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340B DRUG PRICING PROGRAM NOTICE
Release No. 2012-2

**CLARIFICATION OF COVERED ENTITY ELIGIBILITY WITHIN ACCOUNTABLE
CARE ORGANIZATIONS**

This policy release is being issued to clarify the 340B Drug Pricing Program's (340B Program) policy concerning covered entity eligibility as it relates to Accountable Care Organizations (ACOs) and to align with recent regulations promulgated by the Centers for Medicare and Medicaid Services (CMS) regarding ACOs.

Background

Section 602 of the Veterans Health Care Act of 1992 (Public Law 102-585) enacted section 340B of the Public Health Service Act (PHSA), "Limitation on Prices of Drugs Purchased by Covered Entities." The Office of Pharmacy Affairs, within the Healthcare Systems Bureau of the Health Resources and Services Administration (HRSA), is charged with administering the 340B Program established by Section 340B of the PHSA.

Section 3022 of the Patient Protection and Affordable Care Act (Public Law 111-148) established a Medicare Shared Savings Program in which certain groups of providers may collaborate to provide care for certain beneficiaries through ACOs. CMS published final rules for the Medicare Shared Savings Program on November 2, 2011 (76 Fed. Reg. 67802).

340B Program Covered Entities

Section 340B(a)(4) of the PHSA lists the various types of organizations eligible to participate in and purchase discounted drugs under the 340B Program. Eligibility for participation in the 340B Program is limited to the categories of entities specified in this section of the statute. Inclusion of a covered entity within an ACO does not make the entire ACO eligible for receiving discounted drugs under the 340B Program and does not permit ACO associated entities, which do not satisfy the eligibility requirements of section 340B(a)(4), to access 340B Program discounted drugs.

The inclusion of a 340B covered entity within a larger organization, which could occur if a covered entity is a part of an ACO, does not make the entire organization eligible for the 340B Program. Section 340B(a)(6) states that, "[i]n the case of a covered entity that is a distinct part of a hospital, the hospital shall not be considered a covered entity under this paragraph unless the hospital is otherwise a covered entity under this subsection."

As stated in the preamble to the final ACO Rules, “[t]he ACO is not itself a 340B eligible entity. Health care providers in an ACO that participates in the 340B program must continue to meet all the requirements of the 340B statute, including ensuring they are not diverting drugs to non-patients or receiving duplicate discounts. A 340B provider is prohibited from purchasing or transferring drugs to non-340B entities and patients of non-340B providers, including those which are part of an ACO” (76 Fed. Reg. 67802, 67956).

Patients of 340B Covered Entities

340B covered entities participating in an ACO must continue to ensure all patient definition requirements are met. The inclusion of a covered entity in an ACO does not automatically make all of the individuals receiving services from an ACO patients of the covered entity for 340B Program purposes. All individuals receiving 340B discounted drugs must still satisfy the 340B patient guidelines.

Under previously released guidelines, “[a]n individual is a ‘patient’ of a covered entity (with the exception of State-operated or funded AIDS drug purchasing assistance programs) only if:

1. the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual’s health care; and
2. 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
3. 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 Federally-qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.

An individual will not be considered a ‘patient’ of the covered entity for purposes of 340B 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” (61 Fed. Reg. 55157-8, Oct. 24, 1996).