

Apexus is communicating these recently updated HRSA FAQs with the intention of improving program compliance.

Frequently Asked Questions updated in the last 60 days, effective 12-18-2020					
FAQ ID	Last Modified Date	Category	Sub-Category	Question	Answer
1230	09/30/2020	Eligibility/Registration	Covered Entity	If an entity is funded under more than one grant program that is eligible to participate in the 340B program, must the entity register all programs with the OPA (e.g., the entity is eligible as a Title X Family Planning Clinic and Federally Qualified Health Center)?	Eligible entities should consider all program requirements when deciding how to register for the 340B Program and may register more than one grantee type. Entities may only provide 340B drugs to individuals receiving a service consistent with the scope of the grant program for which the entity is registered. Please note that regular quarterly registration timelines apply, even if only adding or changing covered entity status. For more information on registration and deadlines, visit the Office of Pharmacy Affairs (OPA) web site at: https://340bopais.hrsa.gov/home
1307	09/30/2020	Policy/Implementation	Patient Definition	Does STD testing satisfy the 340B Program's health care services requirement?	STD testing may satisfy the 340B Program's health care services component. HRSA advises covered entities to document meeting all aspects of the 340B patient definition for such health care services in order to use 340B drugs.
1372	09/30/2020	Policy/Implementation	Patient Definition	Must hospitals be able to tie the use of anesthesia gases to a patient if they are purchased under the 340B Drug Pricing Program?	Yes. The hospital is prohibited from diverting 340B drugs to ineligible patients and should be able to document meeting all aspects of the 340B patient definition in order to use 340B drugs. In the case of anesthesia gases purchased through the 340B Program, if hospitals use them in mixed-use settings, they must either have a physically separate inventory or have an auditable accounting mechanism that can show the precise amounts given to every individual patient receiving 340B gases. HRSA has the authority to audit covered entities for compliance with 340B requirements (Section 340B (a)(5)(C) of the PHSA).
1375	09/30/2020	Policy/Implementation	Patient Definition	May 340B drugs be used for individuals who are partners of patients being treated for an STD at a 340B covered entity?	STD partner therapy may be 340B eligible to the extent that they are patients of the covered entity. More information on HRSA's patient definition guidance can be found at https://www.hrsa.gov/sites/default/files/opa/programrequirements/federalregisternotices/patientandentityeligibility102496.pdf .
1384	09/30/2020	Policy/Implementation	Patient Definition	If a 340B covered entity is part of an umbrella company structure and the providers are employed by a different company under the same umbrella structure, can they still prescribe 340B drugs on behalf of the covered entity?	Consider whether the health care provider 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. 340B drugs may be used provided all 340B program requirements are met.
1423	09/30/2020	Policy/Implementation	Patient Definition	What is a compliant way to utilize 340B anesthesia gases in a mixed-use setting?	340B covered entities are responsible for maintaining auditable records which demonstrate that 340B drugs, including gases, are only provided to 340B eligible patients. As a best practice, standard operating procedures would address calculation of the amount of anesthesia gas used, the basis for determining the amount replenished, and the ability to ensure 340B drugs are tracked to specific eligible patients through auditable records. Two operational options for entities subject to the GPO prohibition to consider are to: maintain a separate and distinct physical inventory for inpatients (GPO) and 340B eligible outpatients (340B), or utilize a central WAC account to make an initial purchase of product to later be replenished for inpatients (with inpatient GPO) or for 340B eligible outpatients (with 340B).
1435	09/30/2020	Policy/Implementation	Patient Definition	Are employees of a covered entity eligible to receive 340B drugs?	Covered entities may only distribute 340B drugs to their employees who are eligible patients of the covered entity meeting all 340B program requirements. The 340B Program is limited to patients of the covered entity and has never been a general employee pharmacy benefit or self-insured organization pharmacy benefit. Evidence of an employer relationship or insurer relationship alone is insufficient to determine 340B patient eligibility. Covered entities should document in policies and procedures and maintain auditable records.

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1442	09/30/2020	Policy/Implementation	Patient Definition	May providers that have admitting privileges at our 340B participating hospital be considered eligible providers under the "other arrangements" provision of patient definition?	Covered entities should consider all aspects of patient definition in order to use 340B drugs. http://www.hrsa.gov/opa/programrequirements/federalregisternotices/patientandentityeligibility102496.pdf Covered entities should consider whether the provider has covered entity admitting privileges in providing health care services to a patient of the covered entity such that the responsibility for the care provided remains with the covered entity. A non-covered entity provider's admitting privileges to treat persons at a covered entity hospital alone is not sufficient to demonstrate that any person treated by that provider is a patient of the covered entity hospital for 340B Program purposes. Covered entities should address how they handle providers with privileges in their written policies and procedures.
1454	09/30/2020	Policy/Implementation	Patient Definition	If a 340B hospital loses its 340B eligibility, but later regains eligibility, may the hospital retrospectively place orders for replenishment of product based upon patient visits during its former eligibility period?	These scenarios are addressed on a case by case basis. Covered entities in these situations are encouraged to contact Apexus Answers for technical assistance.
1487	09/30/2020	Policy/Implementation	Patient Definition	Under what circumstances may our 340B hospital use 340B drugs for patients served by our Accountable Care Organization (ACO) partners?	The inclusion of a covered entity in an ACO does not automatically make individuals receiving services from the ACO patients of the covered entity for 340B Program purposes. All individuals receiving 340B drugs must be eligible patients of the covered entity and should adhere to 340B patient definition guidelines. For more information, please review OPA Accountable Care Organizations Policy Release, 2012-02, available at: http://www.hrsa.gov/opa/programrequirements/policyreleases/accountablecare05232012.pdf
1493	09/30/2020	Policy/Implementation	Patient Definition	If we refer a patient to an outside clinic, can we fill their prescriptions from our 340B clinic?	A covered entity may refer an individual for consultation to an outside clinic not registered for the 340B Program and consider that patient 340B eligible if the individual receives health care 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 (61 Fed. Reg. 55156 (October 24, 1996)). If the covered entity can document that it retained responsibility for the health care services provided to the referred individual, then that individual may be eligible to receive 340B drugs from the covered entity. How a covered entity counts referrals under the 340B Program should be addressed in their written policies and procedures.
1526	09/30/2020	Policy/Implementation	Patient Definition	Are covered entities permitted to determine inpatient vs. outpatient status?	Yes. Covered entities may determine inpatient vs. outpatient status such that the determination is in compliance with all 340B Program requirements. Decisions regarding inpatient and outpatient status must be auditable, transparent, and consistently followed. Covered entities should establish written policies and procedures specific to inpatient and outpatient designations and be able to demonstrate compliance with this policy.
1535	09/30/2020	Policy/Implementation	Patient Definition	Does the 340B discount apply to Medicaid patients?	Payer status is not a determining factor for 340B patient eligibility. In other words, a patient is not disqualified from being a 340B eligible patient due to their payer status (third party payer, Medicare, Medicaid, uninsured, etc.). However, when a covered entity is providing 340B drugs to its Medicaid patients, the covered entity must prevent duplicate discounts. Covered entities choosing to use 340B drugs for Medicaid patients must provide the HRSA Office of Pharmacy Affairs with the National Provider Identifiers (NPIs) or Medicaid provider numbers (MPNs) used to bill Medicaid for 340B drugs by listing them on the Medicaid Exclusion File. Covered entities should also follow state billing requirements. For more information and an educational tutorial about Medicaid duplicate discounts, please visit: http://www.hrsa.gov/opa/programrequirements/medicaidexclusion/index.html .

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1538	09/30/2020	Policy/Implementation	Patient Definition	What are elements to consider in development of a tracking system for the use of 340B drugs in a mixed-use setting?	<p>Based on the practice of 340B covered entities, the following are suggested elements to consider in development of a tracking system for use of 340B drugs in a mixed-use setting:</p> <ol style="list-style-type: none"> 1. Outpatient status - hospital billing reports or admission/discharge/transfer reports with date/time stamps 2. Qualified service - patient location/service information from hospital billing reports with date/time stamps 3. Medication(s) used - corresponding copies of pharmacy orders with 11-digit NDC information, amount dispensed/administered as well as prescriber 4. Medication administration or dispensing time while patient was classified as outpatient (depending on what covered entity has defined in policies and procedures as time of patient status determination for 340B purposes). Examples include hospital billing reports, medication administration record, etc. <p>This list is not all-inclusive, and may or may not be applicable based upon the unique situation of any particular entity. The elements included should support adherence to 340B Program requirements and must be clearly auditable. A combination of elements is recommended, as opposed to using any one factor individually.</p>
1559	09/30/2020	Policy/Implementation	Patient Definition	May a hospital use 340B-priced drugs in mixed-use settings, such as a surgery department, where both inpatients and outpatients are treated? If so, what if the hospital cannot track which drugs are used for inpatients and which ones are used for outpatients?	<p>A hospital may use 340B drugs for eligible patients. The hospital must develop appropriate tracking systems to ensure that covered outpatient drugs purchased through the 340B Program are only used for eligible outpatients. It is the responsibility of the hospital to ensure appropriate safeguards are in place to protect against diversion. If a hospital is unable to implement an effective tracking system, it should not use 340B drugs in that setting.</p>
1563	09/30/2020	Policy/Implementation	Patient Definition	Can 340B drugs be used for discharge prescriptions?	<p>340B drugs can be used for discharge prescriptions to the extent that the drugs are for outpatient use. Whether a drug qualifies as outpatient and the individual meets the definition of patient depends upon the factual circumstances surrounding the care of that particular individual. If a covered entity uses 340B drugs, it should be able to explain why the covered entity is responsible for the use of the drugs on an outpatient basis and have auditable records that demonstrate compliance with 340B Program requirements</p>
1565	09/30/2020	Policy/Implementation	Patient Definition	Is a covered entity grantee limited to using or prescribing drugs that address the services or range of services for which grant funding was received?	<p>The 340B Program does not limit the drugs a covered entity can use or prescribe; however, 340B drugs may only be provided to individuals who are patients of the covered entity grantee. All components of the 340B patient definition (61 Fed. Reg. 55156 (October 24, 1996)) should be considered, including the provision that 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 designation has been provided to the entity.</p>
1568	09/30/2020	Policy/Implementation	Patient Definition	Are 318 grantees (STD grantees) that participate in the 340B Program permitted to purchase contraceptives and other 340B drugs for use by grantee patients?	<p>STD (318 grantee) clinics participating in the 340B Program may purchase and dispense 340B drugs (including prescribed contraceptives) to eligible individuals receiving a service consistent with the scope of grant.</p>
1593	09/30/2020	Policy/Implementation	Patient Definition	What details are expected in a contract between a private physician and a hospital to ensure that the patients, seen by the physician "under contract with the hospital," are 340B eligible? Must payments be involved?	<p>HRSA recommends that such contracts would be written to include the provision of services where the entity maintains records of the individual's health care and the responsibility for care provided remains with the covered entity. For more information, please review the 340B Patient Definition final notice in the Federal Register found here: https://www.hrsa.gov/sites/default/files/opa/programrequirements/federalregisternotices/patientandentityeligibility102496.pdf</p>
1599	09/30/2020	Policy/Implementation	Patient Definition	When there is an individual who is an eligible patient of two different 340B covered entities, which entity should claim that individual as a patient?	<p>To the extent that an individual qualifies as a patient of both covered entities, HRSA expects the entities to resolve the issue in good faith. In cases where a covered entity purchased and dispensed a 340B drug to an individual, no other covered entity is permitted to replenish or otherwise assert credit. Covered entities that utilize replenishment are required to ensure that only one covered entity receives a 340B discount on a particular patient transaction.</p>
1674	09/30/2020	Policy/Implementation	Patient Definition	Can non-Medicaid patients receive 340B drugs?	<p>Yes, as long as they are eligible outpatients of the covered entity.</p>

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2692	09/30/2020	Policy/Implementation	Patient Definition	Does HRSA require a child site hospital location to register inpatient locations with observation beds on HRSA's 340B OPAIS?	HRSA does not require a child site hospital location to register inpatient locations with observation beds. However, if a child site hospital voluntarily submits a registration for an inpatient location with observation beds, OPA will review the registration and the hospital must provide Worksheets A and C and the associated trial balance to support the registration. HRSA reserves the right to ask for additional supporting documentation if necessary. The 340B Program is an outpatient drug program. Enrolled covered entities have the responsibility to ensure that drugs purchased under the 340B Program be limited to outpatient use and provided only to eligible patients. HRSA acknowledges that 340B eligible patients may receive healthcare services in observation beds located in inpatient sections of the hospital. If a hospital uses 340B drugs for patients receiving healthcare in observations beds, the hospital must be able to explain how the covered entity is responsible for the use of the drugs on an outpatient basis and have auditable records and policies and procedures that demonstrate compliance with 340B Program requirements. Policies and procedures should specifically address how the hospital defines inpatient and outpatient for purposes of the 340B Program, and how that relates to observation beds. HRSA's audits will ensure the hospital is following those policies and procedures.
1220	09/14/2020	Eligibility/Registration	Outpatient Facility	A clinic is located within the four walls of the parent but has a separate physical address. What is meant by "within the four walls?" Is the same physical address the only limiting condition?	A clinic that shares the parent's physical address is considered within the four walls, even if it has a different suite address. For further clarification, please contact Apexus Answers https://www.340bpvp.com/apexus-answers
1239	09/14/2020	340B Price/Drug	340B Price	If I notice an incorrect price loaded in OPAIS, how do I correct this?	<p>Suggested steps include:</p> <ol style="list-style-type: none"> Check the labeler code on 340B OPAIS (https://340bopais.hrsa.gov/manufacturerearch), and check the Medicaid Drug Rebate Program labeler code (https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data) to help determine if the drug is a covered outpatient drug in the Medicaid Drug Rebate Program and subsequently should have a 340B price. Validate the correct price using the 340B OPAIS pricing system: <ol style="list-style-type: none"> Compare the price in OPAIS to the invoice purchase price using the NDC to look up the product in OPAIS. Remember the following tips: <ul style="list-style-type: none"> The OPAIS Pricing Database displays the 340B ceiling price at the unit level; the covered entity may need to multiply the ceiling price by the package size (this might be the total number of mL, tablets, capsules, grams, etc.) in the package purchased. <ul style="list-style-type: none"> For Prime Vendor participants, verify the selling price by visiting the password-protected Prime Vendor Program Catalog or 340B & PVP Product Selling Price Lookup tool. Package size information is available. Adjust the purchase price for your wholesaler distribution charge/markdown If the OPAIS prices do not match, work with the entity's wholesaler and if not resolved directly with the manufacturer to resolve the pricing issue. If necessary, the entity can contact OPA by completing a Template Notification Tool: Unavailable 340B Ceiling Price/Incorrect Ceiling Price for further investigation by OPA. <p>https://www.340bpvp.com/Documents/Public/340B%20Tools/340B-ceiling-price-unavailable-incorrect-340b-ceiling-price-notification-for-hrsa.docx</p>
1242	09/14/2020	Policy/Implementation	GPO Prohibition	When a covered entity is unable to purchase a covered outpatient drug at a 340B price, may the covered entity subject to the GPO prohibition buy via a GPO?	<p>A covered entity that is subject to the GPO prohibition may not use a GPO for covered outpatient drugs at any point in time. However, if a covered entity is unable to purchase a covered outpatient drug at the 340B price, they should first try and work with the manufacturer to obtain the product at the 340B price. If they are still unable to obtain the product at the 340B price, they should then try to obtain the product at WAC. If they are also unable to purchase the product at WAC, entities may use a GPO only if they then immediately notify OPA detailing the covered outpatient drug(s) involved, the manufacturer, and the communication between the parties as to why the product was not available at 340B or WAC, by submitting the HRSA Template Notification Tool: Unavailable 340B Price https://www.340bpvp.com/Documents/Public/340B%20Tools/340B-ceiling-price-unavailable-incorrect-340b-ceiling-price-notification-for-hrsa.docx. In situations where a product is unavailable at 340B or WAC, and the covered entity can document that all other options have been exhausted, the covered entity should maintain auditable records demonstrating the circumstance, and show they attempted to purchase the product at 340B every time an order was made. Covered entities may not use the fact that they were unable to obtain a product on one day, to then use a GPO for an extended period of time.</p>

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1253	09/14/2020	Policy/Implementation	Purchasing/Inventory/Reimbursement	Under what circumstances would OPA allow multiple grantee sites registered as different 340B IDs with the same grant number purchase 340B drugs under one account and share 340B inventory (for example, several Title X sites/340B IDs under the same Title X grant)?	<p>Each covered entity with a 340B ID is considered a separate entity for purposes of the 340B Program. HRSA assigns 340B IDs in order for stakeholders to confirm eligibility and appropriate shipment of 340B drugs. Due to the complex nature of grantees (other than health centers) and their organizational structures and relationships, the sharing of 340B inventory across 340B IDs is not allowed unless first approved by HRSA. HRSA will consider approval of inventory sharing between unique 340B IDs on a case-by-case basis. Grantees may submit a written request to HRSA to purchase 340B inventory through one account and distribute the inventory to multiple 340B IDs, including a proposal on how the model would ensure all 340B requirements are met.</p> <p>https://www.340bpvp.com/Documents/Public/340B%20Tools/grantee-combined-purchasing-and-distribution-request-for-hrsa.docx</p>
1366	09/14/2020	340B Price/Drug	340B Price	What is the procedure used by manufacturers to refund payment to covered entities who are overcharged for 340B drugs?	<p>Manufacturers should notify HRSA in writing of their intention to issue a refund. This letter should address which drugs are affected and for what time period. This letter may be made public on the HRSA website. Apexus, the 340B Prime Vendor, has a voluntary program to help manufacturers refund money through a distributor credit to the covered entity's 340B wholesaler account. For more information, please contact the 340B Prime Vendor at: https://www.340bpvp.com/apexus-answers or call Apexus Answers at (888) 340-2787.</p>
1418	09/14/2020	Policy/Implementation	Audit/Compliance	How can a 340B entity review internal compliance and prepare for a HRSA 340B program audit?	<p>Tools and resources to help entities self-assess 340B compliance are available here: https://www.340bpvp.com/resource-center/340b-tools</p>
1422	09/14/2020	Contract Pharmacy		What are the audit and compliance parameters under the contract pharmacy guidelines?	<p>HRSA audits of covered entities include contract pharmacy arrangements. The covered entity must have fully auditable records that demonstrate compliance with all 340B Program requirements and the entity remains responsible for ensuring their contract pharmacy arrangements meet statutory obligations to ensure against diversion or duplicate discounts. HRSA recommends that covered entities perform quarterly internal audits and annual independent audits (or more frequent as necessary) of all their utilized contract pharmacies to ensure 340B Program compliance. HRSA also recommends that covered entities maintain written policies and procedures to describe contract pharmacy oversight activities, including effective procedures for review of the patient eligibility determination system used at contract pharmacies, and reconciliation of dispensing, purchasing, and billing records to ensure that diversion and duplicate discounts have not occurred.</p> <p>If the covered entity determines that drug diversion or duplicate discounts occurred or that it is otherwise unable to comply with its responsibility to reasonably ensure compliance, the covered entity can use this Self Disclosure tool to disclose the violation to HRSA https://www.340bpvp.com/Documents/Public/340B%20Tools/self-disclosure-to-hrsa-and-manufacturer-template.docx. This information should be mailed to: Health Resources and Services Administration, Office of Pharmacy Affairs, 5600 Fishers Lane, Mail Stop 08W05A, Rockville, MD 20857.</p>
1433	09/14/2020	Policy/Implementation	Audit/Compliance	I'm new to 340B and need to know some basic resources for how to learn about program compliance. Where should I start?	<p>We recommend individuals attend a 340B University session. Registration information is available here: https://www.340bpvp.com/340b-education. The sessions are free to attend; the stakeholder would just need to get to the meeting. We try to hold these educational events in a variety of locations across the country. Apexus also offers 340B University onDemand, an online version with similar basic content to the live session. Additionally, we would recommend the entity review the tools and resources available here: https://www.340bpvp.com/resource-center/340b-tools. Specific FAQs, available publicly through a keyword search are here: https://www.340bpvp.com/hrsa-faqs. A call center, offering confidential answers to 340B questions, is available and supported by experts in a variety of content areas. If one of the questions requires additional expertise to address, the call center specialists will escalate the inquiry to the appropriate expert. Call center information is available here: https://www.340bpvp.com/apexus-answers, and we look forward to helping you with 340B Compliance; please let us know how we can specifically assist you.</p>

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1453	09/14/2020	Policy/Implementation	Audit/Compliance	What must a covered entity do if it finds 340B non-compliance (during an internal audit or through any other means)?	<p>The covered entity must notify impacted manufacturers and attempt in good faith to resolve issues directly with manufacturers and wholesalers. Further, the covered entity must notify the HRSA Office of Pharmacy Affairs in writing of the compliance issue and include the following information: 340B ID; the violation that occurred; scope of the problem; a corrective action plan (CAP) to fix the problem moving forward; a strategy to inform affected manufactures (if applicable); and a plan for financial remedy if repayment is owed. You are encouraged to use the following tool to report the non-compliance https://www.340bpvp.com/Documents/Public/340B%20Tools/self-disclosure-to-hrsa-and-manufacturer-template.docx</p> <p>This information should be mailed to: Health Resources and Services Administration, Office of Pharmacy Affairs, 5600 Fishers Lane, Mail Stop 08W05A, Rockville, MD 20857.</p>
1464	09/09/2020	340B University	Attendance	Where do I go to register for 340B University?	Register for 340B University by visiting 340Bpvp.com under 340B Education. If the link to register is not yet active, please check back. The links are usually activated ~2 months in advance of the session.
1498	09/09/2020	Medicaid	Duplicate Discounts	How should we bill our Medicaid agency for fee-for-service (FFS) Medicaid when we use 340B drugs to fill Medicaid prescriptions?	<p>HRSA recommends that covered entities refer to their respective state Medicaid agency drug reimbursement guidelines for applicable billing requirements. See http://www.hrsa.gov/opa/programrequirements/federalregisternotices/federalregister12152000.pdf.</p> <p>In addition, to improve transparency and assist stakeholders with 340B compliance, the 340B Prime Vendor has gathered 340B Medicaid information from multiple federal and state Medicaid sources and compiled them in one location. Access this valuable resource here: https://www.340bpvp.com/resource-center/medicaid</p>
1580	09/09/2020	340B PVP		What recommendations can you provide regarding ensuring the information our entity has received regarding 340B policy is accurate?	<p>Covered entities should refer to the 340B statute, HRSA published guidance, and HRSA policy releases (http://www.hrsa.gov/opa/programrequirements/index.html) to confirm the accuracy of 340B policy. HRSA establishes 340B policy and communicates via policy releases, its website and through email communication. In addition, HRSA uses the HRSA contracted 340B Prime Vendor Program, managed by Apexus, to assist in communicating that policy.</p> <p>HRSA cannot ensure the accuracy of information provided by other sources beyond Apexus PVP. Covered entities that are either unsure of past HRSA guidance or information received beyond HRSA or Apexus PVP should contact the Apexus Answers Call Center (https://www.340bpvp.com/apexus-answers) to validate the information. Covered entities should also use their own legal counsel to assist in ensuring compliance with 340B program requirements. Liability for compliance with 340B program requirements resides with the covered entity.</p>
1598	09/09/2020	340B PVP	Distribution	Can you recommend a vendor for our 340B site to work with in purchasing 340B drugs?	All wholesalers are permitted to serve 340B covered entities as drug vendors. Apexus currently has the exclusive agreement with HRSA to serve as the official 340B Prime Vendor for participating covered entities. It continues to expand the number of pharmacy distributors and covered entities participating in the program by using its expertise in negotiating below 340B ceiling pricing, developing efficient distribution networks and competitive bidding processes. The 340B Prime Vendor Program is voluntary, free of charge to entities, and designed to allow entities to participate in the program while still using their current drug distributor. For more information, contact the 340B Prime Vendor Program/Apexus at 888-340-2787 or visit their web site at 340bpvp.com
1650	09/09/2020	340B University	Attendance	When is the next 340B University session?	You can find the upcoming 340B University live sessions on 340Bpvp.com under "340B Education."
1654	09/09/2020	340B PVP	Vaccines	If I do not have an in-house pharmacy, contracted pharmacy arrangement, or relationship with a distributor, do I need to list a distributor when completing the 340B PVP participation agreement?	340B PVP participants do not need to designate an in-house pharmacy or a contracted pharmacy arrangement on the 340B PVP Participation Agreement when only accessing contracted products which are sold direct from the manufacturer. This is the case with most of the vaccines on contract with the PVP. Entities are advised to select a preferred pharmacy wholesaler from those available on the 340B PVP public website in order to have access to the many other discounted products available on the PVP catalog. A listing of Authorized PVP Distributors can be found at https://www.340bpvp.com/distribution/distribution-network .

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1670	09/09/2020	340B PVP	Website Navigation	My facility is already participating in the 340B Prime Vendor Program. How do I make updates to my profile?	Participants are able to update their facility's information at any time by visiting www.340BPVP.com . From the home page of the website, in the upper right hand corner click on "Login". Once you are logged in to the secure section of the PVP website, in the same area, upper right hand corner, click the arrow next to your name, and select "My Profile". If you do not see all entities associated with your organization, please contact Apexus Answers at ApexusAnswers@340BPVP.com or (888) 340-2787 to have your organizations linked correctly. You can update information in the "Apexus Prime Vendor Program (PVP) Participant Data" section at any time. To make updates in the "HRSA Office of Pharmacy Affairs Data" section, you must submit a 340B Change Request to OPA. If you are a PVP participant but do not have access to the secure section of the website, visit: https://www.340bpvp.com/covered-entities/pvp-entity-enrollment . Simple and easy online process to get access to PVP pricing, reports, contract updates and more!
1691	09/09/2020	340B PVP	Website Navigation	How do I add new facilities to my existing participation agreement?	You can register online through the 340B PVP website. Visit: https://www.340bpvp.com/covered-entities/pvp-entity-enrollment and click "Register" to begin enrollment process. Enter in the newly eligible 340B ID to begin enrollment, and fill in all required information before submitting. If you need assistance with the registration process, contact Apexus Answers at (888) 340-2787 and speak to a customer service representative or email ApexusAnswers@340BPVP.com
2583	09/09/2020	340B Database Technical Assistance	OPAIS-Pricing	What are best practices for entities when a product does not have a 340B price available, or the product is unavailable?	Some best practices include: 1. Check the labeler code on 340B OPAIS (https://340bopais.hrsa.gov/manufacturersresearch), and check the Medicaid Drug Rebate Program labeler code https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data to help determine if the drug is a covered outpatient drug in the Medicaid Drug Rebate Program and subsequently should have a 340B price. 2. Review official resources for reported shortages. 3. If the product is NOT listed on the shortage websites, contact the wholesaler and/or manufacturer to confirm unavailability, and assess target date for availability. If an entity is still unable to obtain the product at the 340B price, notify OPA detailing the covered outpatient drug(s) involved, the manufacturer, and the communication between the parties as to why the product was not available at 340B pricing, by submitting the HRSA Template Notification Tool: Unavailable 340B Price https://www.340bpvp.com/Documents/Public/340B%20Tools/340B-ceiling-price-unavailable-incorrect-340b-ceiling-price-notification-for-hrsa.docx
2615	09/09/2020	340B Database Technical Assistance	OPAIS-Pricing	Why may the price be different on OPAIS than what I see on my wholesaler catalog?	The 340B Package Adjusted Price and 340B ceiling price may look different than the 340B selling price (price seen in a wholesaler catalog) for a number of reasons. These may include sub-340B contracts (PVP or individual), wholesaler fees (commonly a percentage added to or subtracted from the total cost of the product), and differences in quantities (for example, between the case size in OPAIS and a package size in the wholesaler system). If a covered entity believes they have been overcharged after researching the issue, they may complete a "340B Ceiling Price Unavailable/Incorrect 340B Ceiling Price Notification for HRSA" form, which can be found on the 340B Prime Vendor's website at https://www.340bpvp.com/resource-center/340b-tools

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2616	09/09/2020	340B Database Technical Assistance	OPAIS-Pricing	If I notice an incorrect price loaded in OPAIS, how do I correct this?	<p>Covered entities with concerns over the accuracy of 340B prices should first exhaust all other avenues to resolve the matter before contacting OPA.</p> <p>Suggested steps include:</p> <ol style="list-style-type: none"> 1. Check the labeler code on 340B OPAIS (https://340bopais.hrsa.gov/manufacturerearch), and check the Medicaid Drug Rebate Program labeler code (https://data.medicaid.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data) to help determine if the drug is a covered outpatient drug in the Medicaid Drug Rebate Program and subsequently should have a 340B price. 2. Validate the correct price using the 340B OPAIS pricing system. 3. For Prime Vendor participants, verify the selling price accuracy by visiting the password-protected Prime Vendor Program website. 4. Work with the entity's wholesaler or directly with the manufacturer to resolve the pricing issue. 5. If necessary, the entity can contact OPA by completing a HRSA Template Notification Tool: Unavailable 340B Ceiling Price/Incorrect Ceiling Price for further investigation by OPA. https://www.340bpvp.com/Documents/Public/340B%20Tools/340B-ceiling-price-unavailable-incorrect-340b-ceiling-price-notification-for-hrsa.docx
2042	07/31/2020	Medicaid	Duplicate Discounts	Absent HRSA guidance, what actions should covered entities take regarding the prevention of duplicate discounts for drugs billed to Medicaid managed care organizations (MCO)?	<p>Duplicate discounts are prohibited for Medicaid FFS and MCO drugs pursuant to section 340B(a)(5)(A) of the Public Health Service Act. The data included in the Medicaid Exclusion File (MEF) applies to drugs billed under Medicaid fee-for-service (FFS). HRSA encourages covered entities to work with states and their respective MCOs to develop strategies to prevent duplicate discounts. In some cases, states have placed certain requirements on covered entities regarding the prevention of duplicate discounts for drugs billed to MCOs.</p> <p>Covered entities report using a variety of methods to prevent duplicate discounts for MCO claims. For example, identification of MCOs by bank identification numbers (BIN) and/or processor control numbers (PCN); use of National Council for Prescription Drug Programs (NCPDP) codes for claims submitted through a pharmacy operating system; use of claim modifier codes for physician administered drugs; and submission of drug costs as part of a bundled or capitated rate.</p>
4312	07/31/2020	Medicaid	Duplicate Discounts	We do not bill Medicaid FFS at all. We do, however, use 340B for these patients; does HRSA expect us to answer "yes" to its Medicaid billing question?	In this situation, the entity should answer "no" to the Medicaid billing question, "At this site, will the covered entity bill Medicaid fee-for-service for drugs purchased at 340B prices?"
1546	07/24/2020	Medicaid		In the HRSA Medicaid Exclusion File (MEF), what does the "start date" and the "term date" mean? Also, when may a covered entity request a change to the information on the MEF, and when will that change be considered "live" on the 340B OPAIS?	<p>The date in the "start date" column is the first date that the entity began participating in the 340B Program. The date in the "term date" column is the effective date the entity is no longer participating in the 340B Program. These dates DO NOT relate to the covered entity's MEF determination as carve in or carve out for Medicaid fee-for-service. To download the MEF for a specific quarter, on the MEF homepage in the 340B OPAIS a quarterly date range must be selected and those dates reflect the effective dates of the selected MEF download. Please note that the MEF only applies to Medicaid fee-for-service.</p> <p>A change to the 340B MEF may be requested at any time, but changes do not take effect until the 1st day of the following quarter and only if approved by OPA before the time it takes a quarterly snapshot of carve-in/carve-out decisions. Covered entities should time their change in actual 340B Medicaid billing practice to coincide with the first day of the quarter that reflects the new billing status. The 340B OPAIS takes a snapshot of carve-in/out decisions at 12:01am ET on the 16th day of the month prior to the start of each quarter, irrespective of weekends or holidays. Covered entities are therefore encouraged to submit carve in/carve out decisions before HRSA takes its quarterly snapshot to provide sufficient time to process and approve the request. To access the current Medicaid Exclusion File, follow the 'Medicaid Exclusion File' link: https://340bopais.hrsa.gov/medicaidexclusionfiles</p>

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1475	07/23/2020	Medicaid	Duplicate Discounts	Our entity is using 340B drugs for Medicaid patients at multiple outpatient facilities, and these patients have Medicaid eligibility in multiple states. How must we list our NPI and/or Medicaid provider numbers on the Medicaid Exclusion File to include all states in which we will use 340B drugs to bill Medicaid?	<p>Covered entities are prohibited by section 340B(a)(5)(A) of the Public Health Service Act from billing 340B drugs to Medicaid if they are subject to a rebate claim by the state. Covered entities should address prevention of duplicate discounts, including state(s)' requirements in their policies and procedures.</p> <p>If a covered entity site (340B ID) answers "yes" to the following question in 340B OPAIS: "At this site, will the covered entity bill Medicaid fee-for-service for drugs purchased at 340B prices?" the site must also provide each Medicaid state it plans to bill and the billing number(s) it will list on the bill to the state. Billing numbers may include the billing provider's national provider identifier (NPI) only, state assigned Medicaid number only, or both NPI and state assigned Medicaid number. This information for each covered entity site (340B ID) is used to generate a quarterly Medicaid Exclusion File, which is an official data source used by stakeholders to determine which covered entity sites bill Medicaid for 340B drugs.</p>
1520	07/23/2020	Medicaid	Duplicate Discounts	A covered entity site carves in for some state Medicaid agencies and carves out for other state Medicaid agencies. How should the covered entity site reflect this on the Medicaid Exclusion File?	The covered entity site should have only the states and associated billing number(s) that it carves in listed on the Medicaid Exclusion File.
2104	07/23/2020	Medicaid	Duplicate Discounts	What do the key fields in the Medicaid Exclusion File mean?	<p>The date in the "start date" column is the first date that the entity began participating in the 340B Program. The date in the "term date" column is the effective date the entity is no longer participating in the 340B Program. These dates DO NOT relate to the covered entity's MEF determination as carve-in or carve-out. The quarterly published MEF is found on the MEF homepage in 340B OPAIS and reflects the decisions of covered entities that have chosen to "carve-in" Medicaid for a given calendar quarter and captures a snapshot of carve-in decisions on the 15th day of the month prior to the start of each quarter, irrespective of weekends or holidays. The MEF can be downloaded for use by program stakeholders. The "Medicaid State" field identifies the state that is billed with the Medicaid Number listed in the MEF. The "State" field simply lists the state jurisdiction where the covered entity is located.</p>
2205	07/23/2020	Medicaid		Does HRSA expect covered entities to enter the Medicaid numbers of all 50 states to avoid duplicate discounts, or just the bordering states?	<p>If a covered entity site does not plan to bill 340B drugs to a particular state Medicaid agency, it should not have the state listed on the HRSA Medicaid Exclusion File (MEF).</p> <p>If a covered entity site (340B ID) answers "yes" to the following question in 340B OPAIS: "At this site, will the covered entity bill Medicaid fee-for-service for drugs purchased at 340B prices?" the site must also provide each Medicaid state it plans to bill and the billing number(s) it will list on the bill to the state. Billing number(s) may include the billing provider's national provider identifier (NPI) only, state assigned Medicaid number only, or both NPI and state assigned Medicaid number. This information for each covered entity site (340B ID) in OPAIS is used to generate a quarterly Medicaid Exclusion File, which is an official data source used by stakeholders to determine which covered entity sites bill Medicaid for 340B drugs.</p>
2213	07/23/2020	Medicaid	Duplicate Discounts	What changes may be made to the Medicaid Exclusion File (MEF) from one quarter to the next?	A covered entity site can remove its 340B ID from the MEF to reflect that it will carve out all state Medicaid for the quarter. A covered entity site can add its 340B ID to the MEF to reflect that it will carve in at least one state Medicaid for the quarter. A covered entity site that carves in may add or remove state(s) it will bill 340B drugs during the quarter. A covered entity site that carves in may add or remove the billing number(s) it will use to bill a specific state for 340B drugs during the quarter.

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4308	07/23/2020	Eligibility/Registration	Covered Entity	What are HRSA's expectations for providing hospital classification documentation to support eligibility of hospitals in the 340B Program?	<p>HRSA is now requesting documentation to support the hospital classification selected at the time of registration to further verify eligibility of parent hospital registrations.</p> <p>The 340B OPAIS will prompt Authorizing Officials and Primary Contacts (AOs and PCs) to upload supporting documentation for the "Hospital Classification" selected at the time of registration of a parent hospital. These include:</p> <ul style="list-style-type: none"> •"Private, non-profit which has a contract with a unit of State or local government." •"Owned or operated by a State or local government." •"Public or private non-profit corporation, which is formally granted governmental powers by a unit of State or local government." <p>If a hospital is changing classifications during recertification, they will also be required to upload supporting documents.</p>
4309	07/23/2020	Medicaid	Duplicate Discounts	When will covered entity sites update their 340B OPAIS records to list each state being billed for 340B drugs, and the billing number(s) listed on the bill to the state?	<p>Covered entity sites will be responsible for updating their response to the modified Medicaid billing question (at this site, will the covered entity bill Medicaid fee-for-service for drugs purchased at 340B prices?) in 340B OPAIS by the end of their next annual recertification submission.</p> <p>Covered entity sites will continue to be responsible for listing the billing number(s) used to bill 340B drugs to Medicaid fee-for-service on the HRSA Medicaid Exclusion File (MEF). In addition, covered entity sites may continue to submit change requests to change their information listed on the HRSA MEF. Note that a covered entity site may request a change to its listing on the HRSA MEF at any time; however, changes only take effect the following quarter, and only if OPA receives, approves, and processes the change request before the 16th day of the month prior to the start of the quarter.</p>
4310	07/23/2020	Medicaid	Duplicate Discounts	If our covered entity site only bills 340B drugs to Medicaid Managed Care Organizations, how should we answer the Medicaid billing question in 340B OPAIS that is used to populate the Medicaid Exclusion File?	<p>The covered entity site should answer "no" to the Medicaid billing question in 340B OPAIS. The data included in the Medicaid Exclusion File (MEF) applies to drugs billed under Medicaid fee-for-service (FFS).</p> <p>Duplicate discounts are prohibited for Medicaid FFS and MCO drugs pursuant to section 340B(a)(5)(A) of the Public Health Service Act. HRSA recognizes the need to address covered entities' role in preventing duplicate discounts when 340B drugs are billed to MCOs. Absent policy on MCOs, HRSA encourages covered entities to work with states and their respective MCOs to develop strategies to prevent duplicate discounts. In some cases, states have placed certain requirements on covered entities regarding the prevention of duplicate discounts for drugs billed to MCOs.</p>
1369	07/22/2020	Medicaid	Duplicate Discounts	Must a covered entity submit its Medicaid provider number (MPN) or National Provider Identifier (NPI) to HRSA for inclusion on the HRSA Medicaid Exclusion File (MEF)?	<p>A covered entity site must first choose whether it will bill Medicaid for 340B drugs for its Medicaid fee-for-service patients.</p> <p>If a covered entity site (340B ID) answers "yes" to the following question in 340B OPAIS: "At this site, will the covered entity bill Medicaid fee-for-service for drugs purchased at 340B prices?" the site must also provide each Medicaid state it plans to bill and the billing number(s) it will list on the bill to the state. Billing number(s) may include the billing provider's national provider identifier (NPI) only, state assigned Medicaid number only, or both NPI and state assigned Medicaid number. This information listed for each covered entity site (340B ID) is used to generate a quarterly Medicaid Exclusion File, which is an official data source used by stakeholders to determine which covered entity sites bill Medicaid for 340B drugs.</p> <p>If a covered entity site will not bill 340B drugs for any Medicaid fee-for-service patients, the covered entity site must answer "no" to the Medicaid billing question (At this site, will the covered entity bill Medicaid fee-for-service for drugs purchased at 340B prices?) In addition, the covered entity site is not required to submit any Medicaid billing number(s) to HRSA, and the covered entity site's 340B ID will not be listed on the MEF.</p> <p>Each covered entity site should notify HRSA prior to any change in Medicaid billing status. In addition, the method(s) used to prevent duplicate discounts, including any state Medicaid requirements should be documented in a covered entity's policies and procedures.</p>

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1374	07/22/2020	Medicaid		May covered entities list the Medicaid provider numbers of healthcare professionals on the HRSA Medicaid Exclusion File (MEF) if that is the only billing identifier submitted on the claim?	<p>A covered entity site may list a health care professional's Medicaid provider number on the Medicaid Exclusion File (MEF) if the health care professional's Medicaid provider number is listed as the billing provider on the Medicaid billing form (for example, box 56 or box 57 on a CMS 1450 (UB-04) claim form).</p> <p>The MEF contains all covered entity sites that will bill Medicaid FFS for drugs purchased at 340B prices, and the state(s) and associated billing numbers listed on the claims to bill Medicaid FFS for 340B drugs. This may include the billing provider's national provider identifier (NPI) only, state assigned Medicaid number only, or both NPI and state assigned Medicaid number.</p> <p>Covered entities should refer to state Medicaid agencies as to whether a particular Medicaid billing identifier is appropriate under the particular circumstance.</p> <p>In addition, if a covered entity site (340B ID) answers "yes" to the following question in 340B OPAIS: "At this site, will the covered entity bill Medicaid fee-for-service for drugs purchased at 340B prices?" the site must also provide, each Medicaid state it plans to bill, and the billing number(s) it will list on the bill to the state. Billing number(s) may include the billing provider's national provider identifier (NPI) only, state assigned Medicaid number only, or both NPI and state assigned Medicaid number. This information listed for each covered entity site (340B ID) in OPAIS is used to generate a quarterly Medicaid Exclusion File, which is an official data source used by stakeholders to determine which covered entity sites bill Medicaid for 340B drugs.</p>
1382	07/22/2020	Medicaid	Duplicate Discounts	Where can I download a list of all 340B covered entity sites that carve in Medicaid fee-for-service (FFS)?	<p>The list of all covered entity sites that carve in Medicaid FFS is called the Medicaid Exclusion File (MEF) and is published by HRSA each calendar quarter. The MEF can be downloaded at https://340bopais.hrsa.gov/reports.</p> <p>In response to the COVID-19 pandemic, HRSA allows some entities, upon request and review, to immediately enroll into the 340B Program. HRSA posts a supplemental MEF every Friday, which began on April 10, 2020, that includes a list of entities who have elected to carve in as a result of obtaining immediate enrollment. This list is posted on the HRSA website at https://www.hrsa.gov/opa/index.html.</p>
1388	07/22/2020	Medicaid	Duplicate Discounts	Can a covered entity that participates in the Prime Vendor Program and carves out Medicaid use any drug loaded to the 340B account for Medicaid patients?	<p>Prime Vendor sub-ceiling pricing on covered outpatient drugs in the 340B account must be excluded from use for covered entities that carve out Medicaid. The 340B Prime Vendor Program's sub-ceiling PHS account prices are considered 340B drugs and all the same requirements apply. Other PVP contract pricing loaded to the non-GPO/WAC account for hospitals subject to the GPO prohibition (PVP sub-WAC, Apexus Generics Program, etc.) may be used in a Medicaid carve-out situation.</p>
1495	07/22/2020	Medicaid	Duplicate Discounts	If a hospital intends to have some clinics carve in (use 340B drugs for Medicaid patients) and other clinics carve out, should each clinic get its own NPI and/or Medicaid provider number?	<p>If a covered entity site (340B ID) answers "yes" to the following question in 340B OPAIS: "At this site, will the covered entity bill Medicaid fee-for-service for drugs purchased at 340B prices?" the site must also submit each Medicaid state it plans to bill and the billing number(s) it will list on the bill to the state. Billing number(s) may include the billing provider's national provider identifier (NPI) only, state assigned Medicaid number only, or both NPI and state assigned Medicaid number. This information for each covered entity site (340B ID) will be used to generate a quarterly Medicaid Exclusion File, which is an official data source used by stakeholders to determine which covered entity sites bill Medicaid for 340B drugs.</p> <p>The information on the MEF should appropriately reflect the actual practice of each covered entity site (340B ID). In addition, the covered entity should document in its policies and procedures, the method(s) it uses to prevent duplicate discounts at each site, including any state Medicaid requirements.</p> <p>If a covered entity plans to bill Medicaid with the same billing number(s) for certain sites (340B IDs) that carve in and other sites (340B IDs) that carve out, the covered entity should contact the state Medicaid agency to determine how Medicaid will distinguish between 340B and non-340B claims.</p>

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1507	07/22/2020	Medicaid	Duplicate Discounts	How does a covered entity change its status on the Medicaid Exclusion File?	<p>A covered entity site that wishes to change its status on the Medicaid Exclusion File (MEF) must submit a change request in 340B OPAIS (available at: https://340bopais.hrsa.gov/). Note that a change request must be submitted for each applicable 340B ID (parent site and each child site or grant-associated site).</p> <p>A change to the MEF may be requested at any time, however changes only take effect the following quarter and only if the change request is received, approved and processed by the HRSA before the time of the OPAIS snapshot (12:01 am on the 16th day of the month prior to the start of the quarter). Covered entity sites should time any changes in actual 340B Medicaid billing practices to coincide with the first day of the next quarterly Medicaid Exclusion File.</p>
1533	07/22/2020	Medicaid	Duplicate Discounts	How does a covered entity carve out Medicaid?	<p>To carve out Medicaid, a covered entity site does not provide drugs purchased at the 340B price to Medicaid patients.</p> <p>In 340B OPAIS, a covered entity site that plans to carve out Medicaid fee-for-service should answer "no" to the question, "at this site, will the covered entity bill Medicaid fee-for-service for drugs purchased at 340B prices?" Covered entity sites that answer "no" in 340B OPAIS (prior to the 16th day of the month prior to the start of the quarter) will not be listed on HRSA's next quarterly Medicaid Exclusion File (MEF).</p> <p>Covered entity sites should time any changes in actual 340B Medicaid billing practices to coincide with the first day of the next quarterly MEF.</p>
1537	07/22/2020	Medicaid	Duplicate Discounts	Which Medicaid provider number and/or National Provider Identifier (NPI) should a covered entity submit to HRSA Office of Pharmacy Affairs for inclusion on the HRSA Medicaid Exclusion File (MEF)?	<p>If a covered entity site (340B ID) answers "yes" to the following question in 340B OPAIS: "At this site, will the covered entity bill Medicaid fee-for-service for drugs purchased at 340B prices?" the site must also provide each Medicaid state it plans to bill and the billing number(s) it will list on the bill to the state. Billing number(s) may include the billing provider's national provider identifier (NPI) only, state assigned Medicaid number only, or both NPI and state assigned Medicaid number. This information listed for each covered entity site (340B ID) in OPAIS is used to generate a quarterly Medicaid Exclusion File, which is an official data source used by stakeholders to determine which covered entity sites bill Medicaid for 340B drugs.</p> <p>For more information, contact the 340B Prime Vendor at 1-888-340-2787 or via email at ApexusAnswers@340BPVP.com.</p>
2187	07/22/2020	Medicaid	Duplicate Discounts	We bill at an all-inclusive rate for Medicaid, no NDC is transmitted to Medicaid, and therefore no duplicate discount will occur. We do use 340B for these patients; does HRSA expect us to answer YES to its Medicaid question?	<p>Covered entities that bill Medicaid fee-for-service for drugs purchased at 340B prices must answer "yes" to the Medicaid billing question, regardless of the rate at which they are reimbursed under Medicaid.</p>
4301	06/04/2020			Are hospital covered entities able to register offsite, outpatient facilities before being listed as reimbursable on their Medicare Cost Report?	<p>In order to register for the 340B Program and be listed on the 340B Office of Pharmacy Affairs Information System (340B OPAIS), HRSA must first verify that the offsite, outpatient facility is listed as reimbursable on the hospital's most recently filed Medicare cost report and has associated outpatient costs and charges as outlined in HRSA's 1994 Outpatient Hospital Facilities Guidelines (see: https://www.hrsa.gov/sites/default/files/opa/programrequirements/federalregisternotices/outpatienthospitalfacilities091994.pdf).</p> <p>HRSA notes that for hospitals who are unable to register their outpatient facilities because they are not yet on the most recently filed Medicare Cost Report, the patients of the new site may still be 340B eligible to the extent that they are patients of the covered entity. More information on HRSA's patient definition guidance can be found at https://www.hrsa.gov/sites/default/files/opa/programrequirements/federalregisternotices/patientandentityeligibility102496.pdf.</p> <p>These situations should be clearly documented in the covered entity's policies and procedures. In addition, a covered entity is responsible for demonstrating compliance with all 340B Program requirements and ensure that auditable records are maintained for each patient dispensed a 340B drug.</p>
1193	06/02/2020	Eligibility/Registration	Outpatient Facility	May an outpatient facility that is reimbursed by CMS as a provider based facility, but not included on the most recently filed Medicare cost report, participate in the 340B Program?	<p>A facility must be both reimbursable and included in the hospital's most recently filed Medicare cost report with associated outpatient costs and charges to access the 340B Program and register in 340B OPAIS. HRSA's outpatient facility guidelines can be found at https://www.hrsa.gov/sites/default/files/opa/programrequirements/federalregisternotices/outpatienthospitalfacilities091994.pdf (59 Fed. Reg. 47884 (Sept. 19, 1994)).</p>

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1184	05/29/2020	Eligibility/Registration	Pharmacy	How must we register our in-house pharmacy that is a separate legal entity under our 340B covered entity?	An in-house pharmacy is not eligible to register as a child site. The in-house pharmacy could be listed as a shipping address. If the covered entity has a contract with the in-house pharmacy because it is a separate legal entity, then it must be registered as a contract pharmacy and may not dispense any 340B drugs until a written contract is in place and the pharmacy is listed as a contract pharmacy for the covered entity on 340B OPAIS.
1190	05/29/2020	Eligibility/Registration	Outpatient Facility	Do clinics/departments/services located within the four walls of a registered 340B hospital have to be registered in 340B OPAIS?	Outpatient clinics/departments/services within the four walls (i.e. same physical address) of the registered parent 340B hospital do not need to separately register/enroll into the 340B Program. However, the covered entity remains responsible for demonstrating that those outpatient clinics/departments/services are listed as reimbursable on the hospital's most recently filed Medicare cost report, are only using 340B drugs for eligible outpatients, meet all 340B Program requirements, and maintain auditable records. Clinics/departments/services at an offsite location from the registered parent must separately register on 340B OPAIS, even if they are located within the four walls of that child site. This applies to hospitals that are registered as child sites - every eligible clinic which will purchase or use 340B drugs within such a hospital must register separately as a child site.
1213	05/29/2020	Eligibility/Registration	Outpatient Facility	As a grantee, if I need to add a new site to our existing 340B entity, what actions should I take?	Entities should register all sites with the 340B Program prior to participating in the 340B Program. The Office of Pharmacy Affairs will verify eligibility by conferring with the appropriate granting agency.
1240	05/29/2020	Eligibility/Registration	Outpatient Facility	If a covered entity has physician clinics, do they need to be registered as child sites?	Only hospital outpatient facilities that appear as reimbursable outpatient cost centers on the hospital's most recently filed Medicare cost report are eligible to be listed and participate in the 340B Program. HRSA requires each hospital to register all of its offsite outpatient facilities where 340B drugs are purchased and/or provided to patients of that facility. This will ensure that each facility has been reviewed and verified by HRSA as eligible to participate in the program, therefore strengthening the hospital's compliance efforts.
1241	05/29/2020	Eligibility/Registration		Can wholesalers / manufacturers refuse to ship to addresses listed in 340B OPAIS?	340B OPAIS is the official source for 340B covered entity information. Billing and shipping addresses listed in 340B OPAIS provide manufacturers and wholesalers positive assurance that the purchasing/receiving site is eligible to obtain 340B drugs. Covered entities are responsible for ensuring that the billing and shipping address information in 340B OPAIS is up to date, and OPA verifies each shipping address listed in the database.
1295	05/29/2020	Eligibility/Registration	Outpatient Facility	How should a hospital covered entity determine if an offsite outpatient facility is eligible for the 340B Program as a child site and should be registered on 340B OPAIS?	<p>An offsite hospital outpatient facility is eligible to be registered as a child site if it is listed as a reimbursable facility on the parent hospital's most recently filed Medicare cost report and has associated outpatient costs and charges. If the facility is a free-standing clinic of the hospital that submits its own cost reports using a different Medicare provider number (not under the covered entity's Medicare provider number) then it would NOT be eligible. Specific guidance was released in the 1994 in the following link: http://www.hrsa.gov/opa/programrequirements/federalregisternotices/outpatienthospitalfacilities091994.pdf. HRSA's utilizes information from the hospital's most recently filed cost report, including information from Worksheet A and Worksheet C and the associated trial balance to determine eligibility. For more information on hospital offsite outpatient facility registration requirements, visit https://www.hrsa.gov/sites/default/files/hrsa/opa/hospital-registration-instruction-details.pdf.</p> <p>All clinics located offsite of the parent hospital, regardless of whether those clinics are in the same offsite building must register as child sites of the parent hospital if they choose to participate in the 340B Program. These clinics must be a reimbursable clinic of the hospital and have associated outpatient costs and charges in order to be able to register as child sites in 340B OPAIS.</p>
1303	05/29/2020	Eligibility/Registration	Pharmacy	Can a covered entity list an in-house pharmacy as a child site?	Pharmacies are not eligible 340B covered entities and therefore should not be listed as child sites within 340B OPAIS. Covered entities should determine whether it is appropriate for the pharmacy to be added as a shipping address for the covered entity in 340B OPAIS.
1319	05/29/2020	Eligibility/Registration	Outpatient Facility	Our hospital has a clinic (within the four walls of the parent) that does not appear on the hospital's most recently filed Medicare cost report. Is this an eligible 340B area?	Only hospital outpatient facilities that appear as reimbursable outpatient cost centers on the hospital's most recently filed Medicare cost report are eligible to be listed and participate in the 340B Program. For additional information, please review: http://www.hrsa.gov/opa/programrequirements/federalregisternotices/outpatienthospitalfacilities091994.pdf

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1364	05/28/2020	Eligibility/Registration	Pharmacy	When does a pharmacy qualify as in-house pharmacy?	An entity-owned pharmacy is owned by, and is a legal part of, the 340B entity. Typically, entity-owned pharmacies are listed as shipping addresses of the entity.
1373	05/28/2020	Eligibility/Registration		What actions does HRSA expect an entity to take if it loses 340B Program eligibility?	<p>Covered entities should stop purchasing 340B drugs immediately upon losing eligibility. The entity must complete a termination request on 340B OPAIS and answer the following three questions:</p> <ol style="list-style-type: none"> 1) The date the entity became ineligible; 2) The circumstances surrounding the loss of eligibility; 3) The last date 340B drugs were purchased. <p>Covered entities should work with the manufacturer to determine the most appropriate method for handling. There may be several options for handling the drug inventory once eligibility is lost. These options will depend upon the specific circumstances but may include transferring the inventory to an associated covered entity site/pharmacy that is still 340B registered, credit/rebill, return, or destruction according to state law. Covered entities should keep auditable records and ensure the process is transparent to manufacturers and wholesalers.</p>
1431	05/27/2020	Eligibility/Registration	Pharmacy	Can the 340B OPAIS registration accommodate simultaneous online covered entity and contract pharmacy registrations?	Yes. For further guidance on how to register, the logged-in user can refer to the user guide located in the "Help" section of 340B OPAIS.
1577	05/27/2020	Eligibility/Registration	Pharmacy	Is a covered entity required to list a pharmacy that is part of the covered entity (i.e. entity-owned pharmacy) on 340B OPAIS?	If a covered entity wants to ship 340B drugs directly to an entity-owned pharmacy, the pharmacy address would need to be listed on 340B OPAIS. This is commonly achieved by listing the pharmacy address as a shipping address of the entity. However, if the pharmacy address matches the address of the parent/main site or a registered offsite facility (i.e. child site, associated site) in 340B OPAIS, a separate shipping address listing is not required. Entity-owned pharmacies cannot be registered as a covered entity parent/main site or offsite facility.
1637	05/27/2020	Eligibility/Registration	Pharmacy	When does a pharmacy qualify as a contract pharmacy?	340B covered entities may contract with a pharmacy to provide services to the covered entity's patients, including the service of dispensing entity-owned 340B drugs. To engage in a contract pharmacy arrangement, the entity and pharmacy must have a written agreement in place and register each contract pharmacy location on 340B OPAIS during an open registration period. Typically, a bill-to (entity)/ship-to (pharmacy) arrangement is used.
1652	05/27/2020	Eligibility/Registration	Pharmacy	If a facility has contract pharmacies serving multiple child sites, does that pharmacy need to be registered on each individual child site's 340B OPAIS profile or is it sufficient to list under the parent site's profile only?	It will depend on the language in the contractual agreement between the pharmacy and the covered entity. If the agreement states that the contracted relationship applies to all entities of a specific organization and the parent site has been designated the billing entity for all of the child sites, it is permissible for the contract pharmacy to be registered under the parent site only, thus not requiring child sites to register the contract pharmacy locations individually.
1687	05/27/2020	Eligibility/Registration	Outpatient Facility	Must an entity remove a child site as soon as it knows it will not be on the next filed cost report, or should an entity remove a child site upon the date that the next cost report will be filed?	<p>HRSA guidance states that an outpatient facility is eligible for the 340B Program if it is a reimbursable facility on the hospital's most recently filed Medicare cost report. If the child site will no longer be a reimbursable facility with associated outpatient costs and charges on the next filed Medicare cost report, it can no longer be listed as a registered entity and therefore, a covered entity should submit a change request in 340B OPAIS to remove the outpatient facility the day the hospital files its next Medicare cost report.</p> <p>The outpatient facility guidance can be found here: https://www.hrsa.gov/sites/default/files/opa/programrequirements/federalregisternotices/outpatienthospitalfacilities091994.pdf.</p>

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2474	05/27/2020	Eligibility/Registration	Outpatient Facility	How does a hospital covered entity register multiple service locations in place of a currently registered clinic?	<p>There are two steps a hospital must take in order to register multiple services located within the same clinic. First, the hospital must register the individual services/clinics during an open registration period. Second, they must terminate the active/current registration. Terminating the active registration can be done in one of two ways:</p> <p>(1) During recertification, or (2) At a date prior to the start date for the new registered service/clinics. Most importantly, hospitals must coordinate the start date of the new registrations with the ineligible date of the terminating registration. For example, if the new registrations begin on October 1, 2019, the 'Termination Date' record for the terminating clinic should look like this:</p> <p>-Termination date: 10/1/2019 -The date the entity became ineligible: 10/1/2019</p> <p>-Last date 340B drugs were or will be purchased under the 340B ID: (must be prior to 10/1/2019)</p> <p>Participants are encouraged to work with their wholesalers to follow best practices for facilitating marketplace/business solutions, which in some cases may involve registering pharmacies as ship-to addresses.</p>
1181	04/29/2020	Eligibility/Registration	Covered Entity	If a 340B covered entity hospital falls under common legal control of an umbrella organization, are all of the other hospitals falling under that same umbrella eligible for the 340B Program?	<p>No. Common legal control of a covered entity does not extend 340B Program eligibility to all units of the umbrella organization. In other words, eligibility of part of an organization or system does not transfer eligibility to the whole. Entities are responsible for ensuring that only eligible facilities or units of their organization participate in the 340B Program and are encouraged to seek legal counsel to review their particular circumstance. In the case of 340B hospitals, the outpatient facility must be an integral part of the hospital and listed on the most recently filed Medicare cost report of the eligible 340B hospital.</p>
1182	04/29/2020	Eligibility/Registration	Covered Entity	Can a community health center (CHC) participate in the 340B Program only for the purpose of purchasing clinic-administered drugs?	<p>Yes, a CHC can participate in the 340B Program to purchase its clinic-administered medications without operating an in-house retail pharmacy or contract pharmacy arrangement.</p>
1215	04/29/2020	Eligibility/Registration	Covered Entity	How does a children's hospital qualify for the 340B Program?	<p>340B Program requirements for children's hospitals are available at http://www.hrsa.gov/opa/eligibilityandregistration/hospitals/childrenshospitals/index.html. For information regarding registration, please visit the HRSA OPA website at: https://www.hrsa.gov/opa/registration/index.html.</p>
1232	04/29/2020	Eligibility/Registration	Covered Entity	If an entity learns it may no longer be 340B eligible, must it notify HRSA?	<p>Yes, it is the covered entity's responsibility to notify the HRSA Office of Pharmacy Affairs immediately if the entity learns it may no longer be 340B eligible.</p>
1258	04/29/2020	Eligibility/Registration	Covered Entity	Can a hospital that is eligible as more than one statutorily-defined hospital type be registered as two different hospital types in 340B OPAIS?	<p>No, a hospital that may qualify as more than one hospital type must select one hospital type for registration in the 340B Program. The hospital must follow and maintain auditable records and have policies and procedures demonstrating compliance for all 340B Program requirements for the hospital type for which it is registered in 340B OPAIS.</p>
1260	04/29/2020	Eligibility/Registration	Covered Entity	Which field in 340B OPAIS should manufacturers use when determining when to stop selling 340B priced products to covered entities (when the entities are terminated from the 340B program)?	<p>Manufacturers should use the termination date field on HRSA's 340B OPAIS to determine when to stop selling 340B drugs to covered entities, unless otherwise noted by HRSA. HRSA provides push notifications to manufacturers on a quarterly basis that include information regarding covered entities that have informed HRSA they made purchases under the 340B Program when they were no longer eligible to do so. The HRSA Office of Pharmacy Affairs expects covered entities to stop purchasing immediately upon loss of eligibility.</p>
1330	04/29/2020	Eligibility/Registration	Covered Entity	Will HRSA accept data from a cost reporting period that is less than 12 months?	<p>HRSA accepts data from the most recently completed, full cost reporting period that has been accepted by CMS. While the cost reporting period is usually 12 months, under certain limited circumstances CMS permits a full cost reporting period to be less than 12 months. HRSA will accept documentation from the Hospital's Fiscal Intermediary/Medicare Administrative Contractor demonstrating approval of the shortened cost reporting period.</p>

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1346	04/29/2020	Eligibility/Registration	Covered Entity	How should a covered entity obtain information regarding 340B registration and inventory issues if the covered entity is changing ownership?	Due to the variety of factors to address as part of a change in ownership, contact the Apexus Answers call center for technical assistance.
1354	04/29/2020	Eligibility/Registration	Covered Entity	If a hospital's disproportionate share adjustment percentage falls below the requirement for 340B Program eligibility, when must the hospital stop placing 340B orders/using 340B drugs?	A 340B hospital with a required disproportionate share adjustment percentage is no longer eligible to participate in the 340B Program on the date it files its most recent Medicare cost report with a disproportionate share adjustment percentage below the 340B Program eligibility requirement. The covered entity is responsible for terminating its participation in the 340B Program and must cease purchasing and using 340B drugs on the filing date.
2436	04/28/2020	Eligibility/Registration	Covered Entity	What are HRSA's expectations regarding hospital eligibility and a contract with State or local government?	A hospital that is private, non-profit with a contract with a state or local government to provide health care services to low income individuals who are not entitled to benefits under Medicare or eligible for State Medicaid is eligible for the 340B Program. The hospital must be able to demonstrate through official documentation that it is private non-profit (e.g. hospital's charter, Articles of Incorporation, Bylaws, other documents from the State that may certify the hospital is non-profit, an official IRS-990 form or other official IRS documentation). A written contract must exist between the hospital and state or local government to demonstrate the hospital's eligibility for the 340B Program. The contract should include names of the hospital and government agency, have signatures of hospital and government agency representatives, and include dates clearly indicating effective dates of the contract. HRSA will request a copy of the contract and documentation demonstrating non-profit status at registration. For more information on documentation requirements for hospital eligibility, visit https://www.hrsa.gov/sites/default/files/hrsa/opa/hospital-registration-instruction-details.pdf .
2693	04/17/2020	Policy/Implementation	Patient Definition	Can a covered entity use 340B for discharge prescriptions from a child site hospital that does not have outpatient clinics to register?	Discharge prescriptions may be allowable to the extent they are for outpatient use and originated from an inpatient unit of a 340B covered entity participating in the 340B Program. Covered entities are responsible to maintain auditable records.
1420	03/26/2020	340B Price/Drug	Manufacturer	May a manufacturer require only 340B entities to purchase covered outpatient drugs through specialty distribution channels?	Consistent with section 340B(a)(1) of the PHSA, manufacturers are expected to provide the same opportunity for 340B covered entities and non-340B purchasers to purchase covered outpatient drugs when such drugs are sold through limited distributors or specialty pharmacies. This extends to the manner in which 340B drugs are made available to covered entities (e.g., direct sales versus through wholesalers, specialty pharmacies, or limited distributors.) Additional information can be found in the following Policy Release (Clarification of Non-Discrimination Policy. Release No. 2011-1.1 (May 23, 2012)). Manufacturers should notify HRSA of its intent to implement a specialty distribution channel to ensure compliance and ensure that entities are aware of the distribution channel for transparency and to limit any disputes.
2447	03/26/2020	340B Database Technical Assistance	Navigation/Use	Will covered entities be able to register their contract pharmacies at the time of covered entity registration in 340B OPAIS?	In 340B OPAIS, contract pharmacy registrations can be submitted concurrently with the associated Covered Entity registration by either the AO or the PC. Only the AO is able to approve and submit the contract pharmacy registration.
2448	03/26/2020	340B Database Technical Assistance	Navigation/Use	What is the current process for recertification in 340B OPAIS?	For recertification in 340B OPAIS, the AO is notified of dates, times, and requirements of recertification via their listed email in 340B OPAIS. The AO has access via their 340B OPAIS user account-landing page where the AO has access to all 340B records their linked to and those that require annual recertification. At the start of covered entity recertification, a task is created in the PC's task list for each 340B record that must be recertified. The same task is created in the AO's task list. Either the PC or the AO can complete recertification for a covered entity record, but only the AO can attest and submit it to OPA. If the PC completes recertification for a covered entity record, that creates a task in the AO's task list. The AO can make changes if necessary before attesting and submitting to OPA.

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2449	03/25/2020	340B Database Technical Assistance	Navigation/Use	How many AOs and PCs can a covered entity or manufacturer have in 340B OPAIS?	Authorized covered entities and manufacturers are only granted one AO and one PC per 340B record. A 340B record is defined as an individual manufacturer labeler code or covered entity 340B ID. For covered entity hospitals and their outpatient facilities, as well as community health centers and their associated grant sites, each record has one AO and one PC per record. There is a requirement for hospital covered entity types that the AO be the same for all child sites, but the PC may be a separate person for each record. For example, hospital A with three outpatient facilities has the same AO for all records, but may select a separate PC for each record. While each record has only one AO and PC, the PC is not required to be the same person on each record. Manufacturers with multiple labeler codes may select different AOs and PCs for each labeler code.
2686	03/25/2020	340B Price/Drug	340B Price	What is the difference between the ceiling price and the package adjusted price?	<p>The 340B ceiling price is defined in statute (section 340B(a)(1) of the Public Health Service Act) and implementing regulations (42 CFR §10.3 and §10.10(a)). The 340B ceiling price is the maximum statutory price a manufacturer can charge a covered entity for the purchase of a covered outpatient drug and is equal to the average manufacturer price (AMP) from the preceding calendar quarter for the smallest unit of measure minus the unit rebate amount (URA). HRSA calculates the 340B ceiling price at six decimal places and then subsequently publishes the 340B ceiling price in the 340B OPAIS rounded to two decimal places.</p> <p>HRSA also publishes a package adjusted price for each covered outpatient drug in the 340B OPAIS. HRSA publishes the package adjusted price as a courtesy to assist manufacturers and covered entities in evaluating the 340B ceiling price. The package adjusted price is calculated using the 340B ceiling price, the package size (PS), and the case pack size (CSP) for a covered outpatient drug, and represents the price that the covered entity actually pays for the drug.</p> <p>Package Adjusted Price = (AMP – URA) * PS * CSP</p> <p>The PS is the quantity of a unit of measure contained in one package sold by a manufacturer under a particular 11 digit NDC. The CSP is the number of salable units in the shipping container. HRSA publishes the package adjusted price in 340B OPAIS rounded to two decimal places.</p> <p>The exception to this rounding convention occurs when the 340B ceiling price is less than \$0.01. In these cases, the 340B ceiling price rounded to two decimal places will be multiplied by the package size and case pack size to equal the package adjusted price. This is consistent with the Final Rule.</p>
4291	03/25/2020	Policy/Implementation	GPO Prohibition	Can Community Health Centers participate in the Prime Vendor Program (PVP) and a group purchasing organization (GPO)?	Yes. All covered entities may participate in the PVP, although disproportionate share hospitals, children's hospitals, and freestanding cancer centers that participate in the 340B Program are prohibited from purchasing covered outpatient drugs through a GPO. 340B Prime Vendor participation is voluntary, and there are no restrictions placed on covered entities electing to participate. Most alternative purchasing groups serving 330 grantees and other entities encourage participation in the 340B PVP to ensure members have access to best pricing on pharmaceuticals while offering members their own contract portfolios of medical/surgical, dental, office, and other non-pharmacy supplies, which tend to be complementary to the 340B PVP pharmacy portfolio. On occasion, there may be an alternative purchasing group that does not permit a member to simultaneously access their own contracts and 340B PVP contracts due to existing business relationships with a supply partner. In this situation, the covered entity may be required to notify the alternative purchasing group to cancel its membership before the selected pharmacy wholesaler will load the 340B PVP pricing available to the entity's pharmacy account.
4292	03/25/2020	Recertification	Covered Entity	How should a covered entity prepare for recertification?	The Authorizing Official (AO) and Primary Contact (PC) should review the covered entity's 340B OPAIS record to ensure the record is accurate and correct. Any inaccurate information should be corrected in advance of recertification by submitting an on-line change request.
4293	03/25/2020	Medicaid		Does HRSA retroactively make changes to the Medicaid Exclusion File (MEF)?	HRSA generally does not make retroactive changes to the quarterly MEF once it is published. On rare occasion, a technical system issue may warrant an immediate modification. If retroactive changes are necessary, HRSA will communicate this to the 340B Program stakeholders.
1437	03/24/2020	Contract Pharmacy		May 340B drugs be used for Medicaid fee-for-service (FFS) patients as part of a 340B contract pharmacy?	340B drugs may not be used for Medicaid FFS patients at a contract pharmacy, absent an arrangement between the contract pharmacy, covered entity, and state Medicaid agency to prevent duplicate discounts. Any such arrangement shall be reported to the HRSA Office of Pharmacy Affairs by the covered entity. Once HRSA reviews and approves the arrangement, HRSA posts contract pharmacies that use 340B drugs for Medicaid FFS patients on the 340B OPAIS. For additional information, see https://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf

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1651	03/24/2020	340B PVP	Membership	What is the 340B Prime Vendor Program?	Section 340B(a)(8) of the Public Health Service Act requires the establishment of a prime vendor program (PVP). The purpose of the PVP is to develop, maintain and coordinate a program capable of distribution, facilitation and other activities in support of the 340B Program. The PVP is a voluntary program for 340B covered entities and serves its participants in three primary roles: 1.Negotiating sub-340B pricing on pharmaceuticals; 2.Establishing distribution solutions and networks that improve access to affordable medications; and 3.Providing other value-added products and services. All covered entities may participate in the PVP including hospitals that are prohibited from purchasing in a group purchasing arrangement.
1177	01/24/2020	Policy/Implementation	GPO Prohibition	A DSH with an in-house pharmacy would like to serve 340B and non-340B eligible patients. May we use a GPO to purchase drugs for our non-340B eligible patients that receive services at sites registered on the 340B OPAIS?	No.
1210	01/24/2020	Policy/Implementation	GPO Prohibition	Our hospital isn't subject to the GPO prohibition. Does the GPO Policy Release impact our hospital?	The GPO prohibition applies to all disproportionate share hospitals, children's hospitals, and freestanding cancer hospitals enrolled in the 340B Program. The GPO Policy Release does not apply to entities registered as any other type of covered entity.
1217	01/24/2020	Eligibility/Registration	Covered Entity	What is a "Pickle" hospital, and is it true that the "greater than 11.75% disproportionate share adjustment percentage" requirement is waived for them?	The 11.75% requirement is waived for a few hospitals known as "Pickle" hospitals (named for a JJ Pickle, a former member of Congress). They are defined in the Section 1886(d)(5)(F)(i)(II) of the Social Security Act as "a hospital that serves a significantly disproportionate number of low income patients and 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 this title or State plans approved under title XIX) during the cost reporting period in which the discharges occur, for indigent care from state and local government sources exceed 30 percent of its total of such net inpatient care revenues during the period."
1229	01/24/2020	340B Price/Drug	340B Price	What is HRSA's "penny-pricing" policy regarding 340B ceiling prices?	When the 340B ceiling price calculation results in an amount less than \$0.01, the 340B ceiling price will be \$0.01. For more information, please visit the 340B Ceiling Price and Civil Monetary Penalties final rule (82 FR 1210, January 5, 2017) at: https://www.gpo.gov/fdsys/pkg/FR-2017-01-05/pdf/2016-31935.pdf .
1259	01/24/2020	Policy/Implementation	GPO Prohibition	If a disproportionate share hospital, children's hospital, or freestanding cancer hospital registers to participate in the 340B Program, when does their participation become effective and the GPO prohibition apply?	The hospital's authorizing official upon enrollment, attests that the hospital "...will not participate in a group purchasing organization or group purchasing arrangement for covered outpatient drugs as of the date of this listing on the OPA website."
1265	01/24/2020	340B Price/Drug	340B Price	Which manufacturers and drugs are subject to 340B pricing, and can participating manufacturers offer only a subset of the drugs they manufacturer at 340B prices?	Manufacturers who participate in Medicaid are required to participate in the 340B Program and provide a 340B ceiling price for all covered outpatients drugs. To view which manufacturers participate in the 340B Program, please visit: https://340bopais.hrsa.gov/searchlanding . A 340B participating manufacturer must provide a 340B price on all the covered outpatient drugs that meet the definition in section 1927(k) of the Social Security Act.
1276	01/24/2020	Policy/Implementation	GPO Prohibition	A hospital system owns and controls many hospitals, some of which are 340B participating hospitals. The 340B participating hospitals each have their own 340B Program identification number. The hospital system would like to negotiate prices for drugs used at their hospitals, including those that participate in the 340B Program. Does the above scenario violate the 340B GPO prohibition? That is, does it constitute a group purchasing arrangement?	The 340B participating hospitals within the hospital system in this scenario have separate 340B registrations. For the hospitals registered for the 340B Program as a DSH, children's hospital or freestanding cancer hospital, conducting price negotiations for covered outpatient drugs with any other hospital would create a prohibited group purchasing arrangement. The hospital system may negotiate prices for inpatient drugs only.

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1285	01/24/2020	Eligibility/Registration	Outpatient Facility	Which health care delivery sites must our 340B covered entity (a non-hospital) register on 340B OPAIS?	All sites that purchase and use 340B drugs for their eligible patients must be listed on 340B OPAIS. In order for non-hospital health care delivery sites to purchase 340B drugs or provide 340B drugs to their patients, they must first be authorized through the (non-hospital) covered entity's grant and listed on 340B OPAIS.
1288	01/24/2020	Policy/Implementation	GPO Prohibition	Can a hospital subject to the GPO prohibition use a GPO to purchase drugs that do not meet the definition of covered outpatient drug (as defined by section 1927(k) of the Social Security Act)?	Yes. Covered entities should maintain auditable records and policies and procedures related to the definition of covered outpatient drug and the use of a GPO that is consistent with the 340B statute.
1310	01/24/2020	340B Price/Drug	340B Price	How is the 340B ceiling price calculated?	Pursuant to section 340B(a)(1) of the Public Health Service Act and the 340B Ceiling Price and Civil Monetary Penalty final rule (82 FR 1210, January 5, 2017), the 340B ceiling price for a covered outpatient drug is equal to the Average Manufacturer Price (AMP) from the preceding calendar quarter for the smallest unit of measure minus the Unit Rebate Amount (URA). The 340B ceiling price is calculated using six decimal places and HRSA publishes the price rounded to two decimal places.
1360	01/24/2020	Policy/Implementation	Purchasing/Inventory/Reimbursement	Does HRSA authorize covered entities to retroactively change previous quarters' purchases from a non-340B purchase into a 340B price transaction, or to convert from a GPO purchase into non-GPO purchase, through credit and rebill process arranged between the covered entity and the wholesaler?	HRSA does not authorize covered entities to reclassify a purchase as 340B eligible after the fact. Covered entities participating in the 340B Program are responsible for requesting 340B pricing at the time of the original purchase. If a covered entity wishes to reclassify a previous purchase as 340B, covered entities should first notify manufacturers and ensure all processes are fully transparent with a clear audit trail that reflects the actual timing and facts underlying a purchase. Drug purchases may be credited and rebilled within the wholesalers contracted and allowed timeframe according to standard business practices, however the covered entity retains responsibility for ensuring full compliance, transparency, and integrity of its use of the 340B Program.
1429	01/24/2020	Policy/Implementation	Audit/Compliance	What is an acceptable way to calculate the amount owed to a drug manufacturer?	HRSA recommends the parties work together to resolve this matter in good faith.
1450	01/24/2020	Contract Pharmacy		What are the record-keeping requirements for contract pharmacies?	<p>The covered entity must have fully auditable records that demonstrate compliance with all 340B Program requirements and the entity remains responsible for ensuring their contract pharmacies meet statutory obligations to ensure against diversion or duplicate discounts. HRSA recommends that covered entities perform quarterly internal audits and annual independent audits (or more frequent as necessary) of all their utilized contract pharmacies to ensure 340B Program compliance, although the exact method of ensuring compliance is left up to the entity. HRSA also recommends that covered entities maintain written policies and procedures to describe contract pharmacy oversight activities, including effective procedures for review of the patient eligibility determination system used at contract pharmacies, and reconciliation of dispensing, purchasing, and billing records to ensure that diversion and duplicate discounts have not occurred.</p> <p>In addition, and as a best practice, the contract pharmacy provides the covered entity with reports consistent with customary business practices (e.g. quarterly billing statements, status report of collections and receiving and dispensing records). The contract pharmacy, with the assistance of the covered entity, establish and maintain a tracking system suitable to prevent diversion of 340B drugs and duplicate discounts on the drugs. The contract pharmacy assures that all pertinent reimbursement accounts and dispensing records, maintained by the pharmacy, will be accessible separately from the pharmacy's own operations and will be made available to the covered entity, HRSA, and the manufacturer in the case of an audit.</p>
1456	01/24/2020	Contract Pharmacy		What is a ship to bill to arrangement?	The ship to bill to procedure refers to an arrangement set up by the covered entity who is responsible for purchasing 340B drugs from wholesalers and/or manufacturers and directs those 340B drugs to be shipped to the contract pharmacy. In other words, the covered entity maintains title of the 340B drugs, but the contract pharmacy houses the drugs and provides dispensing services to patients of the covered entity.

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1524	01/24/2020	340B PVP	Value Added Products/Services	What are verified sources of information about the 340B program?	HRSA and its contracted 340B Prime Vendor Program (PVP) are the only sources of information related to the 340B program that is verified and endorsed by HRSA. The responsibility to ensure compliance with 340B program requirements remains with covered entities and manufacturers that participate. Information received from vendors, consultants and other third parties cannot be assumed to be compliant with HRSA policy. Therefore HRSA recommends all information and guidance received from outside parties is verified by HRSA or the PVP.
1545	01/24/2020	340B Database Technical Assistance		What does HRSA consider as the 340B unique identifier?	HRSA considers the 340B ID the unique identifier. While HRSA does not use Health Industry Numbers as a method of identifying 340B covered entities, we recognize that HIN and DEA numbers may be used by certain stakeholders, in addition to the 340B ID, to operationalize the 340B Program.
1629	01/24/2020	Contract Pharmacy		Are 340B covered entities required to contract with a retail pharmacy?	No. Covered entities are free to choose how they will provide 340B pharmacy services to their patients, subject to federal and state laws. Options include contracting with a retail pharmacy, providing in-house pharmacy services, administering drugs to patients, etc. For more information, including tools and technical assistance in providing 340B pharmacy services, contact Apexus Answers at 888-340-2787, or ApexusAnswers@340bpvp.com.
1634	01/24/2020	Recertification		Once a covered entity submits a change request form, must the covered entity do anything else to recertify?	<p>Yes. A change request form only updates the covered entity's 340B OPAIS information. Recertification requires the covered entity's Authorizing Official to:</p> <ol style="list-style-type: none"> (1) update 340B OPAIS information if necessary and; (2) certify compliance with 340B Program requirements. <p>HRSA strongly recommends that the covered entity review and update its 340B OPAIS entry using the change request form prior to recertification. Both the AO and the PC will receive an "Advanced Notification" email when OPA creates a recertification initiative that includes one or more of their active entities to tell them when the recertification period will begin. Recertification initiatives will not include terminated entities, entities pending termination, or newly registered entities that have not yet reached their participation start date. On the first day of the recertification period, both the AO and the PC will receive an email notification containing the recertification start and end dates.</p> <p>HRSA strongly recommends that the covered entity review and update its 340B OPAIS entry using the change request form prior to recertification. Once recertification starts, the listed Authorizing Official will receive a user name, password, and recertification user guide to perform annual recertification and attest to the covered entity's 340B Program compliance.</p> <p>The Authorizing Official is responsible for ensuring 340B Program compliance for the covered entity. Recertification covers the parent covered entity and all registered child sites in the 340B OPAIS.</p>
1641	01/24/2020	Policy/Implementation	GPO Prohibition	Can our 340B hospital, subject to the GPO prohibition, use a GPO for outpatient drugs at a non-reimbursable clinic within the four walls of the parent hospital?	No.
1657	01/24/2020	340B Price/Drug	340B Price	Are 340B prices available when purchasing inpatient drugs?	No. 340B pricing applies to covered outpatient drugs only.
1669	01/24/2020	Policy/Implementation	GPO Prohibition	If my critical access hospital enrolls and participates in the 340B Program, will we have to stop participating in our group purchasing organization (GPO)?	No. Under section 340B(a)(4)(N) of the Public Health Service Act, as amended by the Affordable Care Act, the prohibition against participation in GPO arrangements does not apply to critical access hospitals, rural referral centers, or sole community hospitals. The GPO prohibition only applies to 340B-enrolled disproportionate share hospitals, children's hospitals, and free-standing cancer hospitals.

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1678	01/24/2020	Policy/Implementation	GPO Prohibition	Our mixed-use area has only inpatients or 340B eligible outpatients. We do not have any 340B ineligible patients. In this setting where the status of a patient (inpatient vs. outpatient) is not known until replenishment occurs by the split ordering software, and our accumulator splits orders into inpatient GPO and 340B, is it required to start with a WAC inventory?	The hospital must keep auditable records demonstrating that accumulation occurs for inpatient GPO or outpatient 340B for eligible patients (as defined by current patient definition guidelines (61Fed. Reg. 55156 (Oct. 24,1996)). A non-GPO outpatient account should be available for replenishment for covered outpatient drugs in the event a 340B product is not available.
2346	01/24/2020	340B Database Technical Assistance	OPAIS-Pricing	What date/quarter are manufacturers required to submit 340B pricing to HRSA?	Manufacturers must submit 340B pricing information to HRSA, which will begin within a two week period starting on or about day 45 of the quarter. The pricing component of the 340B OPAIS will send an email alert to the registered authorizing official and primary contact of the manufacturer when the two-week window for reporting is open, as well as daily reminders that tasks are pending within the pricing component of the 340B OPAIS.
2353	01/24/2020	340B PVP		What educational resources are available to learn more about the 340B Program?	The 340B Prime Vendor Program, as part of its agreement with HRSA, provides online tutorials, templates, and other tools to aid in educating and informing 340B Program stakeholders about the program. Specifically, the 340B Prime Vendor offers educational programs, including 340B University and 340B University OnDemand. They also operate a call-center and have a database of FAQs. These educational materials have been reviewed and approved by HRSA. Please visit the 340B Prime Vendor Program website for more information.
2368	01/24/2020	340B PVP	Pricing	What is the purpose of the Prime Vendor Program (PVP) sub-WAC pricing in the non-GPO/WAC account, and who may access it?	The purpose of the PVP sub-WAC pricing in the non-GPO/WAC account is to support compliance for hospitals subject to the GPO Prohibition. Hospitals subject to the GPO Prohibition (DSH, PED, CAN) access the sub-WAC contracts in the non-GPO/WAC account as part of the Prime Vendor Program. This account was not intended for covered entities such as federally qualified health centers that are not subject to the GPO Prohibition.
2382	01/24/2020	340B Price/Drug	340B Price	Which policies does the 340B Ceiling Price and CMP Regulation replace?	The 340B Ceiling Price and CMP Regulation replaces former "Clarification of Penny Pricing" policy release (2011-2 (November 21, 2011)) and the final guidelines in 1995 describing ceiling price calculations for new drugs [60 FR, 51488 (October 2, 1995)].
2385	01/24/2020	340B Price/Drug	340B Price	Who is tasked with imposing civil monetary penalties against manufacturers who knowingly and intentionally overcharge a covered entity?	Pursuant to a delegation of authority, the HHS Office of the Inspector General (OIG) has the authority to impose CMPs utilizing the definitions, standards, and procedures under 42 CFR Parts 1003 and 1005, as applicable. For additional information, see the delegation of authority Federal Register Notice at https://www.gpo.gov/fdsys/pkg/FR-2017-01-05/pdf/2016-31944.pdf (82 FR 1356, January 5, 2017).
2437	01/24/2020	340B Database Technical Assistance	Navigation/Use	What is the purpose of 340B OPAIS?	The new system increases the integrity and effectiveness of 340B stakeholder information and focuses on three key priorities: security, user accessibility, and accuracy. The new 340B Office of Pharmacy Affairs Information System (340B OPAIS) replaced the legacy 340B Database in its entirety which includes security updates and enhancements used for covered entity/manufacture registrations, change requests, recertification, and other updates. Some of the key features of 340B OPAIS include: 1.Manufacturers and covered entities ability to manage their own 340B record. 2.Improved efficiency through a task-oriented landing page for the covered entity/manufacturers Authorizing Officials (AOs). Additionally, covered entities and manufacturers receive e-mail notifications of pending tasks. 3.Enhanced security features such as two-part authentication for covered entities and manufacturers.
2438	01/24/2020	340B Database Technical Assistance	Navigation/Use	Who has access to the secure 340B OPAIS?	Individuals from manufacturer or covered entity organizations listed as an Authorizing Official (AO) or Primary Contact (PC) of a manufacturer or covered entity record are required to create a secure user account. The AO or PC then has access to the 340B records the AO or PC are associated. There is only one AO and PC per 340B record. A 340B record is defined as an individual manufacturer labeler code or covered entity 340B ID.

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2439	01/24/2020	340B Database Technical Assistance	Navigation/Use	Will I be required to log into 340B OPAIS?	All AOs and PCs for a manufacturer or covered entity are required to log into 340B OPAIS and create a user account before any access is granted to the 340B record. Steps for creating a user account are determined by whether the user is currently listed with a 340B OPAIS record or are a first time user requesting to be associated with a manufacturer or covered entity record.
2440	01/24/2020	340B Database Technical Assistance	Navigation/Use	What type of login credentials will be required for 340B OPAIS?	The login credentials required for 340B OPAIS include a username, which is the email address used to register for 340B OPAIS, and a self-created password. The user will also receive a 6-digit authentication code via email, each time you attempt to login.
2441	01/24/2020	340B Database Technical Assistance	Navigation/Use	How do I create my account in 340B OPAIS?	<p>To create an account in 340B OPAIS, please use the following steps:</p> <ol style="list-style-type: none"> 1.From the 340B OPAIS home page, click the "I am a Participant" icon or click the "Login" icon in the top menu. 2.Click the "Create new account" link. 3.Type your email address in the space provided and click "Search." 4.The "Create a New User" registration page will be displayed: <ol style="list-style-type: none"> a.If your email address is currently associated with an active or approved covered entity or manufacturer record as an AO or PC, your email address, name, title, organization (if available), phone number and extension will be populated automatically. b.If your email address has not been previously associated with a covered entity or manufacturer, enter your name, title, organization name (employer), phone number, and extension in the spaces provided before proceeding. All fields are required except phone extension. 5.For "Parent Entity Type," select either covered entity or manufacturer. 6.Type your password and then type it again to confirm. 7.Type the CAPTCHA code displayed in the image in the text box. 8.Click "Register." <p>The 340B OPAIS will check for an existing account with your email address and validate the account. OPA Staff will review new user account requests and confirm or deny access to the 340B record.</p> <p>These steps along with your account validation activity are found in the 340B OPAIS Public User Guide on the 340B website (https://www.hrsa.gov/opa/files/publicuserguide.pdf) specifically the section on creating an account.</p>
2443	01/24/2020	340B Database Technical Assistance	Navigation/Use	How do I reset my password in 340B OPAIS?	<p>Please use the following steps to reset your password in 340B OPAIS:</p> <ol style="list-style-type: none"> 1.From the login page, click "Recover Your Account" link. 2.Type your email address. 3.Click "Reset Password." 4.An email will be sent to you containing a password reset URL. 5.Click the URL in the email message. 6.Enter and confirm your new password. 7.When reset is complete, you may proceed to log in as usual. <p>These steps can be found in the 340B OPAIS Public User Guide on the 340B website: https://www.hrsa.gov/opa/files/publicuserguide.pdf</p>
2444	01/24/2020	340B Database Technical Assistance	Navigation/Use	My email address changed, how do I update my secure access in 340B OPAIS?	<p>If the user is already registered in 340B OPAIS and the user no longer has access to the registered email address, the user will need to create a new account via the online change request process. HRSA's Office of Pharmacy Affairs (OPA) will review and determine whether to approve the submitted change request.</p> <p>If you are using your current email address to access 340B OPAIS, but would like to change that email address, you will need to submit a change request via the online change request process.</p> <p>The step-by-step instructions for submitting a change request can be found in the 340B OPAIS Public User Guide on the 340B website: https://www.hrsa.gov/opa/files/publicuserguide.pdf</p>
2445	01/24/2020	340B Database Technical Assistance	Navigation/Use	Will the change request process be different in 340B OPAIS?	<p>Except for new account creation, only a covered entity or a manufacturer AO or PC can submit an online change request. Only an AO has the ability to approve on behalf of the covered entity or manufacturer and submit a change request. Manufacturers will no longer have a paper change request process and will follow the same online change request process as covered entities. For help on how to submit a change request please refer to the 340B OPAIS Public User Guide on the 340B website:</p> <p>https://www.hrsa.gov/opa/files/publicuserguide.pdf</p>

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2446	01/24/2020	340B Database Technical Assistance	Navigation/Use	Can I still use 340B OPAIS if I am neither a participating covered entity or manufacturer? What information will I be able to access if I do not have a login account?	340B OPAIS has public search and reports functionalities, with limited public viewing privileges, that will still be available. Covered entity, manufacturer, and contract pharmacy profiles are still accessible for public viewing. All registration, recertification, change and termination requests for covered entities and manufacturers can perform these actions in 340B OPAIS and are only accessible by their respective AO and PC.
2451	01/24/2020	340B Database Technical Assistance	Navigation/Use	What is an associated site for Community Health Centers and Federally Qualified Health Centers (FQHCs)?	An associated site is terminology used by HRSA's OPAIS to indicate sites that share grant numbers (CHCs) or a designation number (Federally Qualified Health Center Look-alikes). Prior to September 2017, these covered entity types had a parent-child relationship. The 340B ID numbers of these entity types will not be changing, only the terminology: from parent-child to "associated sites." No other type of covered entity will have the associated site terminology.
2537	01/24/2020	340B Price/Drug	340B Price	What is the effective date of the 340B Ceiling Price and CMP Regulation?	The effective date for the 340B Ceiling Price/CMP regulation (82 FR 1210, January 5, 2017) is January 1, 2019. The rule will be applied prospectively. Manufacturers that offer 340B ceiling prices as of the quarter beginning January 1, 2019 must comply with the requirements of the final regulation.
2542	01/24/2020	340B Database Technical Assistance	OPAIS-Pricing	What is the file format a manufacturer should use when uploading 340B Pricing?	Manufacturers may log into the 340B OPAIS Pricing application and upload a formatted text/instrument file or manually enter the required data points containing their quarterly data. Specifics on the text/instrument file upload format can be found in the manufacturer user guide.
2553	01/24/2020	340B Database Technical Assistance	OPAIS-Pricing	Will a covered entity that is terminated from the program be able to view the 340B OPAIS pricing system?	No, the 340B OPAIS pricing system is only available to actively participating covered entities. Once terminated, covered entities will no longer have the ability to log into the pricing system.
2558	01/24/2020	340B Price/Drug	340B Price	If a manufacturer determines it overcharged a covered entity for a covered outpatient drug, how soon must the manufacturer refund the affected covered entity?	HRSA requires manufacturers to refund covered entities on all drug overcharges and should work with the covered entities in good faith to make repayments. Specifically for new drugs and as outlined in the CMP final rule, manufacturers are required to calculate the actual 340B ceiling price and offer to refund or credit the covered entity the difference between the estimated 340B ceiling price and the actual 340B ceiling price within 120 days of the determination by the manufacturer that an overcharge occurred. For overcharges on other drugs, HRSA expects repayment procedures to follow similar processes that align with standard business practice and be documented in the manufacturer's policies and procedures.
1481	01/12/2020	Contract Pharmacy		If a contract pharmacy is serving more than one covered entity, and it keeps the inventories physically separate for each entity, may the pharmacy arrange for one inventory to borrow from another if it is running low of a particular drug?	No, a contract pharmacy serving more than one covered entity may not arrange for one inventory to borrow from another if it is running low of a particular drug. In this contract pharmacy situation, the contract pharmacy keeps physically separate inventories for each separate 340B ID# it does not use a replenishment model. The physically separate 340B inventories belong to different 340B entities. Borrowing from one 340B ID/covered entity's inventory to give to another 340B entity's places the entity at risk for diversion.
1496	12/27/2019	Contract Pharmacy		Our contract pharmacy uses a repackager at a separate address from the contract pharmacy to process 340B prescriptions. Must we register the repackager on 340B OPAIS?	The covered entity is not required to register the repackager as a contract pharmacy so long as: (1) the covered entity retains ownership and title to the 340B drugs; (2) the covered entity will not sell its 340B drugs or otherwise transfer ownership to the repackager; and (3) the repackager will not dispense 340B drugs. Based on those specific circumstances, and the fact that the repackager is not a pharmacy and will not dispense drugs, OPA does not require the repackager to register as a contract pharmacy.
1508	12/27/2019	Contract Pharmacy		Is there any information on how to construct a contract between a 340B-eligible entity and a local pharmacy regarding contract pharmacy?	HRSA has provided essential covered entity compliance elements to address in contract pharmacy arrangements (75 Fed. Reg. 10272, Mar. 5 2010). This guideline is available here: https://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf

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1531	12/27/2019	Contract Pharmacy		How do I register a contract pharmacy?	Covered entities that elect to utilize contract pharmacy arrangements must register each contract pharmacy location in 340B OPAIS once a written agreement is executed. Covered entities complete the online portion of the contract pharmacy registration process during an open registration period. For more information regarding contract pharmacy registration, please visit the HRSA OPA website at https://www.hrsa.gov/opa/implementation/contract/index.html
1560	12/27/2019	Contract Pharmacy		In a bill to/ship to scenario, can a replenishment go to a central warehouse (e.g. a chain pharmacy's central warehouse) and not the actual physical location of the pharmacy that dispensed the drug?	Central replenishment to a central warehouse may be appropriate, as long as the covered entity pays for the inventory and appropriate records are kept by the covered entity and pharmacy. The covered entity is responsible for complying with all other applicable State and local laws.
2507	12/27/2019	Contract Pharmacy		When reviewing a contract pharmacy agreement, what does HRSA look for?	HRSA ensures that contract pharmacy agreements: <ol style="list-style-type: none"> 1) are dated prior to the registration period; 2) include a list of all applicable covered entity locations identified by name and address identical to 340B OPAIS records or provide an all-inclusive statement identifying all parent and child/associated sites actively listed in 340B OPAIS; 3) include a list of all pharmacy locations identified by name and address which should identically match those submitted for registration; and 4) include signatures of officials from both the entity and the pharmacy.
1410	12/26/2019	Contract Pharmacy		How can we find out our contract pharmacy effective date?	The HRSA Office of Pharmacy Affairs sends an email notification to the covered entity and the contract pharmacy specifying the effective date of the arrangement. That date is also displayed on 340B OPAIS. Do not assume the date that the organization submitted paperwork is the effective date.
1463	12/23/2019	Recertification		How is the HRSA Electronic Handbook system used in the 340B recertification process?	Section 330 health center grantee and FQHC look-alike site names and addresses will be updated in the recertification process to match those on file in HRSA's Electronic Handbooks (EHB) system. Authorizing officials will be able to review any changes before they are effective; any major discrepancies should be brought to OPA's attention via e-mail to 340b.recertification@hrsa.gov (please include the affected grant number, 340B ID, and BPHC site ID). OPA encourages covered entities to proactively notify their manufacturer/wholesaler partners of any changes in participation and/or name/address that may result from recertification. Questions on recertification can be directed to ApexusAnswers at 1-888-340-2787 or by e-mail to ApexusAnswers@340bpvp.com .
2578	12/13/2019	340B Database Technical Assistance	OPAIS-Pricing	What if a manufacturer does not load prices into 340B OPAIS during the designated period?	As required by section 340B(d)(1)(B)(i) of the PHSA, HRSA developed the 340B OPAIS pricing component as a mechanism to ensure the accuracy of 340B ceiling prices calculated for covered outpatient drugs. Section 340B(a)(1) of the PHSA requires manufacturers to furnish HRSA with quarterly 340B pricing information. The 340B OPAIS pricing component is the sole price reporting mechanism for manufacturers and became available to receive data beginning February, 2019. HRSA does not consider pricing data submitted via email as meeting a manufacturer's obligation to report quarterly pricing information. In the absence of a submission of quarterly pricing data, HRSA will publish a 340B ceiling price based solely on information received from CMS and a third party contract. This will be notated on the price.
1187	11/01/2019	Policy/Implementation	GPO Prohibition	What are some examples of contracting approaches that are potential violations of the GPO Prohibition?	The following situations are not GPO-prohibition compliant contracting practices: - An individual DSH accessing contracts executed by an IDN, in which it is a member. - A wholesaler's generic source program (unless offered as a subcontracted solution to the Apexus Generics Program) - A manufacturer extending a discounted price to a group of covered entities (subject to the GPO prohibition) through a wholesaler, other third party or group purchasing arrangement, that is not supported by an individual contract between the 340B covered entity and the manufacturer. Such agreements should be reproducible for review during an audit of compliant 340B operations.

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1188	11/01/2019	340B Price/Drug	340B Price	How soon after a drug is approved by the FDA is 340B pricing available?	<p>The 340B price is available for a new covered outpatient drug as of the date the drug is first available for sale. For the purposes of the 340B Program, manufacturers must estimate the ceiling price using the methodology described in the 340B Ceiling Price and Civil Monetary Penalties (CMP) final rule (82 FR 1210, January 5, 2017), which requires a new drug's ceiling price to be estimated using wholesale acquisition cost minus the appropriate rebate percentage (i.e., 23.1% for most single-source and innovator drugs, 17.1% for clotting factors and 13% for generics) until sufficient data is available to calculate the actual 340B ceiling price of the new drug.</p> <p>Once the average manufacturer price (AMP) is known, and no later than the fourth quarter that the drug is available for sale, manufacturers must calculate the actual 340B ceiling price based on the AMP. For more information on new drug price estimation, please review the 340B Ceiling Price and CMP final rule at: https://www.gpo.gov/fdsys/pkg/FR-2017-01-05/pdf/2016-31935.pdf.</p>
1206	11/01/2019	340B Price/Drug	340B Price	Does HRSA allow an exemption for de minimis refund amounts when a manufacturer calculates 340B entity refunds following a new drug pricing estimation?	To the extent that a manufacturer and a covered entity agree that a de minimis threshold for refunds should be established, such a threshold can be established.
1228	11/01/2019	Policy/Implementation	Purchasing/Inventory/Reimbursement	If a manufacturer receives a chargeback request for a covered entity site that was not registered on 340B OPAIS as of the date of the chargeback, must the manufacturer honor the chargeback? The address appears with a start date later than that listed on the chargeback.	No, a manufacturer does not have to honor the chargeback if it is for a date prior to registration on 340B OPAIS.
1255	11/01/2019	340B Price/Drug	340B Price	Does HRSA provide a list of the prices for 340B drugs?	Section 340B(d)(1)(B) of the Public Health Service Act requires HRSA to collect information from manufacturers in order to verify the accuracy of 340B ceiling prices, and then make ceiling prices available only to covered entities. The pricing component of the 340B OPAIS is a secure, web-based application and only allows authorized users from manufacturers and covered entities access the system to perform assigned functions.
1282	11/01/2019	Policy/Implementation	Audit/Compliance	How would a 340B covered entity lose its 340B eligibility?	<p>A covered entity that loses eligibility to participate must notify the HRSA Office of Pharmacy Affairs and immediately stop purchasing 340B drugs in the following situations:</p> <ol style="list-style-type: none"> 1) The entity lost the grant funding/designation under which it qualified for 340B Program participation; 2) The hospital's contract with a state or local government has been terminated or expired; 3) The hospital becomes for-profit; 4) The hospital's disproportionate share adjustment percentage falls below the threshold for that hospital type, as of the most recently filed cost report, or a children's hospital that no longer has a CMS 3300 number 5) The hospital subject to the group purchasing organization (GPO) prohibition uses a GPO to purchase covered outpatient drugs; 6) The entity fails to recertify during annual recertification.
1286	11/01/2019	Policy/Implementation	Patient Definition	An infusion center is registered on 340B OPAIS as a participating child site and is listed as reimbursable on the most recently filed Medicare Cost Report of the entity. A drug for infusion is written at a non-eligible location, by a private physician with no relationship with the covered entity. May the hospital use 340B drugs in this scenario?	The hospital may use 340B drugs when all aspects of the patient definition are met. HRSA's patient definition guidance states the individual must receive 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 (61 Fed. Reg. 55156 (October 24, 1996)). HRSA's patient definition guidance also states that an individual will not be considered a 'patient' of the covered entity if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting (61 Fed. Reg. 55156, 55158 Oct. 24, 1996.)
1293	11/01/2019	340B Price/Drug	340B Price	Are 340B prices confidential?	The agreement between HRSA and CMS requires confidentiality on the pricing data submitted to CMS by manufacturers. Prices in the market are not confidential although contractual arrangements between, for example, manufacturers and distributors or other customers may restrict the availability of price data.

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1297	11/01/2019	340B Price/Drug	Covered Outpatient Drugs	If a drug manufacturer signs a pharmaceutical pricing agreement (PPA) with HRSA/OPA, is the manufacturer required to offer all of their products that have NDC numbers at 340B pricing, or does it depend on the product's 5-digit NDC labeler code?	The PPA signed by the manufacturer covers all covered outpatient drugs that meet the definition in section 1927(k) of the Social Security Act for the manufacturer's labeler code.
1302	11/01/2019	340B Price/Drug	340B Price	How far may a covered entity receive 340B prices retroactively?	HRSA policy does not authorize covered entities to reclassify a purchase as 340B eligible after the fact. Covered entities participating in the 340B Program are responsible for requesting the 340B price at the time of the original purchase. However, if a covered entity conducts a reclassification of a previous purchase, it should first notify the manufacturer and ensure all processes are fully transparent with a clear audit trail that reflects the actual timing and facts underlying a transaction. Drug transactions may be credited and rebilled within the wholesaler's contracted and allowed timeframe according to standard business practices; however, the covered entity is responsible for ensuring full compliance, transparency, and integrity of its use of the 340B Program.
1334	11/01/2019	Policy/Implementation	Purchasing/Inventory/Reimbursement	Can we transfer 340B drugs to a site that is unregistered but labeled as a ship-to address on our CEs profile?	Transferring a 340B drug to a shipping address associated with that covered entity's 340B ID on 340B OPAIS is permitted. Covered entities should be aware that listing a location as a shipping address does not make that location eligible to use 340B drugs for any individuals treated there.
1355	11/01/2019	Policy/Implementation	GPO Prohibition	Can a hospital subject to the GPO Prohibition use a GPO for drugs that are part of/incident to another service and payment is not made as direct reimbursement of the drug ("bundled drugs")? For example, diluents for infusions, large volume parenterals used as diluents, etc.	Yes, a GPO may be used for drugs that are not covered outpatient drugs. Covered entities should maintain auditable records and policies and procedures related to the definition of covered outpatient drug and the use of a GPO that is consistent with the 340B statute.
1356	11/01/2019	Eligibility/Registration	Covered Entity	We are a 340B covered entity hospital that qualifies as more than one covered entity type. We have decided to change the status of our registration to be a different entity type, what process should we follow to change our status and ensure no interruption in our 340B services?	In order to change the status of the covered entity type registered in 340B OPAIS, please contact the HRSA 340B Program Operations Branch at 301-594-4353 as soon as possible. It is important to remember that the hospital must meet all program requirements during the transition period or prior to the transition period. A seamless transition can only occur if the hospital is proactive and acts prior to any of the program requirements change for the hospital. Hospitals are required to complete the regular enrollment process including the online registration forms for the entity type of which you wish to become. Once approved as the new entity type, OPA will remove the previous status of the entity. Please note that regular quarterly enrollment timelines apply, even if only changing entity status. Also note that any prohibitions required of the new entity status will apply as of the date of the listing in 340B OPAIS for the new entity type. Once you are listed as the new entity type, it is the responsibility of the covered entity to appropriately update its 340B OPAIS records and accounts with wholesalers and/or manufacturers to ensure the new 340B ID is used to purchase 340B drugs.
1367	11/01/2019	340B Price/Drug	340B Price	Is there a specific formulary for the 340B drugs? What drugs are included under the 340B Drug Pricing Program?	There is no designated formulary for the 340B Program. A manufacturer must offer all covered outpatient drugs at or below the 340B ceiling price. The term covered outpatient drug is defined in section 1927(k) of the Social Security Act. The Centers for Medicare & Medicaid Services provides a list of drugs that are reported by manufacturers under the Medicaid Drug Rebate program and thus subject to a 340B ceiling price, which can be found on its website here: https://data.medicare.gov/Drug-Pricing-and-Payment/Drug-Products-in-the-Medicaid-Drug-Rebate-Program/v48d-4e3e/data .
1386	11/01/2019	Policy/Implementation	Audit/Compliance	I am currently undergoing a 340B Program audit and am concerned the questions asked by the auditor are outside the scope of the 340B Program. Where do I direct my concerns?	Please write to HRSA Office of Pharmacy Affairs with specific information regarding the audit concerns. This information should be mailed to: Health Resources and Services Administration, Office of Pharmacy Affairs, 5600 Fishers Lane, Mail Stop 08W05A, Rockville, MD 20857 - or send email to HRSA OPA at: 340baudit@hrsa.gov
1394	11/01/2019	Recertification		Must a covered entity complete a change request form for recertification if 340B OPAIS is correct?	No change request form will be required if all information in 340B OPAIS is accurate.

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1395	11/01/2019	340B Database Technical Assistance		When does HRSA expect to have all the data in HRSA's 340B OPAIS ready for the quarterly update?	HRSA strives to complete processing of new registrations and terminations no later than two weeks prior to the start of each quarter; changes to existing covered entity records are processed as received throughout the year.
1409	11/01/2019	340B Database Technical Assistance	Navigation/Use	How may a manufacturer generate a 340B entity termination report?	Manufacturers may generate a termination report by selecting one of the options under the 340B OPAIS (https://340bopais.hrsa.gov/home) search screen's 'Advanced Query Options' section, by manually entering a termination date range or by downloading the daily covered entity report and filtering by 'Term Date' of interest. To obtain more specific details about a covered entity's termination, please review that entity's record in 340B OPAIS.
1415	11/01/2019	340B Database Technical Assistance	Change Form	How do I request the termination of an outpatient facility?	<p>Access the 340B OPAIS at https://340bopais.hrsa.gov/. From the Covered Entity Details page for an active entity for which the user is responsible as AO or PC, click the Terminate button. The Covered Entity Termination page will be displayed for the entity. Select a reason from the drop-down list. If none of the terminations reasons apply, e-mail ApexusAnswers@340bpvp.com for additional guidance.</p> <p>Upon clicking the Submit button, the system will display a confirmation message. Click the OK button to complete the termination and return to the landing page. If the AO is submitting the termination requestS The AO should select this box to submit the termination request for OPA approval. Upon OPA approval of the termination, both the AO and the PC will receive a 340B Program Termination email, and the entity's status will be changed to "To Be Terminated." After the termination effective date, the entity's 340B status will be updated to "terminated" in 340B OPAIS.</p>
1438	11/01/2019	340B Database Technical Assistance	Change Form	Our entity would like to change its registration status from one entity type to another. What steps should we take?	<p>For an entity that wishes to change its 340B registration type due to a change in grant program or hospital eligibility category, HRSA advises maintaining the original 340B registration (if continuously eligible) until registration under the new 340B registration type is complete. Once the new registration has been approved but prior to the new registration effective date, the entity must submit a termination request for the original 340B identification number.</p> <p>A covered entity must comply with all 340B Program requirements for the type of entity it is registered as in 340B OPAIS. Covered entities are strongly encouraged to contact APEXUS for technical assistance well in advance when considering this type of change.</p>
1459	11/01/2019	Contract Pharmacy		What pharmacy locations should I register on 340B OPAIS?	Covered entities must register all the pharmacy locations with which the covered entity has a written contract in place to dispense drugs or provide services to patients of the covered entity under the contract.
1468	11/01/2019	Recertification		Why are the changes not listed on 340B OPAIS after the Authorizing Official has certified and updated the 340B OPAIS record?	The Health Resources and Services Administration (HRSA) reviews all information provided during recertification for completeness and compliance with 340B program requirements. Changes submitted during recertification will be reflected in 340B OPAIS once approved by HRSA. HRSA reserves the right to accept, reject, or require additional documentation to verify the changes requested during recertification before processing these changes in 340B OPAIS.
1486	11/01/2019	340B Database Technical Assistance	Navigation/Use	May in-house pharmacies of 340B entities, listed as shipping addresses on the OPA website, be used as a billing address by the wholesalers and manufacturers?	Yes, in-house pharmacies of 340B entities, listed as shipping addresses on the 340B OPAIS, may be used as a billing address by the wholesalers and manufacturers.
1504	11/01/2019	Policy/Implementation	Audit/Compliance	To what extent is a registered 340B covered entity (parent) is responsible for outpatient facilities (child) it has registered?	The covered entity is fully responsible for its registered outpatient facilities' compliance with all 340B Program requirements. The covered entity is also responsible for all contract pharmacy arrangements listed on 340B OPAIS. Audits of 340B covered entities include a covered entity's outpatient facilities and contract pharmacies.

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1523	11/01/2019	Contract Pharmacy		What is the effective date for a contract pharmacy arrangement?	<p>The registration periods and effective dates for 340B Program contract pharmacies are: October 1 – October 15 for an effective start date of January 1; January 1 – January 15 for an effective start date of April 1; April 1 – April 15 for an effective start date of July 1; and July 1 – July 15 for an effective start date of October 1. If the 15th falls on a Saturday, Sunday, or Federal holiday, the deadline for submitting contract pharmacy registrations will be the next business day. HRSA will not post a retroactive date for any contract pharmacy arrangement; as such, the date that the organization submitted the registration request should not be presumed the effective date. A covered entity may not use a contract pharmacy prior to its effective date listed on 340B OPAIS.</p> <p>For more information on how to register a contract pharmacy, please see http://www.hrsa.gov/opa/implementation/contract/index.html.</p>
1549	11/01/2019	340B Price/Drug	Manufacturer	Can a manufacturer place special conditions or restrictions on selling covered drugs to an entity at the 340B price that do not apply to non-340B purchasers?	<p>Consistent with section 340B(a)(1) of the PHSA, manufacturers are expected to provide the same opportunity for 340B covered entities and non-340B purchasers to purchase covered outpatient drugs when such drugs are sold through limited distribution or specialty pharmacies. As outlined in the January 2017 CMP final rule, manufacturers have an obligation to ensure that the 340B discount is provided through distribution arrangements made by the manufacturer. A manufacturer may not place limitations or conditions on the sale of covered outpatient drugs to covered entities under the 340B Program. HRSA issued a policy release clarifying non-discrimination in the Program, which can be found here: http://www.hrsa.gov/opa/programrequirements/policyreleases/nondiscriminati on05232012.pdf.</p> <p>Manufacturers may continue to use limited distribution procedures provided that these arrangements follow HRSA's 340B nondiscrimination policy. If a covered entity alleges it has been overcharged, HRSA will examine whether a manufacturer has submitted an alternate allocation plan to HRSA, whether this plan complies with the 340B nondiscrimination policy, and whether the manufacturer is following its plan.</p>
1564	11/01/2019	340B Database Technical Assistance	Change Form	When can I expect to hear from HRSA about the status of a change request?	<p>HRSA makes every effort to process change requests as soon as possible. Changes take approximately 10 business days to appear in 340B OPAIS, but the actual time frame will depend on the volume of requests pending at HRSA. Also, the process may take longer if verification from a grant official, program officer or other external authority is required.</p> <p>HRSA currently accepts online requests for most types of covered entity changes (e.g., addresses, contact information and/or entity or pharmacy terminations). The requester and the Primary Contact for the entity will receive an acknowledgment at the time of submission; the entity's Authorizing Official will receive a separate e-mail with a link to accept or cancel the request (please check or ask the Authorizing Official to check his or her spam folder if the e-mail has not been received within 24 hours of submission). Requests will be automatically cancelled if not accepted by the Authorizing Official within 15 calendar days of submission.</p> <p>Once accepted by the Authorizing Official, HRSA will review and either approve or reject the change request. The Primary Contact and Authorizing Official will receive notification of either approval or rejection.</p> <p>Updates to the contract pharmacy details should be made through the DEA registry. Manufacturer records can also be updated through OPAIS.</p>
1579	11/01/2019	340B PVP	Vaccines	Please clarify where I can utilize vaccines purchased through the 340B Prime Vendor Program (PVP).	<p>Vaccines purchased through the PVP that are not covered outpatient drugs are classified as value-added products within the Prime Vendor Program. The use of vaccines purchased through the PVP are limited by the terms and conditions of the contract between the PVP and the supplier, including contractual class of trade restrictions. In addition, entities must use vaccines purchased through PVP contracts for patients meeting the "own use" guidelines under the Nonprofit Institutions Act. Each entity should consult its independent legal counsel to ensure compliance with all rules, regulations, and contractual terms.</p>
1601	11/01/2019	340B PVP	Pricing	Once enrolled in the PVP, how will I receive the program's discounted pricing?	<p>After submitting the enrollment online, you will receive an email providing instruction on how to access the 340B PVP secured website where you can view contract and pricing information. The pharmacy distributor you select during the online enrollment process also receives electronic notification of your approved participation agreement, referencing your effective date. Your pharmacy distributor will then link the PVP contract portfolio to your 340B outpatient account(s) and the prime vendor pricing will overlay the PHS/340B-ceiling price for each NDC in the PVP contract portfolio. The prime vendor pricing has a special code for easy identification that varies by distributor. Having the prime vendor price overlay the higher 340B ceiling price on products ensures the participants receive the lowest pricing available on the product.</p>

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1603	11/01/2019	340B PVP	Distribution	Can wholesalers/manufacturers refuse to ship to addresses listed in 340B OPAIS?	No. 340B covered entities are listed on the 340B OPAIS, and those listed are entitled to the 340B ceiling price. The 340B OPAIS should be used by all stakeholders to determine and verify covered entity eligibility.
1611	11/01/2019	340B PVP		Can Apexus deem our process or our 340B vendor "340B compliant"?	<p>The role of Apexus is to help entities understand complex policy situations and help point out areas of risk for non-compliance, as well as compliant approaches used by entities. Apexus is unable to provide assurances or statements of stakeholder compliance. Entities should contact their own legal counsel, have auditable records and policies and procedures in place to reflect compliance with all 340B Program requirements.</p> <p>Regarding vendors: Apexus has secured agreements to offer value-added pharmacy related products and services to its participants. Apexus has reviewed these services and deemed that they have the potential for promoting 340B compliance, but they may have features that entities choose to active or inactivate. For this reason, using a service on this list does not guarantee the entity will achieve 340B compliance and is not an Apexus endorsement.</p>
1614	11/01/2019	340B PVP	Membership	Can a covered entity access the PVP sub-340B contract pricing without registering with the 340B Program through HRSA Office of Pharmacy Affairs?	<p>No, the covered entity must register with HRSA's Office of Pharmacy Affairs prior to participation in the 340B PVP to access the sub-340B contract portfolio.</p> <p>To view more information regarding 340B eligibility, please visit: http://www.hrsa.gov/opa/eligibilityandregistration/index.html .</p> <p>To view more information regarding Registration, please visit the HRSA OPA website at: https://www.hrsa.gov/opa/registration/index.html</p>
1616	11/01/2019	340B PVP	Pricing	What type of companies does Apexus partner with to offer pricing?	<p>The Apexus PVP is an outpatient pharmaceutical contracting program that partners with the following categories of vendors: Branded and generic pharmaceutical manufacturers securing sub-ceiling priced products, Value added suppliers that bring additional value to pharmacies such as blood glucose monitoring supplies, apothecary/operational supplies, (USP) 797 compliance products, vaccines, and more, Value added service partners providing software and hardware pharmacy automation solutions, wholesalers and distributors currently servicing 340B covered entities for pharmaceuticals.</p> <p>Regarding the value-added service providers with whom Apexus has secured agreements: Apexus has reviewed these services and deemed that they have the potential for promoting 340B compliance, but they may have features that entities choose to activate or inactivate. For this reason, using a service on this list does not guarantee the entity will achieve 340B compliance and is not an Apexus endorsement.</p>
1623	11/01/2019	340B PVP	Value Added Products/Services	What opportunity exists for the vendors to partner with the Apexus' Prime Vendor Program?	The Apexus PVP is an outpatient pharmacy program that secures sub-340B contract pricing on medications that by law have a 340B statutory price. The PVP also contracts for other value-added products and services that an outpatient ambulatory pharmacy would use and/or dispense. If your products or services fall outside this scope, we are most likely unable to partner with you. Please contact John Barnes, Assistant Vice President of Contracting Services at 469-299-7311 or via email at John.Barnes@Apexus.com or contact Phil Perry, Director of Pharmacy of Contract Services at 469-299-7350 or via email at PPerry@Apexus.com for additional information.
1630	11/01/2019	340B PVP	Membership	Can our facility (which is not a hospital subject to the GPO prohibition) participate in the Apexus Prime Vendor Program and another group purchasing organization (GPO)?	Unlike hospitals participating in the 340B Drug Pricing Program, there is no GPO prohibition that applies to all other HRSA grantees. Therefore, a grantee may elect to participate in more than one group purchasing arrangement. Apexus Prime Vendor Program (PVP) participation is voluntary, and there are no restrictions placed on those grantees electing to participate. Most alternative purchasing groups serving 330 grantees encourage participation in the PVP to ensure members have access to best pricing on pharmaceuticals while offering members their own contract portfolios of medical/surgical, dental, office, and other non-pharmacy supplies, which tend to be complimentary to the PVP pharmacy portfolio. On occasion, there may be an alternative purchasing group that does not permit a member to simultaneously access their own contracts and PVP contracts due to existing business relationships with a supply partner. In this situation, the grantee may be required to notify the alternative purchasing group to cancel its membership before the selected pharmacy wholesaler will load the PVP pricing available to the entity's pharmacy account.
1632	11/01/2019	340B PVP	Pricing	As an Apexus PVP participant, can my facility keep its existing sub-340B negotiated pricing?	Yes. For hospitals subject to the GPO Prohibition the pricing for outpatient covered drugs should be negotiated independently by the covered entity and not as part of another group purchasing organization.

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1676	11/01/2019	340B PVP	Pricing	Can we share the 340B Prime Vendor Prices with a 3rd party?	Language in the PVP Participation agreement, which is a requirement of participants in the PVP, states that the participant agrees that it will keep strictly confidential and hold in trust all "confidential information" of 340B Prime Vendor, which includes drug pricing. The participant is not permitted to disclose such information to any third party, without 340B Prime Vendor's prior written consent.
1689	11/01/2019	340B Price/Drug	Covered Outpatient Drugs	What drugs are included under the 340B Drug Pricing Program?	All covered outpatient drugs as defined by section 1927(k) of the Social Security Act, are included under the 340B Program. https://www.ssa.gov/OP_Home/ssact/title19/1927.htm
1697	11/01/2019	340B Price/Drug	Covered Outpatient Drugs	Are over-the-counter (OTC) drugs distributed without a written prescription and provided to walk-ins in an in-house or contract pharmacy owned by a DSH hospital considered covered outpatient drugs?	No. Section 340B(a)(2)(B)(ii) of the PHS Act states "the term 'over the counter drug' means a drug that may be sold without a prescription and which is prescribed by a physician (or other persons authorized to prescribe such drug under State law)." Thus, OTC drugs that are distributed pursuant to a prescription are considered covered outpatient drugs.
2178	11/01/2019	Policy/Implementation	Purchasing/Inventory/Reimbursement	If an organization loses Title X funding, but still has STD funding, what has to happen to the inventory purchased on the Title X 340B account?	In general, the Title X purchased 340B inventory should be returned or destroyed according to state law once the eligibility is lost under which the grantee/covered entity purchased the 340B medication. Inventory cannot be transferred from one 340B ID grantee/covered entity to another 340B ID grantee/covered entity when the former entity loses its 340B Program eligibility. Entities with extenuating circumstances should contact HRSA directly for possible alternatives to this approach.
2333	11/01/2019	340B Price/Drug	Manufacturer	How does a manufacturer determine how many PPA Addenda to submit?	Manufacturers will submit a PPA Addendum for each PPA previously submitted to HRSA OPA. HRSA OPA understands that since the original PPA was signed, labeler codes may have been transferred, acquired, or purchased by other manufacturers. The manufacturer can determine the number of PPA Addenda that must be submitted by following these steps: <ul style="list-style-type: none"> •Open the manufacturer search page on 340B OPAIS at https://340bopais.hrsa.gov/manufacturersearch •Enter the manufacturer's name into the "Manufacturer Name" field. A Manufacturer can see, based upon their name, how many labeler codes are listed for that specific manufacturer. •The search results contain a "Signed Date" field. •The number of "Signed Date" fields listed will determine the number of PPA Addenda required. Example: XYZ manufacturer performs a search by their name XYZ. Ten labeler codes appear under the name XYZ. Under the "Signed Date" field there are three unique dates representing the ten labeler codes 1/05/1993, 1/6/2005, and 12/15/2012. This indicates the number of original PPAs HRSA OPA has received from this manufacturer. HRSA OPA will then require receipt of three separate PPA Addenda to coincide with the original three PPAs.
2336	11/01/2019	340B Price/Drug	340B Price	Who from the manufacturer should sign the PPA Addendum?	The PPA Addendum should be signed by the CEO/COO/CFO/President/Vice President or other personnel who has the authority to legally bind the manufacturer into a relationship with the Federal Government. The Authorizing Official may satisfy this standard in most cases. The Primary Contact may not submit the PPA Addendum.
2338	11/01/2019	340B Price/Drug	Manufacturer	When was the submission of the PPA Addendum required previously?	The PPA Addendum was due to be submitted to HRSA by close of business December 31, 2016.
2339	11/01/2019	340B Database Technical Assistance	OPAIS-Pricing	How can a manufacturer update incorrect or missing information in 340B OPAIS?	If a manufacturer needs to update its information on 340B OPAIS, the authorizing official or primary contact for the manufacturer may submit an online change request after creating an initial secure user account in the 340B OPAIS. For assistance on how to submit a change request, once logged into 340B OPAIS, the authorizing official or primary contact can refer to the user guide located in the "Help" section on 340B OPAIS.
2347	11/01/2019	340B Price/Drug	Manufacturer	Can manufacturers and HRSA OPA "digitally sign" the PPA Addendum?	Yes. Furthermore, for new online labeler registrations, a digital signature is required.

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2379	11/01/2019	340B Price/Drug	340B Price	Is a manufacturer still liable for CMPs if the cause of the overcharge was due to a wholesaler error?	Manufacturers are responsible for setting appropriate 340B ceiling prices and therefore are responsible for the conduct of business partners with whom they contract. A manufacturer's failure to ensure that covered entities receive the 340B ceiling price through its distribution arrangements with wholesalers may be grounds for assessment of civil monetary penalties as set forth in the 340B Ceiling Price and Civil Monetary Penalties final rule (82 FR 1210, January 5, 2017).
2383	11/01/2019	340B Price/Drug	340B Price	What are examples of circumstances where HHS would assume that a manufacturer did not knowingly and intentionally overcharge a covered entity?	<p>Examples of circumstances where HHS would assume that a manufacturer did not "knowingly and intentionally" overcharge a covered entity are:</p> <ul style="list-style-type: none"> •The manufacturer made an isolated inadvertent, unintentional, or unrecognized error in calculating the 340B ceiling price; •The manufacturer sells a new covered outpatient drug during the period the manufacturer is estimating a price based on this final rule, as long as the manufacturer offers refunds of any overcharges to covered entities within 120 days of determining an overcharge occurred during the estimation period; •When a covered entity did not initially identify the purchase to the manufacturer as 340B-eligible at the time of purchase; or •When a covered entity chooses to order non-340B priced drugs and the order is not due to a manufacturer's refusal to sell or make drugs available at the 340B price. <p>HRSA notes that these examples are not exhaustive, and are intended to provide an indication of some types of actions that would not be considered "knowing and intentional" overcharges. As a general principle, HRSA will defer to the OIG to determine whether a given situation constitutes knowing and intentional as explained in the 340B Ceiling Price and Civil Monetary Penalties final rule (82 FR 1210, January 5, 2017).</p>
2384	11/01/2019	340B Price/Drug	340B Price	How does HRSA define an instance of overcharging?	<p>An instance of overcharging may occur at the time of initial purchase or when subsequent ceiling price recalculations due to restated pricing data submitted to CMS or new drug price estimations result in a covered entity paying more than the ceiling price due to failure or refusal to refund or credit a covered entity. In accordance with the 340B Ceiling Price and Civil Monetary Penalties final rule (82 FR 1210, January 5, 2017):</p> <p>(1) Each order for an NDC will constitute a single instance, regardless of the number of units of each NDC ordered. This includes any order placed directly with a manufacturer or through a wholesaler, authorized distributor, or agent. (2) Manufacturers have an obligation to ensure that the 340B discount is provided through distribution arrangements made by the manufacturer. (3) An instance of overcharging is considered at the NDC level and may not be offset by other discounts provided on any other NDC or discounts provided on the same NDC on other transactions, orders, or purchases. (4) An instance of overcharging may occur at the time of initial purchase or when subsequent ceiling price recalculations due to pricing data submitted to CMS or new drug price estimations as defined in 42 CFR, Part 10 § 10.10(c) result in a covered entity paying more than the ceiling price due to failure or refusal to refund or credit a covered entity.</p>
2536	11/01/2019	340B Price/Drug	340B Price	How are manufacturers expected to contact covered entities to notify them of a repayment?	Since manufacturers must offer repayments, they must contact affected covered entities as part of the process to attempt good faith negotiations. In addition, the manufacturer must notify HRSA in writing of intention to issue a refund, which may then be made public on the HRSA website.
2538	11/01/2019	340B Price/Drug	340B Price	May a manufacturer use a third party to assist in the refund process?	Yes.
2540	11/01/2019	340B Database Technical Assistance	OPAIS-Pricing	Who has access to the 340B ceiling price data?	Authorized users from manufacturers will only have access to pricing data for their designated labeler codes. Authorized users from covered entities will have view-only access to verified ceiling prices for covered outpatient drugs. Because the system contains proprietary and confidential data, and as required by statute, authorized users are prohibited from re-disclosing information within the pricing system and must sign Rules of Behavior prior to accessing the data contained in the system.
2541	11/01/2019	340B Database Technical Assistance	OPAIS-Pricing	Will the manufacturer AO or PC receive notification of their 340B pricing data submission period?	At the beginning of each quarterly upload period, the manufacturer AO/PC will receive an e-mail notification that the two-week submission period has begun and that the AO/PC can log into the 340B OPAIS Pricing Application to upload the quarterly pricing file. The AO and PC will receive daily reminders during the open loading period until all reconciliation is complete and submitted to OPA.

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2543	11/01/2019	340B Database Technical Assistance	OPAIS-Pricing	What is the purpose of the manufacturer dashboard within the pricing system?	The manufacturer dashboard shows your quarterly reconciliation status, assigned reconciliation tasks, and pre-publication status. Manufacturers will also receive similar information as part of their daily reminder until all reconciled tasks are completed.
2544	11/01/2019			What is the quarterly reconciliation status on the manufacturer dashboard?	This area shows a progress bar with the percent complete of the manufacturer AO's quarterly reconciliation tasks and pricing data upload.
2545	11/01/2019	340B Database Technical Assistance	OPAIS-Pricing	What is a reconciliation task on the manufacturer dashboard?	Tasks are created when the application detects a discrepancy between the manufacturer's data points and HRSA's data points. A task requires a manufacturer to reconcile the pricing data points for a specific NDC. A reconciliation task indicates that a drug product is either missing data points or does not match with HRSA data points.
2546	11/01/2019	340B Database Technical Assistance	OPAIS-Pricing	What is the prepublication status report on the manufacturer dashboard?	This area contains a pie chart that indicates the reconciliation status for the current quarterly upload period, as well as a data grid that shows the statuses, record counts, and percentages.
2547	11/01/2019	340B Database Technical Assistance	OPAIS-Pricing	What are the steps for a manufacturer to upload the quarterly 340B pricing data?	<p>A manufacturer AO or PC must log into the pricing component of the 340B OPAIS.</p> <ul style="list-style-type: none"> -Determine whether you plan to manually upload product data (recommended for limited drug products) or upload a product instrument file as .txt . -Select Manufacturer Quarterly Data Processing > Upload Manufacturer Instrument File option. -The Manufacturer File Upload page is displayed. -Select the Sales Year and Sales Quarter to match the year and quarter of the data upload file. -Click the Select button to navigate to the location of the manufacturer data file on your computer. Selecting the file will start the upload immediately. -Click the Analyze Data button. -The Data Upload Analysis page shows the file statistics for the upload, the number of rows inserted into the database, and the number and type of errors. Upon clicking the Process Files button, the system processes and loads the records and displays the Processing Upload page is displayed. Click the click here link to return to your dashboard.
2548	11/01/2019	340B Database Technical Assistance	OPAIS-Pricing	How does a manufacturer manually upload the quarterly 340B pricing data?	<p>Select the Manufacturer Quarterly Data Processing > Manually Enter Product Data option.</p> <p>The Manual Product Data Entry List is displayed.</p> <ul style="list-style-type: none"> -Selecting a link from the National Drug Code column displays the Product Data Entry page for that NDC. -NDC, product name, labeler code and manufacturer name will be populated by the system. -Enter AMP, URA, PS and CSP in the respective fields or accept HRSA prepopulated fields. -Raw 340B ceiling price and package adjusted price are calculated by the 340B OPAIS pricing component. -Accept data to save your entries.
2549	11/01/2019	340B Database Technical Assistance	OPAIS-Pricing	For manufacturers, what are the steps to access and correct a reconciliation task in OPAIS for ceiling price data?	<ul style="list-style-type: none"> -Select the Task Listing option. -The Tasks Assigned to Manufacturer listing is displayed, showing all tasks assigned to you. Select the link for an NDC to edit its data points. -Selecting an NDC displays the product page with all Manufacturer data points displayed. Only Package Size, Case Package Size, and corresponding Ceiling Price (if it can be calculated) are displayed under HRSA Data Points. -Make changes and enter notes to applicable areas. -Do one of the following: <ul style="list-style-type: none"> (1) Accept data to save your entries. (2) Click No Changes if you do not have enough information to reconcile the record or, (3) Click cancel to return back to you task list.

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2550	11/01/2019	340B Database Technical Assistance	OPAIS-Pricing	What is the product search on the manufacturer dashboard?	A search option to locate a particular product. The product search page displays NDC, ceiling, price, package adjusted price, and flag. Upon clicking on an NDC, the product details page is displayed.
2551	11/01/2019	340B Database Technical Assistance	OPAIS-Pricing	Why am I required to log into the 340B OPAIS pricing system when I am already logged in to my OPAIS user account?	The 340B OPAIS requires a separate login for access to pricing data for security purposes, even if you are already logged in as an AO or PC on the 340B OPAIS registration system. The pricing system will prompt you to log in, authenticate, and agree to the Rules of Behavior again. Important tip: Bookmark the pricing database log in page to avoid having to log into 340B OPAIS twice.
2552	11/01/2019	340B Database Technical Assistance	OPAIS-Pricing	Do I need to create a new, separate, username and password for the 340B OPAIS pricing system?	No, the approved AO/PC will use the same username and password used to log into the 340B OPAIS registration system.
2555	11/01/2019	340B Database Technical Assistance	OPAIS-Pricing	Is there a limit on how many price files a manufacturer can upload during the quarterly submission timeframe?	No, if the manufacturer determines there is an error in the initial uploaded file they may continue to upload corrected files during the 2-week submission timeframe. Once the submission deadline occurs, manufacturers will no longer be able to upload corrected files. Note: if the manufacturer reconciled any price discrepancies on the initial uploaded file and that product data has changed within the newly uploaded file, the completed reconciliation tasks will not be saved and will require the AO/PC to complete this task again.
2560	11/01/2019	340B Database Technical Assistance	OPAIS-Pricing	What constitutes a "discrepancy" in pricing data?	If there is a discrepancy in the pricing data, a notification would be emailed to the manufacturer for reconciliation that one of the five pricing data points (i.e. AMP, URA, package size, case package size, and the 340B Ceiling price) HRSA has listed in the pricing component of 340B OPAIS does not match what was uploaded by the manufacturer.
2562	11/01/2019	340B Database Technical Assistance	OPAIS-Pricing	I am a manufacturer needing technical assistance, where can I obtain assistance?	Please review HRSA's 340B OPAIS web page (https://www.hrsa.gov/opa/340b-opais/index.html) for general information and tutorials. If you need further assistance, please contact the HRSA 340B Prime Vendor Program at (888) 340-2787 or ApexusAnswers@340bvp.com . The 340B Prime Vendor will escalate any issues to HRSA if they are unable to resolve.
2563	11/01/2019	340B Database Technical Assistance	OPAIS-Pricing	Is each manufacturer limited to uploading one instrument file and including all labeler codes in that file?	Manufacturers may upload multiple times during the open period. Manufacturers may upload all of their labeler codes/products in one file or by each individual labeler/product. Manufacturers may also upload instrument files to correct reconciliation tasks. The 340B OPAIS will accept new values for each instrument file upload.
2564	11/01/2019	340B Database Technical Assistance	OPAIS-Pricing	Who can perform pricing uploads and any requests for reconciliation?	Only the Authorizing Official (AO) or Primary Contact (PC) listed for each labeler code in 340B OPAIS may perform the pricing upload, a complete the reconciliation process, and submit to OPA for review. The AO for a manufacturer labeler code record is an individual who can legally bind the company to the terms of the Pharmaceutical Pricing Agreement and is delegated the authority to perform tasks on behalf of the manufacturer (usually of the CEO/CFO/VP/SVP/Executive Director title). The PC is an employee of the manufacturer. Consultants are not authorized to be listed an AO or PC of a manufacture labeler code record. It is up to each manufacturer to ensure they have the right organizational personnel listed for each labeler code.
2565	11/01/2019	340B Database Technical Assistance	OPAIS-Pricing	How many personnel can be on a manufacturer labeler code record?	Due to security concerns, only one Authorizing Official and Primary Contact can be listed for each labeler code record. HRSA recommends that these be two separate individuals.
2568	11/01/2019	340B Database Technical Assistance	OPAIS-Pricing	How do I access the 340B OPAIS Pricing Component?	Authorized officials and primary contacts of a manufacturer may access the pricing component of the 340B OPAIS via secured web link https://340bpricingsubmissions.hrsa.gov and authorized covered entities may access the 340B OPAIS Pricing System via secured web link https://340bpricing.hrsa.gov . Access via the pricing icon on the standard participant registration link is also available for those with a an approved user account at https://340bopais.hrsa.gov/

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2569	11/01/2019	340B Database Technical Assistance	OPAIS-Pricing	What if a manufacturer notices a pricing discrepancy post 340B OPAIS publishing of prices for the quarter?	Manufacturers are to communicate any price discrepancies after publication to 340Bpricing@hrsa.gov. Please include the manufacturer name, contact information, labeler code, 11 digit NDC, and price discrepancy in your communication.
2570	11/01/2019	340B Database Technical Assistance	OPAIS-Pricing	Can a manufacturer or covered entity export the ceiling or package adjusted prices from 340B OPAIS?	Manufacturers and covered entities are not able to export ceiling or package adjusted prices. HRSA excludes an export feature as part of its security measures due to the sensitive nature of the information. Each time a registered user logs-into 340B OPAIS, they are required to attest to a set of rules of behavior, including adhering to the prohibition against unauthorized re-disclosure of data.
2571	11/01/2019	340B Database Technical Assistance	OPAIS-Pricing	Why would a manufacturer use an uploaded instrument file versus using the manual entry method for pricing uploads?	Most labeler codes in 340B OPAIS have 10 or less NDC's per labeler code. In these cases it maybe more burdensome to create a .txt instrument file for submission than perform a manual entry. Several manufacturers with a greater number of NDC's, may prefer to submit a .txt pricing instrument file in the required HRSA file format to prevent a lengthy manual entry process. A manufacturer may choose a combination of both processes.
2572	11/01/2019	340B Database Technical Assistance	OPAIS-Pricing	Can a Manufacturer or multiple labeler codes submit one file for all its labeler codes?	Each manufacturer authorizing official and primary contact can only upload files for which they have approved accounts. If assigned multiple labeler codes the AO or PC may submit one instrument file to cover all labeler codes.
2573	11/01/2019	340B Database Technical Assistance	OPAIS-Pricing	Can the Authorizing Official or Primary Contact for an inactive or terminated labeler code see 340B OPAIS pricing data?	No. Only approved authorizing officials and primary contacts for an "active" 340b labeler code or covered entity record may see pricing information.
2575	11/01/2019	340B Price/Drug	340B Price	What is Manufacturer "reconciliation" as it relates to pricing upload?	Manufacturer reconciliation is requested when any of the five data points are different than what HRSA has preloaded into 340B OPAIS. Products are assigned reconciliation tasks when one or more data point is different from one or more data points that is not consistent with what HRSA has on file. A manufacturer may choose to accept OPA loaded data or select to load new data points. If new data points are loaded, 340 OPAIS requires a reason explaining the difference. Failure to reconcile data will prompt 340B OPAIS to reject the uploaded data points.
2576	11/01/2019	340B Database Technical Assistance	OPAIS-Pricing	Can manufacturers who voluntarily participate in the 340B program (are not in CMS MDRP) submit pricing data?	No. Currently, 340B OPAIS does not allow voluntary uploading of 340B pricing data.
2579	11/01/2019	340B Database Technical Assistance	OPAIS-Pricing	How long will manufacturers have to load pricing data?	Each quarter manufacturers will receive approximately two weeks to perform their portion of pricing data upload.
2580	11/01/2019	340B Database Technical Assistance	OPAIS-Pricing	Does a manufacturer have to perform the pricing load all in one session?	No. A manufacturer may log in and out of the 340B OPAIS Pricing system as many times as needed to complete the loading/reconciliation tasks during the open uploading period.
2581	11/01/2019	340B Database Technical Assistance	OPAIS-Pricing	Can a manufacturer change the authorizing official or primary contact during the open pricing load period?	Yes. A manufacturer may submit a change request at any time during this process. Once approved by OPA the change is effective in real time and the new authorizing official or primary contact will have access to 340B OPAIS. Educational resources/tutorials on how to create a user account and submit an online change request can be found here https://www.hrsa.gov/opa/340b-opais/index.html .

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2582	11/01/2019	340B Database Technical Assistance	OPAIS-Pricing	If my labeler code is licensed to sell only a few NDCs of another labeler code; how can I report pricing for the selected NDCs in the 340B OPAIS pricing component?	For the purposes of 340B OPAIS, every labeler code has the capability to have only two users: one Authorizing Official (AO) and one Primary Contact (PC). The AO must be able to legally bind the labeler in a relationship with the Federal Government. The PC must be able to reasonably demonstrate an affiliation with the labeler for reporting purposes. Users in 340B OPAIS will have access to the entire labeler code. The pricing component is labeler specific, not NDC specific. Therefore, a manufacturer and the labelers for whom that manufacturer sells certain NDC's, would need to work together to determine who will report the pricing, knowing that users listed under that labeler would have access to view pricing for the entire labeler code. If no pricing is submitted for certain NDC's, HRSA will default to the information that was reported to CMS.
2584	11/01/2019	340B Database Technical Assistance	OPAIS-Pricing	From the covered entity view, if there is a blank field for the published ceiling price in 340B OPAIS, please explain why this occurs.	If a blank field appears in 340B OPAIS for the 340B ceiling price, it could mean that the product was inactive/expired at the time it was published in 340B OPAIS or that not all of the data points to calculate either price were available at the time of publication in 340B OPAIS.
2653	11/01/2019	Policy/Implementation	GPO Prohibition	May a Hemophilia Treatment Center (HTC) that is part of a hospital participate in a GPO for outpatient drugs?	<p>The answer depends on how the HTC is registered with respect to the hospital.</p> <p>If the HTC is otherwise an eligible entity and registered as such (with a 340B identification number beginning with HM), then it is not subject to the GPO prohibition and may purchase covered outpatient drugs through a GPO arrangement through its HTC 340B ID and account. This is true whether the HTC is within the four walls of a parent hospital subject to the GPO prohibition or located at an off-site outpatient clinic of a hospital subject to the GPO prohibition. However, in no circumstances may a hospital use the HTC's GPO to circumvent the GPO prohibition.</p> <p>If the HTC is not registered for the 340B Program as a child site of the hospital, it may use a GPO for covered outpatient drugs provided that it meets all of the following: 1. Is located at a different physical address than the parent; 2. Is not registered on the 340B OPAIS as participating in the 340B Program; 3. Purchases drugs through a separate pharmacy wholesaler account than the 340B participating parent; and 4. The hospital maintains records demonstrating that any covered outpatient drugs purchased through the GPO at the HTC are not utilized or otherwise transferred to the parent hospital or any outpatient facilities registered on 340B OPAIS.</p>
2656	11/01/2019	Eligibility/Registration	Outpatient Facility	How should a grantee covered entity determine if a clinic is eligible and should be added to 340B OPAIS?	Clinics that want to purchase 340B drugs for their eligible patients must be included in the grantee's scope of grant and meet the statutory requirements for the entity type for which it is registering.
1191	10/24/2019	Policy/Implementation	Purchasing/Inventory/Reimbursement	When a product's manufacturer changes the NDC (same manufacturer for the old and new NDC and same product) may we replenish the old NDC with the new NDC as long as we keep records?	If a replenishment model is utilized, then it is recommended that the covered entity accumulate 340B purchases for the exact NDC-11 (i.e., NDC and manufacturer) that was originally based on a 340B-eligible patient. The covered entity should have auditable records to demonstrate accumulation in a replenishment model. New products purchased as a new NDC will begin a new replenishment. Manufacturers and covered entities have worked together on mutually agreed to practices, and kept written auditable records.
1662	08/16/2019	340B PVP	Membership	Will our facility need to add extra staff members to implement the Prime Vendor Program?	Prime Vendor Program participation does not require additional staff. However, many 340B entities identify resources needed to provide adequate oversight of 340B Program implementation.
1555	07/29/2019	Contract Pharmacy		If our contract pharmacy has been purchased by another pharmacy, do we need to update our records with OPA?	<p>If a contract pharmacy has changed ownership, HRSA considers this to be a new contract pharmacy arrangement. The covered entity must have a written contract in place with the new contract pharmacy and register the contract pharmacy arrangement on 340B OPAIS prior to use. Covered entities must complete the online portion of the contract pharmacy registration process during an open registration period. For instructions on how to register a contract pharmacy please refer to the user guide under the "Help" section in 340B OPAIS.</p> <p>The covered entity must also terminate the contract pharmacy relationship established under the previous owners. To effectuate the termination, complete an online termination request. Failure to report a change in ownership may result in a lapse in 340B access through the specific contract pharmacy.</p> <p>Failure to report a change in ownership may result in a lapse in 340B access through the specific contract pharmacy.</p>

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1625	06/13/2019	340B PVP	Pricing	Can I access the Apexus Prime Vendor Program's discounted pricing on pharmaceuticals and other services without using the distribution agreements?	No, a covered entity must use the Apexus PVP's distribution agreements to access the program's pricing on products and services. Accessing the PVP's distribution agreement is required to ensure authorized distributors appropriately report all participants' sales to the PVP. All participants' purchases are leveraged to secure additional discounts on products with suppliers. If a covered entity has negotiated a distribution fee with its current distributor that is lower than the PVP distributor agreement, the fee will be "grandfathered" under the existing PVP distributor agreement to ensure the covered entity maintains any individually negotiated discounts.
2607	05/01/2019	340B Database Technical Assistance	OPAIS-Pricing	I use an indirect distribution model and never sell directly to covered entities. I only sell to wholesale distributors in cases of several units. What case package size should I include for my submission to 340B OPAIS?	The package adjusted price is intended to provide a meaningful purchase price in the marketplace; therefore the case pack size should be the minimum purchase amount a single purchaser could buy. For example, a bottle of 100 tablets would have a package size of 100 and case size of 1. Another example is a case where a pack of 10 mL vials is only sold to covered entities in trays of 25. In this case, assuming the AMP is reported in mLs, the package size is 10 and the case package size is 25.
2608	05/01/2019	340B Database Technical Assistance	OPAIS-Pricing	What Case Package Size should I report to 340B OPAIS?	The package adjusted price is intended to provide a meaningful purchase price in the marketplace; therefore the case package size should be the minimum purchase amount a single purchaser could buy. For example, a bottle of 100 tablets would have a package size of 100 and case size of 1. Another example is a case where a pack of 10 mL vials is only sold to covered entities in trays of 25. In this case, assuming the AMP is reported in mLs, the package size is 10 and the case package size is 25.
2612	05/01/2019	340B Database Technical Assistance	OPAIS-Pricing	As a covered entity, how can I search for product prices – what are the searchable fields?	Covered entities can search by NDC. Covered entities may also locate information from the list of all drugs in the 340B OPAIS pricing component by filtering the following column headings: National Drug Code), Product Name, Manufacturer, Market Date, Ceiling Price, Package Adjusted Price, or Flag.
2679	05/01/2019	340B Price/Drug	340B Price	Do I need to report pricing information for a product that will be terminated during the effective quarter?	Yes. If the product is listed on the CMS Medicaid Drug Rebate Program drug product file, and will be active for any days during the effective quarter, a manufacturer should report pricing data for that product. If the product will be terminated prior to the effective quarter, the product will not show a published 340B ceiling price.
2680	05/01/2019	340B Price/Drug	340B Price	How will an NDC with a 340B ceiling price calculation of less than \$0.01 (penny priced drugs) display on the 340B OPAIS pricing component?	For purposes of the pricing component of the 340B OPAIS, the system will display a raw ceiling price (average manufacturer price (AMP) minus the unit rebate amount (URA), before it is rounded to two decimals), in addition to the rounded two decimal ceiling price. In cases where the raw ceiling price is less than \$0.01; only the two decimal value will display. HRSA recognizes that this exception may result in a package adjusted price higher than wholesale acquisition cost in some cases where AMP is reported in small units, and the package size has a large number of units. However, the 340B Ceiling Price and Manufacturer Civil Monetary Penalties Final Rule (Final Rule) (82 FR 1210, January 1, 2017) states that the \$0.01 will be used per unit in these cases. Example: Exception When the 340B Ceiling Price is Less than \$0.01 AMP is 0.874526 URA is 0.866926 Package size is 100 mLs Case package size is 6 vials per carton Raw ceiling price equals (0.874526 - 0.866926) or 0.007600 Since this value is less than \$0.01 it will round up to 0.01 per unit. \$0.01 will display as the ceiling price and will be used in the package adjusted price calculation. Package adjusted price equals 0.01*100*6 or \$6.00
2681	05/01/2019	340B Price/Drug	340B Price	As a manufacturer, we offer sub ceiling prices for some of our products. Will the 340B OPAIS pricing component reflect the pricing submitted by the manufacturer that are lower than the calculated 340B ceiling price?	No. HRSA is required to publish the 340B ceiling price calculated as described in the statute and 340B Ceiling Price & Civil Monetary Penalties Final Rule (the Final Rule). Manufacturers may offer sub-ceiling prices and notify wholesalers and covered entities of these prices outside of the 340B OPAIS pricing component.

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2684	05/01/2019	340B Price/Drug	340B Price	What does Case Package Size (CSP) represent?	<p>CSP is the number of salable units in a shipping container that an individual purchaser could procure (what a covered entity could purchase rather than what a wholesaler would receive from a manufacturer).</p> <p>The package adjusted price is intended to provide covered entities a meaningful purchase price in the marketplace, therefore the case package size should be the minimum purchase amount a single purchaser could buy. For example, a bottle of 100 tablets would have a package size of 100 and case size of 1. Another example is a case where a pack of 10 mL vials is only sold to covered entities in trays of 25. In this case, assuming the AMP is reported in mL, the package size is 10 and the case package size is 25.</p>
2685	05/01/2019	340B Price/Drug	340B Price	What does the raw ceiling price represent?	The raw ceiling price is the average manufacturer price (AMP) minus the unit rebate amount (URA), before it is rounded to two decimals.
1349	04/08/2019	Policy/Implementation	Purchasing/Inventory/Reimbursement	Can a 340B covered entity transfer 340B drugs to another 340B covered entity site, if both are part of the same healthcare system?	<p>No. A 340B covered entity is prohibited from transferring 340B drugs to anyone other than a patient of that covered entity. Accordingly, one 340B covered entity cannot transfer a 340B drug to patients of a different covered entity. Under the statute, health care delivery systems to which an eligible 340B covered entity may belong are not included in the statute as eligible entities. For more information, please review OPA Accountable Care Organizations Policy Release, 2012-02, available at: http://www.hrsa.gov/opa/programrequirements/policyreleases/accountablecare05232012.pdf</p>
2652	03/12/2019	340B Database Technical Assistance	OPAIS-Pricing	We have heard about the publishing of the package adjusted price in OPAIS Pricing system, but I do not see this in the system currently. Why isn't the package adjusted price published?	<p>HRSA has decided to focus on the publication of verified ceiling prices for the first quarter. Therefore, due to the complexities raised through the manufacturer submission process, HRSA will not publish a package adjusted price on April 1, 2019. HRSA plans to continue its efforts with manufacturers in improving the data related to package size and case pack size.</p> <p>In the pricing component of the 340B OPAIS, covered entities will be able to view the published 340B ceiling price at the unit level. Until such time that HRSA determines the publication of additional information related to package is as accurate as possible, covered entities should consult other sources of information to obtain package size and multiply the ceiling price by that value. Other sources may include wholesaler catalogues, FDA searchable NDC directory and the 340B Prime Vendor secure website (for prime vendor participants).</p>
2597	02/06/2019	340B Price/Drug	340B Price	For new drugs, will HRSA allow manufacturers to apply a different estimation than the methodology set forth in the 340B Ceiling Price and Civil Monetary Penalties final rule, which sets the estimated calculation of a new drug as wholesale acquisition cost minus the appropriate rebate percentage?	Manufacturers are required to comply with the estimation methodology as set forth at 42 CFR10.10(c) (82 FR 1210, January 5, 2017). The new drug price estimation, strikes a balance between ensuring that manufacturers have a standard methodology for estimating the 340B ceiling price of a new covered outpatient drug, while also ensuring that covered entities receive the 340B ceiling price on new covered outpatient drug purchases. HRSA notes that while this methodology for estimating the 340B ceiling price is required, it only needs to occur as long as an average manufacturer price (AMP) is not available. As soon a manufacturer knows the AMP, it can calculate and begin offering the actual 340B ceiling price and only refund for the time-period when the estimation occurred.
1539	01/10/2019	Policy/Implementation	Audit/Compliance	How does HRSA define the term "breach" that is used in the recertification statements? (Ref: "the covered entity acknowledges its responsibility to contact OPA as soon as reasonably possible if there is a change in 340B eligibility and/or breach by the covered entity of any of the foregoing...")	The term breach in this context refers to an instance of non-compliance with any of the 340B Program requirements. The covered entity upon recertification attests to contact OPA when there is a breach of 340B requirements. To increase program transparency among all stakeholders and ensure that covered entities can rely on a reasonable threshold to guide consistent and effective self-disclosure decision-making, it is recommended that covered entities define "material breach" for their organizations and establish a process for self-disclosure in their policies and procedures. For more information visit: https://www.hrsa.gov/opa/self-disclosures/self-disclosure.html

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2337	01/10/2019	340B Price/Drug	Manufacturer	How does a manufacturer submit a PPA Addendum?	<p>There are three methods for submission of a PPA Addendum to HRSA OPA.</p> <p>A. Manufacturers, as part of a new labeler registration, will be required to submit an online PPA and PPA Addendum as part of the registration process for HRSA OPA to review.</p> <p>B. Electronic Submission. The manufacturer will fill out the PPA Addendum PDF version, print, sign, and email back this signed version to HRSA OPA at 340bpricing@hrsa.gov . HRSA OPA will route this electronic version through its internal processes to get concurrent HRSA Signature and return an electronic copy of the signed document to the listed Authorizing Official and Primary Contact for the manufacturer's records.</p> <p>C. By mail via wet ink submission. A manufacturer may fill out the PPA Addendum PDF version, print, sign, and mail into HRSA OPA two wet ink PPA Addenda. HRSA OPA will route this wet ink version through its internal processes to get concurrent HRSA Signature and return a wet ink copy to the listed address on the PPA form for the manufacturer's records.</p> <p>Mailing Address:</p> <p>Health Resources and Services Administration Office of Pharmacy Affairs 5600 Fishers Lane, 8W03A Rockville, MD 20857</p>
1624	09/10/2018	340B University	Attendance	Can you hold a 340B University specifically for our group?	<p>We set our event schedule approximately 6 months to 1 year in advance. Please provide all the information pertaining to your request in writing to ApexusAnswers@340Bpvp.com.</p>
1644	09/10/2018	340B University	Attendance	What topics are covered at 340B University?	<p>340B University is an in-depth educational program designed for all 340B stakeholders to learn 340B compliance from industry and entity experts. Topics covered in the training include fundamentals in implementing a compliant pharmacy program from basics to drug pricing and hands on training with tools and resources available to assist with program integrity. Additional topics include audits and the GPO Prohibition. CE credit is available for pharmacists and pharmacy technicians.</p>
1445	11/27/2017	340B Database Technical Assistance	Change Form	How can a manufacturer update contact information in the 340B OPAIS?	<p>A manufacturer can update its Authorizing Official and/or Primary Contact information in the 340B OPAIS by submitting a manufacturer change form. You must be logged in as either the Authorizing Official or the Primary Contact. For help on how to submit a change request, the logged in user can refer to the user guide located in the "Help" section on 340B OPAIS.</p>
1449	11/27/2017	340B Database Technical Assistance	Navigation/Use	What is the appropriate billing address to use for covered entities?	<p>Covered entities are responsible for ensuring the "bill-to" information is up to date and accurate in the 340B OPAIS. The billing address is a location where the wholesalers and manufacturers send invoices for purposes of services rendered, products tendered, or financial statement receipt. Covered entities must maintain ownership and financial responsibility for all drugs purchased through the 340B Program. A billing address can be a P.O. Box.</p>
1525	11/27/2017	340B Database Technical Assistance	Change Form	How can a covered entity update its Authorizing Official in the 340B OPAIS?	<p>The new AO must be fully authorized to legally bind the covered entity. All AO change requests must be approved by OPA. The AO will need to create a user account in 340B OPAIS. Use the Covered Entity Search function to locate the desired covered entity. View the covered entity details and click the Change button for the Authorizing Official. The entity's details are displayed with the user's contact information populated in the Requestor Information section. The AO will then attest to the change and submit it to OPA for approval.</p>
1693	11/27/2017	Recertification		We received recertification materials from HRSA, but no longer plan to participate in the 340B Program. How should a covered entity notify HRSA it does not want its recertification to be processed?	<p>If the recertification period has not yet begun, the PC/AO can prepare an online termination request to terminate the entity from the 340B Program. If the recertification period has begun, the PC/AO can request the entity's decertification from the 340B Program during the recertification process.</p>

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2442	09/18/2017	340B Database Technical Assistance	Navigation/Use	How do I log into 340B OPAIS?	<p>For authorized users with an existing account in 340B OPAIS, you can use the following steps to log into 340B OPAIS:</p> <ol style="list-style-type: none"> 1. Click "Login" in the top menu of the 340B OPAIS homepage or click the "I Am a Participant" icon. 2. Type your email address and password in the spaces provided. 3. Click "Sign In." <ol style="list-style-type: none"> a. If your login credentials are correct and you have an active account, the system will display the "Two-Step Authentication" page and send you an email containing a 6-digit authorization code. 4. Copy the authentication code from that email, paste it in the "Code" text box 5. Click "Submit Code." 6. The system will prompt you to agree to the "340B OPAIS Rules of Behavior." 7. Click on the checkbox next to the acknowledgement of responsibilities statement. 8. Click "Agree" or "Cancel" button. <p>These steps can be found in the 340B OPAIS Public User Guide on the 340B website: https://www.hrsa.gov/opa/files/publicuserguide.pdf</p>
2381	07/14/2017			What is the effective date of the 340B Ceiling Price and CMP Regulation?	The effective date for the 340B Ceiling Price/CMP regulation is October 1, 2017.
1196	04/10/2017	Policy/Implementation	Purchasing/Inventory/Reimbursement	Can a wholesaler load a GPO Private Label product in the WAC account at a WAC price?	No. The GPO private label product is not permitted to be loaded into the Non-GPO WAC or 340B accounts.
1357	01/12/2017	340B Price/Drug	340B Price	How should a covered entity resolve an incorrect ceiling price?	<p>Covered entities should work directly with manufacturers and wholesalers to validate whether the price paid was at or below the 340B ceiling price. Prime Vendor participants can verify pricing accuracy by visiting the password-protected Prime Vendor Program website. HRSA can validate whether the price paid by the covered entity was at or below the 340B ceiling price. The covered entity should send a spreadsheet including the NDC and price paid (including a total) for each drug. The covered entity should also submit invoices to substantiate the price paid. The request must come directly from the covered entity. Please send this request to: Josh Hardin, US Public Health Service, Health Resources and Services Administration, Office of Pharmacy Affairs, 5600 Fishers Lane, Mail Stop 08W05A, Rockville, MD 20857 or jhardin@hrsa.gov.</p> <p>If the covered entity has verified an overcharge has occurred and is unable to resolve the matter with the manufacturer, the covered entity should follow the dispute resolution process, available at: http://www.hrsa.gov/opa/programrequirements/federalregisternotices/disputeresolutionprocess121296.pdf</p>
2345	11/07/2016	340B Price/Drug	Manufacturer	What is the Effective date of the PPA Addendum?	The effective date of the PPA Addendum is the date it is signed by the manufacturer.
2332	11/03/2016	340B Price/Drug	Manufacturer	What is the purpose of the PPA Addendum?	<p>Section 340B(a)(1) of the Public Health Service Act (PHS Act) provides that the Secretary of Health and Human Services (the Secretary) will enter into a pharmaceutical pricing agreement (the Agreement) with each Manufacturer of covered outpatient drugs in which the Manufacturer agrees to charge a price for covered outpatient drugs that will not exceed the average Manufacturer price decreased by a rebate percentage. Section 7102(b) of the Affordable Care Act amended section 340B(a)(1) of the PHS Act to add two new requirements for inclusion in the Agreement with the Manufacturer:</p> <p>A. The Agreement "shall require that the Manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient 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"; and</p> <p>B. The Agreement "shall require that the Manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price."</p> <p>The purpose of the PPA Addendum is to include these new requirements as part of the originally signed Pharmaceutical Pricing Agreement (the "Agreement") between the Secretary and the Manufacturer.</p>
2343	11/03/2016	340B Price/Drug	Manufacturer	How can a manufacturer get further information on the PPA Addendum?	Please send any questions to the 340B Prime Vendor Program at 1-888-340-2787, or by sending an e-mail to ApexusAnswers@340bpvp.com .

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2198	10/28/2015	Policy/Implementation	GPO Prohibition	A 340B covered entity purchases a covered outpatient drug in the non-GPO/WAC account, and it is sold by a distributor or other third party at a price that is less than the list or WAC price, as published by First Databank, Medispan, or other official compendium. Would this entity's purchase of these covered outpatient drugs be considered a violation of the GPO Prohibition?	Yes.
2206	10/16/2015	Policy/Implementation	Orphan Drugs	Since the court ruling on the orphan drug exclusion on October 14, 2015, what actions should my rural hospital take?	The court ruling is available here: https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2014cv1685-29 . Covered entities subject to the orphan drug exclusion should consult legal counsel, and HRSA will publish additional details as they become available.
2207	10/16/2015	Policy/Implementation	Orphan Drugs	To whom does the orphan drug exclusion apply?	The exclusion of drugs with orphan indications applies to free-standing cancer hospitals, rural referral centers, sole community hospitals, and critical access hospitals. The exclusion does not apply to covered entities that meet the 340B Program eligibility requirements and are enrolled under sections 340B(a)(4)(A) through 340B(a)(4)(L) of the PHSA or to a children's hospital described in section 340B(a)(4)(M). Furthermore, if a hospital potentially qualifies under more than one section, such as a 340B(a)(4)(L) disproportionate share hospital and 340B(a)(4)(O) sole community hospital, the hospital selects under which enrollment type it chooses to qualify. During the registration and annual recertification processes, a covered entity certifies that it meets the requirements for such an enrollment type.
2209	10/16/2015	Policy/Implementation	Orphan Drugs	Is the orphan drug list from FDA dosage form-specific (in other words, does the designation apply to ALL of the sponsor's NDCs of the chemical name or just one specific dosage form?)	FDA does not designate orphan drugs for approval by dosage form. FDA confirmed it provides a designation and marketing approval for orphan drugs based on condition. There may be multiple NDCs from one sponsor tied to an individual orphan designation.
2210	10/16/2015	Policy/Implementation	Orphan Drugs	What is an orphan drug?	A drug is designated by the FDA as "a drug for a rare disease or condition" pursuant to section 526 of the FDCA at the request of the sponsor, if FDA finds that the drug is being or will be investigated for a rare disease or condition and, if approved by FDA, the approval will be for that disease or condition. 21 U.S.C. 360bb(a)(1). This designation is referred to as orphan-drug designation. 21 CFR 316.24. The orphan drug designation provides a number of incentives for the development of the orphan drug for the particular disease or condition.
2211	10/16/2015	Policy/Implementation	Orphan Drugs	Our rural hospital participates in the 340B program and carves-in Medicaid. How should we handle not being able to purchase orphan drugs at a 340B price, when we have stated we bill Medicaid for 340B drugs? Orphan drugs are not covered outpatient drugs for us as a 340B entity, but Medicaid still views them as a covered outpatient drug. Must we carve-out?	Covered entities and states should work together in good faith to ensure duplicate discounts to do not occur.
1561	04/15/2015	340B Database Technical Assistance	Change Form	Who is permitted to submit change requests on behalf of the covered entity?	A representative of the 340B covered entity may complete the online change request form to change names, addresses, and contact information. However, all requested changes will be forwarded to the covered entity's Authorizing Official for acceptance prior to HRSA review. The Authorizing Official has 15 calendar days after submission to accept or cancel the change request. On calendar day 16, if no action has been taken the request will be cancelled automatically.
1194	01/08/2015	Eligibility/Registration	Covered Entity	Where can one find a hospital's disproportionate share adjustment percentage?	The disproportionate share adjustment percentage can be found on the hospital's most recently filed Medicare Cost Report in Worksheet E Part A, line 33. CMS is the official source used to verify a hospital's disproportionate share adjustment percentage.

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1352	12/10/2014	Policy/Implementation	GPO Prohibition	For hospitals subject to the GPO prohibition and using a replenishment model, what accounts should be used to purchase the actual physical inventory (on the shelves)?	The accumulation for specific accounts is based upon 340B patient eligibility status, and the hospital must maintain auditable records of its policies, procedures, and transactions. HRSA recognizes that the variety of patient eligibility status categories accumulate to produce corresponding virtual inventories. These accumulations will eventually produce replenishment orders that result in a physical inventory in the mixed-use area that is composed from a variety of contract purchases. Hospitals must maintain auditable records showing that the virtual accumulations are based upon documented 340B patient eligibility status categories.
1335	11/19/2014	Policy/Implementation	Purchasing/Inventory/Reimbursement	When a product is purchased by a new manufacturer, the NDC changes. May we replenish the old NDC with the new NDC (it is not a 9 digit match)?	No. New products purchased as a new NDC will begin a new replenishment. The entity shall not replenish the old NDC with a new or different NDC.
1198	11/11/2014	340B Price/Drug	340B Price	Does the HRSA Office of Pharmacy Affairs have the authority to exempt a drug from 340B pricing?	No. OPA does not have the authority to exempt a drug from 340B pricing requirements.
1272	11/11/2014	340B Price/Drug	340B Price	What is the 340B Program?	The 340B Drug Pricing Program is a federal program that requires drug manufacturers participating in the Medicaid drug rebate program to provide covered outpatient drugs to enrolled "covered entities" at or below the statutorily-defined ceiling price. This requirement is described in Section 340B of the Public Health Service Act and codified at 42 USC 256b. The purpose of the 340B Program is to permit covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992). Please see: http://www.hrsa.gov/opa/eligibilityandregistration/index.html for additional information and a complete list of covered entity types. Participating covered entities report savings that range between 25-50% of Average Wholesale Price (AWP) for covered outpatient drugs as a result of 340B discounts.
1337	11/11/2014	340B Price/Drug	Manufacturer	If a manufacturer determines that it charged in excess of the ceiling price to a covered entity, what is the manufacturer required to do?	All manufacturers are required to comply with the statute and all terms of the Pharmaceutical Pricing Agreement, including the obligation to charge covered entities no more than the ceiling price for covered outpatient drugs. HRSA recommends that manufacturers notify the Office of Pharmacy Affairs of the circumstances surrounding the overcharge, results of good faith negotiation, and any refunds issued. Apexus manages the 340B Prime Vendor Program and offers a return service intended to facilitate the return of funds to the entities. The HRSA Office of Pharmacy Affairs expects stakeholders to work in good faith to resolve any overpayments in accordance with standard business practices. If the stakeholders are unable to resolve the issue, the dispute resolution process should be followed: http://www.hrsa.gov/opa/programrequirements/federalregisternotices/disputeresolutionprocess121296.pdf .
1174	11/10/2014	Policy/Implementation	GPO Prohibition	What constitutes a separate wholesaler account, as referenced in the Policy Notice regarding the GPO prohibition?	A "separate pharmacy wholesaler account than the 340B participating parent," means that the child site sets up an account with the pharmacy wholesaler that is distinct from the parent site. The account that is set up would be in the name of the child site but could be paid by the parent via a central bank account.
1186	11/10/2014	Policy/Implementation	Purchasing/Inventory/Reimbursement	Can a 340B covered entity purchase a final 340B replenishment order after the date it loses eligibility?	No. Once the entity is no longer 340B eligible, it may not place orders for 340B drugs.
1204	11/10/2014	Policy/Implementation	Purchasing/Inventory/Reimbursement	How should a 340B covered entity return 340B-purchased product?	The covered entity should communicate to the reverse distributor or wholesaler any returned drugs that were purchased on a 340B contract. The covered entity may need to refer to historical purchasing records to identify 340B transactions. If the covered entity is a hospital, the entity should separately process returns of 340B inventory and inpatient inventory based on the appropriate contract pricing.
1207	11/10/2014	Policy/Implementation	Purchasing/Inventory/Reimbursement	Is using a reverse distributor permissible for 340B drugs?	Using a reverse distributor is permissible for 340B drugs under the following conditions: Auditable records are maintained by the entity of the transaction; A licensed reverse distributor is used; All state laws are followed; All 340B statute and guidelines are followed; The entity is not attempting to use the reverse distribution with the expectations of generating profit on 340B purchased drugs. If the entity has questions, we recommend that you work with the manufacturer directly

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1222	11/10/2014	Policy/Implementation	Purchasing/Inventory/Reimbursement	Can an entity ever replenish at the 9-digit NDC level?	340B covered entities should replenish at the 11-digit NDC level as standard practice. In exceptional circumstances, when 11-digit replenishment is not possible, a covered entity may replenish at the 9-digit NDC level if the covered entity maintains auditable records demonstrating that the appropriate amounts are replenished from the same manufacturer, regardless of the package size. 9-digit NDC replenishment should not be part of standard operations. A covered entity must maintain policies and procedures and auditable records which demonstrate a compliant replenishment model.
1249	11/10/2014	Policy/Implementation	Purchasing/Inventory/Reimbursement	If two different 340B entities are using the same contract pharmacy, would it be considered non-compliance if a patient's visit of both of the entities generates a 340B eligible prescription at one entity, but both entities claim replenishment?	Two different 340B covered entities cannot generate a 340B eligible prescription and claim replenishment for the same drug. Claiming replenishment credit for a drug that has already been given to a 340B eligible patient by another 340B covered entity is diversion. Be advised HRSA has the authority to audit covered entities for compliance with 340B requirements (Section 340B (a)(5)(C) of the PHSA).
1298	11/10/2014	Policy/Implementation	GPO Prohibition	Does the GPO Prohibition apply to covered entity owned pharmacies?	The GPO prohibition applies to covered entity sites which are registered for the 340B Program. The covered entity should not try to circumvent the GPO Prohibition by accessing GPO purchased drugs via an entity-owned pharmacy or contract pharmacy in a 340B registered location. For additional information, please review: The Statutory Prohibition on Group Purchasing Organization Participation Policy Release http://www.hrsa.gov/opa/programrequirements/policyreleases/prohibitionongp participation020713.pdf The covered entity is expected to have written policies and procedures and maintain auditable records demonstrating compliance with all 340B Program requirements.
1315	11/10/2014	Policy/Implementation	GPO Prohibition	The GPO Policy Notice states: "If a GPO prohibition violation occurs at a parent site, all outpatient clinics, contract pharmacies, or sites enrolled that are related to the covered entity 340B ID will be removed from the 340B Program with the parent." What happens if a child site is in violation, but not the parent? Does that mean that the child site will be removed (but not the parent?)	Decisions about removal of child sites and parent sites will be made on a case by case basis.
1336	11/10/2014	Policy/Implementation	Purchasing/Inventory/Reimbursement	We received a pharmacy reimbursement contract from a payer that we feel discriminates against us based upon our status as a 340B entity. Who may we notify about this issue?	There is no statutory provision in section 340B of the Public Health Service Act prohibiting a payer from reimbursing a 340B covered entity at a level that may be different than a non-340B entity. HRSA OPA strongly encourages the covered entity to reach out to the payer to craft an alternative business solution that permits each of the parties to fulfill their goals.
1341	11/10/2014	Policy/Implementation	Purchasing/Inventory/Reimbursement	May a 340B covered entity give unused 340B drugs to another organization?	No. The 340B statute states that covered entities shall not sell "or otherwise transfer" 340B drugs to non-patients. Providing the drugs to an organization for any purpose is diversion and would violate the statute. The prohibition of diversion applies to all 340B drugs, not just the drugs for which the entity charges a fee.
1343	11/10/2014	Policy/Implementation	Purchasing/Inventory/Reimbursement	Must 340B covered entities maintain separate inventories for 340B drugs and other drugs?	The 340B statute and guidelines do not require separate physical inventories for 340B drugs. The statute and guidelines do require covered entities to have fully auditable purchasing and dispensing records that document compliance with all 340B requirements including the prohibition on drug diversion and duplicate discounts. Additionally, please check with the state's board of pharmacy to determine any state requirements regarding separate inventories.
1370	11/10/2014	Policy/Implementation	Purchasing/Inventory/Reimbursement	Can drugs purchased under the 340B program be used with Medicare Part D?	Yes; nothing in the MMA or 340B statutes or guidelines prevents drugs purchased under the 340B pricing program from being used to fill Medicare Part D prescriptions.
1311	11/07/2014	340B Price/Drug	Covered Outpatient Drugs	Must an over-the-counter (OTC) drug be prescribed to be subject to 340B pricing?	Yes. An OTC drug must be prescribed if purchased under the 340B Program. Section 340B(a)(2)(B)(ii) of the Public Health Service Act states "[t]he term 'over the counter drug' means a drug that may be sold without a prescription and which is prescribed by a physician (or other persons authorized to prescribe such drug under State law)."

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1506	11/05/2014	Policy/Implementation	Purchasing/Inventory/Reimbursement	Can an ADAP covered entity request a rebate on a drug that was purchased at or below the 340B ceiling price by another covered entity?	No. An ADAP is not entitled to request a 340B rebate from a manufacturer where the sale of the drug was at or below the 340B ceiling price. It is also necessary for an ADAP to exclude any prescription reimbursements from rebate claims that an ADAP has made to covered entities purchasing drugs at the 340B point of purchase discount.
1405	10/24/2014	340B Database Technical Assistance	Navigation/Use	Can my shipping address be a P.O. Box?	No. The HRSA Office of Pharmacy Affairs (OPA) only allows PO Boxes for Billing Addresses. The Main and Shipping Addresses must be physical addresses and cannot be a PO Box.
1515	10/24/2014	340B Database Technical Assistance	Navigation/Use	Who can or should be listed as the Authorizing Official?	The Authorizing Official represents the covered entity and must be fully authorized to legally bind the covered entity. The Authorizing Official must annually recertify covered entity eligibility, attest to compliance with all program requirements, verify contract pharmacy arrangements, and receive all communications from HRSA regarding the 340B Program, including audit reports. For many non-hospital covered entities, the Authorizing Official is the grantee of record (e.g., Project Director) based upon Federal funding streams. For hospital covered entities, the Authorizing Official is usually the CEO/CFO/COO/President/Vice President or equivalent.
1385	10/21/2014	340B PVP	Membership	What is Apexus' relationship with the HRSA's Office of Pharmacy Affairs (OPA)?	In 2014, HRSA's Office of Pharmacy Affairs awarded a direct contract to Apexus to serve as the Prime Vendor for the 340B Program. The Prime Vendor works closely with the OPA in promoting the 340B Drug Pricing Program and improving access to affordable medications for covered entities and the patients they serve. Apexus routinely reports on the program's progress to the OPA.
1440	10/10/2014	Policy/Implementation	Audit/Compliance	Can you tell me about the HRSA 340B Program audits?	For information on the HRSA 340B Program audits, see the following policy release: http://www.hrsa.gov/opa/programrequirements/policyreleases/auditclarification030512.pdf . Information about the audit scope and process are available on the OPA website at: http://www.hrsa.gov/opa/programintegrity/index.html
1411	10/09/2014	Policy/Implementation	Audit/Compliance	In an audit, is it sufficient to demonstrate compliance through documentation of the procedures for administration of specific drugs or will we be asked to show medical records?	340B covered entities will be audited for all 340B Program requirements, including the maintenance of auditable records. Auditable records include specific documentation that all 340B Program requirements are met for every 340B drug.
1474	10/09/2014	Policy/Implementation	Audit/Compliance	Can a manufacturer audit a covered entity?	Yes, section 340B (a)(5)(C) of the PHS Act allows manufacturers to audit a covered entity to ensure compliance with 340B drug diversion and duplicate discount prohibitions and requires entities to permit manufacturers to audit records related to compliance with these prohibitions. A manufacturer must first attempt to resolve issues in good faith with the covered entity. If good faith efforts fail, the manufacturer must submit an audit work plan and reasonable cause justification to HRSA prior to conducting the audit. For more information, please refer to the 340B Program Policy Release here: http://www.hrsa.gov/opa/programrequirements/policyreleases/manufacturerauditclarification112111.pdf .
1434	08/14/2014	Recertification		Our entity is not prepared to recertify. What can we expect regarding 340B Program eligibility/termination?	Failure to recertify will result in termination from the 340B Program effective on the first day of the next quarter.
1633	05/09/2014	340B PVP	Vaccines	How do I order vaccines through the 340B Prime Vendor Program (PVP)?	The order procedure depends on the vaccine. Flu vaccines are ordered directly through the vaccine manufacturer or authorized specialty distributor. Other vaccines such as hepatitis A or B can be ordered direct from the manufacturer or through your selected pharmacy distributor. This is why it is important to designate your choice of pharmacy distributor when filling out the PVP Participation Agreement.
1685	05/09/2014	340B PVP	Vaccines	Is there a minimum order quantity when purchasing vaccines via the 340B PVP?	With the exception of flu vaccine, there are no minimum purchase quantities when ordering vaccines through the 340B PVP. (See flu vaccines suppliers on the PVP secure website).

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1666	03/14/2014	340B PVP	Membership	If I am a PVP member, does my agreement with Apexus prohibit me from disclosing acquisition cost to a payer such as Medicaid?	The PVP price can be shared with Medicaid programs and their contractors as long as it is not distinguishable from other 340B contracted products. As per the PVP participation agreement, no identification of a PVP contracted item can be included with the PVP price to ensure pricing confidentiality is maintained.
1681	03/07/2014	Policy/Implementation	GPO Prohibition	For hospitals subject to the GPO prohibition and using a replenishment model, should accumulation occur to specific account types based upon patient eligibility status?	Yes. Accumulation should occur for specific accounts based upon patient eligibility status, and the hospital must maintain auditable records of its policies, procedures, and transactions. For example: 1. 340B eligible patients generate accumulation for orders on the 340B outpatient account 2. Inpatients generate accumulation for orders on the inpatient GPO account 3. 340B ineligible outpatients (or situations where 340B is not available) generate accumulation for orders on an outpatient non-GPO (i.e., Non-340B) account. PVP participants may access the PVP's Non 340B contract.
1642	02/10/2014	Policy/Implementation	Patient Definition	What is the HRSA definition of a patient for 340B purposes?	An individual is a patient of a 340B covered entity (with the exception of State-operated or funded AIDS drug purchasing assistance programs) only if: •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. An individual will not be considered a patient of the covered entity if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting. Exception: Individuals registered in a State-operated or funded AIDS Drug Assistance Program (ADAP) that receives Federal Ryan White funding ARE considered patients of the participant ADAP if so registered as eligible by the State program. For more information: Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility (http://www.hrsa.gov/opa/programrequirements/federalregisternotices/patientandentityeligibility102496.pdf)
1587	08/11/2013	340B University	Reference	May I reuse Apexus tools (ex. 340B University tools and resources)?	Use of Apexus tool material is freely granted for individual organization use; please reference Apexus/340B University as the source if you remove the headers/formatting. For use in educational programming involving more than one organization, please contact Apexus Answers to determine the most updated version as well as the appropriateness of use.
1588	08/11/2013	340B PVP	Pricing	Does the Prime Vendor Program negotiate inpatient discounts for its DSH participants?	The PVP does not negotiate inpatient pricing. Its efforts are dedicated to outpatient products and services. Medicare prescription drug legislation has extended Medicaid best price exemption to disproportionate share hospitals' inpatient drug purchases. Previously, the pricing exemption only applied to the disproportionate share hospitals' outpatient drug purchases. The change enables pharmacy manufacturers to voluntarily offer "340B like" pricing to DSHs within their inpatient settings. The DSHs can secure additional discounts on inpatient drugs through their existing GPOs or by negotiating discounts independently with manufacturers.
1590	08/11/2013	340B PVP	Membership	Does Apexus manage the 340B program?	No, HRSA's Office of Pharmacy Affairs manages the 340B Program. Apexus manages the voluntary Prime Vendor Program through a competitive bid awarded by the OPA.
1596	08/11/2013	340B PVP	Membership	Does it cost to join the Prime Vendor Program?	There are no costs to join the Prime Vendor program. The program is funded through nominal fees charged to distributors and suppliers to avoid any costs to the covered entity.

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1608	08/11/2013	340B PVP	Pricing	How long does it take to gain access to the 340B Prime Vendor Program Pricing?	When 340B PVP membership services at Apexus approves your submitted online agreement you will be activated. Activation dates are made on the 1st of every month. Example: If we receive an application between July 1st and 15th, the activation date will be August 1st. If we receive an application between July 16th and 31st, the activation date will be September 1st. You and the pharmacy distributor you selected during the enrollment process will be sent an email advising you of your effective date, as well as additional information on optimizing savings through the PVP.
1638	08/11/2013	340B PVP	Distribution	We are a small wholesaler and would like to offer 340B pricing. What do we do?	Contact the 340B Prime Vendor Program – (888) 340-2787, option 2 – to discuss contracting options. Please be aware of the following issues. The biggest hurdle a small wholesaler has to overcome is setting up the relationships with all the drug suppliers for the 20,000 line items in the 340B price file. They will have to setup chargeback processes and be able to quickly load these prices every quarter. Many small wholesalers may not have the staff or business processes to handle mass loads like this. Also, the small distributors need to have credit lines setup with drug manufacturers to move to a chargeback model rather than a net-30-payment model, which most of them currently use. Another consideration is that the small distributors' sales reps are typically compensated based on variable markups of items sold. The Prime Vendor agreement requires the distributor to offer customers a fixed, negotiated markup per item sold, which may not be consistent with the distributor's current business model and compensation programs. The Prime Vendor aims to protect the customers by ensuring fixed pricing on the products, so the customers know what they should be paying for distribution.
1643	08/11/2013	340B PVP	Membership	How do I complete my Prime Vendor Program participation agreement when my clinic is registered as both a Title X and Section 318 STD funded clinic?	If a clinic is eligible as both Title X and Section 318 STD, you must complete two separate participation agreements. If you need to link these facilities to your profile, please contact Apexus Answers at (888) 340-2787 or ApexusAnswers@340bpvp.com.
1655	08/11/2013	340B PVP	Distribution	What is the protocol for a wholesaler to begin distributing drugs through the 340B program?	There is no application or registration process for wholesalers. We suggest that wholesalers who are interested in distributing drugs through the 340B Program: Contact Apexus at 1-888-340-2787 or email ApexusAnswers@340BPVP.com to become a distributor in the 340B Prime Vendor Program; and contact manufacturers directly to advise them of your plans and to set up chargeback systems.
1671	08/11/2013	340B PVP	Membership	What are the benefits of the 340B Prime Vendor Program to 330 grantees?	The benefits of participating in the 340B PVP include: no cost to participate, access to sub-340B pricing on outpatient covered drugs to lower drug expenditures, access to discounts on other pharmacy products and services, choice of pharmacy distributor, participating ensures compliance with HRSA's 330 grant requirements.
1688	08/11/2013	340B Price/Drug	340B Price	Does the 340B statute prohibit covered entities from disclosing the price for which they purchase 340B drugs.	The 340B statute does not prohibit a covered entity from disclosing the price at which the covered entity purchased 340B drugs. However, the covered entity remains responsible for complying with all other applicable laws.