

The background of the slide features a close-up, shallow depth-of-field photograph of medical supplies. In the upper portion, a silver stethoscope is visible, with its chest piece resting on a light-colored surface. Below the stethoscope, several pills are scattered on a white, reflective surface. There are several blue and white capsules and one prominent, large, round, red pill in the center foreground. The lighting is bright and clinical, creating soft shadows and highlights on the metallic and plastic surfaces.

Long-Awaited 340B Guidance: What Covered Entities Need to Know





Today's Speakers

Tuesday, September, 22, 2015

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Agenda

- Changes to “Patient” Definition
- Medicaid and 340B
- Key Program Integrity Requirements
- Status of Guidance and Comments
- Questions?



Current 340B Patient Definition

- The covered entity has established a relationship with the individual, such that the *covered entity maintains records* of the individual's health care; and
- The individual receives health care services from a health care professional who is either *employed* by the covered entity or provides health care under *contractual or other arrangements (e.g. referral for consultation)* such that responsibility for the care provided remains with the covered entity; and
- The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or FQHC look-alike status has been provided to the entity. *[Hospitals are exempt]*
- An individual will *not* be considered a patient of the covered entity if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs *for subsequent self-administration or administration in the home setting.*



Proposed 340B Patient Definition

- Patient eligibility determined on a *per-prescription or per order* basis and must meet all of these criteria:
 - (1) The individual receives a health care service at a covered entity site which is registered for the 340B Program and listed on the public 340B Program database;
 - » No longer support for referral arrangements for follow up/specialty care outside the covered entity



Proposed 340B Patient Definition (cont'd)

(2) The individual receives a health care service from a health care provider employed by the covered entity or who is an independent contractor of the covered entity such that the covered entity may bill for services on behalf of the provider;

- » Privileges/Credentials not enough
- » New requirement that covered entity must be able to bill for professional services



Proposed 340B Patient Definition (cont'd)

(3) The individual receives a drug that is ordered or prescribed by the covered entity provider as a result of the service described in (2). The individual will not be considered a patient of the covered entity if the only health care received by the individual from the covered entity is the infusion of a drug or the dispensing of a drug;

- » Necessary relationship between 340B drug ordered and type of service received
- » Exclusion of infusion drugs



Proposed 340B Patient Definition (cont'd)

(4) The individual receives a health care service that is consistent with the covered entity's scope of grant, project or contract

- » Covered entity hospitals exempt
- » Consistent with current definition



Proposed 340B Patient Definition (cont'd)

(5) The individual is classified as an outpatient when the drug is ordered or prescribed, as determined by status when billed to payor;

- » Elimination of ability to purchase 340B drugs for discharged inpatients; reduction of contract pharmacy purchases
- » Patient's payor billing status now critical; administratively burdensome/challenging



Proposed 340B Patient Definition (cont'd)

(6) The individual has a relationship with the covered entity such that the covered entity maintains access to auditable health care records which demonstrate that the covered entity has a provider-to-patient relationship, that the responsibility for that care is with the covered entity, and that each element of this patient definition is met for each 340B drug.

» Generally consistent with current definition



Medicaid and 340B

- 340B Program drugs do *not* include drugs that:
 - » Are provided as part of, or incident to and in the same setting as: inpatient hospital, hospice, dental, physicians, outpatient hospital, nursing facility, other laboratory and x-ray services, or renal dialysis; *and*
 - » Are reimbursed through bundled reimbursement by Medicaid.
- For hospitals subject to GPO prohibition:
 - » If reimbursed by Medicaid and meet the criteria above *can be* purchased through GPO. If reimbursed through bundled payment from other payors, can be purchased through 340B and not GPO.



Medicaid and 340B (cont'd)

- Coordination with the state and HRSA required if 340B is used for Medicaid FFS patients
- New guidance on use of 340B for Medicaid managed care
 - » Current 340B guidance on duplicate discounts applies only to FFS Medicaid; does not address Medicaid managed care
 - » Affordable Care Act expanded Medicaid drug rebate program to Medicaid managed care, creating possibility for duplicate discounts for those patients



Medicaid and 340B (cont'd)

- Systems need to be developed to identify Medicaid managed care patients and report use of 340B
 - » Covered entities would be required to have mechanisms to identify Medicaid managed care patients
 - » Mechanism for reporting use of 340B for Medicaid managed care and the state are not developed
- Contract pharmacy arrangements should exclude Medicaid FFS *and* managed care patients, unless a written agreement is in place for HRSA approval that describes a system that prevent duplicate discounts



Key Program Integrity Provisions

- New 90 day window from identification of 340B drug diversion for covered entities to work with manufacturers regarding repayment
- No discussion of or definition of “materiality” for instances of non-compliance or any clarification of self-disclosure process for non-compliance identified by covered entities



Key Program Integrity Provisions (cont'd)

- New requirement to maintain auditable records for at least five years
- Contract pharmacy quarterly monitoring and annual audits; requirement to report corrective action to HRSA



HRSA & Manufacturer Audits of Covered Entities

- Process generally consistent with current HRSA and manufacturer audit guidelines and processes
- Proposed guidance establishes “notice and hearing process” for responding to HRSA audit findings but no actual “hearing”
- HRSA states that a covered entity’s refusal to respond to manufacturer questions may be “reasonable cause” for manufacturer audit



Status of Proposed Guidance?

- Issued as interpretive guidance
- Enforceability may depend on consistency with 340B statute and amount of deference given to HHS/HRSA
- Potential impact of orphan drug litigation
- Potential to be applied by HRSA prior to finalization



Specific Areas Where HRSA Has Requested Comments

- Alternatives to how off-site hospital outpatient facilities or clinics may demonstrate 340B eligibility
- What type of information could be submitted by a covered entity to HHS to demonstrate compliance sufficient to re-enroll in the 340B program after being removed for violation of an eligibility requirement
- Utility and format of the Medicaid Exclusion File and alternative approaches to addressing purchasing of 340B drugs for Medicaid fee-for-service and Medicaid managed care patients
- Issues related to ADAP rebate requests and ADAP insurance coverage and payment



Upcoming Events

- Kickoff Call: 340B Drug Pricing Program Covered Entity Coalition
 - » Thursday, September 24
 - » 8 a.m. Pacific time
 - » Contact Elizabeth Elson for call-in info, eelson@foley.com

- Business of Personalized Medicine Summit
 - » Wednesday, October 7 at South San Francisco Conference Center
 - » Use code: FOLEYVIP15 to save 40% on registration
 - » personalizedmedicinesummit.com



Questions?

- Thank you for attending today's web conference.
- Speakers will now address questions submitted via the Q&A box.



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