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Client Alert Commentary

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Applicable Manufacturers Face June 30th Deadline for Sunshine Act Reporting

CMS will begin to enforce what could be significant penalties on manufacturers who fail to report required data.

The Centers for Medicare & Medicaid Services (CMS) has announced a short timeframe before detailed payment and ownership data is due and they begin enforcement of the physician payment "sunshine" provisions of the Patient Protection and Affordable Care Act and CMS' final rule interpreting such provisions (collectively, the Act, also known as Open Payments). To avoid substantial non-compliance penalties, applicable manufacturers and group purchasing organizations (GPOs) should promptly familiarize themselves with CMS' Open Payments system and the associated registration, reporting and attestation requirements. CMS' May 23, 2014 announcement about "Phase 2" of the registration and reporting process provides only 30 days — from June 1, 2014 to June 30, 2014 — for final submission of 2013 payment and ownership data. As CMS previously stated that Phase 2 would last for no less than 30 days, drug and device companies have only the minimum amount of time to complete final registration, data submission and legal attestation. Specifically, entities must:

- Complete the Open Payments system's registration process
- Validate the accuracy of profile data submitted by the applicable manufacturer or GPO during Phase 1
- Nominate Open Payments system users to fill three specific user roles
- Complete final data submission
- Attest to the timeliness, completion and accuracy of previously submitted data regarding payments or other transfers of value to covered recipients as well as ownership or investment interests in the applicable manufacturer or GPO

CMS has stated that it will begin to enforce penalties for non-compliance with the Act after June 30, 2014.

The Act's Background and Applicability

The Act requires drug and device companies — classified as "applicable manufacturers" of "covered products" — to report certain payments and transfers of value the manufacturers made to physicians or teaching hospitals as well as certain ownership and investment interests. Our previous client alert, CMS Issues Proposed Regulations Interpreting the Physician Payment Sunshine Act, details the specific requirements of the statute. Our client alert, CMS Announces Final Regulations Interpreting the Physician Payment Sunshine Act, analyses the final rule interpreting the statute.

Phase 1, which concluded on March 31, 2014, required applicable manufacturers and GPOs to register for the CMS Enterprise Portal, create a corporate profile, and submit aggregate information regarding 2013 payments or other transfers of value to physicians and teaching hospitals as well as ownership and

investment interests. An applicable manufacturer or GPO that did not complete Phase 1 must do so immediately in order to begin Phase 2.

CMS defines "applicable manufacturer" as an entity with a physical location or which otherwise conducts activities within the United States, and engages in the production, preparation, propagation, compounding or conversion of a covered drug, device, biological or medical supply, including entities under common ownership (five percent ownership or more) that provide assistance or support with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale or distribution of a covered drug or device for sale or distribution in the United States. Unless exempted or otherwise limited by the Act, an applicable manufacturer must report any payment or other transfer of value to a covered recipient, even if the payment is not related to a specific covered drug or device.

A "covered drug, device, biological or medical supply" is one for which payment is available under Medicare, Medicaid or Children's Health Insurance Program (CHIP) — either separately or as part of a bundled payment such as the inpatient or outpatient prospective payment systems (IPPS and OPPS) — and which requires a prescription to be dispensed (in the case of a drug or biological) or premarket approval by or notification to the FDA (in the case of a device or a medical supply that is a device). Our previous client alert, CMS Announces Final Regulations Interpreting the Physician Payment Sunshine Act, provides a detailed analysis of these definitions, applicable exclusions and information with respect to reportable payments or transfers of value.

Phase 2 Requirements for Applicable Manufacturers and GPOs[1]

During Phase 2 of the Open Payments registration, data submission and attestation process, applicable manufacturers and GPOs must complete two consecutive steps by June 30, 2014. While the first step opens on June 1, 2014, the second step is not available until June 9, 2014.

Step 1 Obligations

Between June 1 and June 30, authorized officials from applicable manufacturers and GPOs must:

- **Complete additional Open Payments system registration for themselves and the reporting entity:** In order to complete the Open Payments system registration process, the applicable manufacturer's or GPO's authorized official must use their EIDM ID created in Phase 1 to log into the Open Payments system. To expedite the process, the first person logging into the Open Payments system should be the authorized official who registered in Phase 1. In this case, the reporting entity's data entered during Phase 1 should appear pre-populated. If the applicable manufacturer or GPO did not register or report required information during Phase 1, such entity's authorized official must complete Phase 1 registration and create a new reporting entity profile.

- **Verify the accuracy of the applicable manufacturer's or GPO's profile data submitted in Phase 1**

- **Assign individuals to be the Officer, Submitter or Attester of the applicable entity's data:** The entity's authorized official may assign himself or herself or other individuals to any of these roles. After the authorized official delegates such roles and prior to June 30, each assigned representative must complete the tasks and responsibilities associated with his or her position for the 2013 data.

- **The Submitter may perform test uploads by submitting sample data files**: If the Submitter wishes to confirm that the data file is correctly formatted, he or she may select the "Submit as Test File" option on the "Upload Payments" page. The Open Payments system will then validate the

structure of the file and confirm that the formatting of the file is acceptable. Any submitted test files and data contained therein will not be uploaded for reporting.

- **The Submitter should use the Open Payments system's error reporting function to fix data errors in any previously submitted file:** To use the error reporting function, the official must submit his or her entity's file to Open Payments on the "Upload Payments" page. The system will validate the submitted file's structure to determine the format acceptability. If the submitted file contains content errors, the user will receive an email alert explaining the errors, with instructions for downloading the error report. The error report provides descriptions of the errors to guide the user to fix the errors manually or through resubmission of the file.

Step 2 Obligations

Assuming all Step 1 obligations are completed, beginning on June 9, authorized officials may begin completing Step 2 requirements. All Step 2 requirements must be completed on or before June 30. During Step 2:

- **Submitters must perform final data submission, including a series of checks to match the reported data to the applicable physicians and teaching hospitals:** At this step, after the authorized official resolves all validation errors identified in Step 1's error reporting test, "Final Submission" functionality will be available in the Open Payments system. After final submission, the submitted payments and ownership interests will match to the applicable physician or teaching hospital. If the system is unable to match some or all of the reported information, the authorized official will be notified and can either correct the data and repeat the matching process or override the failed match status and proceed with the submission.

- **Attesters must attest to the accuracy of the 2013 final submitted data:** Once the Open Payments system successfully matches submitted data to the applicable physician or teaching hospital, or in the event the Submitter overrides the failed matching status, the file becomes "Ready for Attestation."

Attestation Requirements

The final rule interpreting the statute requires that each report, including any subsequent corrections to a filed report, include an attestation by the Chief Executive Officer, Chief Financial Officer, Chief Compliance Officer, or other officer of the applicable manufacturer or GPO that the information reported is timely, accurate, and complete to the best of his or her knowledge and belief. CMS released the Open Payments Attestation language[2] to provide the industry with guidance regarding the legal implications of such attestations.

The Open Payments Attestation Language provides the opportunity for the reporting entity to attest that the entity is only reporting payments or other transfers of value associated with covered drugs, devices, biologicals, or medical supplies based on the various reporting limitations included in the Act. When the official checks this attestation box, he or she must also select the appropriate reason for only reporting payments or transfers of value associated with covered products (*e.g.*, the entity's gross revenue from covered products constituted less than 10 percent of gross revenue during the fiscal year preceding the reporting year).

If applicable, the reporting entity also must attest to the reason the entity is requesting a delay in publication for one or more payments or other transfers of value. Lastly, the reporting entity may attest that it is submitting a consolidated report because the entity is under common ownership with a separate entity or entities that are also applicable manufacturers.

Penalties

CMS has noted that it will begin to enforce penalties for non-compliance with the Act after June 30, 2014. CMS and the Office of Inspector General are authorized to impose aggregate penalties of up to US$1.15 million per applicable manufacturer or GPO, per each annual submission, for failing to timely, accurately, or completely submit the required documentation. Penalties imposed for failures to report and knowing failures to report will be aggregated separately. Applicable manufacturers or GPOs will be subject to a penalty of at least US$1,000, but no more than US$10,000, for each payment or other transfer of value, or ownership or investment interest not reported as required (capped at US $150,000 per annual submission). For knowing failures to report, applicable manufacturers or GPOs will be subject to a penalty of at least US$10,000, but no more than US$100,000 (capped at US$1 million per annual submission).

Conclusion

Phase 2 of the Open Payments registration, data submission and attestation process provides only 30 days for applicable manufacturers and GPOs to complete registration, submit matched final payment or ownership data and submit necessary legal attestation statements. To avoid potentially significant penalties for non-compliance, all applicable manufactures and GPOs must complete Step 1 and Step 2 of Phase 2 by the June 30, 2014 deadline.

If you have questions about this *Client Alert*, please contact he author listed below or the Latham lawyer with whom you normally consult:

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Endnotes

1 http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Downloads/Phase-2-Instructions-Document-[May-2014].pdf

2 http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Downloads/Open-Payments-Attestation-Language-[May-2014].pdf