

## **Responses to Unanswered Chat Questions**

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### 340B and Medicaid

- 1. Can we provide 340B medications to Medicaid clients if we carve out and don't bill Medicaid, or would we need to carve in and bill Medicaid?** Despite your billing practices, an auditor will look to see if your practices match your Medicaid Exclusion File entry. If you intend to use 340B drugs with Medicaid clients—whether you intend to bill Medicaid or not—you should be carved in.
- 2. When carving in how should the product be priced? Is it okay to use the wholesale acquisition cost?** If you have carved in, then you should be purchasing all of your covered outpatient drugs at the 340B ceiling price. When billing Medicaid fee-for-service, you are required to bill at actual acquisition cost, and will sometimes also be paid a professional dispensing fee. You should consult your state Medicaid agency's policies for more information about billing.
- 3. How can I find out if my site is registered as carve in or carve out?** Go to the 340B OPAS database (<https://340bopais.hrsa.gov/>), click on the search button in the middle of the page, and then click on "covered entities." Search for your entity and click on the appropriate record. Near the bottom of the page, there are several tabs you can click on, one of which says "Medicaid Billing." When you click on the Medicaid billing tab, you will see the question, "Will you bill Medicaid for 340B drugs?" with an answer below. If it says "yes," you are carved in. If it says "no," you are carved out.
- 4. If we are carve out and a client with Medicaid managed care needs medication quickly, can we provide 340B?** No. Acting contrary to your chosen carve out status by giving a 340B-priced drug to a Medicaid client will result in a duplicate discount (i.e., the state will collect a rebate on that drug when you have already purchased it at a discounted 340B price). If discovered in an audit, your organization could be required to reimburse the manufacturer the difference between the 340B and non-340B prices on any drugs that were dispensed. If an auditor determines that this is a systematic violation at your organization, you could be required to pay back all of your 340B discounts.
- 5. Should only carve in be placed on the Medicaid Exclusion File? Our organization carves out. There are times when we have a family planning client who has Medicaid, but the provider wants to dispense 340B emergency contraception. Is this okay?** An organization is listed in the Medicaid Exclusion File (MEF) when it has carved in. No entities that are carved out are listed in the MEF. If your organization is carved out, then providing 340B emergency contraception (or any other 340B-priced drug) to a Medicaid client will result in a duplicate discount occurring (i.e., the state will collect a rebate on that drug when you have already purchased it at a discounted 340B price). If discovered in an audit,

your organization could be required to reimburse the manufacturer the difference between the 340B and non-340B prices on any drugs that were dispensed. If an auditor determines that this is a systematic violation at your organization, you could be required to pay back all of your 340B discounts.

- 6. You mentioned that an entity can change its carve out/in designation. Is this a fairly simple process?** An entity can change its designation electronically through the HRSA OPAIS (<https://340bopais.hrsa.gov/home>). It is important to remember that the Medicaid Exclusion File is only updated at the beginning of each calendar quarter. Regardless of when you make the change in the OPAIS system, it will only become effective at the beginning of the following calendar quarter. You should not change your entity's Medicaid carve in/carve out practices until your designation change has become effective.

## 340B Administration

- 7. How can we confirm who is currently listed as the authorized official at our agency that is getting the 340B registration emails?** Go to the HRSA OPAIS website (<https://340bopais.hrsa.gov/home>), click on the search button in the middle of the page, and then click on "covered entities." Search for your entity and click on the appropriate record. Your authorizing official and primary contact are listed there.
- 8. How do you do an external audit?** Apexus, the company that runs the Prime Vendor Program, has many excellent tools available on their website: <https://www.340bpvp.com/education/340b-tools/>), including tools around how to conduct different types of self-audits.
- 9. Where can I find the sample policies and procedures?** All Apexus tools, including the sample police and procedures for family planning entities, are available here: <https://www.340bpvp.com/education/340b-tools/>.
- 10. Would you recommend a separate binder with the policies and procedures specific to 340B?**  
Yes. Having a separate binder with your agency's 340B policies and procedures facilitates easier use for your staff and will be beneficial in the event of a HRSA audit.

## 340B Inventory

- 11. We have a centralized warehouse that we distribute from. All sites are registered entities with the centralized warehouse listed as the shipping address. Your comments about diversion concerned me based on our setup. When we registered last year we were told this was okay.** If HRSA has approved your model for centralized purchasing, then you are okay. However, having this type of centralized purchasing in place does require prior HRSA approval.

- 12. Regarding storage of 340B medications, if multiple state grants allow 340B-funded medications to be used, do the medications for the individual grants need to be kept separately or can they be lumped together to use based on expiration date?** If an organization is purchasing 340B drugs under multiple 340B IDs/funding streams, each of those inventories must be stored and maintained separately and clearly marked. This is critical to ensure that the drugs are not being given to ineligible clients, as each funding stream will have a different set of services that are consistent with each unique grant.
- 13. On 340B inventories, do you have to maintain 318 and Title X 340B-purchased medications separately?** If an organization is purchasing 340B drugs under multiple 340B IDs/funding streams, each of those inventories must be stored and maintained separately and clearly marked. This is critical to ensure that the drugs are not being given to ineligible clients, as each funding stream will have a different set of services that are consistent with each unique grant.
- 14. We perform depression screenings with all of our clients, which is part of our grantee application. Could we stock and provide antidepressants to the clients? How about Narcan?** If you have determined that depression screening is consistent with your grant, then any drugs you prescribe to a client at a visit that contains this service (or any other service consistent with your grant) can be 340B-priced.
- 15. Can contraceptives be purchased through 340B if you only have a 318 certification?** Yes. 340B covered entities are not limited in the types of drugs they can purchase at 340B prices by the funding streams they qualify for the program under. Apexus has an FAQ on this exact question that reads as follows:

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**Last Modified:** 09/15/2014

**Question:** Are 318A grantees (STD grantees) that participate in the 340B Program permitted to purchase contraceptives and other 340B drugs for use by grantee patients?

**Answer:** STD (318A grantee) clinics that participate in the 340B Program may purchase 340B drugs (including prescribed contraceptives), for grantee patients that meet the patient definition criteria (61 Fed. Reg. 55156 (Oct. 24, 1996)). If an individual meets all of the requirements of the definition of patient, including the third requirement that the individual receives a healthcare service or range of services sufficient to establish a provider-to-patient relationship under the 340B Program from the 318A grantee that are consistent with screening, preventing, or treating sexually transmitted diseases, then the covered entity may purchase and dispense any 340B drugs for which the covered entity is responsible, including contraceptives, to that patient.

- 16. Can a Title X-funded clinic provide free condoms to anyone who walks through the door without being seen in the clinic if they are condoms that are purchased through 340B pricing?** Condoms do not meet the definition of a covered outpatient drug and are, therefore, not covered by the 340B program/available at a 340B price (<https://www.340bpvp.com/resource-center/faqs/340b-pricing--covered-outpatient-drugs/>). The Prime Vendor Program sells condoms at a reduced cost to 340B entities as an added value benefit of participating in the Prime Vendor Program. Because condoms are not covered outpatient drugs, the dispensing of them is not governed by the rules of the 340B program.
- 17. Can you use your cost analysis to set the fee higher than your acquisition cost?** In fee-for-service Medicaid, you are required to bill at actual acquisition cost, and for managed care Medicaid, you should consult your state Medicaid agency's billing policies. However, for commercial payers, you absolutely should be setting a fee that is higher than your acquisition cost. Some entities use cost analysis to determine these fees.
- 18. What are the modifiers?** A modifier is a two character (alpha or numeric) code appended to a procedure code during the billing process that provides additional information to a payer. Some states require that 340B-covered entities attach specific modifiers to 340B claims, but that is on a state-by-state basis. Please consult your state Medicaid agency's policies for more information on whether your state requires a modifier, and what that modifier might be.

## Defining Eligible 340B Patients

- 19. If a purchaser presents for Eontra and has STD/contraceptive counseling with a nurse, can the purchaser receive a 340B Eontra drug as long as we have a medical record for that person?** Any drugs given to the client at that visit or as a result of that visit can be 340B-priced if:
- » You have included STD/contraceptive counseling in your policies and procedures as a service you deem to be consistent with your grant,
  - » The counseling/service is provided by someone employed by your agency or under contract with the agency; and
  - » The service is documented in a medical record.
- 20. If an established client requests emergency contraception by phone, would phone counseling be sufficient to provide clinical services if appropriately documented in the client's medical record?** There is no definitive and clear response for this situation. You should consult with your local legal counsel to determine whether counseling provided over the phone can be considered a health care service. If you ultimately make the decision that phone counseling would constitute a health care service, you should clearly enumerate.

## Diversion

- 21. If we have a contract with a federally qualified health center (FQHC) for Title X services but do not provide it with 340B drugs (has its own 340B status), do we need to register the FQHC as a 340B site or is the FQHC responsible for doing that?** Yes, the FQHC should maintain its own registration, ordering, compliance, etc. If you, as the Title X grantee, register the FQHC site yourself, HRSA will consider your entity ultimately responsible for the FQHC's 340B compliance. This is not a recommended practice, because as a separate and unique legal entity, you have little to no control over that FQHC's day-to-day practices.
- 22. Under what type of circumstances has HRSA approved covered entities transferring 340B drugs between different sites or services? Under the Apexus website FAQs, it's noted that HRSA will consider this on a case-by-case basis.** Inventory transfer from one 340B-covered entity to another is only approved under extenuating circumstances and the arrangements to which HRSA has previously agreed are not made public.