Denise Myshko

The Era of TRANSPARENCY

Beginning in January 2013, pharmaceutical, biotech, and medical device companies will be required to track and submit reports on spending associated with physicians.

Now that the Supreme Court has upheld the constitutionality of the Affordable Care Act, pharmaceutical companies must continue to move forward to implement the provisions in the law. One such provision is the Physician Payment Sunshine Act, which requires manufacturers of pharmaceuticals and medical devices to report to the Centers for Medicare & Medicaid Services (CMS) payments of more than $10 made to physicians.

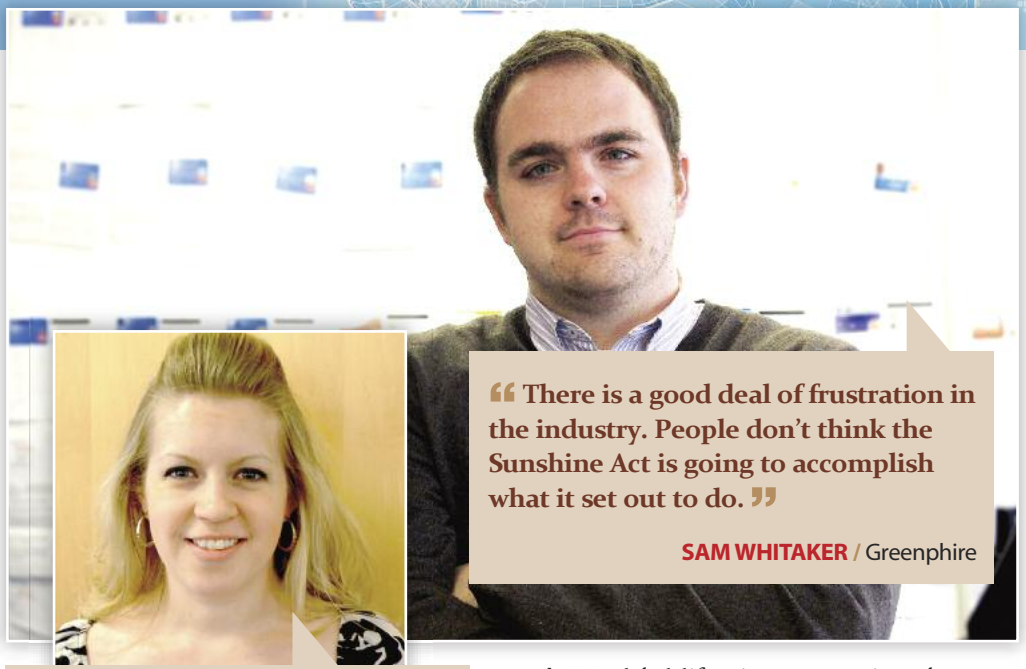
The effort is an attempt to bring transparency to the relationships between companies and physicians. Transparency in payments to physician can go a long way to address the industry's image. Experts say, ultimately, transparency efforts aim to help physicians provide patients with the best and most appropriate care.

Konstantinos Papandrikos, director, transparency operations, US Medical Affairs, Sanofi US, says the Sunshine Act promotes transparency, which is an important part of helping ensure credibility and understanding of the industry's interactions with medical professionals, patients, and others and is likely to be positive for the pharmaceutical industry.

"This will provide for clarity around the age-old question of what we, as companies, are doing with our money," he says. "We're spending money on research. We're spending money on development. We're spending money on independent educational programs."

Liz Lewis, chief compliance officer at Millennium: The Takeda Oncology Company, says it's critical that the healthcare community and patients understand these relationships and that the data collected under the Sunshine Act be reported in a manner that is easily digestible and meaningful to patients.

"We believe in transparency, and we believe that our collaborations with healthcare professionals are important to develop new medicines and to support patient care," she says. "One of the risks of the Sunshine Act is that there is a vast amount of information being collected that will be available to patients, which could be confusing or misinterpreted. It would be beneficial to understand the value patients derive from all this information once it is made available. This, in turn, could cause undue concern and result in less-than-optimal decision making."



> "There is a good deal of frustration in the industry. People don't think the Sunshine Act is going to accomplish what it set out to do."
>
> **SAM WHITAKER** / Greenphire

> "The best way to manage Sunshine Act compliance is to convene a cross-functional team to identify the areas that could potentially qualify for reporting."
>
> **BECKY HOLLOWAY** / Revitas

Deloitte, in collaboration with Forbes Insights, surveyed 110 U.S.-based physicians and 223 global life-sciences executives about transparency and the new reporting requirements. The survey indicates that physicians have concerns over how the data will be interpreted by the public — for example, the context — as well as their own understanding of the requirements. Life-sciences company executives, on the other hand, are less focused on the public's interpretation of the data than the logistics of aggregating and reporting them. Most are still investigating how best to leverage the data for competitive advantage.

Becky Holloway, product marketing manager, at Revitas, says the transparency created by the law could cause pharma companies and device manufacturers to become more strategic.

"When there is greater visibility into what is being spent with various healthcare providers and healthcare organizations, companies have more information to determine if their programs are working," she says.

But she points out that there is ambiguity around certain pieces of the act.

"CMS, which has been tasked with providing the final guidance, has stated it will come-out with the guidance at the end of the year,' Ms. Holloway says. "What we don't know is when companies have to start collecting data."

CMS has delayed reporting requirements until sometime after Jan. 1, 2013. The specific date, as of yet, hasn't been determined. Under the reform law, data collection was supposed to start Jan. 1, 2012.

"The act currently requires reporting any transfer of value to healthcare providers and healthcare organizations," Ms. Holloway says. "This includes everything from in-kind payments to cash payments to loaner equipment and samples to travel and entertainment. It also includes honoraria, gifts, clinical trials, royalty payments, and any type of ownership, including stock, that a provider organization might have in the pharmaceutical or medical device company."

Ms. Holloway points out that even "try-and-buy" programs where a physician or practice has equipment for more than 90 days has to be reported.

Michaeline Daboul, president of MMIS, says there are likely to be unintended consequences of the Sunshine Act.

"It's great for all transactions to be transparent, but there may be some unintended consequences," she says. "Based the rule proposed by CMS, there is a concern that physicians will be reluctant to participate in clinical research and continuing education activities. Ultimately, this will have a negative impact on patient care."

> **"Because CMS has yet to publish a final rule defining exactly what needs to be reported and when for the Sunshine Act, companies have had to prepare without having this essential information."**
>
> **LIZ LEWIS** / Millennium

Philip McCrea, CEO of ClearPoint, agrees, and says physicians may not even be aware of the reporting requirement.

"It's a requirement that manufacturers implement reporting systems and put proper training programs in place, " he says. "But it's less clear who is accountable for communicating and educating healthcare professionals about what this means and what they can expect going forward. I'm not convinced that all healthcare professionals understand what's going to happen. The first time that a doctor sees his or her name on a pharmaceutical company's website with a dollar amount next to it may come as a surprise."

Ms. Daboul goes even further, stating that for physicians the reporting requirement could be a nightmare.

"A physician could speak on behalf of numerous pharmaceutical companies, participate in advisory boards and conduct clinical research," she says. "Reviewing this information

> **"The most tension and confusion will be around the communication and education for healthcare professionals, especially around who is to fund programs for physicians and where this information is published."**
>
> **PHILIP MCCREA** / ClearPoint

to make sure that it is accurate before it is reported in the public domain could be difficult. We worked with the AMA to survey both specialty and primary care physicians to ask them about how they would like to interact with industry. First, more than half of the physicians are not even aware that this law exists. Of the physicians who are aware of the law, 85% said they would want one portal to go to in order to review transactions from multiple companies to ensure accuracy. Respondents also indicated that they would review data in the portal about once a month."

Implementing the Law

Sam Whitaker, CEO of Greenphire says there is a good deal of confusion and frustration in the industry right now.

"The most significant challenge that everyone is struggling with is figuring out how they are going to actually comply," he says. "The main focus is on clinical research payments to covered entities or medical professionals, but the reality is that there are payments being made to entities that need to be reported that are outside of the clinical research environment."

Ms. Holloway says one of the biggest issues for many companies is determining the data that get fed into the reporting system.

"This is where organizations are struggling because this information tends to be spread out across the organization in different data sources; identifying them is hard and bringing them together is even harder," she says.

In fact, data pertaining to one contractual arrangement could sit in several different departments, such as legal, finance, and medical, Ms. Lewis says.

"The Sunshine Act requires companies to identify and report aggregate information pertaining to individual healthcare professionals," she says. "Matching the data to the correct healthcare professional across systems and departments is challenging."

Ms. Lewis also points out that there is no clear standard.

"Because CMS has yet to publish a final rule defining exactly what needs to be reported and when, companies have had to prepare without having this essential information," she says. "Once the final rule is published, companies may need to review the systems/processes put in place to comply with the Sunshine Act to ensure that any assumptions that were made are consistent with the guidance in the final rule."

Animesh Gandhi, practice leader, aggregate spend, Alliance Life Sciences Consulting Group, says the No. 1 issue is making sure that companies are able to collect data correctly from physicians to ensure the accuracy of the data.

"There needs to be awareness on policies and procedures within a company to make sure

SOUND BITES FROM THE FIELD

Industry experts provide their insights on the impact of the Sunshine Act on the pharmaceutical industry.

BILL COONEY is President and CEO of MedPoint Digital, which provides specialized digital services to the global bio/pharma industry.

For more information, visit medpt.com.

"The Sunshine Act is a terrible law with many undesirable consequences. First, there's the unprecedented intrusiveness of this Orwellian act, which requires detailed reporting to federal authorities on millions of lawful interactions annually between private parties. The act will have a chilling effect on interactions between industry and the medical community, but such interactions are essential if we wish to advance medical science and improve patient care.

The act imposes myriad productivity-draining costs on manufacturers, healthcare providers, and the government — estimated by the Department of Health and Human Services at $224 million in the first year — with zero evidence that the act will yield a benefit, at a time of crises in healthcare affordability."

JESSICA DOLFI is a Business Consultant at Medidata Solutions, a global provider of cloud-based clinical development solutions that enhance the efficiency of clinical trials.

For more information, visit mdsol.com.

"The Sunshine Act demands revisions to tried-and-true processes for a traditionally conservative industry. It will challenge manufacturers to critically examine current practices. Software tools can help clinical teams not just back into traditional methods, but help pioneer more efficient, productive workflows. Integrating budgeting, negotiating, and payment processes can ease the transition into reporting of payments, while ensuring fair market value of clinical costs, satisfying a basic provision of the Sunshine Act.

The ultimate goal is to get life-altering treatments to patients more rapidly. Hopefully, the Sunshine Act will facilitate positive, progressive change for manufacturers, caregivers, and patients alike."

JIM ZUFFOLETTI is President of OpenQ, a provider of solutions to enable compliant collaboration with medical networks.

For more information, visit openq.com, or email jimz@openq.com.

"The Sunshine Act could negatively impact KOL participation in clinical development and promotional programs. We conducted a survey that showed potential for a 40% decline in KOL engagement when transparency goes into effect.

The drug development industry will need to leverage social and mobile technologies to enable more efficient and effective collaboration. In addition, the identification of new thought leaders and more influential KOLs is critical for success. Keeping the lines of communication open between industry and providers to explore new ways to collaborate, such as social networking, while safeguarding compliance and risk exposure, are tomorrow's drivers for success in the new era of the Sunshine Act."

that all of the various departments are collecting the data accurately," he says. "Companies have to have a framework in place to promote awareness and help educate the various stakeholders around the importance of these data. Then they can look at how to automate the collection of the data, put in place mechanisms to establish key roles and responsibilities, and establish a way to mediate any problems."

Mr. Papandrikos says Sanofi's challenge is figuring out where info is collected and ensuring that it can be consolidated in one place.

"Much of the focus has been on the salesforce, and we use our CRM tool to automate tracking of that spend," he says. "We also track R&D spend, which is located in different systems, including some vendors (such as CROs). What companies are challenged with is the potential for one-off transactions and how they are collected."

Industry experts say this is not just a technology challenge.

"Organizations such as ours have many different systems containing data and that creates challenges in aggregating data in unique systems where spending may be captured," Mr. Papandrikos says. "Therefore, there needs to be a level of engagement within the company to have a successful program. Then IT comes into play because there need to be ways to automate the process."

Mr. Whitaker also points outs that pharma companies will have to work with their partners, including CROs, sites, and other organizations that manage payments to physicians.

"Some of these payments may be in systems, others may be tracked manually in spreadsheets," he says. "Companies need the data in one place and then be able to aggregate the information so that they know each doctor who was paid by all groups. Ultimately, there needs to be a data warehouse, which then gets aggregated with other sources of payment made to doctors outside of the clinical environment."

Mr. Papandrikos says Sanofi has been doing much to prepare for the Sunshine Act.

"The Sunshine Act is an extension and expansion of requirements in various states," he says "For example, Vermont and Massachusetts require similar sets of data. We are using these as our base from which we integrate our sources and processes, including validating the data."

Ms. Daboul says implementing the requirements of the Sunshine Act requires a 360-degree solution.

"First, the law is going to require that companies correctly identify the covered recipients they are making a payment to," she says.

The Impact of the Sunshine Act

- Physician Payment Sunshine Act and other new regulations are requiring life-sciences companies to make significant infrastructure and compliance program investments.
- Despite the new reporting requirements, neither physicians nor life-sciences companies plan to significantly change the way they currently interact.
- Given how physicians say they learn, there may be opportunities for the life-sciences industry to alter where it expends financial resources; this, in turn, may reduce the issues/objections to healthcare provider financial interactions.
- While a majority of physicians surveyed acknowledge some financial interactions with the life-sciences industry, most do not believe it is material to their overall income.

Source: Deloitte, in collaboration with Forbes Insights.
For more information, visit deloitte.com.

"Then they have to validate that the information is correct. Once they do that correctly, they then have to aggregate all of the different spend transactions that occur within their enterprise, whether it is a grant, an advisory board program, a speaker program, in-service lunch, etc."

She points out that the challenge is tracking any and all payments or transfers of value.

"There are multiple systems that are used within pharmaceutical companies — large or small — and all of the information from all of different systems need to be aggregated into one system," Ms. Daboul says.

CMS originally estimated that the cost for accounting changes and internal controls necessary to track the actions of individual providers will create an estimated $200 million burden per applicable manufacture.

Ms. Holloway points out the accuracy of this estimation has not been verified by an external source.

"Manufacturers would say it is much higher," she says. "Obviously, it is going to depend on the size the company, how many products they have, how many agreements they have with physicians and hospitals. Then there is also the penalty side. For violating the Sunshine Act, penalties start at about $10,000 per infraction and scale up from there. Companies can be charged as much as $1 million in a year for knowingly violating the act."

Mr. Whitaker says cost is also a function of managing compliance.

"Because there is the threat of civil monetary penalties, this is going to ultimately drive the industry to over aggregate data, which is then going to drive more expenditure in terms of resources and systems."

Ms. Lewis says for Millennium, the cost issue also involves time to collect the data.

"For example, to obtain the information required to compile one state report, we needed to review more than 10,000 rows of data," she says. "This review took 10 to 15 employees more than 3,000 man hours of time, and these are employees who typically work on other things, such as NDA filings to the FDA. The report that was generated contained just over 100 covered recipients. The work that was required for reporting to just one state highlights the resources that companies will need to invest in reporting for the Sunshine Act as well as required state reporting."

> **"There are some unintended consequences of the Sunshine Act. Transparency is wonderful, but this law could affect the relationship between physicians and industry, as well as physicians and their patients."**
>
> **MICHAELINE DABOUL** / MMIS

Best Practices

Ms. Daboul says companies need to be proactive, aggregating their spend transactions and putting processes in place to review those spend transactions on a monthly and quarterly basis.

"Every 90 days, companies should push new data to physicians so they can look at their portals and see the information and allow enough time to resolve any issues that may occur with a transaction. This is going to engage the physician and the hospital as part of an ecosystem in a partnership with the industry."

Ms. Holloway suggests companies gather a cross-functional team or committee within the organization to help ensure compliance with the Sunshine Act.

"Companies need to have all departments represented that could be impacted by the law," she says. "This group probably should be led by legal or compliance. Companies need to fully identify all of the upstream processes that feed into the aggregate spend, whether that is speaker programs, grants, clinical trials, royalty agreements with physicians, etc."

Mr. Gandhi says companies have to establish policies to ensure compliance and make sure those policies are documented.

"This means better communications with all employees," he says. "Often compliance executives are in tune with what they need to do, but they have a hard time getting support from the business functions. By having a structured framework, companies can have the oversight that is required starting at the C-level, which then trickles down to the VPs of various departments to make sure everyone is aligned."

Mr. Papandrikos says companies have to secure buy-in from the business side of the organization since this is the side responsible for the money.

"There also needs to be a solid IT structure in place to support the project going forward," he says. "Companies work with a multitude of vendors so if they don't have a core structure in place within their four walls, it's never going to get done."

Ms. Lewis suggests companies need to implement a three-point analysis to assess effectiveness of internal reporting systems, including: systems check to ensure that systems are able to generate the needed reports and house pertinent data; input assessment to ensure that the data are being appropriately, accurately, and timely input into the aggregate spend system; and quality check to make sure that random pulls of the data demonstrate the organization is able to accurately report collected data. PV

EXPERTS

MICHAELINE DABOUL. President, MMIS Inc., a global technology company that develops secure communication solutions. For more information, visit mmis-inc.com.

ANIMESH GANDHI. Practice Leader, Aggregate Spend, Alliance Life Sciences Consulting Group Inc., a management and technology consultancy. For more information, visit alscg.com.

BECKY HOLLOWAY. Product Marketing Manager, Revitas Inc., which delivers integrated solutions for contracts, pricing, and compliance that drive profitability and lower risk. For more information, visit revitasinc.com.

LIZ LEWIS. Chief Compliance Officer, Millennium: The Takeda Oncology Co., a biopharma company. For more information, visit millennium.com.

PHILIP MCCREA. CEO, ClearPoint, which provides learning solutions from product launch to mLearning frameworks. For more information, visit clearpointlearning.com.

KONSTANTINOS PAPANDRIKOS. Director, Transparency Operations, US Medical Affairs, Sanofi US, which discovers, develops, and distributes therapeutic solutions focused on patients' needs. For more information, visit sanofi.us.

SAM WHITAKER. CEO, Greenphire Inc., a provider of clinical payment technology and solutions to biopharmaceutical and device companies. For more information, visit greenphire.com, or email samuel.whitaker@greenphire.com.

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