through kickbacks including bogus consultation agreements in 2007,<sup>27</sup> and ties with the manufacturer of a bone graft product was found to have resulted in biased research that led to acceptance of a product that “provides no significant benefit over traditional bone grafting.”<sup>28</sup>

## Introducing the Sunshine Act

At least partly modeled on the recommendations of the Medicare Payment Advisory Commission (MedPAC), which voted in 2009 to recommend Congressional enactment of a new regulatory program, the first attempt to pass a federal law known as “The Sunshine Act” was sponsored twice by Sen. Chuck Grassley (R-IA) and Sen. Herb Kohl (D-WI) in 2007 and 2008.

As so frequently happened in the formation of the ACA, that unsuccessful legislative initiative was incorporated in the final 2009 law.<sup>29</sup> Initial regulations to fulfill the act were proposed in December 2011, and the final rule was released on February 1, 2013, more than a year after the deadline contained in the ACA.<sup>30</sup>

On one level, the Sunshine Act is similar to the Stark law, in that any ownership or investment interest a physician (or family member) has in an entity subject to the law must be disclosed, including stock, stock options, any other ownership interest, dividend, profit, or other return on investment, all of which will subsequently be reported under the act.

What distinguishes the Sunshine Act, however, is its reach down to the most mundane and small transactions that are endemic between the medical community and subject industries. At its most basic level, what the Sunshine Act requires is that manufacturers of drugs, devices, biologicals, or medical supplies and group purchasing organizations report to CMS any payment or gift of more than \$10 in value to a physician or teaching hospital. Consulting fees, honoraria, entertainment, travel, gifts, education, charitable contributions and money to support research will all be posted.

Patient education materials are not necessarily reportable, but they must directly impact the patient (e.g., wall charts or anatomical models) and

not the physician (e.g., text books, journals and continuing education expenses). Free lunches, one of the best-loved office treats, will now be disclosed if a physician partakes in the meal (and the value per head exceeds \$10).

The presence of the representative is not determinative; food that is dropped off or delivered by a third party must also be reported. Conferences, buffets, and exhibitor goodies all fall under the Sunshine Act. Drug samples, coupons and/or vouchers left by an industry representative in a physician's office may be exempt from reporting, as long as the representative and physician agree in writing that anything distributed will be provided exclusively to patients. Gifts with a value below \$10 do not need to be reported, but if the aggregate total annual value of these gifts exceeds \$100, they will also be subject to reporting.

The reporting requirement under the Sunshine Act falls on the pharmaceutical and device manufacturing industries, not on physicians. Recognizing the significant concern physicians will have over the accuracy of the data reported, however, the Act also provides physicians with a 45-day window to review the reports before they are filed with CMS.<sup>31,32</sup> In addition, summary materials and "Frequently Asked Questions" specific to physicians are available on the CMS website.<sup>33-35</sup>

Annual reporting begins on March 31, 2014, based on data captured after August 1, 2013. The result of the data collection and reporting will be the creation of a website from CMS (scheduled to go live fall 2014), on which any person or patient can search a data bank revealing any value a physician received from the industry.

To put this more plainly, if physicians sat on an exotic beach, attended a professional sporting event, or savored a fine cut of steak through an industry

representative, their patients will know.

The reporting requirements are detailed and specific, and failure to comply will result in penalties for the pharmaceutical or medical device manufacturer. The range of penalties start with failure to submit the required information on a timely basis in the amount of at least \$1,000, but no more than \$10,000, for each payment, other transfer of value, or ownership or investment interest not reported as required.

With respect to each annual submission, the maximum total penalty for failing to report is \$150,000. Penalties increase for deliberate violators, with a range of at least \$10,000, but no more than \$100,000, for each line item not reported as required. The maximum total penalty under the deliberate category is \$1,000,000. Moreover, the initial penalty for failure to report and the

additional penalty for deliberate violation are aggregated separately, so the total potential penalty against a pharmaceutical company or medical device manufacturer under the Sunshine Act for failing to report a single transfer of a gift to a physician could arguably reach a total of \$1,150,000.

## Impact of the Sunshine Act

Given the long history of concern about ties between physicians and the pharmaceutical and device manufacturing industries, it is interesting to note the level of reaction in these sectors to the finalization of the Sunshine Act.<sup>36</sup>

Recent layoffs of pharmaceutical representatives<sup>37</sup> suggest a change in the business model as much as declines in specific drug sales, and the industry on the whole is anticipating entirely new marketing structures.<sup>38</sup>

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For example, Pfizer and GlaxoSmithKline announced they would reduce budgets for physician meals and office visits to instead participate in pharmaceutical marketing and research efforts; office visits by sales representatives are also being reduced.<sup>39</sup>

On the other hand, the medical community's concern may be as much as anything a matter of misunderstanding. Fortunately, there are extensive, clearly understandable resources available for further physician education, including the final rule itself.<sup>40</sup> These resources, however, pay attention to myriad details of the Sunshine Act, when the confusion within the medical community lies more with the heart of the law itself.

Public knowledge is not punishment and disclosure is not prohibition. Will the public truly not understand the barbecue lunch to reward your hard-working office staff? Can patients see logos on posters and understand that the content itself is for their benefit? Can you look a skeptical patient in the eye and justify the industry's role in research in which you are participating? On the other hand, if disclosure of any activity makes you, the physician, wince, it is probably time to stop.

The dual nature of industry ties is recognized in the first pages of the final rule:

“We recognize that disclosure alone is not sufficient to differentiate beneficial financial relationships from those that create conflict of interests or are otherwise improper. Moreover, financial ties alone do not signify an inappropriate relationship. However, transparency will shed light on the nature and extent of relationships, and will hopefully discourage the development of inappropriate relationships and help prevent the increased and potentially unnecessary health care costs that can arise from such conflicts.”<sup>41</sup>

At the same time, the significance of the penalties for failure to report, if nothing else, demonstrates the government's intention to end covert activity and potential conflicts of interest between physicians and the pharmaceutical and device manufacturing industries once and for all.

It should come as no surprise to anyone that the federal government has issued legislation in response to decades of concern about ties among the medical, pharmaceutical, and device-manufacturing industries as well as to reinforce past public and private initiatives to remove conflicts of interest from patient care. Through transparency, any shadow — whether real or perceived — can be lifted from every physician's prescription patterns and device preferences.

The Sunshine Act is not new and it is not unexpected. It is only the final, pivotal call for transparency in behavior that has been decried for decades. It should not cause alarm — only change.



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