WHICH PRESCRIPTIONS ARE 340B-ELIGIBLE

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A.  General Information

According to the 340B statute, FQHCs (and other covered entities) may only provide 340B purchased drugs to individuals who are "patients" of the entity. As a result, policymakers often talk about the "patient definition" as the tool for determining eligibility for 340B drugs.

In practice, however, 340B eligibility determinations are made on a prescription-by-prescription basis, as opposed to a patient-by-patient basis. In other words, under current OPA guidance, the fact that an individual is clearly a FQHC patient does not mean that every prescription he or she receives is eligible to be filled with drugs purchased under 340B. Rather, each of that individual's prescription must be separately evaluated against OPA standards to determine if may be filled with 340B drugs. Using 340B drugs to fill a prescription presented by a health center patient – but which does not meet OPA's eligibility standards – is considered diversion

This chapter discusses current OPA guidelines around which prescriptions may be filled with 340B drugs, and how these guidelines apply to many different categories of prescriptions, including those written:

- in various locations
- by various providers
- at various points along the continuum of care (e.g., referrals to specialists, refills, hospital discharge prescriptions.)

Also, it is important to note that while OPA currently uses three criteria to determine which prescriptions are eligible (see Section 7.A.2), even these are subject to interpretation. Apexus attempts to further clarify the definition of eligible patient by expanding upon OPA interpretations and applying them to questions from covered entities. FQHCs will be best served by trying to adhere to OPA's and Apexus' understanding, while also recognizing that there currently is not clear guidance in all areas.

1.  Why eligibility determinations are critical

If an FQHC uses a 340B-purchased drug to fill a prescription that does not meet the eligibility standards, this is considered diversion – which is strictly prohibited by the 340B statute.

Avoiding diversion – and documenting these efforts – is a critical part of an FQHC's compliance responsibilities. All 340B providers (including FQHCs) are required to maintain purchasing and dispensing records to demonstrate that 340B drugs were provided only for eligible prescriptions. These records must be provided to OPA and manufacturer auditors upon request. More information about avoiding diversion is contained in Section 14.B.2.

2.  OPA's current 3-part eligibility test

1. The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care;
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 FQHC Look-Alike status has been provided to the entity.

An individual is **not** considered an FQHC 'patient' for purposes of 340B if health center does not maintain records or the responsibility of the patient's care. Moreover, an individual is not a "patient" under 340B if the only health care services that the individual receives from the FQHC are pharmacy services ("the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting").

This three- part test is outlined in the Federal Register, Vol 61, No. 207, October 24, 1996, p. 55156.

3. Does where the prescription is generated matter?

Yes, according to OPA, the service site where the drug was ordered/dispensed does matter. With the potential exception of prescriptions generated from patient referrals and/or hospital discharge

prescriptions (see Sections 7.B.2 and 7.B.5, respectively), **only prescriptions written (or drugs dispensed) in clinical sites listed in OPAIS or in conjunction with other services listed as "in scope" on form 5C of the health center's Scope of Project are eligible for 340B pricing** As discussed in Section 5.B.8 a clinical site must be approved under the Health Center's Scope of Project, and listed as active in EHB, in order for it to be registered in OPAIS. Examples of "other services" in scope that may result in eligible prescriptions include home visits, clinical outreach events, and hospital services that result in prescriptions for outpatient use.

4. Does the provider make a difference?

Yes, the provider writing the prescription (or dispensing a 340B drug) must meet **Part 2** of the three-part test outlined in Section 7.A.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;"

Currently, we would advise FQHCs to memorialize in memoranda of understanding even casual arrangements with providers who may prescribe 340B eligible prescriptions. Also see Section 7.B.9 for a discussion of providers who moonlight.

5. Does the type of service make a difference?

Yes, as indicated in the **Part 3** of the three-part test listed in Section 7.A.2, in order for a prescription to be eligible to be filled with 340B-purchased drugs, it must result from a service which is consistent with the service or

range of services for which Section 330 Health Center status (either grantee or look-alike designation) has been provided to the entity. In other words, the service must be “in scope.”

6.  Frequency of visits to be considered a “patient”

There is no specific guidance to determine how frequently a patient must visit the health center in order to be considered eligible for prescriptions filled with 340B purchased inventory; therefore each health center should develop a policy consistent with the needs of its population.

Many health centers consider an individual to be an “active” patient if they have had a visit within the past two years. This policy:

- Is consistent with UDS requirements that patients be seen within the previous two-years to be counted as an unduplicated patient.
- Ensure that patients who require only annual physicals are not deemed “inactive” if -- due to scheduling reasons -- they go slightly longer than a year between physicals.

Another factor that health centers should consider is the frequency of visits recommended for patients with chronic disease.

B. Eligibility of specific types of prescriptions

1. Prescriptions for FQHC employees

An employment relationship alone is not sufficient for 340B eligibility. Health center employees are eligible for 340B only if they meet the definition of a “patient,” as described above. Consider the following questions to determine eligibility:

- Is the employee a patient of the FQHC?

- Is the prescription/dispense the result of a documented encounter with an eligible provider that occurred in a clinical site that is registered and eligible in the 340B database?

FAQ ID: 1435
Last Modified: 09/15/2014
Q: Are employees of a covered entity eligible to receive 340B drugs?
A: Covered entities may only distribute 340B drugs to their employees that meet the patient definition guidelines set forth under the 340B Program. The 340B Program is limited to patients of the covered entity and has never been a general employee pharmacy benefit or self-insured organization pharmacy benefit. Evidence of an employer relationship or insurer relationship alone is insufficient to determine 340B patient eligibility.

2. "Referral prescriptions" (e.g., those written by specialists)

The term "referral prescription" refers to a prescription written for an eligible FQHC patient (as defined under the 3-part test described in Section 7.A.2) that is written by a provider who is not directly employed by or under contract with the FQHC. For example, if the FQHC provider refers a patient to a specialist outside of the FQHC, and the specialist writes the patient a prescription, that prescription is called a "referral prescription." The following question and answer from the Apexus website addresses patient referral prescriptions.

FAQ ID: 1493
Last Modified: 09/15/2014
Q: If we refer a patient to an outside clinic, can we fill their prescriptions from our 340B clinic?
A: A covered entity may refer an individual for consultation to an outside clinic not registered for the 340B Program and consider that patient 340B eligible only if the individual receives health care 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 (61 Fed. Reg. 55156 (October 24, 1996)). If the covered entity can document that it retained responsibility for the health care services provided to the referred individual, then that individual may be eligible to receive 340B drugs from the covered entity. How a covered entity counts referrals under the 340B Program should be addressed in their written policies and procedures.

An FQHC must retain – and document - responsibility for the care provided in order to fill a referral prescription for one of its patients.

The following points of this response merit close attention:

- Responsibility for the care that generated the referral prescription must remain with the FQHC, and
- The FQHC's written policies and procedures for 340B should address how referrals are managed.

Thus, when using 340B drugs to fill referral prescriptions for its patients, the FQHC must:

- Be able to provide documentation of:
  - the referral to the specialist,
  - a summary of the referral visit, including prescriptions ordered by the referring physician – or evidence of its unsuccessful efforts to obtain this summary; and
  - the health center PCP's continued responsibility for the care of the patients.
- Ensure that its 340B Policy and Procedures address the health center's established eligibility criteria for referral prescriptions and

how the Health Center documents its responsibility for care provided in a referral situation.

3. UPDATED FQHC providers should not re-write prescriptions from other providers

Health centers are ***strongly advised against*** having their providers rewrite prescriptions that were written by non-FQHC providers (e.g., specialists) for FQHC patients. This practice raises significant liability concerns. Health centers should consider having an official policy on this issue, in order to demonstrate that your health center has considered this issue and made an official determination of your position.

Peer Perspective

"The FQHC should ensure that its P&P Manual outlines specific steps for documenting the referral in the Electronic Health Record. The In-House Pharmacy must be able to document the referral in the chart and then note on the prescription that the referral documentation is available. It should be able to supply documentation on ED prescriptions and also Hospital Discharge prescriptions."

4. NEW How long is a referral to a specialist considered "active"?

As with the previous question, there is no specific guidance about how long a referral to a specialist considered is "active," and therefore, that

specialist prescriptions resulting from the referral can be filled with 340B drugs. Therefore, each health center should develop a policy that is consistent with its circumstances and the needs of its population. When developing this policy, there are two parts to consider:

1. How long do patients have to act on the referral (aka see the specialist)? While there are no requirements in this area, many health centers have established a six-month window, as anything shorter might not accommodate scheduling barriers. If a patient does not see a specialist within 6 months of receiving the referral, a new referral is required if the resulting prescriptions are to be filled with 340B drugs.
2. Once the patient has the referral visit and a specialist prescription is deemed to be eligible based on the health center's policy, how long does that prescription and its subsequent refills and renewals remain eligible? Again, there are no requirements in this area. However, a health center with a strong 340B compliance program recently provided the following input:

"Given the counsel of our auditing firm, our health center is adopting the position that as long as the health center PCP remains responsible for care and the specialty care is provided under that oversight, and the patient meets the definition of active, there is no need for repeat referrals or a schedule of required visits to the specialist (as this could be a financial and demographic burden for our patients). We have agreed however, that specialist prescription refills should be on an audit schedule to ensure the PCP is documenting knowledge of the continued specialty care and those meds."

5. Hospital discharge prescriptions

The term “hospital discharge prescription” refers to a prescription written for an eligible FQHC patient (as defined under the 3-part test described in Section 7.A.2) that they receive upon being discharged from the hospital. These include prescriptions written upon discharge from both inpatient stays and the Emergency Department.
Guidance related to discharge prescriptions is contained in the following frequently asked question from the Apexus website:

FAQ ID: 1563
Last Modified: 09/15/2014
Q: Can 340B drugs be used for discharge prescriptions?
A: The 340B Program is an outpatient drug program. Enrolled covered entities have the responsibility to ensure that drugs purchased under the 340B Program be limited to outpatient use and provided to individuals who meet the requirements of the current patient definition. 340B drugs can be used for discharge prescriptions to the extent that the drugs are for outpatient use. Whether a drug qualifies as outpatient and the individual meets the definition of patient depends upon the factual circumstances surrounding the care of that particular individual. If a covered entity uses 340B drugs, it should be able to explain why the covered entity is responsible for the use of the drugs on an outpatient basis and have auditable records that demonstrate compliance with 340B Program requirements.

Thus, this FAQ does not clearly indicate whether hospital discharge prescriptions will qualify for 340B eligibility in an FQHC setting. ***Hospital discharge prescriptions that are the result of a hospital visit 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 arguably are eligible.***

Health centers may provide services within their federally-approved scope of project which would be consistent with including a hospital discharge prescription as 340B-eligible. For example, assuming the arrangements meet other Section 330 requirements, the hospital ER may in fact, be the provider of after-hours coverage for the health center or the FQHC’s providers may “round” at a hospital to see their admitted patients both of which may generate a 340B-eligible prescription. Similarly, if upon discharge from a hospital emergency room an FQHC patient is provided a prescription for which the FQHC ultimately will be responsible, such as a

prescription to control asthma after an acute episode has caused the patient to visit the ER, the prescription may be 340B eligible. See the FAQ below:

FAQ ID: 1565
Last Modified: 09/15/2014
Q: Is a covered entity grantee limited to using or prescribing drugs that address the core function of their grant program?
A: The 340B Program does not limit the drugs a covered entity can use or prescribe; however, 340B drugs may only be transferred to individuals who qualify as patients of the covered entity grantee. All parts of the 340B patient definition (61 Fed. Reg. 55156 (October 24, 1996), including the provision that 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, must be met.

Thus, for a hospital discharge prescription to be eligible to be filled using 340B drugs:

- The individual must meet the definition of "eligible patient" of the FQHC.
- The FQHC should be able to explain why it is responsible for the use of the drug. (See examples in previous paragraph.)
- The FQHC should have auditable records that demonstrate its compliance with 340B program requirements.

Also, as with all scenarios, for a prescription to be filled with a 340B drug, the health center must consider whether the facts meaningfully comply with each part of the three-part eligibility test discussed in Section 7.A.2.

6. Refills of an existing prescription

If a health center patient was given a prescription with refills, these refills are eligible to be refilled with 340B drugs as long as the initial prescription was 340B-eligible. The "refill" would be a continuation of health care services provided by the FQHC. The FQHC should document the initial prescription for treatment in the patient's medical record, and the "refill" would be part of the range of health care services provided.

7.  Renewals

When a health center patient requests that a prescription be renewed - i.e. to receive a new prescription that is identical to one that has previously been filled using 340B purchased drugs – "best practice" indicates that it **should be treated as a new prescription for the purpose of determining 340B eligibility**. The FQHC must consider whether the prescription still meets the 340B program definition for eligible prescriptions.

Thus, before using 340B drugs to fill a renewal script, the FQHC is advised to have policies and procedures that the health center's responsibility for the care of the patient continues. These policies and procedures may include verification of the prescription in the EHR and periodic self-audits that include a sample of renewal prescriptions.

8.  Drugs administered during an FQHC patient visit

FQHC providers often administer drugs during patient encounters. (These are often called clinic-administered or physician-administered drugs.) It is important to note that ***the same three-part eligibility test applies in the case of drugs administered during a patient-provider encounter*** as to drugs that a patient takes at home. Specifically: be 340B-eligible:

- the drug must be administered as part of a service that is consistent with the Health Center's scope of project;

- the provider who administers the drug must be employed or under contract with the FQHC;
- the drug must be administered at a site that is registered on OPAIS, or in conjunction with other services listed as "in scope" on form 5C of the health center's Scope of Project

See Section 7.A.2 for more information on the three-part eligibility test. See Section 9.G for a discussion of clinic-administered drugs under Medicaid.

9.  Prescriptions Written by Providers who Moonlight

If a health center has one or more providers who "moonlight" - i.e., work for other health care organizations during the same period of time as the health center -- special care must be taken. This is because the prescriptions that these providers write while working at the health center will be 340B-eligible (assuming they meet the other eligibility requirements), but those written while working for the other provider will not. For these providers, it is necessary to check the location where the prescription was written, in order to determine if it can be filled with 340B drugs.

From an organizational perspective it is recommended to establish a procedure requiring providers requests to be approved by the CMO and to provide written notification to the provider of his or her responsibility to assist in preventing ineligible prescriptions from being filled with 340B drugs (e.g., clearly identify when a prescription is generated through a non-FQHC moonlighting assignment.)

C. For More Information

- As always, the official source of HRSA/OPA-aligned policy information is Apexus. Contact information is available at Section 3.D.1.
- OPA's "final guidelines regarding a definition of covered entity 'patient'" , published in the Federal Register, Vol 61, No. 207/Thursday, October 24, 1996/Notices, p. 55156