

CT DPH STD 340B Program Covered Entity Webinar

March 19, 2019



Agenda

- Brief overview of HRSA webinar from 3/11/19
- Covered Entity Requirements for the CT DPH STD 340B Program
 - Procedures for the upcoming HRSA recertification period
 - Procedures for annual re-enrollment in the CT DPH STD 340B Program
- Forms review
- Resources

Overview of HRSA Eligibility Webinar

CT DPH STD 340B Program Covered Entity Requirements

- Rules for participating in the CT DPH STD 340B Program
- Intent is to ensure compliance with the HRSA 340B Program
- You are agreeing to these requirements when you sign the updated “Medication Enrollment Agreement-STD”

Covered Entity Requirements: Definitions

- Authorizing Official
- Covered Entity
- Diversion
- Duplicate Discount
- Primary Contact
- HRSA

Covered Entity Requirements: Eligibility

- Serve at risk populations for STDs- persons under 25 years old or men who have sex with men
- Serve uninsured or underinsured populations
- Utilize the DPH Public Health Laboratory for STD testing services
- Comply with 340B Program Rules as determined by HRSA
- Implement written policies and procedures
- Comply with the terms of the Requirements Document

Covered Entity Requirements: Recertification

- Follow HRSA guidance for recertification during the annual recertification period as designated by HRSA
- Complete an updated “Medication Enrollment Agreement-STD” and “TB and STD Medication Facility Profile”
 - Once these forms are completed and reviewed by the CT DPH STD Program, the updated grant number will be provided to the covered entity Authorizing Official
- These forms **MUST** be completed and submitted before you recertify your site in the HRSA database (OPAIS)
- The CT DPH STD Program will send out an email on the recertification process when HRSA announces the recertification period for this year

Covered Entity Requirements: OPAIS Database

- The covered entity is responsible for ensuring all information on the OPAIS database is accurate at all times.
- When information on the OPAIS database is updated, a new “TB and STD Medication Facility Profile” and “Medication Enrollment Agreement-STD”, as applicable, must also be updated and sent to the CT DPH STD Program

Covered Entity Requirements: Medication Ordering

- Process unchanged
- Continue using STD Drug Order Form
 - Make sure using most current form
 - Can fax or email (DPH.TB-STDDRUGS@ct.gov)

Covered Entity Requirements: Medication Management and Documentation

- For each CT DPH STD 340B provided medication, Participant shall document such medication from Participant's receipt of the medication through the medication's ultimate disposition.
- Participant shall immediately inspect medication shipments upon receiving the shipments and notify the CT DPH STD 340B Program immediately if a shipment is incorrect or varies from the Participant's STD Drug Order Form that originated the shipment.
- Participant's inspection shall cross-reference the 11-digit National Drug Code (NDC) number for each medication received with the medication ordered.
- Participant shall store medications in a locked area at the Participant's OPAIS identified site.
- Participant shall segregate CT DPH STD 340B provided medications from all other medications.

Covered Entity Requirements: Medication Management and Documentation

- Participant shall maintain all medications not provided by the CT DPH STD 340B Program (340B and non-340B) in separate physical inventories with separate medication logs that clearly allow an auditor to identify which medications were obtained from the CT DPH STD 340B Program and which medications were not obtained from the CT DPH STD 340B Program.
- Participant shall document in the log the disposition and cause of such disposition, including waste or expiration, of all CT DPH STD 340B provided medication.
- Participant must be able to clearly demonstrate to auditors via written document which patients have received CT DPH STD 340B Program medications, the qualifying basis for providing such medicine, and which patients have received other medications.
- Participant shall maintain a log identifying each CT DPH STD 340B provided medication by 11-digit NDC number with corresponding information demonstrating compliance with HRSA and CT DPH STD 340B Program requirements as set forth in this Requirements Document.
- Participant shall send CT DPH STD 340B Program Participant's log upon DPH's request.

Covered Entity Requirements: Patient Eligibility

- Comply with the HRSA Patient Definition
 - 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. Disproportionate share hospitals are exempt from this requirement.
- No diversion of provided drugs
 - Cannot send drugs provided to one site to another site, even if they are a covered entity in the CT DPH STD 340B Program
 - Explicit allowance for expedited partner therapy (EPT)

Covered Entity Requirements: Provider Eligibility

- Must list all healthcare providers who will dispense/provide CT DPH STD 340B provided medications on the “TB and STD Medication Facility Profile”
- Must ensure these healthcare providers are employees of or under contract with the covered entity
- The list of healthcare providers can include anyone that can dispense or administer medications within their scope of practice

Covered Entity Requirements: Billing

- No billing of Medicaid, private insurers or patients for any CT DPH STD 340B medications
- No seeking or accepting of duplicate discounts for these medications

Covered Entity Requirements: Audits- Covered Entity

- Must have written policies and procedures that demonstrate compliance with the 340B Program
- Document and implement self-audit procedures
- Quarterly inventory counts to identify any discrepancies between medication quantity sent to the site and medication quantity logged as administered to patients, wasted or expired;
- Quarterly review of billing documents to ensure no duplicate discounts were obtained or no inappropriate billing occurred;
- Quarterly review to ensure continued usage of the DPH Public Health Laboratory for STD testing;
- Quarterly review to ensure all patients meet the patient definition (prevent diversion); and
- Discrepancy research to determine possible causes and discrepancy reporting to the CT DPH AO.

Covered Entity Requirements: Audits- CT DPH and HRSA

- CT DPH STD Program will audit each covered entity at least once annually
- Can be with or without advance notice
- Need to be able to provide the following:
 - Policies and Procedures
 - Medication logs
 - Clinical encounter information (e.g. notes)
 - Billing information
 - Other relevant information as requested

Resources

- <https://www.340bpvp.com/education/340b-tools/>

Next Steps

- The following will be sent to all covered entities after the webinar:
 - Covered Entities Requirements
 - Medication Enrollment Agreement-STD
 - Facility Profile Form
 - STD Drug Order Form
 - Webinar slides
 - Sample medication log
- Start working on policies and procedures
- Await email from HRSA regarding recertification period

Questions?