

Client Alert

FDA & Life Sciences Practice Group

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CMS Delays Open Payments Data Submission Deadline, Announces Registration Process; Requires Manufacturers and GPOs to Report “Aggregate” Data by March 31, 2014

On Friday, February 7, 2014, the Centers for Medicare and Medicaid Services (CMS) announced that Open Payments registration is scheduled to begin on Tuesday, February 18, 2014 for applicable manufacturers and applicable group purchasing organizations (“GPOs”). CMS released its announcement via email to the Open Payments email distribution list. According to CMS, the Open Payments program is designed to create greater public transparency about financial transactions among doctors, teaching hospitals, drug and device manufacturers, and other healthcare businesses. The agency provided new details about its plans for a two-phased approach to the registration and data submission processes for the first reporting period.

This announcement is tantamount to a delay of the requirement for full data submissions covering the first reporting period until May 30, 2014, at the earliest (and possibly later), although certain interim information (*e.g.*, certain aggregate information about data covering the first reporting period) and registrations must still be provided by March 31, 2014.

Two-Phased Approach to Registration and Data Submission

The phased approach announced by CMS for the first reporting period will consist of the following two phases:

Phase 1 will take place from **February 18 through March 31, 2014**. This phase will require (1) registration within the CMS Enterprise Portal by applicable manufacturers and applicable GPOs that will have data to report; (2) submission of corporate profile information for such applicable manufacturers and applicable GPOs; and (3) submission of certain “aggregate” information regarding reportable data for the first reporting period (Aug. 1 – Dec. 31, 2013).

Phase 2 will begin in **May 2014 and extend for at least 30 days (but no later than August 1)**. This phase will require (1) registration in the Open Payments system (a system separate and distinct from the CMS Enterprise Portal); (2) submission of detailed data covering the first reporting period, *i.e.*, the applicable manufacturer’s or applicable GPO’s complete spend/ownership report covering the first reporting period (using the instructions now available on the Open Payments website); and (3) completion of an attestation regarding the accuracy of data submitted.

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For the 2013 program year, CMS has indicated that:

- The agency will not enforce penalties until after the close of Phase 2 (which appears would be sometime in summer 2014, but no later than August 1, 2014).
- The 45-day covered recipient review period and subsequent 15-day correction period will begin by August 1, 2014.
- No action is required from covered recipients (affected physicians; teaching hospitals) at this time. The announcement did not provide information regarding the agency's timeline for the covered recipient (affected physicians; teaching hospitals) registration period; however, covered recipient registration will presumably need to occur before the 45-day review period begins, which is expected to begin by August 1, 2014.

Aggregate Data Submission

The concept of submitting aggregate information about 2013 data during the first phase is new. The agency has not yet released instructions describing what that information may entail or for submitting that information. The announcement indicates that instructions about the aggregate data reporting will be available only within the CMS Enterprise Portal, and will be accessible to a manufacturer only after it completes registration within the CMS Enterprise Portal.

According to informal guidance from CMS obtained by King & Spalding, the "aggregate" data that applicable manufacturers will be required to report by March 31 will be a few high-level aggregate data points for the reporting period (August 1, 2013 – December 31, 2013) from each of the three reporting templates (*i.e.*, the research payments, general/non-research payments, and ownership or investment interests templates). For the research payments and the general/non-research payments, the reportable aggregate data likely will include: (1) the total amount of payments or transfers of value paid to covered recipients; (2) the total number of payments or transfers of value made; and (3) the total number of covered recipients that were recipients of the payments made. For the physician ownership or investment interest payments, the reportable aggregate data will include the total number of physician ownership or investment interests provided during the reporting period. The data will not be aggregated by covered recipient and applicable manufacturers will not be required to attest to its accuracy.

Next Steps from CMS

CMS is soon expected to announce the date and registration information for an industry-focused webinar on the phased approach to Open Payments registration and data submission. Instructions for completing Phase 1 are available on the Open Payments website, at <https://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Data-Submission-and-Attestation.html>.



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