Nothing Compares
NORTH CAROLINA

Title X and 340B Rules for Family Planning

May 25, 2017

Title X and 340B Rules for Family Planning
Objectives

At the conclusion of this webinar, participants will:

- Distinguish between “dispensing” and “administering” prescription drugs and devices to patients.
- Understand the basics of the 340B drug pricing program
  - 340 B Program Requirements
  - Certification/Recertification and changes to the 340B Database
- Understand billing for 340B drugs
- Understand preparation for HRSA program audits

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Pharmacy Definitions

Local Public Health and Pharmacy Definitions

- ***Dispensing*** means [G.S. 90-85.3(f)]:
  - Preparing and packaging a prescription drug or device in a container, and labeling the container with information required by State and Federal law is "dispensing."
  - Filling or refilling drug containers with prescription drugs for subsequent use by a patient is "dispensing."
  - **Providing quantities of unit-dose prescription drugs for subsequent administration is "dispensing."**
  - *Note: Agencies that dispense drugs must have appropriately trained RNs.* Training information is available at http://www.publichealth.nc.gov/lhd/ under "Dispensing of Drugs by Public Health Registered Nurses"

- ***Administering*** means [G.S. 90-85.3(a)]:
  - The direct application of a drug to the body of a patient by injection, inhalation, ingestion, or other means.

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340B

What is 340B?

- 340B is a Federal drug pricing program that entitles providers of certain medical services to purchase prescription drugs and devices from manufacturers at a discount.

- Each 340B service type has its own 340B ID number. Therefore, one agency may have multiple 340B ID numbers.
  - Family Planning/Title X
  - STD
  - TB
  - State AIDS Drug-Assistance Programs
  - Federally Qualified Health Centers

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340B

What is 340B? (continued)

- The 340B Program is administered by the Office of Pharmacy Affairs (OPA) within the Health Resources and Services Administration (HRSA)
- Participation in the 340B program requires that an agency register and be enrolled in the 340B program and comply with all program requirements.
- Agencies must be registered with HRSA at all times in order to purchase and use 340B drugs and devices.

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340B

340B Program Requirements

https://www.hrsa.gov/opa/programrequirements/index.html

1. Keep 340B database information accurate and up to date. Register new outpatient facilities and contract pharmacies as they are added.
2. Recertify eligibility every year.
3. Prevent diversion to ineligible patients. Covered entities must not resell or otherwise transfer 340B drugs to ineligible patients.
4. Duplicate Discount Prohibition-Manufacturers are prohibited from providing a discounted 340B price and a Medicaid drug rebate for the same drug. Covered entities must accurately report how they bill Medicaid fee-for-service drugs on the Medicaid Exclusion File, as mandated by 42 USC 256b(a)(5)(A)(i).
5. Prepare for program audits. Maintain auditable records documenting compliance with 340B Program requirements. Covered entities are subject to audit by manufacturers or the federal government. Any covered entity that fails to comply with 340B Program requirements may be liable to manufacturers for refunds of the discounts obtained.

The link, above, to the HRSA Program Requirements page contains hyperlinks to resources and pages within the HRSA website.

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340B Program Requirements

1. Keep the 340B Database information accurate and up-to-date.
   - Register, remove, or change clinical sites and off-site contract pharmacies during the quarterly registration period.
   - Registration periods occur during the first fifteen days of:
     - January
     - April
     - July
     - October
   - Each Covered Entity designates two contacts in the 340B Database. These contacts may be changed at any time (not restricted to the registration period).
     - Authorizing Official (A.O.) – this is the individual who has contractual authority for the agency. Typically, this is the Health Director.
     - Primary Contact (P.C.) – this individual receives notifications about 340B updates.
     - We recommend listing two different individuals as A.O. and P.C. to assure adequate communication regarding the 340B program.

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340B Program Requirements

2. Recertify eligibility every year.
   - Covered Entities must recertify annually during a designated recertification period for each program type.
   - Advance email notifications about the recertification process are sent to the Authorizing Official and the Primary Contact.
   - Once the recertification period begins, the A.O. only will receive a username and password to complete the recertification.
   - The A.O. will receive a verification by email after the recertification process is completed. The A.O. must click the "Done" box in the email to finalize the recertification process.
   - If no verification is received, contact Apexus, the 340B Prime Vendor, at 1.888.340.2787
   - For additional information about recertification, visit https://opanet.hrsa.gov/OPA_MOD/MANUALS/PUBLIC/CERecertify.pdf

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340B Program Requirements

3. Prevent diversion to ineligible patients. Covered Entities must not resell or otherwise transfer 340B drugs to ineligible patients.

- Eligible patients must receive healthcare services, other than drugs, from the agency.
- An individual is an eligible patient of a 340B covered entity only if:
  - the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; ***and***
  - 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***
  - 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.

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340B Program Requirements

4. Duplicate Discount Prohibition-Manufacturers are prohibited from providing a discounted 340B price and a Medicaid drug rebate for the same drug. Covered entities must accurately report how they bill Medicaid fee-for-service drugs on the Medicaid Exclusion File, as mandated by 42 USC 256b(a)(5)(A)(i).

- When certifying, the A.O. should indicate that the agency will use 340B drugs for Medicaid clients ("carve-in").
- All North Carolina local public health agencies provide Family Planning services and bill Medicaid for 340B drugs administered and/or dispensed to Family Planning clients. **Therefore, all North Carolina local public health agencies are considered "carve-in" agencies.**
- We recommend providing a written prescription to Medicaid and privately insured clients for oral contraceptive pills, patches, and rings, unless doing so would present a barrier to the patient obtaining these contraceptives.

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340B Program Requirements

4. Duplicate Discount Prohibition (continued)

- Covered Entities may request changes to their "carve-in" decision at any time.
- When changing "carve-in" status, the agency must provide the agency's NC Medicaid and NPI numbers.
- These changes only take effect the following quarter and only if the change request is received, approved and processed by OPA.

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340B Program Requirements

4. Duplicate Discount Prohibition (continued)

- When a 340B drug or device is provided to an eligible Medicaid patient, the agency must append the UD modifier to the HCPCS code for the drug or device.
  - The UD modifier alerts the NC Division of Medical Assistance (DMA) that the drug was a 340B drug that has already been discounted by the manufacturer.
  - In the absence of the UD modifier, NC DMA may seek a rebate from the manufacturer. If the drug was already discounted through the 340B program, any additional discount the manufacturer provides to DMA will be considered a "duplicate discount."
- When setting fees for drugs/devices, the agency must set the fee for Medicaid at the acquisition cost.
- Agencies may set separate fees, based on usual and customary charges, for drugs and devices billed to private insurance or billed to self-pay patients.

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Slide 12

AS2 I think DMA (without periods) is preferable to D.M.A. Please assure consistency throughout.
Atkinson, Sydney, 4/21/2017

FD2 agreed - made changes
Farb, Debbie, 4/21/2017

340B Program Requirements

5. Prepare for program audits. Maintain auditable records documenting compliance with 340B Program requirements. Covered entities are subject to audit by manufacturers or the federal government. Any covered entity that fails to comply with 340B Program requirements may be liable to manufacturers for refunds of the discounts obtained.

- HRSA has conducted three audits of NC local Public Health agencies in the last six years. In 2017, HRSA expects to complete over 600 audits of 340B covered entities nationwide.
- Agencies should conduct periodic self-audits of their 340B programs.
- Agencies should assure that patients who receive 340B drugs or devices are "eligible patients" who meet the HRSA patient definition to prevent diversion.
- Agencies should assure that 340B drugs/devices billed to NC DMA include the UD modifier with the HCPCS code to prevent "duplicate discounts."

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340B Program Requirements

5. Program Audits (continued)

- Agencies should establish a threshold that constitutes a "material breach" for diversion and for duplicate discounts.
  - A "material breach" threshold may be set at a percentage of
    - the agency's clients who receive 340B drugs who are ineligible to do so **and**
    - a percentage of drugs billed to DMA that lack a UD modifier, which may result in duplicate discounts.
  - The threshold should represent an unacceptable level of error.
  - An "Establishing Material Breach Threshold Tool" is available at https://docs.340bpvp.com/documents/public/resourcecenter/Establishing_Material_Breach_Threshold.pdf

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340B Program Requirements

5. Program Audits (continued)

- If, during a self-audit, the agency determines that a "material breach" has occurred (i.e. the threshold percentage has been met or exceeded), the breach must be reported to HRSA. Please notify the State Pharmacy Consultant for guidance.
  - A self-audit tool is available at https://docs.340bpvp.com/documents/public/resourcecenter/Establishing_Material_Breach_Threshold.pdf
  - Information on self-disclosures is available on the HRSA website at https://www.hrsa.gov/opa/updates/september2014.html

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Drugs Eligible for Purchase by a Family Planning 340B Covered Entity

- Oral Contraceptive Pills
- Contraceptive Transdermal Patches
- Vaginal Contraceptive Rings
- Depo Provera
- Intrauterine Devices
- Implantable Contraceptive Devices
- Emergency Contraceptive Pills

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Use of STD 340B Drugs

- State law [G.S. 130A-144 (e)] permits the use of STD 340B drugs in Family Planning clinic
- **Example:** A patient is tested for Chlamydia in Family Planning Clinic. The test is positive. The patient returns to Family Planning Clinic for treatment.
  - The clinic staff treat the patient by administering Azithromycin purchased through the STD 340B program.
  - This drug should be documented in the STD Drug Dispensing/Administration log.
  - The documentation in the STD Drug Dispensing/Administration log should indicate that the patient receiving the drug was a Family Planning patient.

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Use of Family Planning 340B Drugs

- Family Planning 340B drugs can only be used in Family Planning Clinic
  - **Example:** An STD patient expresses an interest in receiving emergency contraception (EC). This patient cannot receive Family Planning 340B drugs/devices in the STD clinic.
  - Three options exist:
    1. The STD patient may receive privately-purchased (non-340B) EC in STD clinic. *Note: 340B and Non-340B stock must be physically separated in the pharmacy and appropriately labeled.*
    2. The patient may be referred to and evaluated in the Family Planning clinic and may receive 340B EC there.
    3. A Family Planning encounter may be opened and completed during the visit, with the encounter billed and coded as a Family Planning visit, and 340B EC may be administered, dispensed, or prescribed. *Note: this is not an option for visits conducted by STD Enhanced Role RNs.*
  - Note: We recommend that Medicaid and privately-insured clients be given a prescription for EC.

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Use of Family Planning 340B Drugs

- Family Planning 340B drugs can only be used in Family Planning Clinic
  - **Example:** A Pregnancy Test Only patient seen in a program other than Family Planning (i.e. Other Services) with a negative pregnancy test result has an indication for Emergency Contraception (EC) or quick-start of a contraceptive method.
  - Three options exist:
    1. The patient may receive privately-purchased (non-340B) EC or privately-purchased (non-340B) contraceptive methods in the non-Family Planning clinic. *Note: 340B and Non-340B stock must be physically separated in the pharmacy and appropriately labeled.*
    2. The patient may be referred to and evaluated in the Family Planning clinic and may receive 340B EC or a 340B contraceptive method there.
    3. A Family Planning encounter may be opened and completed during the visit, with the encounter billed and coded as a Family Planning visit, and 340B EC or a 340B contraceptive method may be administered, dispensed, or prescribed.
  - Note: we recommend that Medicaid- and privately-insured clients be given a prescription for EC or pills/patches/rings.

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Use of Family Planning 340B Drugs

- Family Planning 340B drugs can only be used in Family Planning Clinic
  - **Example:** A Maternal Health postpartum patient is seen in the Maternal Health clinic. The postpartum patient expresses an interest in receiving a contraceptive method.
  - Three options exist:
    1. The patient may receive privately-purchased (non-340B) contraceptive methods in the Maternal Health clinic. *Note: 340B and Non-340B stock must be physically separated in the pharmacy and appropriately labeled.*
    2. The patient may be referred to and evaluated in the Family Planning clinic and may receive a 340B contraceptive method there.
    3. A Family Planning encounter may be opened and completed during the visit, with the encounter billed and coded as a Family Planning visit, and a 340B contraceptive method may be administered, dispensed, or prescribed.
  - Note: we recommend that Medicaid- and privately-insured clients be given a prescription for pills/patches/rings.

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340B Template Policies

- Template policies are designed to assure that required Title X and Health Resources and Services Administration (HRSA) content is addressed in agency policy.
  - The template policies will require personalization, and may require ***minor*** revisions and/or additional content to meet agency needs.
  - Pink-highlighted areas must be tailored with the agency name.
  - Yellow-highlighted areas must be tailored with agency-specific content.
  - **Please assure the entire policy is reviewed and that the content is appropriate for your agency.**
- Consider including references to Sexually Transmitted Disease (STD) and Tuberculosis (TB) 340B programs in this policy.

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340B Template Policies

- Sample Pharmacy Policies are located on the WHB website, Manuals, Family Planning Manual, Section 2, 2.13
- Two Template 340B Policies are available on the WHB website
  - Sample 340B Policy, In-House
    - Agency has Public Health Registered Nurses trained in Dispensing
    - Agency maintains a Pharmacy Permit from the NC Board of Pharmacy for the local public health agency's pharmacy
  - Sample 340B Policy, Off-Site
    - Agency uses a pharmacy to dispense 340B drugs to eligible patients
    - Agency does not maintain a Pharmacy Permit
- Two additional documents are available on the WHB website
  - Sample Pharmacist Contract (for agencies with In-House pharmacies)
  - 340B Contract Pharmacy Service Agreement (for agencies that contract with off-site pharmacies)

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Miscellaneous Pharmacy Issues

- **Effective with purchases starting June 1, 2017**, Women's Health Service Funds (WHSF) may only be used to purchase Long Acting Reversible Contraceptives (LARCs, including Intrauterine Devices and Implantable Contraceptive Devices ONLY) and to insert/remove LARCs. These WHSF devices may only be used for non-Medicaid patients.
- Agencies that use an off-site pharmacy to dispense to self-pay clients who are responsible for some portion of their bill on the Sliding Fee Scale must:
  - Receive confirmation from the pharmacy that the patient has picked up her pills/patches/rings/EC before billing the patient for the pills/patches/rings/EC.
  - Develop a process for notifying the patient at the time of the appointment that she is responsible for the cost of the methods and may receive a bill for the method at a later date. (Confidential patients may receive a bill at their next visit.)

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Miscellaneous Pharmacy Issues

- Two additional Pharmacy webinars are planned.
  - One will address use of the revised Drug Inventory Spreadsheet, available on the WHB website.
  - Another webinar will address upcoming changes to the Board of Pharmacy rules regarding dispensing.

Questions

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