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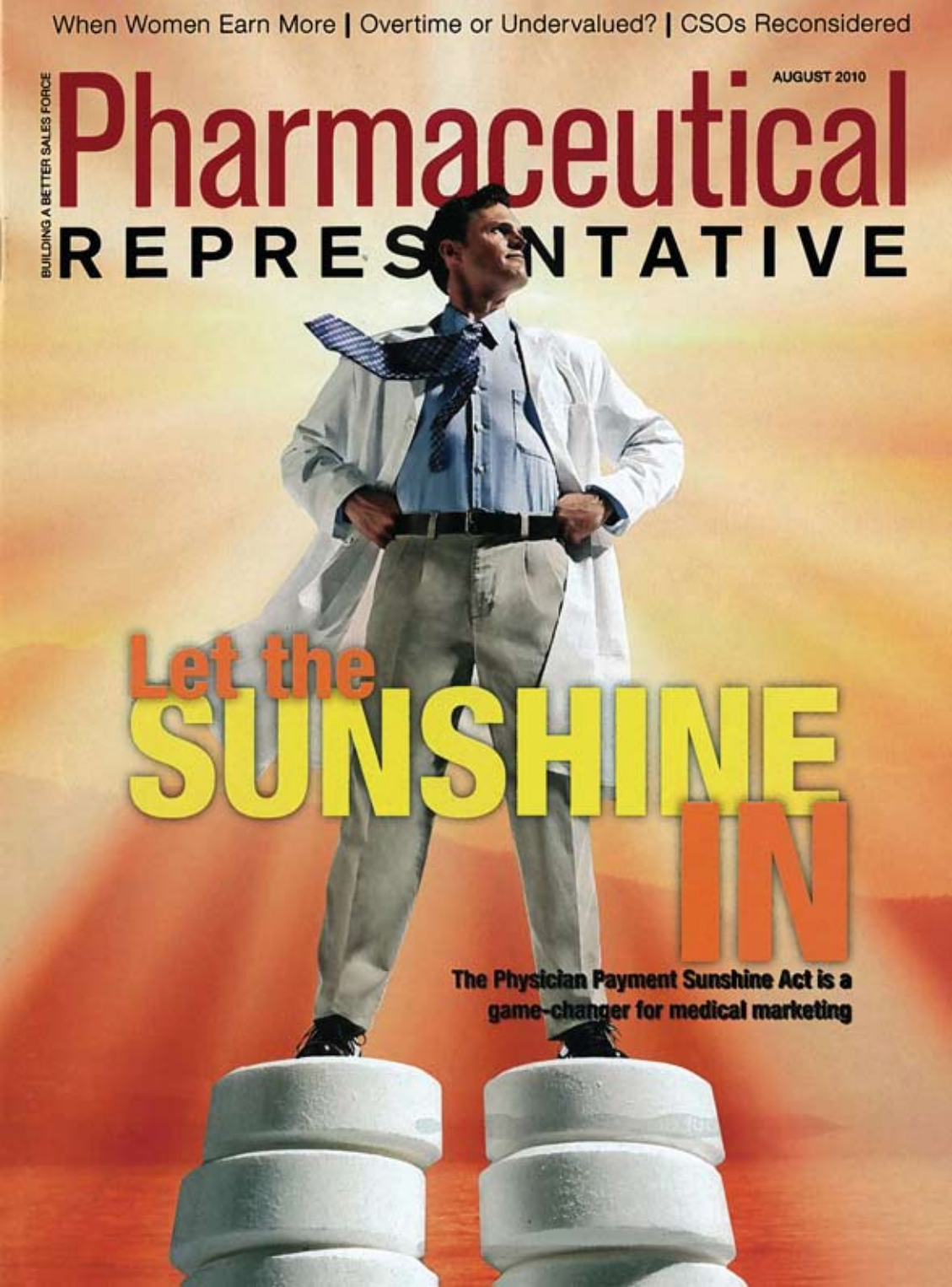

Let the SUNSHINE IN

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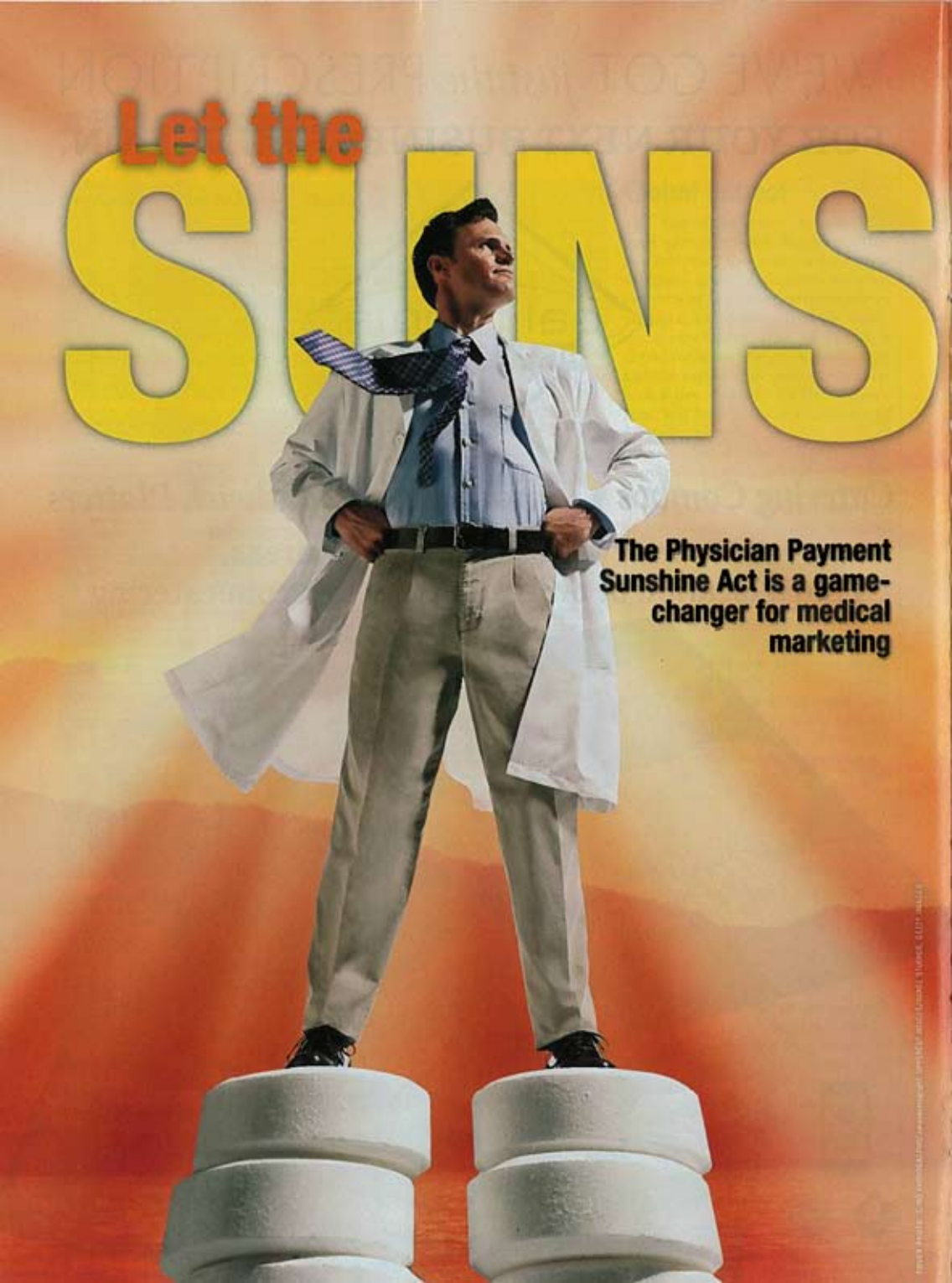
Let the SUNS



The Physician Payment Sunshine Act is a game-changer for medical marketing

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By Bill Cooney

When Congress passed the controversial healthcare reform bill in March 2010, the Physician Payment Sunshine Act (PPSA), embedded within the bill, also became law. In the shadow of the sprawling healthcare act, the PPSA has drawn modest attention from the companies it will regulate, that seem to view it as only a federal version of similar, current state reporting programs. A close look at the PPSA, however, shows it may be a game-changer for major areas of marketing activity by pharmaceutical and biotech companies.

The profound aspect of the PPSA is not the reporting aspect; almost all biopharma companies have developed reporting systems to address the regulations of a handful of states. What sets the PPSA apart is the unprecedented visibility of data, which will be readily accessible to the general public via a website managed by the federal government.

PPSA Data per Transaction

Every report of a payment or transfer of value to a physician must include:

- Recipient name
- Business address
- Physician specialty
- National Provider Identifier
- The amount of the payment or TOV
- The dates of the payment or TOV
- A description of the form of the payment (cash, stock, in-kind services, etc.)
- A description of the nature of the payment (honoraria, food, travel, etc.)
- The name of the covered drug, device or biological, if the payment is related to marketing, education or research specific to a covered drug, device or biological
- If a travel TOV, the specified destination(s)

The Act

To understand this, let's recap the PPSA Act. Versions of the PPSA have been floated in Congress for the last two years, so the Act is familiar, and some pharma companies endorsed earlier versions of the PPSA in 2009. The version as enacted, however, sets significantly tougher penalties and thresholds for reporting than prior drafts.

Basically, the PPSA requires medical manufacturers to submit annual reports on payments and transfers of value (TOVs) to U.S. physicians. The Act specifically requires reporting all individual TOVs of $10 or more, or all TOVs, including those less than $10, if cumulative payments and TOVs to an individual physician exceed $100 in a calendar year. The $100 annual cap effectively means that manufacturers must track all TOVs, even those under $10.

TOV is broadly defined and notably includes meals (See "PPSA Payments and transfers of Value" for a list of items the Act defines as TOV). The Act spells out what data must be reported for each TOV transaction, and the data are extensive (See, "PPSA Data per Transaction" sidebar).

The Act sets forth significant penalties for violations. The penalties differ for intentional versus unintentional violations, and range from $1,000 to $100,000 for each instance, and $150,000 to $1 million in total. Although these fines don't approach the billion-dollar range industry has experienced with OIG, the fines are large and the PPSA has teeth. Expect your in-house lawyers to impose a strict regime of PPSA compliance.

The PPSA goes into effect on January 1, 2012, when manufacturers must start recording all payments and TOVs. Manufacturers must submit all data to U.S. HHS by March

2013, and the Act requires HHS to have the data available on a website by September 2013. Those dates may seem far off in the future, but in reality there's only 16 months to plan, test and implement reporting systems and/or new approaches to sales and marketing.

The PPSA compels manufacturers to submit reportable data to HHS, and no doubt HHS will specify an electronic format for submissions. The Act requires HHS to post all payment and TOV data on a public website that HHS maintains. The Act specifies that the PPSA website "is searchable and is in a format that is clear and understandable" and "contains information that is able to be easily aggregated and downloaded." This is the most powerful aspect of PPSA: a public website providing data that's easily accessible and searchable, for aggregation and downloading by any party.

Stated simply, the PPSA will create near-perfect public transparency for all payments and TOVs by manufacturers. The media and various anti-pharma factions are certain to jump on this data and spin it their way. The big question is: How will such unprecedented transparency affect various stakeholders in U.S. healthcare?

Consider the PPSA from the standpoint of stakeholders, starting with individual physicians. Starting in January 2012, a physician attending a speaker program at a local restaurant will trigger a record on the PPSA website that he/she received a dinner worth $100 paid for by a pharma company. The information can be searched and aggregated, so anyone can view the payments and TOVs that a physician has accepted from any and all biopharmaceutical companies in 2012.

PPSA Payments and Transfers of Value

Manufacturers must report a wide range of payments and transfers of value:

- Consulting fees
- Compensation for services other than consulting
- Honoraria
- Gifts
- Entertainment
- Food
- Travel
- Education
- Research
- Charitable contribution
- Royalties or licenses
- Current or prospective ownership or investment interests
- Direct compensation for faculty or speakers for medical education program
- Grants
- Any other nature of payment or other transfer of value, as defined by the Secretary of HHS
- NOT required for reporting: samples intended for patients; patient educational materials

The Stakeholder Perspective

So how are physicians going to feel about "free $100 dinners" becoming public knowledge? Recent research shows that most physicians feel that meals and similar amenities from industry are often acceptable and appropriate. However, in today's environment of public distrust toward Big Pharma, few physicians want free meals and other "gifts" to be on public display.

It's easy to envision consequences such as local newspapers running articles on "Top Ten Local Physicians Accepting Free Dinners from Drug Companies." Also, PPSA data could become a convenient tool for plaintiffs' attorneys engaged in medical malpractice cases.

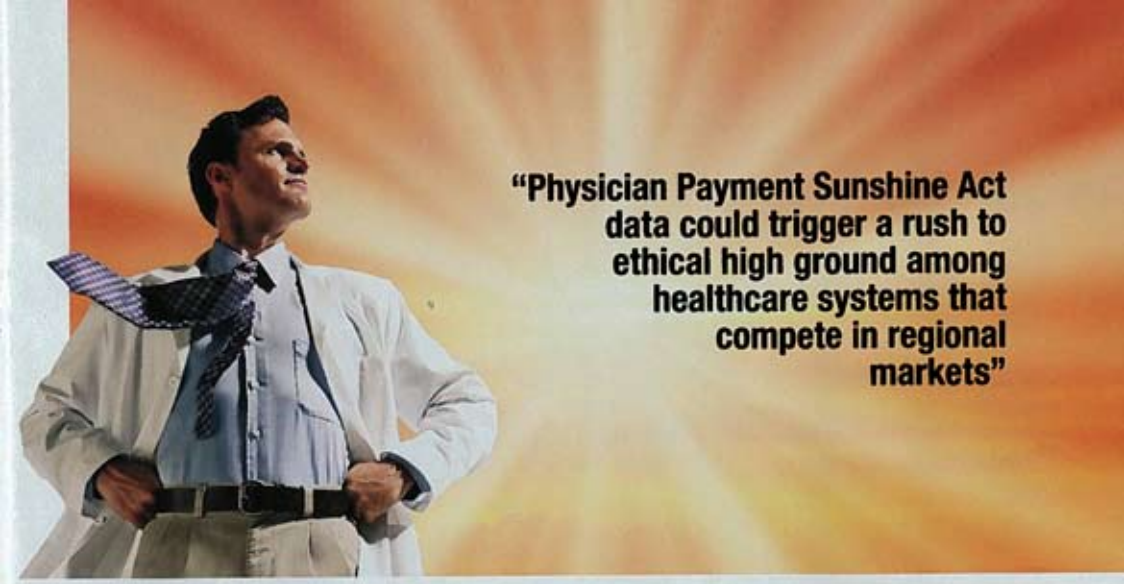
Next, consider institutional stakeholders, such as group practices and regional healthcare systems or state and national medical societies. These organizations are concerned about public trust and want to avoid the perception that they're influenced by the pharma industry. In recent years, many institutions have placed restrictions on how pharma reps can interact with their healthcare professionals. These institutions are going to be uncomfortable with the unprecedented exposure created by the PPSA, and may be motivated to lower or eliminate TOV activity among their physicians.

Finally, consider the pharma, biotech and medical product companies that must submit TOV data. Although some of these companies currently disclose honoraria payment data, free meals are harder to defend to a suspicious public. The PPSA website may make it possible to look at the total TOVs by company, so that the public can see that major pharma companies spend tens of millions of dollars in free meals to physicians each year. How will pharma companies react to that kind of transparency and publicity?

Areas of Spending

To understand the likely impact of the PPSA, it's important to consider the scale of spending on TOVs that the Act will cover, such as:

- **Dinner Meetings.** For many brands, local speaker programs is the biggest area of spend other than samples and the sales force itself. Although direct spend data on meals are not available, published data on overall activity suggests that several of the largest pharma companies have spent $15 to $25 million annually on meals associated with speaker programs.
- **Lunch and Learns.** Data on spending in this category is hard to come by, but annual spending on meals brought into physician offices by pharma reps at the largest companies can be conservatively estimated at range of $10 to $20 million.



"Physician Payment Sunshine Act data could trigger a rush to ethical high ground among healthcare systems that compete in regional markets"

- **Destination Meetings**. This category includes advisory boards, consultant meetings, speaker training meetings and similar activities. Although some pharma companies have begun to voluntarily disclose payments to HCPs, they have generally not disclosed travel costs except to meet the requirements of a few states. Spending on air and ground travel, meals, hotel lodging, etc., generally amounts to a range of $1,500 to $2,500 per attendee.

The details of what constitutes a TOV may not shock people working within industry, but the general public may have a different view of annual spending on "gifts" to U.S. physicians by a single pharma company of $20 or $30 million. In the name of transparency, the PPSA will create a level of exposure regarding TOVs that few physicians, institutions or manufacturers are going to welcome.

No one knows how stakeholders will react to PPSA transparency, but one possibility is that various parties in the U.S. healthcare system will pledge to become "TOV Free," that is, prohibit physicians from engaging with industry in interactions that include unjustifiable TOVs.

Transfers of Value Backlash

Institutions are the first place where we're likely to see TOV Free policies. Many prominent medical schools/medical centers already have similar policies in place, and the PPSA will provide a convenient structure for banning "unethical" interactions with industry. Several national and state medical societies have also enacted tough ethical guidelines, and the federal designation of TOV is something they are likely to include when defining unethical behavior.

PPSA data could trigger a rush to ethical high ground among healthcare systems that compete in regional markets. The PPSA website might be used to yield data on the total TOVs accepted by all physicians within a regional healthcare provider. To protect their image among their public constituents, regional healthcare providers have strong incentives to go completely TOV Free, and little reason not to.

Pharma companies also may be motivated to go TOV Free. The industry suffers from a poor public image and direct challenges from regulators on marketing practices. Several leading pharma companies have publicly committed to transparency and marketing reform.

PhRMA might lead an effort to eliminate TOVs such as free meals that are unrelated to bona fide consulting activities. This would resemble the revised PhRMA Code of 2008, which eliminated entertainment and non-medical give-aways such as pens and coffee mugs. Such reform is good for public perception and good economics since it lowers the bar on promotional costs evenly across the biopharmaceutical marketplace.

If physicians, healthcare institutions and pharma move toward a TOV Free world, what are the implications for pharma marketers and sales reps? Speaker programs are a win-win for pharma and the medical community, and lunch-and-learns have been staple field sales activity for decades. Ending these activities would put a big dent in peer-based marketing, reduce access to physicians for pharma reps, and take away major components of the current marketing mix for many brands.

Biopharmaceutical companies would need to respond with variants of current programs that are transfer of value free. Examples include virtual speaker programs that deliver peer interaction online, and rep-delivered clinical education services that provide real value to caregivers and patients.

The Physician Payment Sunshine Act challenge will soon confront the entire pharma industry, and may prove to be a transformational force. As in the past, pharma and biotech companies will need to adapt to this new challenge with innovation and a commitment to serving the healthcare community.

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