The 340B Drug Pricing Program, administered by the Health Resources and Services Administration (HRSA), allows community health centers to purchase outpatient medications at significantly reduced costs, enabling them to provide affordable, discounted, or free medications to uninsured and underinsured patients.¹

Health center patients may be eligible for 340B medications prescribed through services received within the health center, or through an outside provider. For services received outside of the health center, referral capture processes are an essential component of health centers 340B program policies and procedures.

All health center covered entities are responsible for ensuring compliance with the 340B program, which, among other requirements, includes ensuring that only eligible patients receive 340B medications and that auditable records are maintained to illustrate compliance.² While covered entities are responsible for determining their own 340B program operating policies and procedures, and for defining patient eligibility, NACHC recommends that health center covered entities adopt policies and procedures that align with HRSA’s 1996 patient definition guidance.
Leveraging Health Center Referral Management Processes for 340B Referral Capture

HRSA 1996 Patient Definition Guidance: 3

• The health center must have established a relationship with the patient (i.e., the health center maintains records of the patient’s health care),

• The patient must have received health care services from a health care professional who is either employed by the health center or provides health care under contractual or other arrangements (e.g., referral for consultation), and

• The patient must have received a health care service or range of services that is consistent with the service or range of services for which grant funding or FQHC look-alike status has been provided.

For services provided within the health center, information such as the treating provider, the service provided, and the medication(s) prescribed is likely documented within a patient visit in the health center’s Electronic Health Record (EHR), but for services provided outside of the health center, this information is likely documented within the report from the outside provider that is shared with the health center through referral processes.

Referral tracking and follow up is essential to supporting patients who obtain services outside of the health center. Generally, referral tracking and follow up is managed by health center staff with care coordination responsibilities. These staff members are often responsible for creating the referral within the EHR, attaching relevant patient demographic and clinical information, sending the referral to the outside provider, and after the patient appointment has occurred, ensuring the report containing documentation of the care provided by the outside provider is received by the health center. Though referral capture processes related to the 340B program may closely parallel a health center’s general referral management processes, 340B referral capture processes are sometimes managed separately by 340B administrative or pharmacy staff. This can lead to inefficiency and duplication of staff efforts, as well as misalignment of policies and procedures across health center processes. Through a systems approach, health centers can leverage their referral management processes and align 340B referral capture.

**HOW can health centers leverage referral management processes and engage care coordination staff for successful 340B referral capture?**

This Action Guide outlines a series of steps health center administrators can take to align referral management policies and procedures, leverage processes, and engage care coordination staff for successful 340B referral capture. Note: While health centers can also process prescriptions written by outside providers if they did not directly refer the patient, this Guide focuses specifically on when the health center initiates a referral.

**STEP 1** Review Health Center Scope of Services for Referral Arrangements. Update agreements, as needed, to include how referrals will be made and managed; and the process for tracking and referring patients back to the health center for appropriate follow-up care.

**STEP 2** Align referral management and 340B referral capture policies. Review and update health center referral management policies and procedures to ensure they meet FTCA requirements, incorporate best practices from PCMH guidelines, and outline the information needed for 340B referral capture to align with health center 340B policies and procedures.

**STEP 3** Educate Staff in Referral Management Processes and Documentation Requirements. Train staff in 340B referral capture.

**STEP 4** Monitor Performance and Drive Improvement. Conduct self-audits and referral tracking and follow up reports; use data to drive improvement.
Leveraging Health Center Referral Management Processes for 340B Referral Capture

**STEP 1**

**Review Health Center Scope of Services for Referral Arrangements.** When following the definition of 340B program patient eligibility as stated in the 1996 guidance, it is essential that health centers have a clear understanding of their HRSA approved scope of services and that any necessary referral arrangements are in place. According to the [HRSA Health Center Program Compliance Manual](#), the health center must provide access to all services included in its HRSA-approved scope of project (Form 5A: Services Provided) through one or more of these service delivery methods:

- **Direct:** A required, or additional, service is provided directly by health center employees or volunteers.
- **Formal Written Contract/Agreement:** A required, or additional, service is provided on behalf of the health center via a formal contract/agreement between the health center and a third party. In addition, the health center ensures that such contractual agreements for services address how the service will be documented in the patient's health center record.
- **Formal Written Referral Arrangement:** A required, or additional, service is provided and billed for by a third party with which the health center has a formal referral arrangement. The health center is responsible for the act of referral for health center patients and any follow-up care for these patients provided by the health center after the referral. In addition, the health center ensures that such formal referral arrangements for services address:
  - How referrals will be made and managed
  - The process for tracking and referring patients back to the health center for appropriate follow-up care

When assessing patient eligibility for the 340B program as stated in the 1996 guidance, the health center must know the relationship of the prescribing provider to the health center (whether they are employed or providing care under a contractual or referral arrangement), and whether the health care services provided by the prescribing provider fall within the range of services for which the health center has been approved. A health center may refer a patient to any outside provider or health care facility when care and services that the health center does not provide are needed by a patient, regardless of whether the health center has a referral arrangement in place. However, not all referrals will meet the patient eligibility requirements for the 340B program as stated in the 1996 guidance. Thus, knowledge of the health center's approved scope of services, and any referral arrangements that are in place, is foundational to 340B referral capture.

**Action Step:** Review health center scope of services for any referral arrangements; update, as needed. Ensure agreements address: how referrals will be made and managed; and the process for tracking and referring patients back to the health center for appropriate follow-up care.

**STEP 2**

**Align referral management and 340B referral capture policies.** Review and update health center referral management policies and procedures to ensure they meet FTCA requirements, incorporate best practices from PCMH guidelines, and outline the information needed for 340B referral capture to align with health center 340B policies and procedures. The management of patient referrals is a critical care coordination workflow. Referrals are generally created and tracked by health center care coordination staff utilizing the EHR. According to PCMH guidelines, referrals sent to outside providers should include information such as:

- The name of the provider the patient is being referred to (or the name of the health care facility if the name of the treating provider is not yet known)
- The reason for the referral
- The type of referral (e.g., consultation, request for co-management of patient, treatment of a specific condition)
- The urgency of the referral
- Relevant clinical information such as current medications, diagnoses, allergies, medical and family history, substance use, clinical findings, test results, and current treatment
Depending on the provider being referred to and the patient’s insurance coverage, the health center could be required to complete a prior authorization or other documentation when a referral is initiated. The health center may also assist in scheduling the date and time of the appointment with the outside provider on behalf of patient. Once the appointment with the outside provider has occurred, the health center will need to ensure the outside provider sends a report with documentation of the care provided back to the referring provider at the health center. If an outside provider does not send a report, the health center care coordination staff have a responsibility to follow-up and request the report. All efforts to retrieve the report should be documented within the EHR. When the outside provider’s report is received, review to ensure all relevant clinical follow up information has been provided.

Health centers are required to have policies and procedures in place that address referral management processes. As a component of the Federal Tort Claims Act (FTCA) deeming process, health centers are required to attest that they have implemented procedures that address mitigating risk through referral tracking and to upload those procedures as part of the application. Policies and procedures should outline that referral documentation from outside providers must include the name of the treating provider, a description of the services provided, and the name of the medication(s) prescribed (along with other relevant care information) to ease the process of determining 340B patient eligibility (following the 1996 guidance). Your policies and procedures may also include information regarding the number of attempts that the care coordination staff will make to retrieve a report from an outside provider, and the timeframe in which these attempts will be made. It is best practice for this information, along with other relevant care information, to be received for all referrals regardless of whether the patient may be eligible for the 340B program.

When all referrals are managed by care coordination staff according to an aligned set of policies and procedures, pharmacy staff can leverage this referral documentation to determine 340B eligibility and fill medications. This eliminates the need for pharmacy to separately manage 340B referrals and increases the coordination and efficiency across programs.

**Action Step:** Review and update health center referral management policies and procedures to ensure they meet FTCA requirements, incorporate best practices from PCMH guidelines, and outline the information needed for 340B referral capture to align with health center 340B policies and procedures.

**STEP 3**

**Educate Staff in Referral Management Processes and Documentation Requirements.** Engaging health center care coordination staff in 340B program referral management is key to in ensuring these processes are occurring as part of day-to-day care and to easing the burden of follow up on health center 340B program administration and pharmacy staff. First, provide general education to health center staff about what the 340B program is and why the program is essential to the health center and health center patients. This NACHC Report, *340B: A Critical Program for Health Centers*, and this *C-Suite Guide to the 340B Program* provided by the 340B Prime Vendor Program managed by Apexus, are helpful resources for understanding the importance of the program and for covering program basics, respectively.

Additionally, provide education on the role of health center care coordination staff in 340B referral capture in addition to general education on the referral tracking and follow up policies and procedures developed in **Step 2**.

Assign care coordination staff with responsibility for referral tracking and follow up to the review of reports of care provided by outside providers to ensure the necessary documentation has been included. To ease documentation and reporting processes, consider creating structured fields within referrals in the EHR in which care coordination staff can document these required elements.

**Action Step:** Educate health center care coordination staff about referral management processes and documentation requirements for 340B referral capture.
**Monitor Performance and Drive Improvement.** To ensure your health center referral management policies and procedures are being followed, routinely monitor reports that indicate the number of total ‘open’ referrals. It may be necessary to filter and/or sort this report by the urgency of the referral, the numbers of days past the scheduled appointment, the number of days the referral has been open, the referring provider, the provider referred to, or provider specialty, to further drill down and initiate performance improvement activities as needed. Additionally, developing and maintaining a list of outside providers that the health center frequently refers to is a helpful way to monitor the types of services that health center patients are receiving outside of the health center. To streamline the process of assessing which outside providers have contractual or referral arrangements with the health center, include this information for each provider within the list for easy reference. This list of providers will be helpful when monitoring 340B program performance. Maintain this list in a spreadsheet for the ability to cross reference with a report of 340B prescription records.

Monitoring performance through 340B program “self-audits” and through referral tracking and follow up reports is essential to ensuring the health center is following its policies and procedures and to reducing the risk of adverse outcomes that could result in medical malpractice because of poor referral tracking and follow up. To monitor 340B program performance, a Self-Audit Tool for Prevention of Diversion can be accessed within the 340B Tools provided by the 340B Prime Vendor Program managed by Apexus. Following this self-audit tool, health centers will review 340B prescription records (health centers may choose to review all records or a sample of records) to assess the relationship of the prescribing provider to the health center – whether they are employed or providing care under a contractual or referral arrangement (use the provider list developed), whether the health care services provided by the prescribing provider fall within the range of services for which the health center has been approved, and whether the prescribed medication and the services provided are documented within the health center’s EHR.

Through the monitoring of referral tracking and follow up reports and the completion of 340B program self-audits, initiate performance improvement activities and provide additional staff education as needed. Additionally, incorporating referral management goals into your health center’s quality improvement plan can also help to prioritize and focus efforts on optimizing health center referral management processes.

**Action Step:** Monitor performance through self-audits and referral tracking and follow up reports; use data to drive improvement.

This Action Guide was developed with support from the Centers for Disease Control and Prevention (CDC) cooperative agreement #NU38OT000310. The contents are those of the author(s) and do not necessarily represent the official views of, nor an endorsement by, the CDC or the U.S. Government.

**References**