

What Are You Doing for That Company?

Why contextual information should be included in your open payments report.

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A much-noted early collaboration between a physician and “industry” took place in the 1950s in Minnesota. C. Walton Lillehei, MD, the famous cardiac surgeon and professor at the University of Minnesota, searched for successful ways to conduct open heart surgery to correct defects of the heart. One challenge was to keep the blood flow oxygenated during the duration of the surgery. With Dr. Richard A. DeWall, Dr. Lillehei introduced the first clinically successful bubble oxygenator, a crucial medical tool used for decades. As techniques for repairing heart defects were refined, more tools were needed. Dr. Lillehei envisioned a transistorized device that could regulate heartbeats. He asked Earl Bakken, whose then small company, Medtronic, designed and repaired electronics for the University of Minnesota hospital. In 1958, their collaboration resulted in the world’s first use of a small, portable, battery-powered pacemaker inserted under the skin to provide electrical stimulation to the heart.

As important as such collaborations have been, concerns have grown over the past decade regarding the potential conflicts of interest that can arise and the ultimate impact on public trust. Although there have been laws on the books for decades that dealt with these issues (Stark, anti-kickback, etc.), a renewed debate on the issue led to the passage of the Sunshine Act in 2010 (implemented as Open Payments, a part of the Affordable Care Act).

The new legal requirements of Open Payments are intended to provide greater transparency around payments from industry to physicians. The idea has been that providing more information to the public about the payments being made will help to ferret out improper activities. Little, however, has been said about the other side of the coin: Greater disclosures of the underlying purpose of collaborative work can have a positive impact on public trust. This article shows how physicians can use these new tools to do just that.

CONTEXTUAL INFORMATION

When the Centers for Medicare & Medicaid Services (CMS) first published proposed rules concerning transparency reports on December 19, 2011, there was no provision

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—CMS

for explaining the purpose for the work that led to the disclosed payments. As part of the public commenting process, Primacea and two other entities agreed with CMS that “disclosure alone is not sufficient to differentiate beneficial, legitimate financial relationships from those that create conflict of interests or are otherwise improper.” Stating that more information about the relationship could be beneficial, we suggested that disclosures should be accompanied with an optional explanation of the nature of the relationship.

The good news is that CMS included our suggestion in the final regulations by saying:

“We agree that information on the context of a payment or other transfer of value could be useful. We believe it could help the public better understand the relationships between the industry and covered recipients . . .”

CMS did voice a concern that too much information could be overwhelming. As a result, the final regulations state that each consulting payment may be reported with an optional 500-character field containing “any free text which the reporting entity deems helpful or appropriate regarding this payment or transfer of value.” Each research payment may be reported with an optional 500-character field containing “textual description of research context or research objectives.”

DISCLOSURES BEFORE AND AFTER CONTEXTUAL INFORMATION

CMS has defined the format of industry disclosures in terms of up to 47 data fields. For disclosures that do not

include contextual information, we believe that the public and the press are likely to focus on just a few of those fields. For example, let's go back to the relationship between Medtronic and Dr. Lillehei and plug in numbers for purposes of illustration. In 1958, Dr. Lillehei invested \$20,000 in Medtronic; he sold his holdings in 1974 for more than \$1,000,000. If Open Payments existed in 1974, there might have been a disclosure like this regarding their relationship (bearing in mind that the amounts are approximate):

Physician Name	C. Walton Lillehei, MD
National Provider Identifier	0123456789
Amount of Payment	\$1,000,000.00

Assuming we had something like the Internet, such a payment likely would have caused some headlines. Without any contextual information, a reader could easily conclude "Dr. Lillehei just earned a huge sum of money from industry." That would be a true but incomplete understanding of the facts. With the contextual information, we believe the public and the press would focus on a more complete picture:

Physician Name	C. Walton Lillehei, MD
National Provider Identifier	0123456789
Amount of Payment	\$1,000,000.00
Contextual Information	Investment in and inventor of redesigned pacemaker that transformed cardiac care

After the inclusion of contextual information, the reader can now understand that the company paid Dr. Lillehei \$1,000,000 for work that resulted in a sea change in cardiac care. Given this information, the public at large is now in the position to evaluate the payment to Dr. Lillehei to determine whether his contributions to helping to extend the lives of millions of patients is worth it. We are very comfortable having that conversation.

CONTEXTUAL INFORMATION SHOULD BE INCLUDED IN CONTRACTS

For some time, informed physicians have sought exceptions to nondisclosure terms that allowed them to report industry activities to their medical institutions. Primacea has gone a step further for the physicians it represents by advocating to include terms that allow physicians to disclose their relationships publicly. We now recommend that all physicians take the additional step of including the contextual information to be disclosed under Open Payments in the legal agreements that define each of their engagements.

We also suggest that physicians propose the wording for contextual information. That wording should be free of jargon; many members of the press and the general public are likely to be unaware of the meaning of "percutaneous coronary intervention" or, worse yet, "PCI." Instead, if the wording states, "attempting to

improve the balloon catheters used in nonsurgical treatment of clogged blood vessels," the connection between physician and the medical device industry will become immediately apparent to any reader of the public report. Other examples might be:

- Participate in an educational symposium designed to train cardiovascular specialists on the evaluation and management of patients with peripheral artery disease.
- Develop a technology to safely manage an arterial access site with nonsurgical techniques.
- Facilitate the assay of metabolomic profiling to identify early stage glycemic disorders.

CONTEXTUAL INFORMATION SHOULD BE REVIEWED AS PART OF THE DISPUTE PROCESS

Physicians have a 45-day window in which they can review Open Payments submissions. Each consulting payment, for example, has up to 47 fields of data supplied by the reporting entity. In addition to the amount and type of payment, the contextual information field should be scrutinized.

There is no specific guidance from CMS as to how to resolve disputes concerning contextual information. Given how important that information is to the reputation of each physician, time spent with device manufacturing or pharmaceutical firms that addresses the importance of supplying the context for the relationship between physicians and industry is time well spent.

WHY SHOULD EACH PHYSICIAN FOCUS ON CONTEXTUAL INFORMATION?

In short, your reputation may depend on it. Leaving the field blank could lead to misunderstandings by the press, government officials, and, most importantly, your patients. Because reporting "contextual information" is both new and optional, it is reasonable to fear that industry will ignore it. On the flipside, misstating the context of the services provided is probably just as bad (or worse) as not including anything at all. The information listed here will be the public record of your reason for the collaboration. It is your opportunity to explain to the world why the work you are doing is important.

In short, do yourself and your peers a favor: leverage the goodwill with your industry contacts and ask them to include the contextual information. ■

Primacea provides tools to physicians and leading hospitals to facilitate transparency in innovation and manage compliance obligations.

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