THE PROMISE AND PERIL OF THE OPEN PAYMENTS ACT

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The behemoth known as Obamacare trudges ever forward – reviled by some, revered by others, and misunderstood by many. The October 2013 launch of enrollment was a study in the fallout of failure to prepare. With so many substantial issues – political, financial and medical – demanding attention, some provisions of the Act, and their potential impact escaped attention. One such provision is called the Physician Payments Sunshine Act, or Open Payments, which some say threatens medical innovation and clinical research.

According to Michael J. Koren, M.D., immediate past president of the Academy of Physicians in Clinical Research, the Open Payments Act is “just another problem, a bureaucratic process, that, at the end of the day, won’t make a difference in public health, but creates a hassle factor for physicians.”

Open Payments requires manufacturers of drugs, devices, medical and biological supplies to report to the Secretary of Health and Human Services, payments, transfers of value, ownership, and investment interests made to physicians and teaching hospitals. It failed to pass Congress twice, but was one of the provisions advocated by individual legislators before consenting to support the Patient Protection and Affordable Care Act in its entirety.

Marketing of drugs, devices and medical supplies to physicians and teaching hospitals has often included gifts of things costing as little as stickers and ink pens or as costly as meals at high-end restaurants, extravagant vacations and more. The concern is that some recipients may use the products associated with gifts, when something equivalent or even better for the patient, and possibly less expensive, could have been used. Public posting of the payments, or transfers of value, are intended to inhibit such self-serving patient care. Open Payments also requires reporting of consulting, lecturing and other work-for-hire payments. Research has its own rules for reporting, and very often the value of the reported transactions has scant correlation to the physicians’ responsibilities for, or participation in, clinical research. Thus, the so-called “Transparency Reports” mislead the public, hinder medical research, and don’t provide the protection which was intended. Delineation of Open Payments is as follows.

The Patient Protection and Affordable Care Act, Section 6002, establishes a system for reporting payments and transfers of value from manufacturers of drugs, devices,
medical and biological supplies to physicians and institutions, including those established for the purposes of medical training and clinical research. It amends Title XI of the Social Security Act and introduces Section 1128G, applicable to payments from Medicare, Medicaid and the Children’s Health Insurance Program (CHIP). It also requires the reporting of physician investment and ownership in applicable manufacturers.

REPORTING PAYMENTS AND TRANSFERS OF VALUE
For simplification, “payment(s)” includes transfers of value, ownership and investment interest; “recipient” is defined as a covered physician, teaching hospital, entity, or an individual designated as a proxy for a covered recipient.

Manufacturers were required to report for the first time, by March 31, 2013, and thereafter on the 90th day of each calendar year. Reports pertaining to payments of the preceding calendar year must be submitted in electronic form, to the Secretary of Health and Human Services, including the following information:

› Name of the recipient
› Business address of the recipient – when recipient applies to a physician, the specialty and National Provider Identifier must be included
› Amount of payment
› Date payment was delivered to the recipient
› Form of payment: cash or equivalent; items or services; stock and/or any ownership interest and its yield
› Any payment defined as such by the Secretary
› Nature of payment: consulting fees; honoraria; gifts; entertainment; food, travel, specifying destination; education; research; charitable donation; royalty; license; current or prospective investment or ownership; faculty or speaker for medical education; of any nature defined by the Secretary
› Payment related to marketing, education, research specific to a drug, device, biological or medical supplies
› Any categories determined appropriate by the Secretary

Physician (or immediate family member) ownership or investment interest must be reported in the dollar amount invested, value of what is invested in or owned, and payment provided to the physician owner or interest holder. The word “physician” must be substituted where the word “recipient” was used in previous itemized reporting.
The Secretary can require other information about ownership or investment as deemed appropriate.

**PENALTIES FOR NONCOMPLIANCE**

- Failure, or delay, for a manufacturer or purchasing organization to submit information as required is subject to a civil penalty of $1,000–$10,000 for each payment not reported as required. The total penalties per annum is not to exceed $150,000.
- Intentional failure to report is subject to a civil penalty of $10,000–$100,000 for each payment not reported. Total civil penalties are not to exceed $1 million annually.
- Funds collected from penalties are used for expenses associated with enforcement of this provision.

**SUBMISSION FORMAT AND PUBLIC DISCLOSURE**

The Secretary must make the reported information available to the public by June 30 of each calendar year. It is to be made available on an Internet website that:

- is in a format that is clear, understandable and searchable;
- contains information as delineated in the requirements for submission to the Secretary;
- is easily retrieved;
- describes any enforcement actions, including penalties, imposed during the preceding year;
- reports information on industry-physician relationships;
- lists separately information associated with and specifically intended for clinical research;
- contains information the Secretary deems helpful to consumers;
- does not contain the National Provider Identifier of the recipient; and
- has allowed the recipient 45 days in which to review and submit corrections to the information to be disclosed, but does not delay making the information available to the public.

Publication of payments made, when associated with the research and development of new medical technology, drug, device, biological or medical supply, or in connection with clinical research, may be delayed until the date that the new product is approved or cleared by the Food and Drug Administration, or 4 years after the date of payment, whichever is earlier. Information pursuant to product development agreements or
to clinical investigations may be considered confidential and will not be subject to disclosure until on or after the date when the information is available to the public. The Secretary shall consult the Inspector General of the Department of Health and Human Services and other interested parties to ensure that the information available to the public is presented in its overall context.

EXCLUSIONS

An applicable manufacturer is not required to submit information in some situations, including:

- Payments less than $10 (Aggregate payments in a calendar year are not to exceed $100. The dollar amounts will be increased annually consistent with the consumer price index.)
- Product samples not intended to be sold but to provide for patient use
- Educational materials intended for patient use
- Loan of a device for a clinical trial of not more than 90 days, to permit evaluation of the device
- Items or services under contractual warranty for purchase or lease
- Discounts or rebates
- Items used for providing charity care
- Dividend or other profit from a publicly traded security or mutual fund
- Payment for services of a recipient with respect to civil or criminal action

IMPACT OF THE OPEN PAYMENTS ACT ON CLINICAL RESEARCH

Research-related payments are misleading. Some types of payments are simply the cost of the food, travel, lecture, etc. Research payments, however, include the entire research grant, all of which is attributed to the physician designated as principal investigator. That includes items that the physician may never see or that are unknown to him or her, such as practice overhead, salaries for clinical support staff, ethics committees, participant stipends, and subcontracted services required by the research, such as hospitalization, diagnostic imaging, lab work, and supplies. Many physicians are employees of hospitals, clinics, universities, foundations, or laboratories, and their salaries are not affected by the grant. Opponents of the act believe reporting gives the impression that a physician was paid the value of the research grant, which may be hundreds of thousands, even millions of dollars. True transparency would mean that Open Payments should reflect what payments a physician actually received, providing information that might be of use to patients.
Compliance costs divert research funds. The cost of compliance and administration of the act are $269 million in its first year, and $180 million annually thereafter, which is believed by many to be a gross underestimation. A lot of time and money are required to enforce the act. That money will likely be diverted from patient care, research budgets, and other costs of education and innovation. Reduced research funding would threaten medical advances that could improve the quality of health care. Reports indicate that Open Payments may make physicians less likely to collaborate with the research industry. A 2010 survey conducted by the Association of Contract Research Organizations (ACRO) and the Academy of Physicians in Clinical Research (APCR) found that 13 percent of respondents would be “less likely to participate” or “would not participate at all” in future clinical research trials as a result of Open Payments.

Opponents also lament that Open Payments reports offer consumers little understanding of how research dollars are spent, potentially fueling skepticism on the part of consumers and apprehension on the part of researchers and physicians concerned that reporting may damage their reputation.

There seems to be intentional stirring of emotional issues associated with offering Super Bowl tickets and trips to the tropics, assuming the gifts are in exchange for increasing prescriptions, and equating that to fair market value payments made to compensate for the laborious work done for legitimate research. Scientific American states that, “No empirical data has tied researchers’ financial interests in a study to negative outcomes for patients.” The Centers for Medicare and Medicaid Services made the startling admission that they have no empirical basis for estimating the frequency of such problems, the likelihood that transparency will reduce them, or the likely resulting effects on reducing the cost of medical care.

The act’s methodology is not timely at informing patients of payments to physicians. A report is entered 6 to 18 months after the payment is made. For some types of research, disclosure is delayed up to 4 years. By the time the patient learns of the payment, it is clearly too late to take any of the information into consideration for the treatment that they need. Initiatives should work to enhance the integrity of care and the patient-physician trust at the time care is rendered.

Legislative regulatory solutions should adjust Open Payments in such a way that compliance will not detract from clinical researchers’ ability to do their jobs, allows medical research to continue advancing for the benefit of patients, and informs patients in a timely way of the relationship between physicians/hospitals and manufacturers’ collaborations for research purposes. These changes will require no less than an act of Congress and signature from the President if we really want to meet the intent of the act of protecting patients and making care more affordable.
ABOUT THE AUTHOR

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Dr. Coleman is a valued contributor to the Imperial writing team. She earned a Bachelor of Arts in journalism from the University of New Mexico (UNM), then joined the editorial staff of Medical Economics Company, Inc., a medical publishing company. She earned her medical degree from the UNM School of Medicine, and trained in family practice at Beaumont Hospital, a Top 100 Hospital with locations in Royal Oak and Troy, Michigan. Coleman has published in many periodicals and on the web.

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REFERENCES


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9) David Vulcano, LCSW, MBA, CIP, RAC, AVP and Responsible Executive for Clinical Research, Clinical Services Group/HCA.