

Children's Hospitals: 340B Eligibility, Enrollment, and Participation



Background

- The 340B Program, established in 1992 by federal statute, provides for discounts on outpatient drugs to specific eligible entities.
- Section 6004 of the Deficit Reduction Act (DRA) of 2005 made it possible to add qualifying children's hospitals to the list of covered entities eligible to access 340B discounted drugs.
- Children's hospitals are defined in the Social Security Act as **a hospital whose inpatients are predominantly individuals under 18 years of age**. CMS has officially reserved the 3300 series of Medicare Provider Numbers for children's hospitals that meet the statutory definition.

Purpose

The purpose of the final notice in the Federal Register is to inform interested parties of final guidelines regarding the addition of children's hospitals that meet certain requirements, specifically:

- (1) The process for the registration of children's hospitals to the 340B Program; and
- (2) the obligation of manufacturers to provide the statutorily mandated discount to those children's hospitals.

Key Points for Eligibility & Enrollment as outlined in the Federal Register

340B Program Requirement	How To
1. Demonstrate that the hospital is a "children's hospital" as defined by section 6004.	The hospital must have a 3300 series Medicare provider number and it must provide evidence of this number on the 340B Program Registration Form for Children's Hospitals.
2. Certify that the hospital is: a) is a private non-profit hospital under contract with State or local government to provide health care services to low income individuals who are not eligible for Medicare or Medicaid; or (b) owned or operated by a unit of State or local government; or (c) is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government.	Complete and submit the 340B Program Registration Form for Children's Hospitals. <ul style="list-style-type: none"> • For 2(a) provide Certification of Contract Form. • For 2(b) and 2(c), provide supporting documentation as directed on form
3. Certify that the hospital either: (a) had a disproportionate share adjustment percentage greater than 11.75 percent for the most recently filed cost report (b) the hospital is eligible under an a separate indigent care calculation, which meets specific criteria including: location in an urban area, has 100 or more beds, and can demonstrate that its net inpatient care revenues (excluding any of such revenues	3 (a). Children's hospitals may satisfy the requirement of demonstrating a DSH adjustment percentage greater than 11.75 by providing either of the following to the OPA: i. An official document from the Department of Health and Human Services or a contractor that is authorized to make official determinations, showing that the hospital meets the DSH adjustment percentage requirement for the most recent cost reporting period, or, ii. If a Medicare cost report is filed, a copy of the relevant

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340B Program Requirement	How To
<p>attributable to Medicare), during the cost reporting period in which the discharges occur, for indigent care from State and local government sources and Medicaid exceed 30 percent of its total of such net inpatient care revenues during the period.</p>	<p>pages of the most recently filed Medicare cost report that contain data necessary to calculate</p> <p>3(b). Entities wishing to receive more information about this option should contact PSSC for details.</p>
<p>4. Certify that the hospital will not participate in a group purchasing organization (GPO) or group purchasing arrangement for covered outpatient drugs as of the effective date of participation as listed in the 340B covered entity database.</p>	<p>Complete and submit the Certification of Non-Participation in a GPO form.</p>
<p>5. Certify that outpatient clinics meet eligibility criteria.</p>	<p>The hospital must be able to attest that 340B eligible outpatient clinics are integral parts of the hospital and either</p> <p>(a) hospitals that file Medicare cost reports must certify that the outpatient facility is reimbursable on the Medicare cost report; or</p> <p>(b) hospitals that do not file Medicare cost reports must certify that the outpatient facilities meet specified CMS provider based status criteria. The guidelines permit the entity to attest that the clinics meet all CMS Provider Based Status criteria whether or not the entity has received the official designation of provider based for the clinics. The relevant criteria are outlined by CMS in 42 CFR 413.65 (d) & (e) and more detailed information is available by Contacting PSSC.</p>
<p>6. Certify that the hospital will abide by all requirements of section 340B of the Public Health Service Act (e.g., prohibition on resale of covered outpatient drugs; prohibition on duplicate discounts or rebates).</p>	<p>Complete and submit the 340B Program Registration Form for Children’s Hospitals.</p>

Additional Resources

<p>OPA website Link to the Final Notice on Children’s Hospital in the Federal Register & registration forms</p>	<p>http://www.hrsa.gov/opa/ http://www.hrsa.gov/opa/children.htm</p>
<p>Answers.gov Access to a list of FAQs about children’s hospitals and the new Federal Register Notice</p>	<p>http://answers.hrsa.gov Search for “Children’s Hospitals”</p>
<p>PSSC The HRSA Pharmacy Services Support Center (PSSC) provides program guidance and free technical assistance to all 340B covered entities. A fully narrated power point presentation about children’s hospitals and the new FRN.</p>	<p>Call 1-800-628-6297 or email pssc@aphanet.org</p> <p>Go to http://tinyurl.com/340BChildrensHospitals and click on the Children’s Hospitals Folder under “Getting Started” to locate the presentation .</p>
<p>PVP Access to prices below the 340B prices on certain drugs & distribution networks</p>	<p>Call (888) 340-2787 or email 340CustomerService@340bpvp.com www.340bpvp.com</p>