Patient Definition

- Language starts with a patient definition for hospitals (pg 1).
- Grantees are not covered by this patient definition. The language instead requires HRSA to issue a regulation with a patient definition for all hospitals, and thus the intent is that the patient definition applicable to grantees would be the existing definition as set forth in HRSA's 1996 Final Notice (this intent is made explicit by the addition of a grandfathering clause) (pg. 2).

Contract Pharmacy

Contract pharmacy language is meant to enhance program integrity. For all hospitals, it limits the number and location of contract pharmacies.

- **For all hospitals**, generally limits the number and location of contract pharmacies to five, including mail order (pg. 4).
- Requires covered entities to register contract pharmacy agreements, establish a patient eligibility verification system, and conduct annual independent, on-site audits of contract pharmacies **(grantees are exempted)** (pg. 3-4).
- Establishes a moratorium on further expansion of contract pharmacy arrangements **for all hospitals** until the Secretary issues final regulations addressing OIG recommendations on compliance issues with contract pharmacies (pg. 5-6).
- Establishes a requirement for HHS to conduct a study of compliance risks associated with mail order contract pharmacies and issue regulations to adopt any additional safeguards and limitations on mail order contract pharmacies recommended in the study. These regulations **would apply to all hospitals' mail order pharmacies (grantees are exempted)** (pg. 5).
- Amends 340B law to require that **all hospitals** establish sliding fee scales for providing covered outpatient drugs under the 340B program (directly, or indirectly through contract pharmacies) to low-income patients without minimum essential coverage (**we understand that grantees already have these scales in place, and thus they are exempted**) (pg. 6).
- Requires HRSA to issue regulations defining "low-income individuals" and providing a methodology for establishing a sliding fee schedule, applicable to hospital covered entities dispensing covered outpatient drugs directly, through a child site, or through a contract pharmacy (**grantees exempted**) (pg. 7).

Duplicate Discounts

- Requires new regulations, applicable to all covered entities (**including grantees**), to prevent duplicate discounting. The methods would include the use of 340B-specific claims identifiers and **claims-level data** provided by covered entities to states and manufacturers (pg. 6).

Hospital and Child Site Eligibility

Develop revised eligibility criteria for private, non-profit DSH hospitals.

- Asks GAO for a report and recommendations on a better metric for eligibility that would reflect outpatient charity care (pg. 8).
- Moratorium on enrollment of new private, non-profit DSH hospitals and child sites until the GAO's recommendations for alternatives to DSH are either addressed in legislation enacted by Congress or (if Congress does not act within one year of GAO's report) by HHS regulations to be issued within 180 days after the one-year anniversary of the issuance of GAO's report (pg. 8).

Child site eligibility: Requires that a child site of any 340B hospital (not just private, non-profit DSH hospitals) be wholly-owned by a covered entity, generally meet certain cost report requirements, meet Medicare provider-based standards, provide a full range of outpatient health care services (not just drugs and/or drug administration), and adhere to charity care policy/sliding fee of parent (pg. 9).

Hospital Reporting Requirements

Goal is to have 340B hospital reporting requirements that are similar to what we understand that grantees already report under their grants.

- Requires hospitals to submit on an annual basis several data points in an electronic format (**grantees not included**). Data to be required includes, for example (pg. 11):
    - Number and percentage of patients disaggregated by insurance status;
    - Data on the amount and percentage of charitable care;
    - Aggregate amount of gross reimbursement received for 340B drugs, including reimbursement received for child sites and in contract pharmacy arrangements;
    - Aggregate acquisition cost for 340B drugs;
    - Aggregate amount paid to contracted entities (TPAs, contract pharmacies) for dispensing of 340B drugs and related services;
    - Information on how entities prevent duplicate discounts and drug diversion;
    - Volume of 340B drugs dispensed by the covered entity and any contract pharmacies.
- Gives the Secretary authority to remove a hospital if it is in knowing and intentional violation of program laws (Secretary decides what is a reasonable amount of time before the hospital can participate in 340B again) (pg. 12).
- Requires Secretary to promulgate regulations implementing reporting requirements (pg. 12).
- Requires Secretary to make data reported by applicable covered entities publicly available in the aggregate and broken down by parents, child sites, and contract pharmacies (but not individually identifiable) (pg. 12).

Reports To Congress

- Secretary report on data provided pursuant to **hospitals'** reporting requirements described above, e.g., relating to contract pharmacies, duplicate discounts, etc. (pg. 12).
- Secretary report on audits conducted of covered entities (**grantees already subject to audit, so no new requirements are being imposed**), including actions taken by Secretary in response to audits conducted by manufacturers (pg. 12).
- Comptroller General report on use of contract pharmacies by [covered entities (analysis to be broken down by type of covered entity[,]). Report also would include data analyzed by contract pharmacy location from the respective covered entity location (pg. 12-13).
- OIG annual report on contract pharmacies. First report to include recommendations on diversion and duplicate discounting and on ensuring benefits are targeted at helping low-income or vulnerable patients (pg. 13).

User Fee

- Secretary shall assess and collect a user fee from **all hospitals (excluding grantees)** that will not exceed 0.1 percent of the covered entity's total purchases of drugs under the 340B program during the previous year. User fees will go towards general costs of oversight and administration. The Secretary shall promulgate regulations implementing user fee collection, and the OIG will conduct an annual review of the user fee program and submit a report to Congress each year, beginning in 2017 (pg. 13-14).

Improving HRSA Resources

- Gives the Secretary direct hiring authority for not more than 10 staff (pg. 14).