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"Transparency Reports" on Industry Payments to Physicians and Teaching Hospitals

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PUBLIC AWARENESS OF INDUSTRY PAYMENTS TO PHYSICIANS and teaching hospitals in the United States is about to markedly increase. As required by the "Sunshine" provisions of the Patient Protection and Affordable Care Act, by September 2013 the Centers for Medicare & Medicaid Services (CMS) is to publish "transparency reports" that disclose these industry payments on a public website; the information must be "searchable," "clear and understandable," and "able to be easily aggregated and downloaded."[1] Unlike most disclosures of physician-industry relationships to date, the reports will include the amounts of payments or other "transfers of value." Payments large and small should be revealed, including the drug or device that the payment was related to.

CMS issued the proposed regulations in December 2011, after a delay of several months, and they are open for public comment until February 17, 2012.[2] The FIGURE summarizes the information about industry payments that is proposed to be publicly available; comparable information would also be available about physician ownership or investment interests in manufacturers and group purchasing organizations. Because CMS has committed to issue the final rule in 2012, the initial transparency reports could disclose information about payments made later this year.[3] It would not be surprising, however, if the government delays the timetable.

Some financial relationships between physicians and teaching hospitals and the pharmaceutical and medical device industries can benefit patients, primarily those that are related to bona fide basic and clinical research. But as the preamble of the proposed rule states: "Close relationships between manufacturers and prescribing providers can lead to conflicts of interest that may affect clinical decision-making. Increased transparency of these relationships tries to discourage inappropriate relationships, while maintaining the beneficial relationships."[2]

To help control conflicts of interest, the transparency report website—a prototype is not yet publicly available—should fulfill expectations for accuracy, clarity, and ease of use. So far, online disclosures of industry payments to physicians, such as those from orthopedic device makers to orthopedic surgeons, have often frustrated and disappointed those who have read them.[4] Experiences with state disclosure laws have highlighted the difficulties of accessing the information and the limited quality of the data.[5] ProPublica assembled disclosures of payments made to physicians between 2009 and 2011 that 12 pharmaceutical companies had publically posted, creating a single comprehensive database (http://projects.propublica.org/docdollars/) that is searchable for individual physicians. The reporters noted that the work "was not easy. Some of the firms constructed their sites in a way that made it near impossible to analyze or, in some cases, even download their data."[6]

The proposed rule interprets the statutory language sensibly. The rule covers any entity that manufactures a drug, device, biological, or medical supply for sale or distribution in the United States that is available for payment by Medicare, Medicaid, or the Children's Health Insurance Program. It defines a teaching hospital as any hospital that receives any payment from Medicare for medical education. The rule also covers both direct and indirect payments, those that a company makes to a third party, such as a medical society, a contract research organization, or a medical education and communication company, but that are intended for a physician or other recipient covered by the law. When the manufacturer knows who the eventual recipients are, it must report their identities. Disclosing both direct and indirect payments is important to meet the goals of transparency; when money intended for physicians or teaching hospitals is routed through a third party, the actual source of the funds must be clearly identified. Disclosures of indirect payments should further illuminate manufacturers' total research payments, as well as industry's role in funding continuing medical education (CME).[7] Total commercial support for CME has declined since it peaked in 2007 at $1.21 billion. But in 2010, commercial support was still $830.8 million, or 37.1% of the $2.24 billion of total income for CME providers.[8]

The transparency reports should disclose industry payments from about 1150 applicable manufacturers to about 1100 teaching hospitals and an unknown number of the estimated 892 000 health care professionals covered by the legislation.[2] In addition to teaching hospitals, covered recipients are doctors of medicine and osteopathy, as well as dentists, podiatrists, optometrists, and licensed chiropractors. Payments to nurses, physician assistants, pharmacists, and others in the medical field are not subject to the reporting and disclosure requirements, nor are payments to most hospitals; 5754 hospitals meet the American Hospital Association's criteria for registration as a hospital facility.[9]

The law permits delayed publication of certain payments for bona fide product research and development and clinical investigations, which if made public might damage the manufac-

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Figure. Proposed Information in Public Transparency Reports

Industry payments to physicians and teaching hospitals

- Name of manufacturer
- Recipient name, business street address (practice location), specialty (for physicians)
- Date and amount of payment (in US dollars)
- Form of payment
  Forms of payment are cash or cash equivalent; in-kind items or services; and stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment
- Nature of payment or other transfer of value
  Natures of payment are consulting fee, compensation for services other than consulting, honoraria, gift, entertainment, food, travel and lodging, education, research, charitable contribution, royalty or license, current or prospective ownership or investment interests, direct compensation for serving as a faculty member or as a speaker for a medical education program, grant, or other. Payments are to be classified into the 1 category that best describes them.
- Name of the covered drug, device, biological, or medical supply, if applicable
- Name of the entity that received the payment or other transfer of value, if not provided directly to the recipient

Physician ownership and investment interests

- Name of manufacturer or group purchasing organization
- Name of physician owner, specialty, and business street address
- Whether the ownership or investment interest is held by the physician or an immediate family member
- Dollar amount invested (in US dollars)
- Value and terms of each ownership or investment interest

For any industry payment or other transfer of value to a physician owner or investor, the same rules apply as they do for other payments.

turers' business interests. Delay is until the earlier of US Food and Drug Administration approval of the product that is the subject of the research or 4 years after the payment date. Manufacturers must report these payments to CMS each year; only the disclosure of the information on the website is delayed. The law also provides for exclusions, for example, product samples and educational materials intended for patient use, the loan of a covered device for a short-term trial period, not to exceed 90 days, and discounts, including rebates. But in general, the law only exempts payments or transfers with a value of less than $10, unless the annual aggregate total from 1 company to 1 recipient exceeds $100, in which case all the payments are to be reported and disclosed. CMS notes that if a sales representative were to bring "$25 worth of bagels and coffee to a solo physician's office for a morning meeting," the meal must be reported.[2]

Before the information is made public, manufacturers, physicians, and others subject to reports would have at least 45 days to review the information, correct errors, or contest the data, through a process that is still being developed. However, CMS would not resolve disputes; if a dispute could not be resolved, the information would be noted as disputed and both amounts would be published. Penalties for manufacturers are capped at $150 000 for failure to report and $1 million for knowing failure to report; records and documents would have to be retained for at least 5 years and would be subject to federal compliance audits.

The transparency reports will be confusing and difficult to use unless all payments to physicians are easily aggregated under their correct name and a single practice location. A physician's address should be his or her most common place of practice. ProPublica found that companies listed an individual in different cities and that 1 company "in some cases used different middle initials for the same individual."[6] Recognizing the need "to accurately distinguish covered recipients," the proposed rule requires that manufacturers report the physician's National Provider Identifier (NPI) and CMS requested comments on whether manufacturers should report a state license number or "another unique identifier" for physicians who have no NPI.[2] The NPI or other unique identifiers for physicians would not be included in the public database. If users of the website are unable to directly search for physicians by a unique identifier, CMS should use such identifiers in the background so that each physician is found with 1 name and 1 business address. Similar considerations apply to the reports for teaching hospitals.

Transparency reports could shed a bright light on the extensive financial relationships between industry and physicians and teaching hospitals. The final rule, however, must remain strong. CMS should maintain the essential elements of the draft, incorporate constructive suggestions, resist pressure to weaken the regulations, and unveil a state-of-the-art website. The medical profession and the public deserve no less.

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