substantiating claims made in the advertisements; to provide copies of the order to certain of their personnel; to notify the Commission of changes in corporate structure that might affect compliance obligations under the order; to notify the Commission of changes in residence, employment, or business affiliation; to file compliance reports with the Commission; and to respond to other requests from FTC staff. Part VII provides that the order will terminate after twenty (20) years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

By direction of the Commission.

Donald S. Clark

Secretary.

[FR Doc. E9–20976 Filed 8–31–09: 2:25 pm]

BILLING CODE 6750–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice Regarding 340B Drug Pricing Program—Children's Hospitals

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Final notice.

SUMMARY: Section 340B of the Public Health Service Act (section 340B) and section 1927(a) of the Social Security Act (section 1927(a)) implement a drug pricing program in which manufacturers who sell covered outpatient drugs to covered entities must agree to charge a price that will not exceed an amount determined under a statutory formula. Section 6004 of the Deficit Reduction Act of 2005 (Pub. L. 109–171) (section 6004) added certain qualifying children's hospitals to the list of covered entities eligible to access 340B discounted drugs. The purpose of this notice 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.

FOR FURTHER INFORMATION CONTACT: Mr. Jimmy Mitchell, Director, Office of Pharmacy Affairs (OPA), Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Parklawn Building, Room 10C–03, Rockville, MD 20857, or by telephone through the Pharmacy Services Support Center at 1–800–628–6297.

DATES: *Effective Date:* September 1, 2009.

SUPPLEMENTARY INFORMATION:

(A) Background

Proposed guidelines for children's hospitals were announced in the **Federal Register** at 72 FR 37250 on July 9, 2007. A comment period of 60 days was established to allow interested parties to submit comments. HRSA, HSB, acting through the OPA, received 20 comments concerning the proposal.

Section 602 of Public Law 102–585, the Veterans Health Care Act of 1992, established section 340B of the Public Health Service Act and added certain implementation provisions for the 340B Program to section 1927(a) of the Social Security Act. Section 340B contains the majority of the requirements for covered entities participating in the 340B Program, while the relevant provisions of section 1927(a) of the Social Security Act provide primarily for the requirement that manufacturers provide the statutorily mandated discount to covered entities.

Section 340B contains a list of covered entities that are eligible to receive discounts through the 340B Program. The list includes entities such as Federally Qualified Health Centers, State-operated AIDS drug purchasing assistance programs, and certain disproportionate share hospitals. Children's hospitals were not included as covered entities under section 340B in the Veterans Health Care Act of 1992 as enacted.

Section 6004 of the Deficit Reduction Act (DRA), Pub. L. 109–171, added certain qualifying children's hospitals as covered entities eligible to access 340B discounted drugs. Section 6004 did not amend section 340B (which contains many of the requirements for covered entities), however, the DRA provision amended section 1927(a) of the Social Security Act (which primarily contains requirements for manufacturers' participation) to add children's hospitals to the 340B Program.

To be eligible for the 340B Drug Pricing Program, section 1927(a), as amended by section 6004 of the DRA, requires children's hospitals to meet the requirements of clauses (i) and (iii) of section 340B(a)(4)(L) of the Public Health Service Act, which contain provisions for State or local government affiliations and non-participation in group purchasing organizations. In addition, children's hospitals must meet the requirements of clause (ii) of such section, which contains requirements for the provision of indigent care, if such section ''were applied by taking into account the percentage of care provided by the hospital to patients eligible for medical assistance'' under Medicaid.

We received several comments in support of the proposal. Supporting comments agreed with the proposed guidelines and that section 6004 of the DRA brings eligible children's hospitals into the 340B program. Several commenters agreed with requiring children's hospitals to demonstrate their status as defined by the Social Security Act section 1886(d)(1)(B)(iii) and to obtain a Medicare provider number in the 3300 series. Many comments supported obtaining an independent audit to certify eligibility requirements and to help ensure program integrity. Comments supported HRSA's position that current Pharmaceutical Pricing Agreements (PPAs) are already broad enough to include children's hospitals as covered entities.

Additional comments challenged HRSA's legal authority and compliance with the Administrative Procedure Act as well as contractual authority with existing PPAs. Other comments raised issues of retroactive discounts, prevention of duplicate discounts, and alternative eligibility criteria such as using disproportionate patient percentages and independent audits. All comments discussed the potential impacts on covered entities, patients, and manufacturers.

The following section presents a summary of all major comments, grouped by subject, and a response to each comment. All comments were considered in developing this final notice and changes were made to content when appropriate.

(B) Comments and Responses

(1) HRSA's Legal Authority

Comment: HRSA lacks authority to add children's hospitals to the 340B program through guidelines.

Response: HRSA disagrees. The Department publishes guidelines in the **Federal Register** providing a public comment period to obtain input into guidance development. Congress did not prescribe the process by which children's hospitals would be added into the 340B program. HRSA has authority to provide guidelines interpreting the statute and its intended administration of the 340B program. The guidelines are not subject to the

Administrative Procedure Act's notice and comment requirements; however, the Department chose to solicit and respond to public comments. These guidelines help to fulfill the Secretary's obligation to provide for the operation of the program under section 340B.

Comment: It is unclear that Congress has authorized the Secretary to enter into PPAs that include children's hospitals. Contractual obligations of the PPA are directly tied to section 340B, which has not been amended to include children's hospitals as covered entities.

Response: HRSA acknowledges that section 6004 of the DRA did not amend section 340B to include children's hospitals as covered entities. However, Congress did add children's hospitals to the 340B program by amending section 1927(a) of the Social Security Act which requires that manufacturers provide the statutorily mandated discount to covered entities. Congress specifically defined the term covered entity as including certain qualifying children's hospitals. Considering the statutory scheme as a whole, it is clear that the Secretary has been authorized to include children's hospitals within the program.

Comment: Since the appropriate legislative changes were not made, it is out of the scope of authority of the Secretary and HRSA to read the current PPA as including children's hospitals.

Response: The existing PPAs do not need to be amended to include children's hospitals. The PPAs require manufacturers to extend 340B pricing to all covered entities listed by HRSA in its database. The PPA also requires that it be interpreted in a manner that best effectuates the underlying statutory scheme. As previously discussed, including children's hospitals as covered entities for purposes of the PPA best effectuates the statutory scheme and therefore children's hospitals are covered entities for purposes of the PPA.

(2) Certification of Eligibility

Comment: Clarify the Social Security Act definition of children's hospitals to mean that in any fiscal year or calendar year, no less than 80 percent of patient days involve patients under 18 years of age.

Response: We disagree with a suggestion that HRSA utilize an 80 percent figure. It is unclear on what basis such a figure would be determined. The statute indicates that section 1886(d)(1)(B)(iii) of the Social Security Act defines the term children's hospital for purposes of 340B eligibility. This section defines a children's hospital as ''a hospital whose inpatients are predominantly individuals under 18 years of age.'' In using the statutory definition, HRSA has taken into account the CMS interpretation of this provision and the context of the 340B Drug Pricing Program.

Comment: The guidelines should require participating children's hospitals to demonstrate that the entity is a children's hospital as defined by the Social Security Act and obtain a Medicare provider number in the 3300 series identifying it as a children's hospital.

Response: We agree. The statute defines ''children's hospitals'' by reference to section 1886(d)(1)(B)(iii) of the Social Security Act. CMS has reserved the 3300 series of Medicare Provider Numbers for children's hospitals that meet the statutory definition. The guidelines have been changed accordingly to make this clearer.

Comment: Clarify how the disproportionate share adjustment percentage eligibility criteria can be applied to children's hospitals since children's hospitals do not receive Medicare disproportionate share hospital (DSH) payment adjustments. Children's hospitals should be permitted to rely on its disproportionate patient percentage (DPP) as defined by CMS for purposes of Medicaid. The DPP formula demonstrating a percentage of greater than 27.32 percent is just as reliable as the required greater than 11.75 percent disproportionate share adjustment percentage.

Response: HRSA agrees with the comment that children's hospitals that do not receive Medicare DSH payment adjustments may have difficulty in showing their disproportionate share adjustment percentage. As an alternative, children's hospitals can show compliance with this requirement if they provide independent verification that if the disproportionate share adjustment percentage were calculated, it would be greater than 11.75 percent. Under current law, one method for reaching such a conclusion would be to have a DPP greater than a threshold amount that equates to a disproportionate share adjustment percentage greater than 11.75 percent. DPP for this purpose is defined at 42 CFR 412.106 and is used in the current applicable statutory formula to calculate the disproportionate share adjustment percentage for DSHs.

Comment: Many children's hospitals do not file any or full Medicare cost reports. If no cost report exists, children's hospitals should be permitted to rely on their own independent auditors to confirm their DPP.

Response: If a children's hospital does not file a Medicare cost report, HRSA agrees that children's hospitals can confirm eligibility through the findings of an independent auditor and certification by the covered entity as to the appropriate value of the hospital's disproportionate share adjustment percentage, as based upon the DPP.

Comment: In addition to requiring verification from independent auditors from children's hospitals that the entity meets 340B eligibility requirements, a comment was made to require this verification to OPA annually because the data used in the calculation to meet the requirements of section 340B(a)(4)(L)(ii) are subject to change.

Response: HRSA agrees that there is a need for ongoing verification as to whether this eligibility requirement continues to be met over time. After enrollment, children's hospitals, as do all covered entities, have an ongoing responsibility to immediately notify the OPA in the event of any change in eligibility for the 340B Drug Pricing Program. No less than on an annual basis, children's hospitals will need to demonstrate that the children's hospital continues to have the required disproportionate share adjustment percentage or DPP. The OPA will provide additional guidance as it develops its plans to annually certify covered entities. To the extent that the OPA is able to obtain periodic documentation of data similar to that provided by CMS with respect to DSHs, it may notify the covered entity that information need not be provided.

(3) Eligibility for Rebates Back to February 8, 2006

Comment: The eligibility criteria for receiving retroactive discounts are overwhelming and confusing to both manufacturers and covered entities. HRSA should remove the ability to receive retroactive discounts from the final rule or, at a minimum, clearly define these criteria.

Response: Although the statute can be complex, we disagree that it is overwhelming or that unilaterally disallowing any ''retroactive'' discounts is appropriate. The parties are in the best position to understand and resolve claims over these issues. In this guidance, HRSA believes it has provided an appropriate level of detail as to its view on how covered entities can qualify for rebates on purchase back to February 8, 2006, the date of enactment of the DRA.

Comment: HRSA should post on its on-line database the date when a children's hospital satisfied the 340B eligibility criteria for manufacturers to

verify if and when the children's hospital was entitled to receive retroactive discounts.

Response: HRSA does not currently plan to provide the eligibility date on its Web site for purposes of retroactive rebates. HRSA intends to follow the current practice of listing the date of eligibility for direct purchase under the 340B Drug Pricing Program as is consistent with the purpose of that database. The addition of retroactivity dates would be outside the established purpose of the database and lead to potential confusion. If a covered entity and manufacturer are unable to agree on the date that the covered entity complied with program requirements or otherwise disagree, HRSA believes that it is most appropriate to follow its published dispute procedures that require the parties to resolve any disputes in good faith. HRSA's first priority is to have eligible children's hospitals register for the 340B Drug Pricing Program. HRSA has concluded that this approach is the most efficient and that HRSA will assist parties to resolve disputes through the published dispute resolution process to the extent resources permit.

Comment: HRSA should clarify ''appropriate'' documentation to demonstrate that drugs did not generate Medicaid rebates.

Response: This is a fact-specific inquiry that may vary from case to case and State to State. The children's hospital should demonstrate that the covered outpatient drugs for which it seeks retroactive discounts were not subject to Medicaid rebates because they were not billed to Medicaid or it can otherwise show the State did not seek a rebate on the drugs for which a retroactive claim is sought.

Comment: Children's hospitals lack access to Medicaid drug rebate invoices/claims data needed to establish the requirement that covered outpatient drugs did not generate Medicaid rebates during retroactive periods.

Response: HRSA believes it appropriate to require that children's hospitals seeking refunds provide sufficient factual evidence to demonstrate compliance with statutory requirements. Children's hospitals seeking retroactive discounts should have access to records of which drugs were billed to Medicaid and which drugs were not billed to Medicaid. HRSA suggests that children's hospitals consider contacting State Medicaid agencies for supporting documentation as is appropriate.

Comment: HRSA should coordinate with CMS to provide guidance regarding monthly Average Manufacturer Price (AMP) and quarterly Average Sales Price (ASP) calculations already submitted, if retroactive discounts are given.

Response: HRSA will do what it reasonably can to assist in the process; however, the issue of resolving whether retroactive discounts are appropriate should be resolved to the full extent possible by the covered entities and manufacturers. Manufacturers will need to consult with CMS with respect to the separate issue on how to handle calculations reported to CMS.

Comment: Children's hospitals should not be penalized for use of Group Purchasing Organizations (GPOs) during the long interval that has elapsed since enactment of section 6004. Initially, HRSA allowed DSHs to use GPOs and to receive 340B retroactive discounts as long as discounts were not for drugs obtained through the GPO. Similarly, children's hospitals should be eligible to receive retroactive discounts for covered outpatient drugs that were not purchased through a GPO.

Response: HRSA disagrees and finds the proposed treatment of retroactive rebates to be inconsistent with the applicable standards for DSHs. The statute makes clear that children's hospitals must meet the same criteria applicable to DSHs. In 1994, final guidance was published on the GPO exclusion that expressly provides that any participation in a GPO or other group purchasing arrangement for covered outpatient drugs by a DSH results in loss of eligibility as a covered entity. HRSA believes that under the statute and under current guidance it should exclude from eligibility for retroactive rebates any purchases while the children's hospital purchased covered outpatient drugs through a GPO or other purchasing arrangement.

The guideline for retroactive rebates published in 1994 (59 FR 25110) was consistent with the GPO exclusion guideline in place for the period of retroactivity. Likewise, this guideline for retroactive rebates is consistent with the GPO exclusion guideline in place for the period of retroactivity.

Comment: Retroactive discounts should only apply to children's hospitals that comply with statutory prohibition against use of a GPO. Furthermore, a comment was received stating that children's hospital should not be able to request retroactive rebates on a covered outpatient drug that was not purchased under a GPO contract if the entity used a GPO contract for other covered outpatient drugs during that same time period.

Response: HRSA agrees and has changed the guidelines to make this issue clear.

Comment: HRSA should be required to establish a process to document the eligibility and compliance of these new entities for any time period of eligibility, including retroactive periods. HRSA should create an audit or certification process to determine the actual date that the facility met all requirements. Manufacturers should be allowed to audit the processes and documentation before they are obligated to provide the retroactive discounts.

Response: HRSA believes that the process outlined in the guidelines provides enough safeguards to ensure program integrity. To the extent that a manufacturer has a specific concern about a covered entity's status, the manufacturer should bring those concerns to HRSA's attention. Manufacturers also have the option of bringing a dispute through the dispute resolution process as addressed in previous guidance (61 FR 65406). The issue of manufacturer audits has also been previously addressed in finalized guidance (61 FR 65406).

Comment: HRSA should shorten the proposed 120-day period allowed to submit requests for retroactive discounts to 30 days, similar to its **Federal Register** notice dated May 13, 1994, following the enactment of section 340B in 1992, where HRSA permitted eligible covered entities to request retroactive discounts within 30 days of publication of guidelines.

Response: While HRSA understands that after enactment of the 340B statute and the implementation of the initial guidances, there was only a 30-day retroactivity period, there are materially different circumstances between the situations in 1994 and today. HRSA must take into account the potential time necessary to obtain sufficient evidence to demonstrate eligibility (requirements which did not exist in 1994) as well as the delay between the time of application to the 340B Drug Pricing Program and listing in the Covered Entity Database at the beginning of the quarter. Upon further review, taking into account changes to this final guidance, HRSA has determined that in order to ensure that all eligible hospitals have reasonable time they should have three full calendar quarters after publication during which they must get registered and officially listed on the 340B Covered Entity Database. To be eligible a children's hospital must register and be listed on 340B Covered Entity Database within one year of publication of this notice. This amount of time will

ensure that all eligible children's hospitals will have reasonable time to obtain the necessary documentation, enroll, and be listed on the 340B Drug Pricing Program Database as eligible to purchase under 340B. Children's hospitals will need to abide by all applicable deadlines for registration and will only be added to the list at the time of standard quarterly updates. Once listed on the 340B Drug Pricing Program Database, a children's hospital will have 30 days to notify manufacturers in writing to preserve their claims.

(4) Eligibility of Off-site Facilities of Children's Hospitals

Comment: HRSA did not address how off-site locations of children's hospitals may participate in 340B. The DSH requirement states that the off-site location be an ''integral'' part of the hospital and be reimbursable on the Medicare cost report. HRSA should be partially guided by Medicare provider-based standards to establish an alternative to the cost report for off-site facilities of children's hospitals to be eligible for 340B.

Response: To the extent possible, eligibility for off-site locations will be determined through the same method applied for DSHs in the 340B Program. Additional clarification on this issue has been provided in the final guidance.

(5) Hemophilia Treatment Centers

Comment: Several commenters asked that HRSA require, as prerequisite, that children's hospitals agree to maintain Hemophilia Treatment Centers as independent purchasers under 340B.

Response: HRSA does not find that such a requirement is necessary to ensure against duplicate discounts or diversion, and does not find sufficient basis to issue such a requirement in this guidance.

(6) Miscellaneous Comments

Comment: There should be a dispute resolution process if a manufacturer has reason to believe that HRSA's determination of eligibility period for a children's hospital is incorrect.

Response: HRSA is not initially making such a determination. HRSA does have guidance on its dispute resolution process.

Comment: HRSA should require explicitly that children's hospitals abide by program guidance relating to the patient definition.

Response: HRSA agrees and finds that the guidance as proposed already makes that explicit.

(C) Obligation of Manufacturers To Provide 340B Discounts to Children's Hospitals

Section 1927(a)(5)(A) of the Social Security Act requires manufacturers to enter into agreements with the Secretary that meet the requirements of section 340B with respect to covered outpatient drugs purchased by a covered entity. Section 1927(a)(5)(B), as amended by section 6004, defines covered entities for purposes of section 1927(a)(5) as those covered entities listed in the Public Health Service Act and certain children's hospitals. As section 1927(a)(5)(A) requires manufacturers to enter into agreements ''with respect to covered outpatient drugs purchased by a covered entity,'' and covered entity is defined as including children's hospitals for purposes of section 1927, manufacturers are required to extend 340B pricing to eligible children's hospitals.

The PPAs between the Secretary and each manufacturer require manufacturers to provide 340B discounted covered outpatient drugs to covered entities. Given the clear congressional intent in section 6004 to expand the category of covered entities, the PPAs currently in place effectively require manufacturers to provide 340B discounts to children's hospitals without need for further amendment to currently existing PPAs.

(D) Process for Admission of Children's Hospitals to the 340B Program

(1) Children's Hospitals Participation

Children's hospitals participation in the 340B Drug Pricing Program is voluntary. Consistent with the participation of other covered entities, once a children's hospital has elected to participate in the program, it must wait to enter or withdraw from the program until the next official update of the 340B covered entity database. Participating children's hospitals must comply with all program guidelines for covered entities until the date they are removed from the 340B covered entity database. The OPA will accept applications from children's hospitals for entry into the 340B Program as of the date of publication of the final notice of these guidelines. Hospitals that submitted documentation seeking recognition as a children's hospital eligible for the 340B Drug Pricing Program prior to the publication of the guidance should apply again in accordance with the procedures described in this guidance.

(2) Certification by Children's Hospitals Prior to 340B Drug Pricing Program Entry

As with other covered entities, prior to entry into the 340B Drug Pricing Program, children's hospitals will be required to provide OPA with a certification regarding several different program requirements. As a threshold matter, a hospital wishing to qualify for the 340B Program as a children's hospital must demonstrate that the hospital is a ''children's hospital'' as defined by section 6004. Section 6004 requires that a hospital wishing to qualify as a children's hospital covered entity must satisfy the definition of ''children's hospital'' contained in section 1886(d)(1)(B)(iii) of the Social Security Act; and meet minimum requirements for the receipt of an additional payment under Medicare pursuant to section 1886(d)(5)(F)(i) of the Social Security Act (if such clause were applied to the children's hospital while taking into account the percentage of care provided by the hospital to Medicaid patients).

(i) Certify That the Hospital Is a Children's Hospital as Defined by Statute

Given the reliance of section 6004 on Medicare payment provisions for the definition of ''children's hospital'' and the requirement that a children's hospital must demonstrate that they would meet the same requirements as a DSH, if they were eligible for DSH payments, a hospital will need to demonstrate that it has been assigned a Medicare provider number identifying the hospital as a ''children's hospital'' (*i.e.,* a hospital with a 3300 series Medicare provider number).

(ii) Certify That the Hospital Will Abide by All Requirements of Section 340B of the Public Health Service Act

Prior to entry into the 340B Program, a children's hospital must certify that it will abide by all the requirements of section 340B that all other covered entities abide by (*e.g.,* prohibition on resale of covered outpatient drugs; prohibition on duplicate discounts or rebates). While children's hospitals are not explicitly mentioned in section 340B, it is implicit in section 1927(a) of the Social Security Act that children's hospitals abide by the requirements of section 340B. Section 1927(a) provides that manufacturers must have entered into agreements with the Secretary that meet the requirements of section 340B and several of the provisions contained in these agreements concern covered entities' compliance with provisions of

section 340B. Furthermore, it is within the Secretary's authority under section 340B to create guidelines necessary for the implementation of the program. Unless children's hospitals are subject to all of the same rules as other covered entities, the inclusion of children's hospitals in the 340B Program would be difficult, if not impossible.

(iii) Certify Compliance With 340B(a)(4)(L) as Modified by Section 6004 of the DRA

Prior to entry into the 340B Program, a children's hospital must certify compliance (along with the date of compliance) with clauses (i), (ii), and (iii) of section 340B(a)(4)(L) (in accordance with section 1927(a)(5)(B) of the Social Security Act) in the following manner:

(A) Meets the requirements of section 340B(a)(4)(L)(i).

To comply with the requirements of section 340B(a)(4)(L)(i), a children's hospital will have to certify (and include such supporting documentation as requested by OPA) that the hospital is (1) owned or operated by a unit of State or local government; (2) is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government; or (3) 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.

(B) Meets the requirements of section 340B(a)(4)(L)(ii).

To comply with section 340B(a)(4)(L)(ii), as modified by section 6004, a children's hospital will have to certify (and include such supporting documentation as requested by OPA) that the children's hospital (1) is located in an urban area, has 100 or more beds, and can demonstrate that its net inpatient care revenues (excluding any of such revenues 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; or (2) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Social Security Act) greater than 11.75 percent.

Supporting documentation must include a signed statement by an appropriate official (*e.g.*, Chief Financial Officer) of the children's hospital that he/she is familiar with the requirements under section 340B(a)(4)(L)(ii), has examined the documentation, and certifies that to the best of his/her knowledge that the children's hospital satisfies the requirements. In addition, the documentation must include: (1) An official document from the Department of Health and Human Services (HHS) or a HHS contractor that is authorized to make official determinations, showing that the children's hospital meets one or both criterion listed above; (2) if the organization files a Medicare cost report, the report filed does not contain a disproportionate share adjustment percentage, and the report includes sufficient information to calculate the disproportionate share adjustment percentage, include a copy of those pages of the filed Medicare cost report with the data necessary to calculate the disproportionate share adjustment percentage; or (3) if the organization does not file a Medicare cost report with sufficient information to calculate the disproportionate share adjustment percentage, a statement from a qualified independent auditor certifying that the auditor performed an audit on the records of the children's hospital, that the auditor is familiar with Federal rules and regulations relevant to its findings, and found that the hospital would meet one or both of the criterion in section 340B(a)(4)(L)(ii), as modified by section 6004 (described in the previous paragraph). The supporting documentation for (1), (2) or (3) should identify the basis for that conclusion including the actual percentage value upon which the determination is made (*e.g.*, disproportionate patient percentage defined at 42 CFR section 412.106), a concise description of any mathematical calculations, and the quarter for which the determination was made. The children's hospital should notify OPA if (1), (2) or (3) result in different conclusions as to eligibility of the children's hospital.

(C) Meets the requirements of section 340B(a)(4)(L)(iii).

To comply with section 340B(a)(4)(L)(iii), a children's hospital will have to certify that it 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.

(3) Inclusion of Children's Hospitals' Off-Site Outpatient Facilities

Children's hospitals must meet the applicable requirements for DSHs as described in the guidance published in 59 FR 47884 (Sept. 19, 1994).

(i) Children's Hospitals That File Medicare Cost Reports With CMS

Children's hospitals that file Medicare cost reports will be required to utilize the same process to add outpatient facilities as DSHs (59 FR 47884). A children's hospital, eligible for the 340B Drug Pricing Program, must first request that the OPA include in its covered entity database the outpatient facilities that are included as reimbursable in its Medicare cost report. A list of these outpatient facilities along with Medicare and Medicaid billing status information must be included with the request. Second, an appropriate official (*e.g.,* Chief Financial Officer) of the children's hospital must sign a statement that he/she is familiar with CMS guidelines concerning Medicare certification of hospital components as one cost center, has examined the list of outpatient facilities, and certifies that the facilities are correctly included on the Medicare cost report of the children's hospital. When these outpatient facilities are added to the master list of eligible and participating covered entities, the off-site facilities will be able to access 340B Drug Program pricing. Outpatient facilities that are not included as reimbursable on the Medicare cost report or file independent Medicare cost reports will not be eligible for 340B pricing as part of the children's hospital.

(ii) Children's Hospitals That Do Not File Medicare Cost Reports With CMS

Children's hospitals that do not file a Medicare cost report with CMS must first request that the OPA include in its covered entity database the outpatient facilities that are integral parts of the hospital. A list of these outpatient facilities along with Medicaid billing status information must be included with the request. Second, an appropriate official (*e.g.,* Chief Financial Officer) of the children's hospital must sign a statement that he/she is familiar with CMS guidelines concerning Medicare certification of hospitals as a cost center, has examined the list of outpatient facilities, and certifies that each facility is an integral part of the children's hospital whose patients are considered patients of the children's hospital, according to the most current published guidelines on patient definition, and would have been correctly included on the Medicare cost report if the hospital filed such a report and that the outpatient facility meets the requirements of a provider-based facility within a DSH under 42 CFR 413.65.

(E) Annual Re-Certification by Children's Hospitals To Maintain Eligibility Status in 340B Drug Pricing Program

Children's hospitals have an ongoing responsibility to immediately notify OPA in the event of any change in eligibility for the 340B Drug Pricing Program. No less than on an annual basis, children's hospitals will need to demonstrate continued maintenance of the required disproportionate share adjustment percentage or disproportionate patient percentage. OPA will provide additional guidance as it gains experience and develops its plans to annually certify covered entities. To the extent that OPA is able to obtain periodic documentation of such data similar to that provided by CMS with respect to DSHs, it may notify the covered entity that such information need not be provided.

(F) Eligibility for Discounts Back to February 8, 2006

Section 6004 of the DRA indicates that the amendment authorizing entry of children's hospitals into the 340B Program ''shall apply to drugs purchased on or after the date of the enactment of this Act.'' The DRA provision was enacted on February 8, 2006. Therefore, once children's hospitals are admitted to the 340B Program and listed on the Covered Entity Database, they are eligible for 340B drug pricing back to February 8, 2006. However, a children's hospital will be eligible for such retroactive discounts only to the extent that it has satisfied all requirements for participation in the 340B program back to the date discounts are requested.

Children's hospitals may request retroactive discounts (discounts, rebates, or account credit) directly from pharmaceutical manufacturers for covered outpatient drugs when all the following conditions are satisfied:

(1) The children's hospital is listed on the 340B Covered Entity Database as eligible to purchase under 340B within one year of publication of this notice.

(2) The children's hospital sent a request in writing to each manufacturer of the drug(s) for which retroactive discounts are sought within 30 days of the children's hospital having been listed as eligible to purchase under 340B on the 340B Covered Entity Database;

(3) The covered outpatient drugs must have been purchased on or after February 8, 2006;

(4) The covered outpatient drugs must not have generated Medicaid rebates (the children's hospital must have appropriate documentation to demonstrate this);

(5) The covered outpatient drugs must not have been sold or transferred to a person who was not a patient of the children's hospital; and

(6) The covered outpatient drugs must have been purchased on or after the date on which the children's hospital satisfied all requirements for participation in the 340B Program as outlined in section (D) of this notice.

In order to satisfy the last condition listed above, a children's hospital must be able to demonstrate, at a minimum, that as required by section 340B(a)(4)(L)(iii) of the Public Health Service Act, the children's hospital did not have a group purchasing agreement for covered outpatient drugs and satisfied the requirements of section 340B(a)(4)(L)(i) and 340B(a)(4)(L)(ii) at the time the covered outpatient drugs for which rebates are requested were purchased. Participation in a GPO for any covered outpatient drugs would disqualify a children's hospital for retroactive rebates during any quarter that the children's hospital purchased any covered outpatient drug through a GPO or other group purchasing arrangement. Consistent with section 340B(a)(5)(C) of the Public Health Service Act, children's hospitals must have auditable records that support claims for retroactive discounts and permit the Government or manufacturers to audit those records (in accordance with procedures established by the Secretary relating to the number scope and duration of such audits (61 FR 65406)).

In fulfilling the conditions listed above, any children's hospital that believes it is entitled to retroactive discounts may preserve its rights by sending manufacturers a letter requesting such refunds, explaining how they meet the requirements in this notice, and providing adequate documentation of purchases within 30 days being listed on the 340B Covered Entity Database as eligible. Such children's hospitals should engage in good faith efforts to resolve any disputes with manufacturers. To the extent they are unable to resolve disputes and wish to pursue further involvement with the OPA, they are encouraged to follow the guidance on the dispute resolution process as described in the **Federal Register** (61 FR 65406).

Dated: August 26, 2009.

Mary K. Wakefield,

Administrator.

[FR Doc. E9–21109 Filed 8–31–09; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: ''Health IT Community Tracking Study 2009.'' In accordance with the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A), AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on June 30th, 2009 and allowed 60 days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by October 1, 2009.

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395–6974 (attention: AHRQ's desk officer) or by e-mail at *OIRA_submission@omb.eop.gov* (attention: AHRQ's desk officer).

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by e-mail at *doris.lefkowitz@ahrg.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Health IT Community Tracking Study 2009

Electronic prescribing (e-prescribing) is a central focus of efforts to promote health information technology (IT) and is of particular interest to AHRQ because of its potential to improve patient safety by reducing medication errors. Despite many public- and private-sector initiatives to support e-prescribing, to date, physician adoption and use has been limited (Friedman, Schueth and Bell 2009). Recently, Section 132 of the Medicare Improvements for Patients and