PREVISIONPOLICY

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Sunshine Regs Will Contribute To Repositioning of Pharma Promotion Budgets

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On December 19, the Centers for Medicare & Medicaid Services took the first step in promulgating disclosure regulations called for by Section 1128G of the Patient Protection & Affordable Care Act (Obama health care reform law).

The purpose of the disclosure ("transparency") provision was to address the alleged conflict of interest of industry support for health care practitioners (physicians and teaching hospitals) through extensive disclosure of payments or in-kind goods valued at more than $10.

The long-term effect of the disclosure proposal may be clearer than the short-term.

The added burdens and specific rules of the disclosure provisions will continue to nudge pharma budgets away from the broad dispersal of speaking and research funds for practitioners and towards other forms of spending. The likely beneficiaries of the shift will be more spending on outcomes studies with major user groups, patient contact activities and new media/social media.

The key short-term impacts of the proposed regs:

(1) **Confirms a delay in required collection of the payment information**. CMS will not expect manufacturers and group purchasing organizations to implement the collection of information at the beginning of 2012.

(2) **Initiates another round of extensive comment** on the procedures, distinctions and definitions necessary to implement a reporting process. CMS generally indicated a preference for one choice for each key choice/interpretation but left open the opportunity for an opposing choice.

For example, on whether to allow a delay in public reporting on ongoing research contracts for all products or a delay just for products seeking first-time approvals, CMS appears to favor the broader interpretation that the "delayed publication" exemption should apply to R&D on both new products and approved products seeking a new indication. However, CMS acknowledges that "conversely" the agency is also ready to propose limiting the delayed publication option to clinical investigations for only "new" products.

This "delayed publication" exemption is to help companies protect legitimate proprietary information during product development activities.

Speaker fees were one of the clear catalysts of the disclosure provisions in ACA, and CMS takes a

broad view of speaker payments that would include CME (continuing medical education) programs in the same disclosure category as other speaking engagements. CMS does again acknowledge that its tentative interpretation is a point for debate and asks for further comments on whether to "report other speaking engagements in another category."

The agency repeats this one-or-the-other approach numerous times in the proposed regs. That indicates the importance of the response period to this stage proposal and creates a strong impression that CMS recognizes a continuing lively debate on the interpretation of key elements of the disclosure rules. The deadline for comments on the proposal is February 17, 2012.

Indicative of the burdens that will come with the new public disclosure rules is the proposed handling of bagel-breaks provided by manufacturers for medical practices. The regs discuss at surprising length how to determine whether the provision of bagels to a group practice exceeds the $10 maximum level per person.

Bagel Economics a la CMS:

> "We recognize that in instances where group meals are being provided in group settings (for example, buffet-style food in a physician's office), it may be more difficult to keep track of which covered recipients are partaking in the food and beverage. We propose that in this type of scenario, applicable manufacturers should report the cost per covered recipient receiving the meal (even if the covered recipient does not actually partake of the meal).
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> "For example, if once during the calendar year, a sales representative from an applicable manufacturer brings $25 worth of bagels and coffee to a solo physician's office for a morning meeting, regardless of the number of individuals who partake (such as non-covered recipient staff members), the per covered recipient cost is $25. Since this falls above the $10 minimum threshold for reporting a payment or other transfer of value, which is statutorily required and discussed in detail in section II.A.1.h.(1). of this proposed rule, this meal must be reported.
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> "However, if the practice group includes five physicians, then the per-covered recipient cost is $5 (regardless of whether all five physicians actually consumed any of the food provided), so the payment would not need to be reported. We recognize that this may be difficult for large group practices or hospital-based physicians, where an applicable manufacturer may be bringing bagels for a meeting with two specialists. We are considering whether to adopt a different approach for these situations, such as counting the number of physicians by department."

That type of micro-management and the estimated burden of the whole process of tracking, recording and verifying payments are likely to combine to make this form of expenditure even less attractive than it has been in recent years for pharma.

Gifts and honoraria have already lost favor following the disclosure lists made public by individual companies as part of Corporate Integrity Agreements with the Department of Justice and Inspector General's Office at Health &

Human Services and from the adoption of those public lists as fodder for active public investigations by groups like the new investigative journalism organization, ProPublica. Payments will remain a headline issue as other groups like PEW Trust are recruiting analysts to follow the disclosures and keep them in public discourse.

CMS estimates that the costs to manufacturers to comply with the new requirements – even given the previous experience with CIA agreements – will be just short of $200 million in the first year. A large pharma firm will have to devote about 10 FTEs to the task of collecting and putting the payment information into the appropriate format for delivery to the CMS public disclosure site.

Perhaps more importantly, doctors and teaching hospitals will also have large costs: $24 million for physicians and $715,000 for teaching hospitals in the first year of the program. CMS does anticipate that costs will diminish as systems are put in place.

However, the added costs on both sides will serve to degrade the attractiveness of payments versus other expenditures.

A potential benefit to funding outcomes research is reflected in one passage of the proposed CMS regs. In an attempt to limit disclosure requirements to "bona fide research activities," CMS suggests requiring disclosure only of research done under a written agreement and/or research protocol. CMS acknowledges that some post-marketing research activities and "other research and studies" occur without a written contract and without a research protocol. CMS asks for comments as to whether "research" should be broadened to include these activities. If not, they might be favored as a less public form of research funding.

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