

# Extending the Sunshine Act From Physicians to Patient Advocacy Organizations



See also McCoy, p. 1026.

In the mythical past, health care was about patients and physicians. Then, insurers and pharmaceutical companies intruded. Patient advocates interceded. Legislators intervened. The health care system became crowded and complex.

We now find ourselves in a convoluted system in which pharmaceutical companies are financing the activities of patient advocacy organizations. In this issue of the *AJPH*, McCoy (p. 1026) contends that these permeating financial relationships are harmful, argues for transparency of these financial ties, and proposes a federal-level system of reporting payments that pharmaceutical companies make to patient advocacy organizations. His proposal would extend existing law,<sup>1</sup> known informally as the Physician Payments Sunshine Act, that requires pharmaceutical companies to report, for public disclosure, payments that they make to physicians. Open Payments, the administrative program that aggregates and publishes physician payment information, is now in its fifth year of operation.<sup>2</sup>

Broadening the Sunshine Act and Open Payments to include payments to patient advocacy organizations may seem like a natural extension. Industry payments to physicians and to patient advocacy organizations have the potential to distort decisions in apparently similar

ways, leading both parties to act in their own financial interest rather than in the interest of their patients and patient-constituents. To the extent that transparency is a way to address the payment-to-physicians problem, it may be a way to address the payment-to-patient-advocacy-organizations problem. Furthermore, the presence of existing law<sup>1</sup> and regulations<sup>3</sup> means that amendments would be relatively simple, and Open Payments infrastructure and personnel could be scaled up with few administrative obstacles.

Yet, expanding the scope of industry payment reporting to include patient advocacy organizations is not as straightforward as one might hope. McCoy makes a well-reasoned case for applying the Sunshine concept to patient advocacy organizations. But complex regulations can impede uncomplicated, sensible ideas. The Sunshine Act might be one of these impeding regulations if care is not taken.

## MEDICARE, MEDICAID, AND THE SUNSHINE ACT

In an ideal world, the Sunshine Act would have come about because of an enthusiastic legislative embrace of transparency. In the real world, the federal government compels

pharmaceutical companies to disclose payments to physicians because it is concerned about the drug costs borne by its Medicare and Medicaid programs. To explain: Medicare and Medicaid, as public insurance programs, pay for the prescription drug costs of their beneficiaries. Because these programs pay pharmaceutical manufacturers for prescription drugs, the Centers for Medicare and Medicaid Services (CMS) is acutely interested in, monitors, and regulates the activities of pharmaceutical firms that might affect CMS drug expenditures. Marketing and promotional efforts that lead to excessive and inappropriate drug prescribing—such as payments to physicians—is a concern for CMS, and it is the main reason that pharmaceutical companies are required by the Sunshine Act to disclose payments that they make to physicians. To summarize, the Sunshine Act's authority is (1) grounded in the fact that CMS reimburses pharmaceutical companies and (2) predicated on restraining pharmaceutical company behaviors that affect CMS's bottom line. This means that proposed expansions of the

Sunshine Act likely would have to be justified on the basis of their effect on CMS's drug expenditures. Although the original Sunshine provision makes no mention of Medicare or Medicaid, it is no accident that CMS—rather than some other federal agency under the US Department of Health and Human Services—administers the Open Payments program.

Thus, the challenge in incorporating patient advocacy organizations in the Sunshine Act is how to tie industry payments to these organizations to CMS's drug spending. Industry financing of patient advocacy organizations may have many deleterious effects, but the nature of the activities of patient advocacy groups means that industry payments to these groups have a distal tie to CMS's drug bill. For example, although patient advocacy organizations can promote the use of favored medications among their membership, patients must obtain a prescription through their physicians, so physicians are still the direct link to CMS drug spending. Industry-influenced patient advocacy organizations can lobby for the approval of drugs that do not meet the usual efficacy standards,<sup>4</sup> but drug approval falls within the domain of the US Food and Drug Administration rather than CMS, and here again, patients require a prescription from their physicians; a dubious drug can be

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approved but incur zero costs to CMS if no one prescribes it. Finally, patient advocacy organizations can work against their members' pocketbook interests by refraining from criticizing pharmaceutical manufacturers' high drug prices. But it will be difficult to compel pharmaceutical manufacturers to disclose their payments to patient advocacy organizations based on the argument that CMS is directly harmed by the inactivity of these advocacy groups. Because the Sunshine Act draws its authority from the harm to (the bottom line of) CMS, expansions of the scope of the act would seem to require evidence of such harm.

## ILLUSTRATIVE EXAMPLES

So far, patient advocacy organizations have been treated as a homogeneous lot, but there is great heterogeneity among these groups. To clarify the challenges of expanding the Sunshine Act, it may be helpful to examine specific types of patient advocacy organizations more closely. Consider cancer-focused organizations, which are among the largest and most influential advocacy groups, and organizations focused on pain conditions, whose advocacy for greater access to pain medications is believed to have contributed to the current opioid crisis.<sup>5</sup>

Cancer-focused patient advocacy organizations lobby for the approval of cancer treatments, provide grants for research, and match members with the appropriate clinical trials. Industry influence in any of these activities could introduce bias into the development and approval of drugs, leading to the introduction of less safe or less effective treatments. These premarket matters would appear, however, to be outside the purview of CMS, which concerns itself with postmarket prescription drug value. Drug prices, on the other hand, are a focal postmarket concern for CMS, and cancer medications are among the highest-priced prescription drugs currently on the market. Critics have noted that cancer-focused patient advocacy groups have remained silent on the issue of drug prices,<sup>4,6</sup> but a reluctance of advocacy groups to engage an issue does not seem to be a compelling justification for requiring payment disclosure. By contrast, efforts by industry-influenced advocacy groups to block access to competing generic or biosimilar medications, thus keeping prices high, could do harm to CMS interests and could be used as a basis for requiring disclosure of payments to patient advocacy organizations.

Pain-focused patient advocacy organizations have lobbied for greater access to pain-relieving medications, including opioids. Even as evidence is

accumulating on the highly addictive properties of opioids and the human toll of their misuse, industry-influenced advocacy groups continue to campaign against measures that restrain the overprescribing and distribution of opioids.<sup>5</sup> Because inappropriate prescribing and overprescribing of opioids have a direct effect on CMS expenditures, there is a much stronger case here for compelling the disclosure of payments to these patient advocacy organizations.

## NEXT STEPS

These examples illustrate and the preceding arguments contend that extending the Sunshine Act is not a simple search-and-replace exercise, inserting "patient advocacy organizations" into legislative texts. Because the act's authority resides in the reimbursement relationship between CMS and drug manufacturers, consolidating the case for industry payments to patient advocacy organizations adversely affecting drug spending will be important for practically expanding the scope of "Sunshine." Although the consequences of industry influence on patient advocacy groups are more multifaceted than CMS's pocketbook, legislative remedies may not be.

McCoy has made a case for transparency in industry payments to patient advocacy

organizations. The next step is to translate the metaphor of sunshine to the monetary costs of concealment. *AJPH*

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