Patient Definition: Referral Relationships

Purpose: 340B Policy to Practice Guide provides samples of entity approaches to placing 340B policy into practice with compliance. 340B Policy to Practice Guides reflect actual practices in place at 340B entities with leading practices or that have recently been audited by HRSA with no adverse audit findings. This particular Policy to Practice Guide is intended for 340B entity leaders and provides information about referrals to outside health care professionals and the 340B Patient Definition.

Instructions: This guide is does not represent the only approach to applying this particular policy to practice. Entities are encouraged to consult their compliance and legal staff to determine how to best implement 340B policies into practice at their site. Endorsement of the content of This Guide by the Office of Pharmacy Affairs is not stated or implied.


“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...”

Practice: Entities report increased confidence that referral prescriptions are being documented in a compliant and auditable manner by including criteria below as part of their operational process:

- The 340B entity maintains documentation in the entity’s record of health care that justifies the 340B entity had responsibility for the health care resulting in the 340B prescription.
  - Documentation of the both the request for referral, as well as a summary of the referral visit, is accessible in the patient’s medical record.
  - Entities typically require that documentation or verification of referral and the resulting summary of referral visit be accessible to the pharmacy filling the prescription.
  - Some entities do not have adequate systems in place to consistently document referrals, and have faced challenges in implementing referral prescriptions using 340B. Attributes that entities have discussed as contributing to these challenges include: large/complex health systems, high number of health care professionals used for referrals, lack of confidence that staff documents referrals consistently in the patient’s medical record, lack of pharmacy (or contract pharmacy) access to accurate information about referral care, etc.). These organizations often exclude referral prescriptions from 340B.
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Action Steps: Entities report taking the following actions to establish systems to document referrals for 340B patients:

• Contact select priority health care professionals/groups that are important to the continuity of patient care to establish referral contracts.

• Meet with health care professional/group which the entity wants to establish a referral contract, to make sure they understand the entity’s responsibilities associated with the 340B Patient Definition.

• Create a referral agreement that explains the 340B entity’s responsibility for care and expected communication between organizations.

• Sketch out process (possibly including medical record’s staff, health care professional staff, and pharmacy staff) to make sure the covered entity can input and access required documentation consistently, be able to retrieve the documentation and/or view it, to demonstrate the patient referral from the entity health care professional.

• Ensure the covered entity pharmacy has an easily accessible list of health care professional names and NPI #’s for each contracted referral health care professional or group of health care professionals, as well as access to the patient’s medical record.
  • Specific data documented may include:
    • Verification of patient eligibility;
    • Verification of approved prescribing health care professional’s NPI on file, and
    • Verification of originating referral from entity health care professional.

• Develop a process to ensure that prescriptions written by any health care professional without a pharmacy referral agreement are excluded from 340B eligibility by policy and are not included in entity’s list of approved NPIs.

• Draft, approve, and follow policies and procedures to match referral verification practice.

Sample strategies covered entities use to ensure verification of eligibility of referral:

• Appoint specific 340B entity staff as responsible for verifying the referral documentation is appropriate/meets defined criteria for documentation.

• Arrange real time access to electronic patient records by pharmacy staff, to allow the ability to verify eligibility and documentation of referral.

• Develop system to ensure contract pharmacy or claims processing vendor receive or obtain access to entity-verified referral information.
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- Include in any 340B contract pharmacy arrangement language describing procedure for verifying the health care professional is part of a documented referral.
  - One option entities have taken includes utilization of a PBM/340B Vendor to verify eligibility, with a system in place to regularly send health care professional eligibility files from the entity to the contract pharmacy.
  - Other entities have allowed for a real time transaction edit, and if lack of documentation is found later, then the claim must be reversed and not included with 340B eligibility.

Items covered entities have included in a referral agreement with a health care professional:

- Definition of parties to the referral agreement.
- Agreement of all parties to follow all 340B statute/guidelines/regulations, including the 340B Patient Definition, as well as state, local and federal law.
- Itemization of the responsibilities of each party.
- Details of the terms of communication required for entity and referral health care professional communications/documentation (i.e., medical record note, care or treatment plan, follow-up instructions, summary of referral care, etc.).

See Appendix A for Example of Referral Agreement Template.

This tool, written to align with OPA policy, is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by the Office of Pharmacy Affairs and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B program compliance and compliance with all other applicable laws and regulations. Apexus encourages each stakeholder to include legal counsel as part of their program integrity efforts.

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Appendix A

Example of Referral Agreement Template

I. Parties

This Agreement is between [Covered Entity Name] and [Health Care Professional Receiving Referral Name] for the purpose of defining referral relationships and establishing patient eligibility as required by Sec. 340B of the Public Health Service Act (Pub. L. 102-585).

II. Definition of a Patient


“(C) Definition of a Patient

An 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…”

III. Statement of Purpose and Responsibilities of Parties

[COVERED ENTITY] is participating in the 340B Drug Pricing Program. [COVERED ENTITY] provides health care to men, women and children in the [city name] and surrounding communities through an integrated model of care, which includes [define services offered] and pharmacy.
Consistent with the needs of its patients, [COVERED ENTITY] refers its patients to [Health Care Professional Receiving Referral Name] as needed for consultation and medical care related to [describe general categories of care].

[Health Care Professional Receiving Referral Name] agrees that in accepting such referrals from [COVERED ENTITY], the responsibility for the overall care of the [COVERED ENTITY] patients referred, as well as the use of any 340B drugs transferred to an individual patient, remains with [COVERED ENTITY]. Care and documentation will be provided to the entity regarding referred patients, in accordance with process outlined below.

[Health Care Professional Receiving Referral Name] agrees to the following terms in treatment of COVERED ENTITY patients:

1. At the request of the covered entity, the [Health Care Professional Receiving Referral Name] will provide a list of National Health care professional Number (NPI) for applicable health care professionals, as determined by covered entity, who write prescriptions to [COVERED ENTITY] patients. This list should be updated no less than quarterly and forwarded to [COVERED ENTITY] for updating the entity’s documentation systems.
2. [Health Care Professional Receiving Referral Name] agree to document all medical encounters with [COVERED ENTITY’S] patients in a manner consistent with current professional standards and which meet record requirements as set forth by federal and state statutes and regulations;
3. Notes on patient care and treatment will be entered directly into the [COVERED ENTITY] Electronic Health Record (EHR) system, where available, so that it can be accessed electronically, real-time by [COVERED ENTITY] health care professionals for patient follow up, or;
4. Copies of all medical encounter notes shall be forwarded to [COVERED ENTITY], if above documentation cannot be completed electronically.

I. Miscellaneous Terms

This agreement will remain in effect until there is termination by either party with thirty (30) days written notice.

Both parties have the power and authority to enter into and perform its obligations under this Agreement.

Signed this________________ day of________________, 20____

[for COVERED ENTITY]                        [for Health Care Professional Receiving Referral]