Regulatory Alert

PHYSICIAN PAYMENTS SUNSHINE ACT ALERT NO. 2

This alert follows the alert that CASRO, MRA and PMRG issued on August 29, 2013 in response to critical questions and concerns raised by our members regarding compliance with the Physician Payments Sunshine Act and with the Final Rule promulgated by the Centers for Medicare and Medicaid Services (CMS) in implementing that statute.

Reporting obligations under the Sunshine Act began on August 1, 2013. Our first alert emphasized that the law does not require the reporting of research honoraria paid to physicians (and other covered health care providers, or HCPs) whenever the pharmaceutical or device manufacturer is unaware of the HCPs' identities -- the statutory exclusion from the reporting obligations is not limited to "double-blind" studies. The first alert also emphasized that CASRO and MRA ethical guidelines require that research companies must obtain the informed consent of HCP-respondents before sharing their identities and their honoraria amounts with clients for any reason, including for purposes of reporting to the government and public posting on the Internet.

This second alert addresses three additional issues that have arisen in recent weeks, as manufacturers and their research companies undertake to comply with the Sunshine Act. This second alert is provided in the format of Frequently Asked Questions. As to each of the questions, the law is unsettled, and we are not offering legal advice upon which our members should rely. Rather, we are offering practical insights and suggestions based on our knowledge of the settled law and of industry practice.

1. Manufacturer-Provided Sample.

Q. If a manufacturer provides a list of HCPs for the research company to recruit, is the manufacturer deemed to be "aware of" the HCPs' identities for Sunshine Act purposes, and thus obligated to report all the HCPs' names and honoraria?

A: It depends on what portion of the list will ultimately participate in the actual research. If almost all on the list will participate, probably yes – the manufacturer effectively is "aware of" the identities. If only a small percentage will participate, probably no. Any percentage in between could give rise to a judgment call for the manufacturer and the research company to make

2. Adverse Event Reporting and Sunshine Act Reporting.

Q. If an HCP discloses an adverse event that a research company then reports to a manufacturer for FDA compliance purposes, must the research company also report the identity of the HCP to the manufacturer for those purposes? If so, is the manufacturer then "aware of" the HCP's identity, such that the manufacturer must also report the HCP's identity and honorarium amount to CMS for publication on the Internet pursuant to the Sunshine Act? If so, must each and every HCP -- in each and every study in which HCPs could disclose adverse events -- consent to the *potential* reporting and publicizing of his/her name and honorarium amount for Sunshine Act purposes, in anticipation of the possibility, however small, that he/she might disclose an adverse event during the course of the study?

A. To our knowledge, the law does not require research companies to identify to manufacturers the names of HCPs who report adverse events; nor does it address any of the other questions raised above. But from a policy perspective, **we believe that linking adverse event (AE) reporting of names to Sunshine Act reporting obligations is inadvisable:**

(a) Because the manufacturers' AE staff are different from their marketing staff, no undue influence on prescribing behavior is likely to issue from any AE reporting; and thus no positive purpose would be served by way of the link.

(b) Advising HCPs that their AE reporting could trigger Sunshine Act reporting could chill AE reporting – which is probably the last thing that the FDA would want to happen.

(c) Advising *all* HCPs that their names and honoraria *could* be reported on the Internet could seriously chill research participation (thus making recruiting more expensive and less representative).

(d) If HCPs learned that the manufacturer would have a greater chance of coming to know their identities, that could bias research responses and make for bad research science.

(e) Reporting the HCPs' identities to the manufacturers could facilitate the manufacturer unduly influencing the HCPs' prescribing behavior, contrary to the purposes of the Sunshine Act.

In any event, if so many HCPs were advised when being recruited for a survey that their names and honoraria amounts could be posted on the Internet, as a business proposition the manufacturer and the research company would likely want to establish between themselves who would bear any increased recruiting costs that could ensue from HCPs' reluctance to participate in the research, and whether sample design should be restructured so as to adapt to a depleted respondent pool.

Given those issues, a less burdensome solution to the questions posed in this FAQ could be for the research company to seek HCP consent for identification – both for AE reporting and Sunshine Act reporting purposes – only from those very few HCPs (if any) who will have actually mentioned AEs during the course of the research; i.e., following the research session, not when recruiting for it.

And the least burdensome approach would be for the research company, when reporting AEs to the manufacturer, to simply not identify the HCPs who have mentioned those AEs during the

course of the research, since that identification, to our knowledge, is not required by AE reporting law.

3. Recognizing HCPs During Qualitative Sessions.

Q. The Sunshine Act's exclusion of market research honoraria from the reporting obligation applies only when the manufacturer is unaware of the identity of the HCP respondent. If a manufacturer's employee who is evaluating a research study by observing a focus group session from behind a one-way mirror or through a video recording of such a session happens to recognize one of the participating HCPs, must the honorarium paid to that HCP be reported?

A. To our knowledge, instances of such recognition are infrequent to rare; and when they do occur, in the spirit of marketing research ethical requirements, they are not exploited by the manufacturers for sales or marketing purposes. We meanwhile believe that the manufacturers' ability to observe focus groups without impediment is of enormous value to the development and deployment of pharmaceutical products and medical devices, and thus to the delivery of quality health care to Americans and the world community. Indeed, we believe that that value far outweighs the negligible risk of undue influence on prescribing behavior that could arise from the infrequent recognition scenario. We also believe that disclosing HCPs' identities to manufacturers for Sunshine Act purposes could compromise the candor of the focus group discussions, thus compromising the integrity of the research and its value to health care delivery. And just as fervently, we believe that pointedly disclosing the identities of focus group participants to manufacturers under these circumstances would be more likely to create an opportunity for undue influence than would not disclosing their identities; and thus that non-disclosure would be more consistent with the policy goals of the Sunshine Act.

We acknowledge that the Sunshine Act and the CMS Final Rule do not speak directly to the focus group recognition scenario. But rather than either limiting manufacturers' access to focus groups or undertaking to report some or all focus group honoraria pursuant to the Sunshine Act, in a showing of good faith, and in an abundance of caution, research companies and manufacturers may choose to ensure that no undue influence will arise by pursuing one or all of the following practices:

(a) The research company requiring every manufacturer-observer to sign a one-sentence promise not to reveal the name of any HCP that he/she recognizes to his/her company, and not to sell or market to such an HCP on the strength of that recognition; and/or

(b) The manufacturer-client promising the research company (e.g., within its master service agreement with the research company) that (a) the manufacturer will instruct its focus group observers not to reveal the identity of any HCP that they recognize to other staff of the manufacturer, and (b) the manufacturer will not market to any HCPs on the strength of focus group recognition; and/or

(c) Manufacturers implementing written, internal confidentiality protocols relative to this matter, to the extent they have not already done so.

Should a manufacturer forego the above approach and instead require that the research company disclose the identities of focus group participants to the manufacturer for purposes of Sunshine Act reporting, we would urge research companies and manufacturers to adopt the following protocols:

(i) The research companies and the manufacturers should report the honoraria paid only to those focus group participants that the manufacturer-observer actually recognizes, not all participants. That is because reporting all honoraria would clearly go beyond the requirements of the law, while potentially creating significant disruptions in the quality and economics of focus group research.

(ii) The research companies should advise the HCPs at the outset of each study session that they may reduce the chances of being recognized, and thus of having their identities and honoraria amounts reported to the government and published on the Internet, if they avoid identifying themselves by name during the session.

(iii) The manufacturers, not the research companies, should take responsibility for determining which HCPs the manufacturers' employees recognize (whether during the research session or afterwards when viewing a video), and for reporting those identities to the government. The research company need not be involved in any aspect of the identification or reporting relative to these "recognition" episodes.

(iv) As stated in the preceding FAQ, manufacturers and research companies may wish to candidly discuss whether the new reporting protocols are likely to chill physician participation in the research; and if so, whether and how the sample design should be adjusted to correct for that, and who (as between manufacturer and research company) should bear any additional recruiting costs.

Contact us

Members are again encouraged to contact CASRO, MRA and PMRG if they have any questions about the Sunshine Act 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.