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Legislative Update

PHYSICIAN PAYMENT SUNSHINE ACT ALERT

On August 1, 2013, the first reporting period under the Physician Payment Sunshine Act began. The commencement of that reporting period has caused some members of PMRG, CASRO and MRA to focus more closely on complying with the Sunshine Act's requirements, and to consider deploying new protocols for the conduct of market research. In the process, a number of critical questions have arisen, among both the manufacturers and their research consultants. This alert addresses the questions that PMRG, CASRO and MRA consider to be most urgent. All three associations will continue to communicate with members about the Sunshine Act as developments unfold.

A. Background: The Sunshine Act.

- Purpose and Mandate.

The Sunshine Act, enacted by Congress in March 2010 as part of the Patient Protection and Affordable Care Act, requires pharmaceutical and medical device manufacturers to report to the federal government many types of payments that they make to physicians. The government will, in turn, publicly post those payments and the names of the individual recipients on the Internet. The purpose of the law is to create greater transparency around manufacturer-physician relationships, so as to minimize any undue influence on physicians' prescribing behavior. The first reports must be filed in March 2014, for payments made between August and December 2013.

- Successful Efforts to Exclude Pharmaceutical Market Research from Reporting Requirements.

PMRG – with the support of CASRO and MRA – worked closely with the drafters of the Sunshine Act in Congress to ensure that typical market research honoraria would not have to be reported. Our concern was that reporting and publicizing the physicians' identities could: (a) reduce the pool of willing respondents, thereby adversely impacting both the cost and the quality and efficacy of research, to the detriment of our industry and health care consumers; (b) threaten the candor of responding physicians, as a result of disclosure of their identities to research sponsors, thereby (again) impeding the quality and efficacy of the research, to the detriment of our industry and consumers; and (c) contravene the very purposes of the Sunshine Act, by – for the first time in the history of market research – enabling manufacturers to routinely know the identities of those physicians whom they were paying, thus creating new opportunities for influencing prescribing behavior.

We also explained to the drafters that typical market research poses no risk of undue influence on prescribing behavior, in that, pursuant to CASRO and MRA ethical codes, (1) the manufacturers don't know the identities of the physicians who participate as respondents in the research and thus are unable to market directly to them as a result of the research, and (2) the researchers themselves are forbidden from marketing to research subjects.

To our great satisfaction, Congressional staff appreciated all of those observations; and as a consequence, a provision was inserted in the Sunshine Act excluding market research honoraria from the reporting obligations. The exclusion, written at PRMG's suggestion and with its material input, appears in the official compilation of federal laws at 42 USC 1320a-7h(e)(10)A, where the statute defines the types of payments that are and are not subject to the reporting requirements, as follows:

> The term "payment or other transfer of value" ... 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. (Emphasis added.)

Because pharmaceutical market research payments are typically made by the research companies rather than the manufacturer-sponsors, and to physicians whose identities are unknown to the manufacturer-sponsors, those payments meet the statutory exclusion criteria. When the law was enacted, that exclusion was widely regarded within the pharmaceutical market research industry as having saved the industry from debilitating consequences.

Importantly, the exclusion, as written, clearly applies to both double-blind research, where neither the manufacturer nor the physician knows the other's identity, and to single-blind research, where the manufacturer doesn't know the identities of the physician participants but the participants may know, or might infer, the identity of the manufacturer.

B. <u>The CMS Final Rule.</u>

In February 2013, the Centers for Medicare and Medicaid Services ("CMS") – a unit of the Department of Health and Human Services – announced its Final Rule interpreting and implementing the Sunshine Act. (The text of the Final Rule appears in the codification of federal regulations at 42 CFR Parts 402 and 403.)

Among the topics included in that announcement was CMS's response to comments that it had received regarding how the Final Rule would address aspects of the exclusion from reporting, including how a manufacturer's knowledge of the identity of physicians would be assessed for purposes of determining if the exclusion applied. In the context of that discussion, CMS stated, at p. 9490:

> [I]f a payment meets the definition of an indirect payment or other transfer of value in [42 C.F.R.] §403.902, then the payment can only be excluded from the reporting requirements if the applicable manufacturer did not "know" the identity

> of the covered recipient, as defined in [42 C.F.R.] §403.902. . . . . 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.

While that excerpt contains some errors in its characterization of market research, PMRG was heartened when the Final Rule was promulgated to see that CMS had expressly recognized the exclusion from reporting of market research honoraria.

C. <u>Concerns and Suggestions.</u>

Unfortunately, some members of the industry have focused on CMS's reference in the example to "a double-blinded market research study," and have been prompted to question whether single-blind research honoraria are likewise excluded from the statutory reporting requirement as expressed under the Final Rule. We strongly believe that they are. CMS's use of the phrase "a double-blinded market research study" in its example was unfortunate, and was incidental to the test that the example was presumably being used to illustrate – the lack of *manufacturer* knowledge of the physicians' identities. We simply do not believe that the phrase was intended, either expressly or implicitly, to limit the reporting exclusion to double-blind research honoraria.

Nonetheless, we understand that, in a good faith effort to comply with the Final Rule, some manufacturers are considering requiring their research consultants to disclose, for public reporting on the Internet, the identities of the physicians who receive honoraria in single-blind research studies.

PMRG, CASRO and MRA are deeply concerned about the effects of the industry acting on the basis of what we believe is a misinterpretation of the Final Rule. It would effectively vitiate most of the benefit of the reporting exclusion that Congress enacted, to the detriment of market research and ultimately, the delivery of sound health care solutions. Accordingly, for the benefit of our members, the associations are seeking a confirmation from CMS that the reference to double-blind research is mere commentary and an "example" – not a statutory or regulatory requirement – and that both double-blind and single-blind honoraria are exempt from reporting. We will advise our members if and when that confirmation materializes.

We meanwhile urge that our members adhere to the statutory language that clearly excludes from the reporting requirement any research in which physician research participants are paid by an intermediary (i.e., a market research firm) and their identities are not disclosed to the study sponsor. *Both of those criteria are routinely met by conventional market research.*

It is important to reiterate:

• The Sunshine Act is clear, on its face, that honoraria for physicians' participation in such research are excluded from the reporting requirement.

• CMS, as a regulatory agency of the executive branch of the federal government, is not *lawfully* able to supersede an act of Congress, even if it wished to do so.

We would like to remind our members that, pursuant to the ethical codes of CASRO and MRA, *research companies may not report the physicians' identities (or identifying information) to the manufacturers without first disclosing to the physicians that such reporting will occur and what it will be used for – i.e., public posting on the Internet with honoraria amounts* – even if that disclosure could chill research participation and increase recruiting costs. Thus, regardless of the reason for reporting physician identities to the manufacturers, it would be a clear violation of our industry codes were a market research company to turn over the identifying information of physician research participants after the completion of the data collection in cases where prior consent had not been obtained.

D. Summary.

In summary, PMRG, CASRO and MRA urge our members to:

1. Follow the letter and spirit of the Sunshine Act as it is written, excluding market research from public reporting requirements so long as our industry's routine policies and conventions are followed – i.e., respondents are paid by the market research firm and their identities remain unknown to manufacturer-sponsors.

2. Take careful steps in designing studies to avoid any possibility that manufacturer-sponsors could inadvertently become aware of the identities of research participants.

3. Adhere to industry ethical requirements that the identities of (physician) research participants not be disclosed to (manufacturer) clients without the participants' express consent regarding both disclosure and use of information.

4. Share this information with colleagues who are confused or have a different interpretation of the Sunshine Act. We believe that careful reading of the statute leaves no doubt as to its meaning and its intent.

Members are encouraged to contact PMRG, CASRO and MRA if they have any questions about this matter or if they would like to schedule additional discussions. We would particularly welcome discussions with manufacturers' legal and compliance departments, so as to maximize the opportunity for and efficiency of dialogue, given the critical importance of these issues to our industry. PMRG's contact is Executive Director Stephanie Reynders, at stephanie@pmrg.org, telephone 352-243-8585. CASRO's contact is President Diane Bowers, at dbowers@casro.org, telephone 631-928-6954. MRA's contact is CEO David Almy, at david.almy@marketingresearch.org, telephone 202-800-2545. Members are also advised that the Sunshine Act pertains only to research conducted with physicians in the U.S. Other countries may lack such laws, or may have stricter laws.