

The Physician Payments Sunshine Act

On August 1, 2013, the first reporting period under the Physician Payment Sunshine Act began. Part of the Patient Protection and Affordable Care Act (aka, “Obamacare”), it requires pharmaceutical and medical device manufacturers to publicly report many types of payments made to physicians, which will be public. The Sunshine Act was intended to bring transparency to these relationships, in order to minimize manufacturers’ influence on physicians’ prescribing behavior.

Excluded: Payments to physicians for participating in survey, opinion and marketing research

Because payments to physicians for participating in pharmaceutical and medical device marketing research are typically made by research companies rather than manufacturer-sponsors, and to physicians whose identities are unknown to the manufacturer-sponsors, those payments are excluded from reporting under the Sunshine Act law: **SEC. 1128G (e)(10)(A)**: *The term ‘payment or other transfer of value’ means a transfer of anything of value. Such term does not include a transfer of anything of value that is made indirectly to a covered recipient through a third party in connection with an activity or service in the case where the applicable manufacturer is unaware of the identity of the covered recipient.*

The Centers for Medicare and Medicaid Services (CMS) issued final rules implementing the Sunshine Act and reiterated this exclusion: **42 CFR § 403.904(i)(1)**: *Indirect payments or other transfers of value... where the applicable manufacturer is unaware of the identity of the covered recipient. An applicable manufacturer is unaware of the identity of a covered recipient if the applicable manufacturer does not know... the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year.*

Confusion: Single blind vs. double blind research

CMS explained the impact of the rules on marketing research: *“For example, an applicable manufacturer may hire a market research firm to conduct a double-blinded market research study, which includes paying physicians \$50 for responding to a set of questions. The applicable manufacturer clearly intends a portion of the payment to be provided to physicians, but given that the reason for the third party’s involvement is specifically to maintain the anonymity of the respondents and sponsor, we do not intend this to be considered a reportable indirect payment or other transfer of value.”*

Unfortunately, CMS created uncertainty for manufacturers by referencing in the example “a double-blinded market research study,” prompting some to wonder if single-blind research incentives are likewise excluded from reporting. The law, the regulations and the legislative history are clear: the focus of the Sunshine Act is on manufacturers’ knowing about the physician recipients of payments, not vice versa.

CASRO, MRA and PMRG’s position on the Sunshine Act

1. The letter and spirit of the Sunshine Act as it is written excludes marketing research payments from public reporting requirements so long as research’s routine policies and conventions are followed – i.e., physician respondents are paid by the research firm and their identities remain unknown to manufacturer-sponsors.
2. Carefully designed studies avoid any possibility that manufacturer-sponsors could inadvertently become aware of the identities of physicians participating in research.
3. Our ethical codes require that the identities of physician research participants not be disclosed to manufacturer-sponsors without the participants’ express consent regarding their disclosure and use.

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