NPA Avoiding Conflict-of-Interest in Medicine Leadership Development Call Series Archive
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Let the Sun Shine In: Disclosing Industry Payments to Physicians Under the Physician Payment Sunshine Act

Notes

Facilitator: Rachel DeGolia, Board Member of the National Physicians Alliance and Executive Director of the Universal Health Care Action Network (UHCAN)

Rachel: This Conflict-free Leadership call is hosted by the National Physician's Alliance as part of its Unbranded Doctor project, which takes place under the Partnership to Advance Conflict-Free Medical Education (PACME) grant. The PACME grant is the result of a state Attorney General settlement regarding the inappropriate marketing of the drug Neurontin. Partners for the grant include the National Physicians Alliance, American Medical Student Association, Community Catalyst and the Pew Charitable Trust, and staff for all these organizations are on this call.

The goal of the project is to reduce conflicts of interest created by the pharmaceutical industry in the medical profession and medical research. The partners on this grant promote a number approaches to raise awareness of the issue and to build leadership in the medical profession to eventually eliminate some conflicts. For more information visit the NPA Unbranded Doctor Website at: **npalliance.org/conflict-free**

Our speaker tonight is **Wells Wilkinson, JD, Director of the Prescription Access Litigation (PAL) project and staff attorney with Community Catalyst.** The call tonight is aptly titled, *Let the Sunshine In*. At long last, the final rules requiring public disclosure of pharmaceutical company payments to doctors have been issued under the **Physician Payment Sunshine Act**. The law, which was passed as part of the Affordable Care Act, will start tracking all gifts and financial transactions between doctors and industries as of August 1 this year, and public disclosure follows starting in Sept 2014.

Overview - Partnership for the Advancement of Conflict-free Medical Education (PACME)
Ann Woloson, Director of Education, National Physicians Alliance, ann.woloson@npalliance.net
Ann: This is the 7th of a series of calls taking place on a bi-monthly basis hosted by the NPA as part of this partnership described. NPA offers a number of educational opportunities as part of this project, including these calls and National Grand Rounds These are archived on the website at **npalliance.org/conflict-free**. April 9th is the next National Grand Rounds at Georgetown University Hospital and will focus on the updating of the AMSA PharmFree Scorecard.

Wells Wilkinson, J.D., Director of the Prescription Access Litigation (PAL) project and staff attorney with Community Catalyst
Wells: Thank you for inviting me to speak tonight. Community Catalyst works with groups in 40 states and I have been working on and advocating for the Physician Payment Sunshine Act for the past 3 years. We are very pleased a month ago when CMS released the long over-due final rules for the "National Physician Payment Transparency Program." This program will open a much-needed window regarding the hundreds of thousands of financial and other transactions between the drug and device manufacturers and the physicians who prescribe them.

I want to introduce **Marcia Hamms, Director of Prescription Access and Quality at Community Catalyst**, to provide some history since she was our lead organizer on the effort to pass the Sunshine Act since we started that work back in 2007.

Marcia: In 2007, the PEW Charitable Trust funded the Prescription Project at Community Catalyst. We were concerned about how the high cost of drugs was undermining access to health care and also about medical professionalism. We focused on changing state policy around conflicts of interest and began to work on the Sunshine Act when it was first filed in 2007. We worked hard to expand state level disclosure laws starting with MN, VT, ME, VA, MA and also CT. All of that created pressure for a national solution because the industry was not happy about having different disclosure systems in different states. That helped gain some industry support for the Sunshine Act for final passage as part of the ACA. We were also working with medical schools and academic medical centers on internal policies focused on conflicts-of-interest.

Wells: In addition to the useful pressure the state disclosure laws exerted, the Department of Justice had been actively investigating 5 out of the 6 largest pharmaceutical manufacturers in the country and found many forms of payments and forms of kick-backs that were occurring. The investigations and the prosecutions and settlements that followed required that these manufacturers would have to report all their future payments to providers on public websites. So there was a certain amount of public disclosure going on anyway and this helped insure that the Pharma trade association would not stand in the way of a national disclosure or transparency program.

After the ACA passed in March 2010, the Sunshine Act landed over at CMS. We thought this law would help the agency, which oversees Medicare and Medicaid, better look for patterns of payments to physicians and alert the public to what they might see. Unfortunately, CMS missed the October 2011 deadline to finalize the procedures to implement the program, but did issue lengthy draft rules 2 months later. These were very transparent about the kinds of decisions the agency would make to implement the Sunshine program, but after public comments were taken, we had to wait almost a year for the final rule. Thus, the program will launch 1 1/2 years late, on August 1, 2013.

In a nutshell, what will happen is that starting August 1st, the makers of drugs, devices and biologics will be required to report and describe in detail nearly all payments or other transfers of value made to any physician or teaching hospital. They must report the amount, date, name of recipient and address, and other descriptions -- cash, in-kind, check, travel, and also what the payment is for, such as consulting, gift, education, grant, or compensation for speaking. They will have to describe if it's related to any specific drug or more than one drug and name the product. That's very important. As for penalties, if the manufacturer inadvertently fails to report a payment, they must pay $1,000-10,000 per incident which is capped at $150,000 for the year. If it's an intentional failure to report, they pay between $10,000-$100,000, but, unfortunately, there is a $1 million cap for fines in one year. There are no reporting requirements nor penalties or fines for physicians under the law.

The detailed data reported by the industry to CMS will become publicly available on a CMS website starting in September 30, 2014 and ever year thereafter on June 30th. This is a huge victory. We will be able to track payments by industry and by physicians and teaching hospitals. The mechanics of the reporting are that every year on March 31, the industry has to report all payments for the prior calendar year. Then, physicians will have 45 days to review the information, submit corrections, and a 15-day dispute resolution process is provided for.

We did get a number of good rules from CMS to rethink and narrow loopholes that had existed in the statute. For example, lump sump payments from manufacturers have to be reported in its divisible parts. They also narrowed a loophole that delayed public disclosure of information if payments related to research on new products or new uses of existing products. We did not get a number of other things we wanted in the final rule, however. The third party marketing loophole, for example, allows manufacturers to not have to report payments through a third-party institution when they don't know the names of the physicians that actually get

the funds – for example, CMEs. We are still reviewing the final rule. Given the amount of money the drug industry spends marketing to physicians, we could see medical educational committees and other third parties or some new entities getting money and popping up. Overall, we are working with patients and stakeholders like students and doctors to understand what this new tool does and how to maximize its potential to improve care and enhance professionalism.

I want to take questions now, and would love to discuss the potential impact this broad transparency could have and how doctors and medical students would be interested in using this information themselves.

Q: How do we find out when a manufacturer has not reported a gift?

A: Based on past practices, it's usually disgruntled employees, whistleblowers, who file a legal action and this can occur in these cases as well. This is usually what happens when there is evidence of widespread fraud that costs the federal government a lot of money. There could be a mechanism for providers to report this kind of information.

Q: Are samples included as something that needs to be reported?

A: Not under the Sunshine Act, but a separate provision requires the reporting of samples to HHS. Not aware of the rule-making process for that, nor if it will be made public. A number of educational materials intended for patient use are excluded, such as an anatomical model used with patients. A textbook or other things used by the physicians must be reported. Payments below $10 do not have to be reported, such as a pen or small meal, unless they amount to an aggregate of more than $100 in the year.

Q: What about organizations that are provided funding by the industry when some of the money goes to a speaker, such as a keynote for a conference, and the speaker receives the funds from the conference host which is the entity that got the funds from the drug company?
A: If it's payment for a speaking event, it does have to be reported, except if it's an ACCME accredited event and the industry does not pick the speaker. If the person is part of a speakers' bureau and is paid by the manufacturer, the manufacturer does have to report the payments.

Q: Is the $1million cap per year sufficient, or will it just be part of the cost of doing business?
A: This is somewhat of a weakness. However, these are not the only legal means the federal government has to enforce this law. If the manufacturer is intentionally misrepresenting payments, there are other statutes that might allow for criminal investigation.

Q: Will doctors have any recourse if they feel the report about them is inaccurate?
A: Yes. After the payments are reported to CMS, it is creating a portal for physicians and teaching hospitals to see the information about just themselves. The physicians will have 45 days to do this, and then an additional 15 days to resolve the dispute. Even if the dispute is not resolved by then, CMS will present the facts of the dispute as well as the report. This provides some protection for physicians who feel the report is inaccurate.

Q: How other medical groups reacted to the Sunshine Act? Any support?
A: CMS describes the comments they received on the rule from different sectors, some of which were not relevant to the law itself. CMS did a good job of trying to implement the most comprehensive program they could given the statute they had and have maximized public disclosure.

Marcia: A number of medical center leaders who have been implementing COI policies see this law as a means to audit what their physicians are reporting to move the ball down the court.

Q: How do you think the residency exception will interact with the requirements for reporting for teaching hospitals?

A: I'll explain the residency exception, but not sure how they relate. The law excepts medical residents from reporting payments probably for administrative reasons because they do not have an "NPI or state medical license #." This is a weakness and we are going to discuss whether to challenge this. Payments to teaching hospitals will have to be reported and disclosed. It seems that if a big payment is made and it's used for various fellowships, payments to fellows who are residents will not have to be reported under a fellow's name if the industry does not know their name. They still have to report the payment if it's made to a teaching hospital.

Q: How will the availability of the information be promoted and do you think patients will take the time to look up their doctors?
A: CMS went to some length to describe how they will let physicians know when the information is avialbale for review – email lists, thru their teaching hospitals, on the CMS website. I think there will be a lot of public interest, as when the propublica website was launched a few years ago. Consumer advocates will need to help with this. Reporters will scrutinize this information, as will researchers, especially when physicians do things like sit on review committees or public entities. How patients will use this is a real question. There is no study yet on how ProPublica is being used, but anecdotally we do hear that patients are using it. It is not, however, as comprehensive as the Sunshine Act.

Q: What is ProPublica?
A: Look up"Dollars for Docs" and you will find a website created by a nonprofit organization called ProPublica that pulled together all available information from Department of Justice-required and state-required disclosure and put it into one database. You can search by physician name and state. It has been a useful resource for reporters and researchers to discover what relationships there are. Studies show that when doctors personally disclose payments they've received to their patients it actually contributes to greater, not less, trust on the part of the patient. Whether this lack of skepticism of patients as to what it means when their physician received large amounts of payments from industry will continue over time remains to be seen.

Q: Given that Dollars for Docs has been around for awhile, can we predict how the Sunshine Act might change physician behavior?
A: When the Sunshine Act appeared to be imminent a year and a half ago, it seemed to have a chilling effect on physicians' willing to accept payments from industry for fear of public disclosure – only anecdotal.

Q: When a drug company is fined, will this be posted somewhere so people know?
A: I believe that is supposed to be public as well, and that there will be an annual report on Congress from CMS that will include violations and enforcement actions.

Ann: In May, we had someone who sits on our Drug Utilization and Review Board who was one of the most highly paid doctors according to ProPublica and he no longer take funding from the drug companies now. However, he has been hired by the state's PMB.

Wells: What are any of you on this call hearing about the Sunshine Act? And how would medical students and physicians use the information it will be providing?

Rishma from AMSA: A medical school dean I spoke with today cited the impact the Act will have on their reporting system for payments to faculty and figuring out how to cross-check the information from the Sunshine Act to see if faculty are disclosing all their payments.

Mark Ryan, family physician in Richmond, VA: I have not heard any great concern or communications from my hospital. Perhaps it is not registering yet or still being processed. I work with a specialty organization and has not heard it come up there either.

Wells: The rules is only 27 days old and it's 280 pages, so it could be that institutions are still working through what the implications are. CMS will create a process for physicians to register ahead of time to look up

disclosures related to them. They have not started reaching out to them yet. I do think that at a point institutions should let physicians know that starting on Aug. 1st their interactions with the industry that involve a transfer of value are going to become public.

Marcia: I am a consumer representative on a committee at a teaching hospital that reviews similar payments. There is a high level of awareness about this there and want their faculty to understand it, so I imagine this will happen nationally.

Wells: It will be a challenge for groups like NPA and consumer groups to educate the public as to what this law means – we do not want over-reaction and we don't want the industry to gloss it over.

Ann: Thank you to Marcia and Wells. I am sure there will be more questions down the road on this. Recordings and notes of this and our past calls , as well as our National Grand rounds, are archived online at http://npalliance.org/conflict-free/. Our next Conflict-Free call will be in approximately two months – watch your email for the date and information.

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Participants from the following states were included on this call: AL, CT, DC, FL, GA, MA, MD, ME, MI, NC, NJ NY, OH, OR, PA, VA, WA

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