Expanded Participation in 340B Program

**Summary:** Extends 340B participation to certain children’s hospitals, cancer hospitals, critical access and sole community hospitals, and rural referral centers. Establishes new auditing, reporting, and other compliance requirements for the Secretary, and for pharmaceutical manufacturers and 340B covered entities. Requires the GAO to make recommendations to Congress within 18 months on improvements to the 340B program.

**Status Updates:**
- On March 29, 2011, the Supreme Court upheld a decision that hospitals and clinics cannot sue drug companies to enforce their rights under the 340B program.
- On May 20, 2011, the Department of Health and Human Services (HHS) issued a proposed rule regarding the orphan drug exclusion included within the updated program, with comments due July 19, 2011.

**Next steps:**
- January 1, 2010 – Effective date of the expansion of 340B discounts to additional entities
- September 20, 2010 – Health Resources and Services Administration (HRSA) issued two Advanced Notices of Proposed Rulemaking and Requests for Comment announcing its preliminary plans, and requesting stakeholder input, on how best to implement new authorities over the 340B Drug Pricing Program.
- November 19, 2010 – Comments due to HRSA’s September 20 Federal Register notices
- September 23, 2010 – Secretary shall promulgate regulations to establish and implement an alternative dispute resolution process.
- December 7, 2010 – The New York Times ran an article highlighting the odd policy decision to expand the 340B program to children’s hospitals, while also excluding orphan drugs from that expansion.
- December 15, 2010 – the President signed H.R. 4994, the “Medicare and Medicaid Extenders Act of 2010” (PL 111-309), which among other things clarified that orphan drugs would be included in the expansion to children’s hospitals.

---

1 SEC. 204. CONTINUED INCLUSION OF ORPHAN DRUGS IN DEFINITION OF COVERED OUTPATIENT DRUGS WITH RESPECT TO CHILDREN'S HOSPITALS UNDER THE 340B DRUG DISCOUNT PROGRAM.
(a) Definition of Covered Outpatient Drug-
(1) AMENDMENT- Subsection (e) of section 340B of the Public Health Service Act (42 U.S.C. 256b) is amended by striking ‘covered entities described in subparagraph (M)’ and inserting ‘covered entities described in subparagraph (M) (other than a children’s hospital described in subparagraph (M)).’
(2) EFFECTIVE DATE- The amendment made by paragraph (1) shall take effect as if included in the enactment of section 2302 of the Health Care and Education Reconciliation Act of 2010 (Public Law 111-152).
(b) Technical Amendment- Subparagraph (8) of section 1927(a)(5) of the Social Security Act (42 U.S.C. 1396r-8(a)(5)) is amended by striking ‘and a children’s hospital’ and all that follows through the end of the subparagraph and inserting a period.
• January 9, 2011 -- *New York Times* ran an article stating that the Obama Administration has told the Supreme Court that the hospitals and clinics cannot sue drug companies to enforce their rights under the 340B program.
• March 29, 2011 -- Supreme Court upheld a decision that hospitals and clinics cannot sue drug companies to enforce their rights under the 340B program.
• May 20, 2011 -- HHS issued a proposed rule regarding in the orphan drug exclusion included within the updated program
• July 19, 2011 – Comments due to May 20 proposed rule
• September 23, 2011 – GAO report due regarding 340B improvements.

**Additional information:**
• Supreme Court ruling – http://www.supremecourt.gov/opinions/10pdf/09‐1273.pdf
• Information regarding PL 111‐309 -- http://hdl.loc.gov/loc.uscongress/legislation.111hr4994
• HRSA background on the 340B program -- http://www.hrsa.gov/opa/introduction.htm

**Long summary:**

**Sec. 7101. Expanded participation in 340B program (as modified by 2302 of HCERA).**
Expands the entities that qualify for the 340B program to: (1) children's hospitals who are excluded from the Medicare prospective payment system, (2) free-standing cancer hospitals who are excluded from the Medicare prospective payment system, (3) critical access hospitals, (4) rural referral centers and (5) sole community hospitals that have a disproportionate share adjustment of 8% or more. Excludes orphan drugs for rare diseases or conditions for these expansion entities, except that children's hospitals can have access to orphan drugs for rare diseases under this program.2

**Sec. 7102. Improvements to 340B program integrity.**
Establishes new auditing, reporting, and other compliance requirements for the Secretary, and for pharmaceutical manufacturers and 340B covered entities. For manufacturers, the Secretary will (1) develop precisely defined standards and methodologies for the calculation of ceiling prices, (2) regularly compare the ceiling prices calculated by the Secretary with the manufacturer's quarterly pricing data, (3) perform spot checks of sales transactions as well as selective auditing, (4) inquire into any pricing discrepancies, (5) establish procedures for issuing refunds when there is an overcharge by the manufacturer as well as other procedures regarding rebates, discounts, credits,

---

2 Changes indicated (with new language in bold) due to modifications within PL 111-309, the "Medicare and Medicaid Extenders Act of 2010."
etc., (6) allow covered entities to access applicable ceiling prices through a website, and (7) establish civil monetary penalties (CMPs) for non-compliance. For covered entities, the Secretary will (1) require covered entities to regularly update their information, with the Secretary verifying the accuracy of the information, (2) develop guidance available to covered entities for billing covered drugs to State Medicaid agencies, (3) establish an identification system for covered entities, and (4) establish CMPs for non-compliance.

*Alternative dispute resolution.* HHS shall set up an alternative dispute resolution process for claims by manufacturers or covered entities that the other has committed a violation of the program requirements.

**Sec. 7103. GAO study to make recommendations on improving the 340B program.**

Requires GAO report to Congress within 18 months on whether individuals served by covered entities under 340B program are receiving optimal health care services. Recommendations are to include whether the program should be expanded, whether mandatory sales of certain products through the program hinder access to therapies through any provider, and whether income from the program is used by covered entities to further program objectives.

**Legislative text:**

**SEC. 7101. EXPANDED PARTICIPATION IN 340B PROGRAM.**

(a) EXPANSION OF COVERED ENTITIES RECEIVING DISCOUNTED PRICES.—Section 340B(a)(4) of the Public Health Service Act (42 U.S.C. 256b(a)(4)) is amended by adding at the end the following:

“(M) A children’s hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(ii)(I) of the Social Security Act, or a free-standing cancer hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(v) of the Social Security Act, that would meet the requirements of subparagraph (L), including the disproportionate share adjustment percentage requirement under clause (ii) of such subparagraph, if the hospital were a subsection (d) hospital as defined by section 1886(d)(1)(B) of the Social Security Act.

(N) An entity that is a critical access hospital (as determined under section 1820(c)(2) of the Social Security Act), and that both meets the requirements of subparagraph (L)(i) and has a disproportionate share adjustment percentage equal to or greater than 8 percent.”.

(e) EFFECTIVE DATES.—

(1) IN GENERAL.—The amendments made by this section and section 7102 shall take effect on January 1, 2010, and shall apply to drugs purchased on or after January 1, 2010.

(2) EFFECTIVENESS.—The amendments made by this section and section 7102 shall be effective and shall be taken into account in determining whether a manufacturer is deemed to meet the requirements of section 340B(a) of the Public Health Service Act (42 U.S.C. 256b(a)), notwithstanding any other provision of law.

“(e) EXCLUSION OF ORPHAN DRUGS FOR CERTAIN COVERED ENTITIES.—For covered entities described in subparagraph (M) (other than a children’s hospital described in subparagraph (M)), (N), or (O) of subsection (a)(4), the term ‘covered outpatient drug’ shall not include a drug designated by the Secretary under section 526 of the Federal Food, Drug, and Cosmetic Act for a rare disease or condition.”.

**SEC. 7102. IMPROVEMENTS TO 340B PROGRAM INTEGRITY.**

(a) INTEGRITY IMPROVEMENTS.—Subsection (d) of section 340B of the Public Health Service Act (42 U.S.C. 256b) is amended to read as follows:

“(d) IMPROVEMENTS IN PROGRAM INTEGRITY.—

“(1) MANUFACTURER COMPLIANCE.—

“(A) IN GENERAL.—From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by manufacturers with the requirements of this section in order to prevent overcharges and other violations of the discounted pricing requirements specified in this section.

“(B) IMPROVEMENTS.—The improvements described in subparagraph (A) shall include the following:

3 Changes indicated (with new language in bold) due to modifications within PL 111-309, the “Medicare and Medicaid Extenders Act of 2010.” Section 204 also had two additional changes – (1) the effective date (“The amendment made by paragraph (1) shall take effect as if included in the enactment of section 2302 of the Health Care and Education Reconciliation Act of 2010 (Public Law 111-152).”) and (2) a technical amendment (i.e., “Subparagraph (B) of section 1927(a)(5) of the Social Security Act (42 U.S.C. 1396r-8(a)(5)) is amended by striking ‘and a children’s hospital’ and all that follows through the end of the subparagraph and inserting a period.”).
“(i) The development of a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers under subsection (a)(1) and charged to covered entities, which shall include the following:

“(I) Developing and publishing through an appropriate policy or regulatory issuance, precisely defined standards and methodology for the calculation of ceiling prices under such subsection.

“(II) Comparing regularly the ceiling prices calculated by the Secretary with the quarterly pricing data that is reported by manufacturers to the Secretary.

“(III) Performing spot checks of sales transactions by covered entities.

“(IV) Inquiring into the cause of any pricing discrepancies that may be identified and either taking, or requiring manufacturers to take, such corrective action as is appropriate in response to such price discrepancies.

“(ii) The establishment of procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the manufacturers, including the following:

“(I) Providing the Secretary with an explanation of why and how the overcharge occurred, how the refunds will be calculated, and to whom the refunds will be issued.

“(II) Oversight by the Secretary to ensure that the refunds are issued accurately and within a reasonable period of time, both in routine instances of retroactive adjustment to relevant pricing data and exceptional circumstances such as erroneous or intentional overcharging for covered drugs.

“(iii) The provision of access through the Internet website of the Department of Health and Human Services to the applicable ceiling prices for covered drugs as calculated and verified by the Secretary in accordance with this section, in a manner such as through the use of password protection that limits such access to covered entities and adequately assures security and protection of privileged pricing data from unauthorized re-disclosure.

“(iv) The development of a mechanism by which—

“(I) rebates and other discounts provided by manufacturers to other purchasers subsequent to the sale of covered drugs to covered entities are reported to the Secretary; and

“(II) appropriate credits and refunds are issued to covered entities if such discounts or rebates have the effect of lowering the applicable ceiling price for the relevant quarter for the drugs involved.

“(v) Selective auditing of manufacturers and wholesalers to ensure the integrity of the drug discount program under this section.

“(vi) The imposition of sanctions in the form of civil monetary penalties, which—

“(I) shall be assessed according to standards established in regulations to be promulgated by the Secretary not later than 180 days after the date of enactment of the Patient Protection and Affordable Care Act;

“(II) shall not exceed $5,000 for each instance of overcharging a covered entity that may have occurred; and

“(III) shall apply to any manufacturer with an agreement under this section that knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the maximum applicable price under subsection (a)(1).

“(2) COVERED ENTITY COMPLIANCE.—

“(A) IN GENERAL.—From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by covered entities with the requirements of this section in order to prevent diversion and violations of the duplicate discount provision and other requirements specified under subsection (a)(5).

“(B) IMPROVEMENTS.—The improvements described in subparagraph (A) shall include the following:

“(i) The development of procedures to enable and require covered entities to regularly update (at least annually) the information on the Internet website of the Department of Health and Human Services relating to this section.

“(ii) The development of a system for the Secretary to verify the accuracy of information regarding covered entities that is listed on the website described in clause (i).

“(iii) The development of more detailed guidance describing methodologies and options available to covered entities for billing covered drugs to State Medicaid agencies in a manner that avoids duplicate discounts pursuant to subsection (a)(5)(A).

“(iv) The establishment of a single, universal, and standardized identification system by which each covered entity site can be identified by manufacturers, distributors, covered entities, and the Secretary for purposes of facilitating the ordering, purchasing, and delivery of covered drugs under this section, including the processing of charge backs for such drugs.

“(v) The imposition of sanctions, in appropriate cases as determined by the Secretary, additional to those to which covered entities are subject under sub- section (a)(5)(E), through one or more of the following actions:

“(I) Where a covered entity knowingly and intentionally violates subsection (a)(5)(B), the covered entity shall be required to pay a monetary penalty to a manufacturer or manufacturers in the form of interest on sums for which the covered entity is found liable under subsection (a)(5)(E), such interest to be compounded monthly and equal to the current short term interest rate as determined by the Federal Reserve for the time period for which the covered entity is liable.

“(II) Where the Secretary determines a violation of subsection (a)(5)(B) was systematic and egregious as well as knowing and intentional, removing the covered entity from the drug discount program under this section and disqualifying the entity from re-entry into such program for a reasonable period of time to be determined by the Secretary.

“(III) Referring matters to appropriate Federal authorities within the Food and Drug Administration, the Office of Inspector General of the Department of Health and Human Services, or other Federal agencies for consideration of a appropriate action under this section that knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the maximum applicable price under subsection (a)(1).

“(2) COVERED ENTITY COMPLIANCE.—

“(A) IN GENERAL.—From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by covered entities with the requirements of this section in order to prevent diversion and violations of the duplicate discount provision and other requirements specified under subsection (a)(5).

“(B) IMPROVEMENTS.—The improvements described in subparagraph (A) shall include the following:

“(i) The development of procedures to enable and require covered entities to regularly update (at least annually) the information on the Internet website of the Department of Health and Human Services relating to this section.

“(ii) The development of a system for the Secretary to verify the accuracy of information regarding covered entities that is listed on the website described in clause (i).

“(iii) The development of more detailed guidance describing methodologies and options available to covered entities for billing covered drugs to State Medicaid agencies in a manner that avoids duplicate discounts pursuant to subsection (a)(5)(A).

“(iv) The establishment of a single, universal, and standardized identification system by which each covered entity site can be identified by manufacturers, distributors, covered entities, and the Secretary for purposes of facilitating the ordering, purchasing, and delivery of covered drugs under this section, including the processing of charge backs for such drugs.

“(v) The imposition of sanctions, in appropriate cases as determined by the Secretary, additional to those to which covered entities are subject under sub- section (a)(5)(E), through one or more of the following actions:

“(I) Where a covered entity knowingly and intentionally violates subsection (a)(5)(B), the covered entity shall be required to pay a monetary penalty to a manufacturer or manufacturers in the form of interest on sums for which the covered entity is found liable under subsection (a)(5)(E), such interest to be compounded monthly and equal to the current short term interest rate as determined by the Federal Reserve for the time period for which the covered entity is liable.

“(II) Where the Secretary determines a violation of subsection (a)(5)(B) was systematic and egregious as well as knowing and intentional, removing the covered entity from the drug discount program under this section and disqualifying the entity from re-entry into such program for a reasonable period of time to be determined by the Secretary.
drugs to State Medicaid agencies in a manner that avoids duplicate discounts pursuant to subsection (a)(5)(A).

(iv) The establishment of a single, universal, and standardized identification system by which each covered entity site can be identified by manufacturers, distributors, covered entities, and the Secretary for purposes of facilitating the ordering, purchasing, and delivery of covered drugs under this section, including the processing of charge backs for such drugs.

(v) The imposition of sanctions, in appropriate cases as determined by the Secretary, additional to those to which covered entities are subject under sub- section (a)(5)(E), through one or more of the following actions:

(I) Where a covered entity knowingly and intentionally violates subsection (a)(5)(B), the covered entity shall be required to pay a monetary penalty to a manufacturer or manufacturers in the form of interest on sums for which the covered entity is found liable under subsection (a)(5)(E), such interest to be compounded monthly and equal to the current short term interest rate as deter- mined by the Federal Reserve for the time period for which the covered entity is liable.

(II) Where the Secretary determines a violation of subsection (a)(5)(B) was systematic and egregious as well as knowing and intentional, removing the covered entity from the drug discount program under this section and disqualifying the entity from re-entry into such program for a reasonable period of time to be determined by the Secretary.

(III) Referring matters to appropriate Federal authorities within the Food and Drug Administration, the Office of Inspector General of Department of Health and Human Services, or other Federal agencies for consideration of a appropriate action under other Federal statutes, such as the Prescription Drug Marketing Act (21 U.S.C. 353).

(3) ADMINISTRATIVE DISPUTE RESOLUTION PROCESS.—

(A) IN GENERAL.—Not later than 180 days after the date of enactment of the Patient Protection and Affordable Care Act, the Secretary shall promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section, and claims by manufacturers, after the conduct of audits as authorized by subsection (a)(5)(D), of violations of sub- sections (a)(5)(A) or (a)(5)(B), including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described in paragraphs (1)(B) and (2)(B).

(B) DEADLINES AND PROCEDURES.—Regulations promulgated by the Secretary under subparagraph (A) shall—

(i) designate or establish a decision-making official or decision-making body within the Department of Health and Human Services to be responsible for reviewing and finally resolving claims by covered entities that they have been charged prices for covered drugs in excess of the ceiling price described in subsection (a)(1), and claims by manufacturers that violations of subsection (a)(5)(A) or (a)(5)(B) have occurred;

(ii) establish such deadlines and procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously;

(iii) establish procedures by which a covered entity may discover and obtain such information and documents from manufacturers and third parties as may be relevant to demonstrate the merits of a claim that charges for a manufacturer’s product have exceeded the applicable ceiling price under this section, and may submit such documents and information to the administrative official or body responsible for adjudicating such claim;

(iv) require that a manufacturer conduct an audit of a covered entity pursuant to subsection (a)(5)(D) as a prerequisite to initiating administrative dispute resolution proceedings against a covered entity;

(v) permit the official or body designated under clause (i), at the request of a manufacturer or manufacturers, to consolidate claims brought by more than one manufacturer against the same covered entity where, in the judgment of such official or body, consolidation is appropriate and consistent with the goals of fairness and economy of resources; and

(vi) include provisions and procedures to permit multiple covered entities to jointly assert claims of overcharges by the same manufacturer for the same drug or drugs in one administrative proceeding, and permit such claims to be asserted on behalf of covered entities by associations or organizations representing the interests of such covered entities and of which the covered entities are members.

(C) FINALITY OF ADMINISTRATIVE RESOLUTION.—The administrative resolution of a claim or claims under the regulations promulgated under subparagraph (A) shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction.

(4) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection, such sums as may be necessary for fiscal year 2010 and each succeeding fiscal year.”.

(b) CONFORMING AMENDMENTS.—Section 340B(a) of the Public Health Service Act (42 U.S.C. 256b(a)) is amended—

(1) in subsection (a)(1), by adding at the end the following: “Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the ‘ceiling price’), and shall require that the manufacturer offer each covered entity covered drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.”; and

(2) in the first sentence of subsection (a)(5)(E), as redesignated by section 7101(c), by inserting “after audit as described in subparagraph (D) and” after “finds,”.

SEC. 7103. GAO STUDY TO MAKE RECOMMENDATIONS ON IMPROVING THE 340B PROGRAM.

(a) REPORT.—Not later than 18 months after the date of enactment of this Act, the Comptroller General of the United States shall submit to Congress a report that examines whether those individuals served by the covered entities under the program under section 340B of the Public Health Service Act (42 U.S.C. 256b) (referred to in this section as the “340B program”) are receiving optimal health care services.

(b) RECOMMENDATIONS.—The report under subsection (a) shall include recommendations on the following:

(1) Whether the 340B program should be expanded since it is anticipated that the 47,000,000 individuals who are uninsured as of the date of enactment of this Act will have health care coverage once this Act is implemented.

(2) Whether mandatory sales of certain products by the 340B program could hinder patient access to those therapies through any provider.

(3) Whether income from the 340B program is being used by the covered entities under the program to further the program objectives.