

Chapter 9

Medicaid and 340B

A. Introduction UPDATED

1. The complex intersection of Medicaid and 340B

The intersection of 340B and Medicaid is one of the most complex and significant areas within any health center's 340B program, for two reasons:

- There are significant administrative and operational complexities involved, under both carve-in and carve-out models, that don't apply with other payers. These issues are discussed in [Section 9.B](#).
- Health centers' ability to retain 340B savings on drugs dispensed to Medicaid patients is decreasing among states, and retaining those savings may require significant engagement. Under recent CMS policy, 340B providers (including health centers) are now unable to retain 340B savings for drugs reimbursed under Medicaid fee-for-service, and an increasing number of states are applying the similar policies for drugs reimbursed under Medicaid managed care. These issues are discussed in [Section 9.D](#).

Important note: While this chapter includes a general discussion of Medicaid/ 340B issues, *this discussion is not state-specific*. FQHCs should contact their PCA and/or State Medicaid office to determine the unique requirements and arrangements in their state. Also, Apexus maintains a database of each state's Medicaid agency contact information. This information can be obtained by calling the Apexus Answer Center at 888-340-2787.

2. Why the Medicaid/ 340B relationship is so complex



In short, both Medicaid and health centers are legally entitled to receive a discount on the price of drugs provided to health center patients with Medicaid. However, only one of these organizations can actually receive the discount, and the law is not clear about which one should receive it. This creates both:

- financial tension – which organization receives the financial benefit? – and
- administrative hassles – how to ensure that manufacturers are not charged for two separate discounts on the same drug?

At present, Medicaid is the only government program with a statutory right to drug discounts that overlaps with health centers' right to discounts on the same drugs. While other organizations are increasingly seeking to access the 340B savings (see [Section 4.F](#)), Medicaid is unique due to its overlapping statutory right to discounts on outpatient drugs.

3. Recent complications to the Medicaid/340B relationship

There are at least three reasons why the Medicaid/ 340B relationship so much more complex in recent years:

- Prior to 2010, state Medicaid program were only entitled to discounts on outpatient drugs that reimbursed under Fee-For-Service. However, in 2010, Congress expanded discounts to drugs reimbursed under Medicaid Managed Care. Initially, many states were slow about seeking discounts on Managed Care drugs; however, in recent years the combination of state fiscal pressures and pressure from Federal agencies has led states to become much more active in seeking these discounts.
- A CMS regulation finalized in February 2016 requires all state Medicaid agencies to pay no more than the 340B ceiling price for drugs purchased under 340B and reimbursed under **fee-for-service**. As a result, health centers are no longer able to retain any 340B savings on Medicaid FFS drugs, and they are increasingly having to work proactively to retain savings on Medicaid managed care drugs. (See [Section 9.D](#) for a discussion.)
- The significant increase in attention to the 340B program overall has led to an heightened focus by manufacturers, Congress, etc., on potential duplicate discounts.

4. How Medicaid drug rebates differ from 340B discounts

Both 340B discounts and Medicaid rebates are financed by manufacturers (as opposed to the state or Federal government), and are calculated using the same formula. However, they operate in different ways, and at different points in the process. As previously discussed, 340B discounts are provided at the time a drug is purchased, and take the form of a lower purchase price. In contrast, Medicaid rebates are made after a drug has been purchased and the state Medicaid office (or its designee) provides the manufacturer with proof that it has dispensed rebate-eligible drugs.

5. What are “duplicate discounts”?

Duplicate discounts (aka “double dipping”) occur when a manufacturer:

- Provides a discounted 340B price to the FQHC (or other covered entity) at the time of purchase and
- Pays a rebate to the state under the Medicaid Drug Rebate Program for the same unit of drug after the purchase.

Duplicate discounts are explicitly prohibited under the 340B statute, so ensuring that duplicate discounts do not occur is a key element of 340B compliance.

6. From the perspective of State Medicaid agencies

When working with your state Medicaid agency on 340B issues, it is important to understand their perspective on two key points:

- **Duplicate discounts:** Avoiding duplicate discounts requires a lot of administrative effort on the state’s part. First, they need to collect information on which of their patients’ drugs were purchased under 340B. Next, they need to subtract these drugs from their list of all drugs provided under Medicaid, and submit only the remaining drugs to the manufacturer for discounts. They must also respond to manufacturer inquiries about potential duplicate discounts, and are at financial risk if they occur. For these reasons, State Medicaid agencies often prefer a “carve-out” model (where no 340B drugs are used for Medicaid patients), as it eliminates the effort and risk involved in seeking to avoid duplicate discounts.

- **Spending:** Like providers, State Medicaid agencies are under significant pressure to reduce drug costs. Pharmaceuticals are now the fastest-growing part of health care spending, and States are becoming increasingly focused on finding ways to reduce this spending.

7. Responding to State Medicaid agencies' concerns



Health centers and PCAs can respond to their State's concerns (outlined above) by:

- **Minimizing the administrative effort involved in avoiding duplicate discounts:** Health centers are well-positioned to help their State to avoid duplicate discounts. This could involve working to streamline the system for collecting and processing information on what drugs were purchased under 340B, and responding promptly to any inquiries around duplicate discounts.
- **Emphasizing how health centers use 304B savings to benefit underserved populations – including those who cycle on and off Medicaid:** As discussed in [Section 3.E](#), every health center should be able to succinctly demonstrate how it uses their 340B savings to improve access for its community. It can be helpful to demonstrate to Medicaid officials what the loss of 340B savings on Medicaid managed care drugs would mean to your patients and your community.
- **Noting that drug savings that accrue to health centers remain entirely within the state's health care system, while those that accrue to Medicaid do not.** When the state Medicaid agency receives the benefits of discounts on outpatient drugs, these savings must be shared with the Federal government (CMS.) At a minimum, 50% of the savings are returned to CMS, and the percentage is often higher. In contrast, if health centers retain the savings, 100% of them are reinvested into activities that increase access to medically underserved patients in the state.

B. Carve-in versus Carve-Out

1. What do “carve-in” and “carve-out” mean?

There are two general models that FQHCs (and other covered entities) use to describe how they treat drugs provided to Medicaid patients.

- **Carve-In:** The FQHC includes its Medicaid patients in their 340B program, dispensing drugs purchased under 340B to these patients.
- **Carve-Out:** The FQHC excludes its Medicaid patients from its 340B program; in other words, the drugs it dispenses to these patients were purchased outside of the 340B program.

In short, “carve-in” models include Medicaid patients under 340B; “carve-out” models leave Medicaid patients outside of 340B.

2. Pros and cons of a “carve-out” model

Under a carve-out model, the FQHC does not use 340B purchased drugs to fill Medicaid prescriptions; therefore the health center does not receive any discounts under 340B. FQHCs that carve out:

- must maintain “separate” inventories for their 340B-eligible patients and their Medicaid patients. (See [Chapter 10](#) for a discussion of “separate” inventories.) Note that FQHCs with in-house pharmacies and an open door model (see [Section 8.A.3](#)) already maintain a separate non-340B inventory for their non-FQHC patients.

- must have compliance systems in place to ensure that no 340B drugs are being provided to Medicaid patients.
- have no possibility of achieving 340B-related savings on drugs provided to Medicaid patients.
- must correctly indicate this “carve-out” status *for fee-for-service* on the OPA database. FQHCs risk an audit finding if the Medicaid Exclusion File listing is incorrect. See [Section 9.C.1](#) for more information.

3. Pros and cons of a “carve-in” model

In general, the pros and cons of a carve-in model are the mirror reflection of those of a carve-out model. In short, the pros are:

- There is the possibility of achieving savings on drugs dispensed to Medicaid patients. However, the actual level of savings - *if any* - will depend on the level of reimbursement received from Medicaid – see [Section 9.D](#).
- There is no need to maintain separate inventories for Medicaid patients versus other FQHC patients.

On the other hand, a FQHC that uses a carve-in model:

- Must inform the state Medicaid agency (or its designee) that it is dispensing 340B drugs to Medicaid beneficiaries.
- Must have systems in place to prevent duplicate discounts. See [Section 9.F](#) for a discussion of models to prevent duplicate discounts, and [Section 14.B.3](#) for tips to avoid audit findings around duplicate discounts.
- Cannot use a contract pharmacy to dispense to **fee-for-service** Medicaid beneficiaries unless:
 - an arrangement to prevent duplicate discounts has been agreed to by the FQHC, the contract pharmacy, and the State Medicaid agency.
 - This written agreement has been submitted to OPA. (It will be listed on OPAIS.)
- See [Section 9.E.1](#) for more information on this issue.
- Must correctly indicate this “carve-in” status *for fee-for-service* on the OPA database – which feeds into the Medicaid Exclusion File (see [Section 9.C.1](#).) FQHCs risk an audit finding if the Medicaid Exclusion File listing is incorrect.

4. Does it make financial sense to “carve-in” for Medicaid?

The answer to this question depends on many factors, several of which are specific to your state. These factors include, but are not limited to:

- How many Medicaid patients you serve, and how many are in fee-for-service versus managed care.
- How you will be reimbursed for 340B drugs to Medicaid patients. Note that reimbursement is often different for patients in fee-for-service (see [Section 9.D.2](#)) versus managed care (see [Section 9.D.3](#)).
- The costs and compliance issues involved with each model.

Given all these factors, FQHCs should carefully weigh the costs and benefits of each option before making a decision.

5. Different carve-in/out choice permitted for FFS vs managed care

At present, OPA does not require FQHCs to make the same carve-in/ carve-out decision for both Medicaid fee-for-service (FFS) and managed care. However, some states may try to require this, or may incorrectly assume that the Medicaid Exclusion File applies to managed care. (See [Section 9.C.4](#).) Therefore, FQHCs should work closely with their state Medicaid agency and MCOs to ensure a mutual understanding of whether they are carving MCO patients in or out, in order to avoid the possibility of duplicate discounts.

C. Registering Your Carve-in/ Carve-out status on OPAIS

1. Must we tell OPA if we are carving in or out?

At present, there are different answers for Medicaid fee-for-service versus Medicaid managed care:

- **Fee-for-Service:** When registering on OPAIS, and completing the annual recertification process, FQHCs must answer the question, “Will you bill Medicaid for 340B drugs?” **Despite the generic language, OPA has clarified that this question refers only to Medicaid fee-for-service (FFS).** If the FQHC answers “yes”, it must provide its both its Medicaid provider number (if its state issues one) and its NPI to OPA. By doing so, the FQHC is making an election to carve-in prescriptions that are reimbursed under Medicaid FFS.

It is the FQHC's responsibility to ensure that the information in the Medicaid Exclusion File is accurate. Incorrect information in the MEF can lead to an audit finding, as well as to duplicate discounts.

OPA uses this information to create the Medicaid Exclusion File (MEF) which is discussed in [Section 9.C.3](#)

Note that failure to correctly indicate your Medicaid fee-for-service billing status on the OPA database can lead to an audit finding.

- **Managed Care:** At present, there is no official process or requirements for indicating to OPA if you are carving in or carving out for Medicaid Managed Care clients.

2. Changing your Medicaid billing status for fee-for-service

An FQHC can change its Medicaid billing status (aka carve-in versus carve-out – see [Section 9.B.1](#)) **for fee-for service** by making a change request on OPAIS. Such changes will be effective at the start of the following quarter provided that the change request is received, approved, and processed by OPA before the 15th day of the month prior to the start of the quarter (the “snapshot” time). See [Chapter 6](#) for information on how to make changes to information in OPAIS.

3. The Medicaid Exclusion File

The [Medicaid Exclusion File](#) (MEF) is an online list, maintained by OPA and available on OPAIS, that lists health centers (and other covered entities) that carve-in Medicaid for fee-for-service. The MEF was developed by OPA and the Centers for Medicare and Medicaid Services (CMS) as a means to prevent duplicate discounts for drugs subject to Medicaid rebates. If a health center organization is listed on the MEF, then state Medicaid agencies and manufacturers know that drugs provided by that organization were purchased under 340B.

This MEF listing provides public notice that all drugs billed to Medicaid FFS under the Medicaid number listed are purchased through the 340B Program, and therefore that Medicaid rebates should not be requested for them. If the FQHC's Medicaid provider number or NPI is not listed, no drugs billed using these identifying numbers should be purchased through the 340B Program. State Medicaid agencies are expected to review the MEF and remove claims from listed entities when requesting the manufacturer rebates.

Note that the MEF lists health center organizations by NPI number, rather than individual sites.

The Medicaid Exclusion file is available on OPA's public website at: https://340bopais.hrsa.gov/help/D_ReportsFiles/MedicaidExclusionFile.htm

4. The MEF applies only to fee-for-service

As discussed in [Section 9.C.4](#), **at this time the MEF applies only to fee-for-service claims**. There is currently no official list of organizations that carve in for Medicaid managed care (just as there is currently no official process at present for informing OPA whether an FQHC is carving Medicaid managed in or out.)

The official OPA document stating that the MEF currently applies only to fee-for-service is available at: <http://www.hrsa.gov/opa/programrequirements/policyreleases/clarificationmedicaidexclusion.pdf>.

5. Does the MEF require a unique Medicaid number for each site?

The Medicaid Exclusion file uses the FQHC's Medicaid billing number for identification. If all of the 340B-eligible FQHC sites use the same Medicaid number for billing, then a single Medicaid number will appear on the MEF. However, if an FQHC has multiple sites and only some of them are 340B-eligible and it wants to carve-in, the health center must obtain separate Medicaid provider numbers for the sites that do not participate in the 340B Program. For those states which cannot generate additional Medicaid provider numbers for entities, an alternative arrangement with the respective state to accomplish this objective would be needed.

D. Reimbursement for “carved-in” Medicaid drugs

1. Is reimbursement the same under both FFS & managed care? UPDATED

Possibly, but **not necessarily**. As discussed in detail below:

- **Fee-for-Service:** The reimbursement rules for drugs reimbursed under FFS are set in regulation, and not subject to negotiation (except “around the edges” — e.g., the level of the professional dispensing fee.)
- **Managed Care:** At present, there are national requirements — no statutory or regulatory — around how State Medicaid agencies must pay for outpatient drugs reimbursed under Medicaid managed care. As a result, there is significant negotiation and potential for change in this area.

The regulatory requirements for reimbursing FFS drugs ensure that Medicaid — not the health center — receives the benefit of the manufacturer discount. Therefore, ideally the reimbursement rules for managed care drugs are different from those for FFS — and enable the health center to retain at least some of the 340B savings. However, **many states are currently seeking to apply the FFS reimbursement rules on drugs reimbursed under managed care — despite not being required to do so.**

2. Drug Reimbursement under Medicaid Fee-for-Service UPDATED

In February 2016, CMS issued a final regulation (commonly called the “Medicaid Covered Outpatient Drug Rule” – see Section 9.H for a link) on the Medicaid drug rebate program. This regulation stated that under Medicaid fee-for-service, states must reimburse 340B covered entities for drugs at an amount equal to their “actual acquisition cost” (AAC) plus an “appropriate professional dispensing fee.” These requirements became effective on July 1, 2017, and effectively ensured that Medicaid receives the full benefit of the mandatory manufacturer discount.

Regarding the AAC, in the event that a FQHC (or other covered entity) negotiates a sub-ceiling price (a price that is below the 340B ceiling price – see [Section 4.A.1](#)), the state has the option to pay the FQHC the 340B ceiling price. If the state chooses this option, the FQHC will retain the difference between the 340B ceiling price and the actual sub-ceiling price they paid. However, states are not required to choose this option.

The regulation does not establish specific dispensing fees, but indicates that these fees should reflect “the cost of the pharmacist’s professional services and cost to dispense the drug product to a Medicaid beneficiary.” (See Section 9.H for a link to CMS’ official policy around professional dispensing fees under the Covered Outpatient Drug rule.)

During the period between the publication of the regulation (February 2016) and its effective date (July 2017), PCAs and health centers across the country worked diligently with their state Medicaid agencies to:

- Encourage them to permit health centers to retain any “sub-ceiling discounts” they received (by reimbursing at the 340B ceiling prices instead of AAC), and
- Ensure that the professional dispensing fee (pdf) appropriately reflected health centers’ costs

Due to the difficulties in determining and verifying the 340B ceiling price, it can be challenging for states to implement his policy.

The official Medicaid.gov website provides an overview of Federal Medicaid prescription drug policies that directly influence states’ reimbursement of prescription drugs, including an in-depth look into each State’s coverage and reimbursement methodologies" at <https://www.medicaid.gov/medicaid/prescription-drugs/state-prescription-drug-resources/index.html>.

3. Drug Reimbursement under Medicaid Managed Care UPDATED

As discussed in [Section 9.A.3](#), the expansion of Medicaid drug rebates to managed care patients is a relatively new development, and there is little official policy in this area. In particular – and **unlike in FFS — there are no national rules about reimbursement, and/or which organization (FQHC or Medicaid) should receive the financial benefit of the single discount** that is provided on a 340B-eligible drug provided to a Medicaid managed care patients. There are also no clear rules about how 340B providers and Medicaid are to share information to ensure that duplicate discounts are avoided.

This lack of clarity is exacerbated by the relatively high stakes involved, including States’ need to avoid duplicate discounts, and their interest in controlling spending on pharmaceuticals. (See [9.A.6](#).) As a result, many States are currently reexamining and revising their policies in this area. **FQHCs, in partnership with their PCAs, are strongly advised to monitor developments in their state, including Medicaid and MCOs policy conversations and proposals.**

There are many different ways in which state Medicaid agencies can revise their rules such that the benefit of the drug discount is transferred from the health center to the State: For example:

1. Forcing FQHCs to carve-out Medicaid MCO patients

There are at least three ways to do this:

- The State Medicaid agency requires FQHCs (and other covered entities) to carve-out all their Medicaid MCO patients; in other words, FQHCs are prohibited from using 340B drugs for any managed care patients.
- **The State Medicaid agency prohibits carving in managed care patients at contract pharmacies.** While this leaves open the possibility (but not certainty) of retaining 340B savings for MCO patients who use in-house pharmacies, it can still result in significant financial losses for health centers – particularly those without in-house pharmacies.
- The Medicaid managed care organization (MCO) requires carve-out as a condition of contracting with an FQHC.

In addition to transferring the benefit of the drug discount to Medicaid, these mandatory carve-out arrangements also eliminate the State's concerns about duplicate discounts.

2. Permit (or require) carve-in, but reimburse only the 340B or actual acquisition cost

Some states permit or require FQHCs to carve-in 340B under Medicaid managed care, but then require MCOs to reimburse for these drugs at levels that ensure that part or all of the 340B savings accrues to the state/MCO. In addition, where states have not adopted such reimbursement policies, some MCOs require them as a condition of contracting with an FQHC.

In these situations, it is important to consider how the reimbursement rates compare to the FQHC's actual acquisition costs (AAC). If an FQHC is reimbursed its AAC for a drug (as is currently required under FFS), then all benefits that result from the 340B ceiling price or sub-ceiling price accrue to the payer (the state/MCO.) However, some states and/or MCOs will set reimbursement for some drugs at levels that are slightly higher than the FQHC's AAC (e.g., at the net Medicaid price, or 340B ceiling price for a drug purchased at sub-ceiling.) In these situations, the FQHC is able to retain a portion of the savings resulting from the 340B program.

4. Our state is seeking the savings for managed care drugs....

This issue is addressed in [Sections 9.A.6](#), and [9.A.7](#).

E. Special Requirements for Carving In Contract Pharmacy Arrangements UPDATED

1. Can contract pharmacies “carve in” Medicaid fee-for service?

Yes — but only if the FQHC, the contract pharmacy, and the State Medicaid agency have all proactively agreed on a strategy to prevent duplicate discounts, and this agreement has been submitted to OPA.

A contract pharmacy typically bills all of its claims to Medicaid using one NPI number, regardless of whether it is a 340B claim or non-340B claim. For this reason, it is impossible for the state to determine which prescriptions were filled with 340B drugs based just on the NPI. Thus, an additional way to identify 340B claims is needed.

In March 2010, OPA issued a Final Notice regarding contract pharmacy services. (See [Section 11.E](#) for a link to this Notice.) These guidelines state that contract pharmacies are prohibited from using 340B drugs to fill Medicaid fee-for-service prescriptions unless the FQHC, the contract pharmacy, and the State Medicaid agency have established an arrangement to prevent duplicate discounts.

Once the agreement is finalized, the health center is responsible to submit it to OPA, who will then list it on OPAIS.

Contract pharmacies are prohibited from dispensing 340B drugs to Medicaid fee for service patients unless the FQHC, the contract pharmacy, and the State Medicaid agency have established an arrangement to prevent duplicate discounts. The agreement must be on file with HRSA, and OPAIS includes a list of all agreements HRSA has received.

2. Can contract pharmacies “carve in” Medicaid managed care?

At present, the rules for carving in Medicaid MCO patients are different from those for Medicaid FFS patients. Unlike FFS, it is allowable to carve in MCO patients at contract pharmacies even if there is no signed agreement among the FQHC, contract pharmacy, and State Medicaid agency on how to prevent duplicate discounts. OPA proposed adding such a requirement in the draft Mega-Guidance, but the proposal was never finalized.

Nonetheless, FQHCs who carve in Medicaid MCO patients at contract pharmacies are **strongly advised** to ensure that both they, and the contract pharmacy, are providing the MCOs and/or state with the data needed to avoid duplicate discounts. FQHCs are also encouraged to reach out to the state to request guidance on the preferred method for avoiding duplicate discounts.

F. Methods for Avoiding Duplicate Discounts UPDATED

Some states (and/or MCOs) require FQHCs and other covered entities to use specific methodologies to avoid duplicate discounts. So **FQHCs should start by determining if their state Medicaid agency and/or MCO requires them to use a specific method.**

Methods of avoiding duplicate discounts include:

- When registering on the OPA database, be certain to indicate that you will be using 340B drugs for Medicaid fee-for-service patients. (See [Section 9.C](#) for more information.)
- Ensure that Medicaid billing numbers and NPIs are accurately reflected in the OPA database and the Medicaid Exclusion File
- Perform on-going internal audits of both in-house and contract pharmacy dispenses to verify that 340B accumulations do not include Medicaid patients
- Provide the necessary documentation when adjudicating a claim to identify it as “340B”. Many states require inserting a “20” in 420DK field when processing the prescription in a pharmacy. There are similar ways to identify 340B use in the clinic setting when submitting billing.

Also see [Section 14.B.3](#) for tips on avoiding common audit findings involving duplicate discounts.

G. Clinic Administered Drugs under Medicaid NEW

Reimbursement for clinic administered drugs (CAD) may be one of the most confusing and complex aspects related to the intersection of Medicaid and 340B. This is because the rules may vary, not only from state-to-state, but also from health center to health center, and even across different scenarios in the same health center. For this reason, **health centers are advised to reach out to their PCA, State Medicaid agency, and/or legal counsel for guidance specific to their unique circumstances.**

The appropriate treatment of CADs under Medicaid is by several variables including:

- Whether the costs for all CADs are bundled into your Medicaid PPS rate, or some are billed separately – sometimes referred to as a “bill-above”;
- Your state’s and MCOs’ rules and practices; and
- Whether your health center has unique NPIs for each medical site and for each in-house pharmacy.

1. Carving In versus Carving Out CADs

When a health center lists a care delivery site on OPAIS, they are asked whether they will carve in or carve out Medicaid fee-for-service. **The answer to that question applies to everything billed to Medicaid under the NPI for that specific site.** The health center is forced to make a single choice for that site/NPI; this means that if any 340B drugs are administered to a Medicaid patient at that site/NPI, and Medicaid pays for those drugs in any way – either as a component of the PPS or a bill-above – the answer to the question must be yes. OPA has indicated that the carve-in/out decision applies both to drugs that are separately reimbursed versus those that are reimbursed via a bundled payment (e.g., PPS.) Therefore, if you have listed a site on OPAIS as carving out, OPA expects that you will not use 340B for CADs reimbursed under fee-for-service at that site.

However, at this time you still have the option to make a different carve-in/out decision for CADs reimbursed under managed care than for those reimbursed under fee-for-service.

Health centers with in-house pharmacies may carve Medicaid in for CADs, while carving Medicaid out for prescriptions dispensed from their in-house pharmacy ONLY if the in-house pharmacy is billing under its own unique NPI and not under the NPI of the service delivery site that it is a part of.

This issue is so complex, and the answers vary so greatly, that health centers are advised to consult with their PCA, state Medicaid agency, or other resources to obtain clarity. ***In the absence of a clear reimbursement methodology, health center are well-advised to proactively outline how they are billing for CADs and provide that in writing to the Medicaid agency.***

2. Medicaid Reimbursement for CADs

It is important to note that, at present, there are no limits on how much Medicaid can reimburse for CADs under fee-for-service. This is different from dispensed drugs, for which reimbursement under FFS is limited to no more than AAC. (See [Section 9.D.2.](#))

Nevertheless, some states are considering or pursuing 340B reimbursement limits on FFS CADs even though such limits are not required; this is similar to how they are considering or pursuing limits on all 340B drugs reimbursed under managed care even though they are not required to do so under Federal law. (See [Section 9.D.3.](#))

H. For More Information

- The final Medicaid Covered Outpatient Drug Rule is available at: <https://www.federalregister.gov/articles/2016/02/01/2016-01274/medicaid-program-covered-outpatient-drugs>
- Official Medicaid.gov website with information about state prescription drug programs, at <https://www.medicaid.gov/medicaid/prescription-drugs/state-prescription-drug-resources/index.html>.
- As with all things related to Medicaid and CHIP, many requirements and processes vary at the state level. So check with your PCA or state Medicaid agency.
- As previously discussed, the official source of OPA-aligned policy information is Apexus. Contact information is available at [Section 3.D.1.](#)
- OPA has a webpage on Medicaid exclusion: <http://www.hrsa.gov/programrequirements/opa/medicaidexclusion/index.html>

Chapter 10

Maintaining “Separate” Inventories

A. Need and Models for “Separate” Inventories:

1. When does a pharmacy need “separate” inventories?

If a pharmacy serves both 340B-eligible individuals and non-340B-eligible individuals, it must be able to document that 340B drugs were dispensed only to 340B-eligible patients; failure to do so raises significant compliance concerns. Documenting this compliance requires maintaining “separate” inventories for drugs purchased under 340B versus those purchased through other channels. (See [Section 10.A.3](#) for methods of maintaining “separate” inventories - physical or virtual.)

The following are some situations in which a pharmacy would need to maintain “separate” inventories for 340B versus non-340B drugs:

- In-house pharmacies with an “open door retail” component (see [Section 8.A.3](#) for a discussion of open door retail)
- In-house pharmacies in which Medicaid patients are “carved out”, meaning that their prescriptions may not be filled with 340B drugs (see [Section 9.B.1](#) for a definition of “carve out”.)
- Contract pharmacies (which by definition serve more than the health center’s patients)

2. Why are “separate” inventories needed in these situations?

When a pharmacy serves both patients who are 340B-eligible and those who are not, “separate” inventories are needed to avoid raising concerns about:

- Diversion – that drugs purchased under 340B were provided to patients who are not eligible for the program; and/or
- Duplicate discounts – that manufacturers are being asked to provide both a 340B price and Medicaid rebate on the same unit of drug. This would occur if a patient receives a 340B drug, and then the state bills the manufacturer for a Medicaid rebate on that same unit of drug.

As previously discussed, both diversion and duplicate discounts are explicitly prohibited under the statute.

3. Models for maintaining “separate” inventories

There are two options for pharmacies that serve both 340B-eligible patients and other individuals to maintain “separate” inventories:

- maintain separate **physical** inventories for 340B drugs versus non-340B drugs
- use a **virtual** inventory and **replenishment** method.