The Long-Awaited 340B Drug Pricing Program Omnibus Guidance: Part I

A More Restrictive Definition of "Covered Patient"

September 1, 2015

On August 28, 2015, the Health Resources and Services Administration ("HRSA"), the federal agency that administers the 340B Discount Drug Pricing Program ("340B Program"), issued its long-awaited 340B Program Omnibus Guidance (the "Guidance"). The proposed Guidance clarifies various aspects of covered entity and drug manufacturer compliance with Section 340B of the Public Health Service Act ("PHSA"); topics that are currently addressed in a number of HRSA guidance documents published in the Federal Register dating back to 1992. Comments on the proposed Guidance are being accepted until October 27, 2015. Dykema will provide a series of short updates on the Guidance, beginning with its most highly-anticipated portion, the updated definition of "covered patient."

The PHSA prohibits a covered entity from reselling or transferring drugs purchased under the 340B Program to individuals who are not eligible patients of the covered entity (or "covered patients"). Such sales or transfers are considered diversion of 340B drugs. The Guidance clarifies that covered entities are required to offer repayment to all manufacturers for any improperly obtained discounts caused by diversion, and to notify the Department of Health and Human Services of its corrective actions regarding diversion. Covered entities that engage in significant diversion may face termination from the 340B Program.

The definition of covered patient currently in effect was issued in 1996, and contains the following three requirements:

> (a) the covered entity has a patient relationship with the individual, such that it maintains records of the individual's care;
>
> (b) the individual receives services from a professional who is either employed by or under contract, with the covered entity, such that responsibility for the individual's care remains with the covered entity; and
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> (c) the individual receives care or services from the covered entity that is consistent with the range of services for which the covered entity receives federal funding. (This requirement does not apply to hospital covered entities.)

340B covered entities have struggled for years to apply this cryptic definition to the myriad of scenarios under which patients may receive care from a covered entity.

The Guidance expands the current three-prong definition to the following more specific six-part test:

1. The individual receives a health care service at a facility or clinic site that is registered for the 340B Program and listed in the 340B database.
2. The individual receives a health care service provided by a covered entity provider who is either employed by or is an independent contractor to the covered entity, such that the covered entity may bill for the provider's services.
3. The individual receives a drug that is ordered or prescribed by the covered entity provider described in 2, above. An individual is not considered a patient of the covered entity if their only relationship is the dispensing or infusion of a drug.
4. The individual's health care is consistent with the scope of the Federal grant, project, designation or contract. (This requirement does not apply to hospitals.)
5. The individual's drug is ordered or prescribed pursuant to a health care service classified as "outpatient." The individual is considered an outpatient (a) if the patient is insured, the care is billed as outpatient to a third party payor, or (b) if the patient is private pay, uninsured or receives charity care, the patient qualifies as an outpatient under the covered entity's policies and procedures.

6. The individual's patient records are accessible to the covered entity and establish that the covered entity is responsible for care.

Commentary to the Guidance provides information about more nuanced aspects of these six requirements, including such issues as the use of telemedicine, eligibility of covered entity employees, the status of health care entities that are affiliated with and share medical records with the covered entity, application to infusion therapy and the status of individual providers who have privileges at the covered entity but who are not employed or contracted by the covered entity.

Dykema will present additional updates on other aspects of the Guidance, including: eligible covered entities, registration and termination; covered drugs, replenishment models, contract pharmacies and the GPO prohibition; and recording keeping requirements and audits.

Dykema attorney Kathleen A. Reed (231.348.8134), kreed@dykema.com, is available to assist your organization in understanding the proposed Guidance and implementing anticipatory compliance efforts.

All 340B covered entities should evaluate their current practices under the proposed Guidance in preparation for any adjustments that may be required once the Guidance is finalized.

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Practice Areas

Health Care