

**Tab 2-11**



DEPARTMENT OF HEALTH & HUMAN SERVICES  
BUREAU OF PRIMARY HEALTH CARE

Public Health Service

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Health Resources and  
Services Administration  
Bethesda MD 20814

The Public Hospital Pharmacy Coalition  
c/o William H. E. von Oehsen, Esq.  
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1212 New York Avenue, NW, Suite 800  
Washington, DC 20005

Dear Bill:

This letter is in response to your August 5 letter in which you requested, on behalf of the Public Hospital Pharmacy Coalition, written guidance regarding six issues discussed in the 340B Coalition Conference break-out session and the seven scenarios which discuss potential 340B program disqualification. The following is a list of the six issues and the seven scenarios that you faxed to our office for discussion and a response to each:

**QUESTIONS**

1. **QUESTION** May a hospital dispense 340B discounted drugs to individuals who fall within the Office of Drug Pricing's (ODP) definition of patient but whose care is not billed by the hospital (so that the cost of the care does not appear on the Medicare cost report)?

**ANSWER** Such individuals would not fall within the ODP definition of patient if they receive care from a hospital outpatient clinic that is not included on the hospital's Medicare cost report. First, a hospital could not dispense section 340B discounted drugs to an individual until a number of requirements are met. First, the hospital must meet the section 340B(a)(4) & (5) requirements to become a covered entity identified on the ODP eligibility list. Second, pursuant to 59 Fed. Reg. 47884 (final notice published on September 19, 1994), only those patients of such covered entity hospital outpatient clinics which are listed on hospital's Medicare Cost Report are eligible to receive 340B discounted drugs. Third, an individual receiving care from such an eligible clinic would fall within ODP's definition of patient if the covered entity maintained records of the individual's health care from the eligible clinic and the individual was receiving health care services from a health care professional who is either employed by the covered entity or under contractual or other arrangements (e.g., referral for consultation) such that the responsibility for the care provided in this eligible clinic remains with the covered entity. The final notice of this patient definition was published in the Federal Register on October 24, 1996, 61 Fed. Reg. 55157.

2. **QUESTION** Assuming that the BMC decision does not preclude hospitals from dispensing to patients who are nursing home patients, is a drug dispensed to a resident of a hospital-based nursing home still an outpatient drug eligible for a discount or would the drug be considered an inpatient drug? Please note an ODP letter dated July 15, 1997, which "recognized the rights of hospitals to dispense to nursing home residents."

**ANSWER** In the July 15 letter, ODP recognized the eligibility of a nursing home patient to receive 340B discounted drugs only if that nursing home patient was receiving outpatient services from "a covered entity and meets all other requirements for definition as a patient of the entity." Clearly, a nursing home patient would be eligible to receive 340B discounted drugs if the outpatient health care service is provided by a covered entity hospital, the outpatient clinic providing the health care service is listed on the Medicare Cost Report, the covered entity is maintaining the records of the nursing home patient's health care from the eligible clinic and the nursing home patient is receiving health care services from a health care professional who is either employed by the covered entity or under contractual or other arrangements (e.g., referral for consultation) such that the responsibility for the care provided in this eligible clinic remains with the covered entity.

3. **QUESTION** May a hospital purchase and use an outpatient drug through the 340B program even though it is not eligible for a Medicaid rebate?

**ANSWER** Section 340B refers only to section 1927(k) of the Social Security Act (Medicaid Drug Rebate Program) for the definition of "covered outpatient drug." The definition includes two parts. First, section 1927(k)(2) provides a FDA-like generic definition of covered drug, including most drugs and biologicals (except vaccines) which are dispensed only by prescription and which require approval by the FDA or a license under section 351 of the PHS Act. Second, section 1927(k)(3) excludes any drug provided as a part of or incident to certain listed health services if the payment for such a drug is bundled with other payments in an all-inclusive rate payment or the like and not as direct reimbursement for the drug itself. This definition of "covered outpatient drug" was published as a final notice in the Federal Register on May 13, 1994, 59 Fed. Reg. 25113.

4. **QUESTION** If a clinic-administrated drug is purchased through the 340B program and used on a Medicaid patient, must the hospital bill at acquisition cost?

**ANSWER** When a covered entity hospital submits a bill to the State Medicaid agency for a 340B discounted drug purchased by or on behalf of a Medicaid beneficiary, the amount billed must not exceed the entity's actual acquisition cost for the drug, as charged by the manufacturer, at a price consistent with section 340B requirements, plus a dispensing fee established by the State Medicaid agency. This assures that the discount to the covered entity hospital is passed on to the State Medicaid agency. This is consistent with section 340B requirements and the limitations established in the Medicaid regulations, 42 CFR section 447.331- 447.334, which limit the amount the State Medicaid agency may reimburse providers. See 58 Fed. Reg. 27293, May 7, 1993, and 59 Fed. Reg. 25110, May 13, 1994.

5. **QUESTION** If a clinic-administered drug is not billed separately, but rather billed as part of a bundled fee, may the hospital purchase the drug through a group purchasing organization (GPO)?

**ANSWER** For hospital covered entity status, section 340B(a)(4)(L)(iii) requires that a hospital must not obtain covered outpatient drugs through a group purchasing organization (GPO) or other group purchasing arrangement. However, the term "covered outpatient drug" does not include those drugs which are provided as part of, or as incident to and in the same setting as certain restricted services specified in section 1927(k)(3) of the Social Security Act, and for which payment for drugs is bundled with the service and not as direct reimbursement for the drug. Consequently, a covered entity hospital may purchase such drugs that are not covered outpatient drugs through a GPO and not lose its eligibility to purchase covered outpatient drugs through the 340B Drug Pricing Program.

6. **QUESTION** If a hospital is currently being paid a Medicare disproportionate share adjustment above 11.75 percent and both the Medicare fiscal intermediary and the hospital can document this, may the hospital be admitted into the 340B program even though its last settled cost report indicates an adjustment below 11.75?

**ANSWER** As you are aware of the current lawsuit against HHS regarding this same issue, you know that we are not in a position to discuss this matter. I refer you to our brief submitted to the Court (and in your possession) which clearly outlines in great detail our position on this matter.

## **SCENARIOS**

**Do the following scenarios related to the section 340B hospital prohibition against participating in any group purchasing organization (GPO) put the hospital at risk for program disqualification?**

1. **SCENARIO** Hospital elects to participate in the 340B prime vendor program which negotiates pricing on behalf of all prime vendor participants.

**ANSWER** NO

2. **SCENARIO** Although Hospital has withdrawn from its GPO with respect to drug purchased and dispensed by its outpatient pharmacy, it still uses its GPO for some or all drugs administered in Hospital's outpatient clinics.

**ANSWER** YES, if the drugs purchased through the GPO are covered outpatient drugs.

3. **SCENARIO** One or more manufacturers refused to give 340B discounted pricing on their drugs because they mistakenly believe that the discounts are not required. They believe, for

example, that Hospital is ineligible, that the drug is not covered by the program, etc. Hospital buys the drugs at the GPO price until the manufacturer's noncompliance is addressed.

**ANSWER** YES. If a hospital purchases a covered outpatient drug through any group purchasing arrangement, the hospital has not met the 340B (a)(4)(L)(iii) requirement for covered entity eligibility. If a manufacturer refuses to provide such drugs at the 340B price and the hospital believes that it is eligible for such pricing for its eligible patients, the hospital must call or write the ODP for resolution of this problem.

4. **SCENARIO** One or more manufacturers are late in loading in their quarterly price changes. Hospital buys the drug at GPO prices until the new 340B prices are made available.

**ANSWER** YES. If a hospital purchases a covered outpatient drug through any group purchasing arrangement, the hospital has not met the section 340B(a)(4)(L)(iii) requirement for covered entity status. If a manufacturer is late in loading its quarterly price changes, the hospital must call or write ODP for resolution of this problem

5. **SCENARIO** Hospital does not add one of its outpatient pharmacies to ODP's covered entity list on the electronic bulletin board. Hospital does not sign up the pharmacy because it does not realize that the pharmacy is eligible to participate. It is concerned that the pharmacy lacks the necessary safeguards to protect against diversion. It is considering closing down or selling the pharmacy. The Hospital has trouble with 340B paperwork. The Hospital relies on its GPO for the non-participating pharmacy until it signs up the pharmacy for the program.

**ANSWER** YES. If a hospital purchases any covered outpatient drugs through a GPO, it has not met the section 340B(a)(4)(L)(iii) requirement for covered entity status.

6. **SCENARIO** Hospital either occasionally or routinely uses its inpatient drugs for outpatient use and then replaces the inpatient drug stock later. Hospital is accidentally one or two drugs short or otherwise makes a mistake in implementing its stock replacement system.

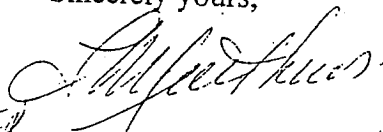
**ANSWER** YES. Any drug purchased at or below the 340B ceiling price by a hospital covered entity through the 340B program must be dispensed only to eligible patients, otherwise the hospital will have violated the section 340B(a)(5)(B) prohibition against drug diversion. In the case of a violation of this section, the hospital will not have met the section 340B(a)(5)(B) requirement for covered entity status. Please note that this requirement does not require separate inventories.

7. **SCENARIO** Hospital participating in the 340B program elects not to purchase its Medicaid drugs at the 340B discounted prices. Indeed, Hospital would not participate in the 340B program if it could not "carve out" the Medicaid drugs since it would lose too much revenue by having to bill Medicaid at acquisition cost. Rather than pay retail prices for Medicaid drugs, Hospital buys the drug through a GPO.

**ANSWER** YES. If a hospital purchases any covered outpatient drugs through a GPO, it has not met the section 340B(a)(4)(L)(iii) requirement for covered entity status. See also, issue seven of the July 15 letter from ODP.

We hope that this information is helpful. Please do not hesitate to call this office through our Office of the General Counsel at (301) 443-2006, should you have further questions.

Sincerely yours,



*J. Mitchell*

*JCM*  
CAPT Jimmy Mitchell  
Director  
Office of Drug Pricing

cc: Kathy Lotfi, OGC