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Analysis of the Proposed Sunshine Rule: Legal Considerations

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Policy Overview

- Concern within Congress and among prosecutors and other enforcement officials regarding conflicts of interest and inappropriate influence
- Purposes of Sunshine Act disclosure include:
 - Transparency and public awareness
 - Discourage inappropriate conflicts of interest from developing
- CMS soliciting comments on the intricacies of the disclosure obligation and balancing the need to discourage inappropriate conflicts of interest without dissuading the development of beneficial arrangements

Potential Legal Issues

- Numerous proposals with significant legal implications, including:
 - Delayed Reporting
 - Definitions of Applicable Manufacturer and Common Ownership
 - Reporting Educational Material
 - Reporting Research
 - Reporting Compensation for Speaking Arrangements
 - Submission of Assumptions Letters
 - Disputed Reports and Opportunity to Amend Previously Reported Data
- Potential for Sunshine Act reporting to create Federal Anti-Kickback and False Claims Act risks, among others, for manufacturers
 - Sunshine Act reports provide a significant data mining opportunity for Congress and prosecutors
- Among the many challenges – compliance, operational, and implementation – will be designing and implementing safeguards to mitigate AKS, FCA, and other legal risks

Delayed Reporting

- CMS purports to delay the need to begin tracking payments until after the final rule is promulgated
 - States that manufacturers may begin to collect information “voluntarily”
 - Proposed 90-day “preparation period,” following the issuance of the final rule to afford manufacturers additional time to comply with the final rule’s data collection requirements
- Legal considerations:
 - What is meant by CMS’ suggestion that manufacturers might voluntarily collect information? What are the implications for manufacturers who do so?
 - Is the proposed preparatory period sufficient for the manufacturer to adjust its systems? What if the system isn’t ready following the conclusion of the preparatory period? Consider back-up plans to meet legal obligations

Definitions:

Applicable Manufacturer and Common Ownership

- Expansive proposed definitions
 - Applicable Manufacturer:
 - Global reach: Physical location or country of incorporation is not relevant; what is relevant is whether the entity sells or distributes a covered product in the U.S.
 - All payments: Applicable manufacturers must report all relevant payments, even on non-covered products so long as the manufacturer has at least one covered product
 - Common Ownership:
 - Proposal One (Broader): When the same person directly or indirectly owns any portion of two or more entities
 - Proposal Two (Slightly Narrower): When the same person directly or indirectly owns 5% or more of two or more entities
 - Intricate rules about under what circumstances entities under common ownership must report separately versus together
- Important legal implications for entities with global operations, brand and non-Rx products, and complex corporate structures

Reporting Educational Material

- Statute specifies an exception for “[e]ducational materials that directly benefit patients or are intended for patient use”
 - The implication is that other educational materials that do not fall within another exception must be reported
- CMS states that the exception is limited to “materials” (including written and electronic materials), but excludes “services or other items”
- CMS solicits comment on whether educational materials provided to covered recipients (for example, a medical textbook) should be interpreted as educational materials that ‘ ‘directly benefit patients’ ’
- Legal considerations include:
 - Implications for education materials for covered recipients
 - Examples: manufacturer-sponsored disease management or reimbursement information programs; reprints
 - PhRMA and AdvaMed-Code compliant educational items to covered recipients

Reporting Research

- CMS solicits comments on the definition of “research”
 - Should there be a separate category or categories for certain research activities such as post-marketing research, studies without research protocols, or studies not conducted pursuant to a written contract?
- Important proposal for delayed publication:
 - Proposal One: delay publication of research payments to covered recipients for services in connection with research on, or development of new covered products, as well as new applications of existing covered products
 - Proposal Two: limit delayed publication for those payments in connection with clinical investigations for new covered products only
- Reporting direct and indirect research payments; dual reporting for research payments to teaching hospitals; lump sum reporting for indirect research payments
- Considerations include data mining opportunities, disclosure of payments related to confidential clinical studies, and potential for consumer misinterpretation of payments subject to dual reporting and lump sum reporting

Reporting Compensation for Speaking Arrangements

- Sunshine Act requires that applicable manufacturers report direct compensation to physicians serving as speakers or faculty for a “medical education program”
- CMS proposes to broaden this requirement to reach any speaking arrangement
 - e.g., dinner programs
- CMS is weighing creating a separate payment category for speaking arrangements that are outside the context of a medical education program
- Legal considerations include data mining opportunities if additional payment category is established and additional reporting obligations that are not specified in the statute

Submission of Assumption Letters

- CMS seeks comment on its proposal to permit applicable manufacturers to submit assumptions letters with their annual reporting form to describe the manufacturer's practices with regard to categorizing the nature of the various payments and transfers of value it reports
- CMS also seeks comment on whether the submission of assumptions letters should be mandatory
- Legal considerations include:
 - If assumptions are not mandatory, whether such assumptions should be documented at all, documented internally, or documented and submitted to CMS
 - Potential enforcement risk mitigation tool
 - Content of such assumptions (should they cover just the manufacturer's practices with respect to categorizing payments, as specified under the proposed rule, or should they cover other issues as well such as operational or implementation limitations?)

Disputed Reports and Opportunity to Amend Previously Reported Data

- CMS seeks comment on its proposed dispute procedure
 - Covered recipient's understanding of the payment amount is what will be used by CMS to provide aggregated totals to the public
 - CMS is also considering aggregating totals using the manufacturer's understanding of the payment amount
- CMS also seeks comment on its procedure for manufacturers to amend previously reported data
 - 45-day review period for then-current and prior reporting year
- Legal considerations include data mining based on disputed data and whether to report to CMS corrections to data that are identified following the close of the review period

Safeguards to Mitigate Legal Risks

- Developing robust tracking and reporting systems, with regular compliance audits and monitoring
- Establishing appropriate policies and procedures for “front end” reporting and “back end” data review and correction
- Implementing effective compliance training for affected personnel
- Consider:
 - Analyzing payment trends prior to submission of reported payments to CMS
 - Undertaking legal review of payment data prior to submission to CMS
 - Documenting assumptions
 - Submitting assumptions and any limitations on certification to the government

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