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New Registration Process for 340B Entities — Another Sign of Changes in the Program

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Over the past year, the [Office of Pharmacy Affairs](#) (OPA), the agency within HHS' Health Resources and Services Administration (HRSA) that administers the 340B Drug Discount Program (340B Program), has implemented significant changes that affect covered entities that participate in the 340B Program. Largely in response to direction from the Government Accountability Office (GAO) and pressure from certain Republican members of Congress, OPA has taken numerous steps that affect covered entities — particularly those participating as Disproportionate Share Hospitals (DSH).

These changes to the 340B Program reflect a clear focus on compliance, probably the most significant attention to compliance by OPA in the history of the 340B Program. In addition to the various actions taken by OPA in the past year, which include auditing selected DSH hospitals and creating a new program-integrity oath for hospitals re-certifying in the 340B Program, the OPA has recently created a new website which was launched on October 5. The theme and tone of the new website clearly demonstrate an emphasis on compliance.

HRSA published its new guidance on registration in the Federal Register on July 24, 2012. Under the new system — effective as of October 1, 2012 — DSH hospitals are required to register themselves (if they are a new covered entity), their outpatient facilities, and each contract pharmacy that dispenses 340B drugs to their outpatients within a two-week window that occurs quarterly. To be eligible by January 1, 2013, DSH hospitals must have filed the appropriate forms with OPA between October 1 and October 15. Those covered entities that missed the

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deadline will have to wait until the next window (January 1 through January 15, 2013) to be eligible April 1, 2013. The next two windows will occur on April 1 – 15 (for eligibility on July 1), and July 1 – 15 (for eligibility on October 1).

Under the old registration process, OPA enrolled entities on a rolling basis, with a shorter lag time, i.e., covered entities applying before October 1, could expect to be enrolled by November 1. While many DSH hospitals scrambled to finalize contract pharmacy agreements before the new quarterly enrollment process began on October 1, OPA experienced some problems on its website that made it impossible for entities to print the signature page form that is required for enrollment. Notice on the website at that time informed users that OPA would contact those entities who were unable to print the necessary forms for signatures.

Ober|Kaler's Comments

DSH hospitals — along with other covered entities — that participate in the 340B Program should expect to continue experiencing these and other new challenges as OPA becomes more active in the area of compliance, particularly with respect to diversion of 340B drugs. For DSH hospitals that participate in the 340B Program and that use one or more contract pharmacies to provide 340B drugs to outpatients, or for hospitals that want to expand 340B pricing to patients of one or more of their provider-based outpatient clinics, the new registration requirements are probably the most immediate concern.