DISCLAIMERS

This document does not necessarily reflect the views or policies of the National Association of Community Health Centers (NACHC) regarding HRSA's implementation of the 340B Program.

The information presented in this Manual is intended to provide the reader with guidance on operational and compliance issues related to the 340B Program. The materials do not constitute, and should not be treated as, professional advice regarding compliance with laws or regulations. The National Association of Community Health Centers and the authors do not assume responsibility for any individual's reliance upon the information provided in this Manual. Regulators and auditors may choose to interpret rules and regulations in a manner different from that reflected in this Manual.

Every effort has been made to assure the accuracy of these materials. However, readers and users should independently verify the applicability of all statements before applying them to a particular fact situation, and should independently determine the correctness of any directive before recommending or implementing it on the health center's behalf.
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Foreword to the Second Edition

March 2018

The NACHC 340B Manual for Health Centers was initially published in March 2016. Since that time, the level of attention that the 340B program is receiving — from policymakers, the pharmaceutical industry, Medicaid, Medicare, private payers, and the media — has increased exponentially. For this reason, there is a need to significantly expand and update the Manual to reflect recent developments.

The revisions to this version of the Manual include:

1. A new chapter on why and how the C-Suite must focus on 340B. (See Chapter 2.)

2. A new chapter on Prices, Charges and Savings. (See Chapter 4.) This chapter includes discussions on:
   - the critical importance of health centers being able to demonstrate how they use 340B savings. (Section 4.D and 4.E)
   - efforts by outside organizations to access 340B savings intended for health centers. (Section 4.F.)

3. A discussion of how and why the 340B world is different for health centers than for other types of eligible providers. (Section 3.B.)

4. Major updates and expansions to the chapters involving:
   - The OPA database – to reflect the transition to OPAIS (Chapters 5 & 6)
   - Which prescriptions written for health center patients are eligible to be filled with 340B drugs (Chapter 7)
   - Medicaid – to reflect the on-going issues around:
     - clinic-administered drugs (Section 9.G.)

There are also smaller revisions throughout the document. Sections with significant changes or additions are marked as either NEW or UPDATED.

We hope that these updates will help all health centers ensure the continued viability of their 340B programs and the benefits it provides to medically-underserved persons across the country.
Chapter 1
Introduction

A. Sources

This Manual is based on analysis and input from a range of sources, most notably:

- Section 340B of the Public Health Service Act, and its accompanying Congressional Report.

- Official documents issued by the Health Resources and Services Administration (HRSA)’s Office of Pharmacy Affairs, which oversees the 340B program. These include, but are not limited to: Federal Register Notices; proposed and final regulations; and FAQs.

- Guidance provided by Apexus, which is the HRSA-designated Prime Vendor for 340B, and supports 340B program integrity by providing education and technical assistance to all stakeholders.

- The experiences of individual health centers, Primary Care Associations, legal counsel, and accountants with extensive involvement in the 340B Drug Discount Program.

- The direct experiences of several health centers with significant, long-term experiences in running 340B program. (See Acknowledgements, below.) The text boxes labeled “Peer Perspectives” reflect their direct insights and suggestions.

- The experience of NACHC staff and consultants who work regularly on 340B issues.

B. Purpose and Limitations

This Manual is intended to provide Federally Qualified Health Centers (FQHCs) with relevant information to assist them with managing their 340B programs to ensure compliance with the federal requirements. The Manual is based on the best information available to the authors at the time of publication and in many instances, the best interpretation of how that information translates into compliant 340B operations. However, it is important to note that:

This Manual does not constitute, and should not be treated as, professional or legal advice regarding compliance with laws or regulations. Health centers are encouraged to seek external, expert counsel, legal or otherwise, that can adequately take into account the specific factual details of any given situation. Regulators may interpret rules and regulations differently than this Manual. Therefore, the Manual is intended as a reference but not a substitute for individualized, professional advice.

The Health Resources and Services Administration’s (HRSA) rules and expectations around 340B programs change on a frequent basis. Similarly, HRSA’s interpretations for compliant operation of 340B programs are dynamic. Therefore, the information in this Manual may be superseded by new developments.

In many key areas of the 340B program, there is currently a lack of clear policy on what HRSA and its Office of Pharmacy Affairs (OPA) expect. In addition, in some areas there is conflicting information on the same issue. In these areas, we have sought to point out the lack of clarity and consistency, and to summarize the range of information received. See Section 1C for more information. Again, and especially in uncertain areas, we advise health centers to seek out experts to answer questions specific to their circumstances.
This Manual discusses Federal statutes, regulations, and expectations applicable to all Health Centers; however, health centers must also familiarize themselves and comply with state laws and regulations specific to the practice of pharmacy, and the Medicaid program, in their state.

C. A Very Important Note about 340B Compliance

Relative to other Federal programs — such as the Health Center program, Medicaid, and Medicare — the official rules and expectations around 340B are significantly less clear and evolving rapidly. In many important areas, there is currently a lack of clear policy on what HRSA/OPA expects, and/or how FQHCs are to demonstrate that they are complying with those expectations. At the same time, the level of oversight of the 340B program — including audits by HRSA and manufacturers, and investigations by Congress — is increasing significantly. As a result, health centers often find it challenging to know what they must do in order to operate in compliance and minimize audit risks.

This Manual is designed to provide accurate information in regard to the subject matter covered. However, in areas where clear expectations do not exist — and where FQHCs and outside experts may have had varied experiences and/or received conflicting information — health centers will need to carefully evaluate various approaches, considering the benefits and risks of each. On these types of issues, this Manual seeks to highlight the lack of clear policy, the various approaches that a FQHC could take, and the risk/benefits of each. While the Manual is based on the principles of federal law and guidance, this resource is published with the understanding that it does not constitute, and is not a substitute for, legal, financial, or other professional advice. Health centers should consult knowledgeable legal counsel and financial experts to structure and implement their 340B programs in a manner that is appropriate given the particular parties’ respective goals, objectives, and expectations.

D. Acknowledgements

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E. A Note about FQHC/Health Center Terminology

The terms “FQHC” and “health center” are used interchangeably in this Manual. These terms are used to refer to entities which are funded under, or have been designated as meeting the requirements of, the Consolidated Health Centers Program, located at Section 330 of the Public Health Service Act. As such, these terms include both grantees and “look-alikes” which also encompass health centers that target special populations (persons experiencing homelessness, migrant and seasonal farmworkers, and residents of public housing) as well as health centers that target a general area or population. While clinics operated by tribes, tribal organizations, and Urban Indian Health Organizations qualify as FQHCs, their unique circumstances are not addressed in this Manual.
Chapter 2

Why and How the C-Suite Must Focus on 340B

Note: This entire chapter is new as of the Second Edition of this Manual.

A The Strategic Imperative for C-Suite engagement in 340B

The 340B program sits at the intersection of three essential goals shared by all health centers:

1. 340B and Access

A fundamental characteristic of all health centers is the commitment to ensure access to affordable health care for all individuals, regardless of ability to pay, particularly for populations who would otherwise be underserved. An effective 340B program is a core element of achieving that goal, as it enables health centers to ensure that their patients can afford the medications that they are prescribed.

2. 340B and Quality

Pharmaceutical care is a core component of primary care – and patients’ ability to consistently access the medications they are prescribed is a critical driver of improved clinical outcomes. If patients cannot afford their prescriptions, health centers will be limited in their ability to treat acute conditions, manage chronic disease, and optimize their patients’ health outcomes.

3. 340B and Financial Viability

The relationship between 340B and health centers’ financial viability is more complex than what may be initially thought. These connections include:

• The savings achieved through an effective 340B program enable health centers to support key patient care services that would otherwise be unfunded, and therefore unavailable to patients. (See Section 4.D.5 for some examples of how health centers reinvest their 340B savings to increase access.)
In turn, the services supported with 340B savings often reduce other costs for the health center, and for the health care system more broadly. For example, using 340B savings to support clinical pharmacy services improves patients’ compliance and outcomes, reducing the need for health care services in the future.

- As more health centers move into the world of value based reimbursement (VBP) in the form of performance or outcomes-based incentives, the impact of an effective pharmacy program on financial viability is significantly increased. As discussed above, access to affordable prescription medication drives improved clinical outcomes; and improved outcomes position the health center to achieve performance-based incentives.

- As discussed in Section 2.B.3 below, 340B is an extremely complex program to administer. Failure to understand and adhere to all compliance requirements could result in a health center being required to repay substantial sums to manufacturers.

Given the critical role that 340B plays in ensuring access, quality, and financial viability, it is strategically imperative for the C-Suite to actively engage with the program. The following sections address four key points that the C-Suite should know about 340B, as well as six core responsibilities in this area.

**B. Four Key Points to Know about 340B**

1. **Health centers’ ability to retain 340B savings is decreasing**

   In recent years, a growing number of outside organizations are accessing some or all of the savings that health centers (and other 340B providers) accrue under 340B. For example:

   - Effective July 2017, health centers are no longer able to retain any 340B savings on drugs dispensed to Medicaid fee-for-service patients. (See Section 9.D.2)

   - Health centers in many states are no longer able to retain 340B savings on drugs dispensed to Medicaid managed care patients. (See Section 9.D.3.)

   - Some for-profit organizations in the pharmaceutical supply-and-payment chain (e.g., contract pharmacies, PBMs, TPAs, commercial third party payers) have found ways to transfer the benefits of 340B savings from health centers to themselves, and health centers have limited ability to prevent this from happening. (See Section 4.F.)

As health centers lose the ability to retain 340B savings, the important programs funded with those savings are increasingly at risk.

2. **340B compliance is highly complex and resource-intensive**

   Relative to other Federal programs -- e.g., Section 330, Medicaid, and Medicare -- the official rules and expectations for 340B are significantly less clear, and even more complex. In addition, these rules and expectations are evolving rapidly. As a result, ensuring that your 340B program is fully compliant -- and maximizes the benefits for underserved patients -- requires an on-going investment of significant resources and attention.
In recent years, oversight of 340B providers has increasing dramatically. For example:

- HRSA now audits hundreds of 340B providers annually, and plans to keep expanding its audit activity. (See Section 13.C.)

- Drug manufacturers are expanding their oversight, including hiring outside firms to do research on their behalf. (See Section 13.C.)

- Congress, the GAO, the OIG, and other federal entities are conducting their own investigations into 340B.

- BPHC has incorporated basic 340B oversight into the Operational Site Visit. (See Appendix Two.)

3. What you don’t know about 340B can really hurt you

Some 340B providers who failed to stayed up-to-date on the program’s rules and expectations have been required to repay significant amounts to drug manufacturers, and even lost eligibility for the program. In other words, what you don’t know – and don’t realize that you don’t know – about 340B compliance can hurt your organization.

4. It is increasingly important to demonstrate how 340B benefits your patients

In recent months, the level of public attention on the 340B program has grown exponentially. Much of this attention has focused on the degree to which 340B providers ensure that low-income patients can afford their medications, and whether they use their 340B savings in ways that improve access for underserved populations. In response to these concerns, health centers are well-advised to be able to demonstrate the specific ways in which they use 340B pricing and savings to improve patient access. See Section 4.D and 4.E for more information on this topic.

C. Seven Core C-Suite Responsibilities around 340B

It is the role of leadership to protect and optimize the health center’s pharmacy program, including its use of the 340B Drug Pricing Program. Following are seven core responsibilities of the C-Suite around 340B:

1. Have a basic understanding of core 340B requirements

The basic rules you must know include:

- **No diversion.** “Diversion” means using a drug purchased under 340B to fill a prescription that does not meet the 340B eligibility criteria. Questions of which prescriptions are eligible can be very nuanced, particularly for prescriptions that originated outside the four walls of the health center. See Chapter 7 for more information.

- **No duplicate discounts.** “Duplicate discounts” occur under when a health center purchases a drug at the 340B price and provides it to a Medicaid patient, and then the State Medicaid agency requests a manufacturer rebate on the same drug. Avoiding duplicate discounts is another complex issue; see Chapter 9 for more information.

- **Maintain “auditable records” that document compliance:** Health centers are required to maintain records demonstrating compliance with all 340B Program requirements for all of its sites, as well as for all contract pharmacy locations that dispense 340B drugs. Both HRSA and drug manufacturers can request to examine these records. While HRSA has not clearly defined “auditable records”, Section 13.A.3 and Appendix 9 provide guidance in this area.
Chapter 2 ▪ Why and How the C-Suite Must Focus on 340B

• Registering, updating, and recertifying on the HRSA Database (OPAIS):
  – **Registering:** All care delivery sites and contract pharmacy arrangements must be registered on the HRSA Office of Pharmacy Affairs Information System (OPAIS), and have reached their “effective date”, before they may begin participating in 340B. (See Chapter Five.)
  – **Updating HRSA database:** All information in OPAIS must be kept up-to-date at all times; failure to do so can result in audit findings. See Section 6.A.
  – **Recertifying:** On an annual basis, HRSA requires health centers to verify the accuracy of their information in OPAIS, and to attest to their compliance with all 340B requirements. Failure to recertify in a timely manner leads to a loss of 340B eligibility. See Section 6.B.

*Every member of the C-Suite should be able to articulate the compliance rules described above.*

2. Develop and maintain robust P&Ps to ensure full 340B compliance

Both BPHC and OPA (the HRSA office that oversees 340B) expect health centers to formalize key aspects of their 340B program in their Policies and Procedures – particularly those aspects that address the compliance issues described above. This Manual contains the following resources to assist in these efforts:

• **Chapter 11** discusses aspects of your 340B program that should be addressed in your P&Ps, and **Appendix Seven** provides a checklist for reviewing them.

• **Appendix Six** contains a sample Board-level policy related to 340B.

• **Appendix Two** lists the specific P&Ps that BPHC looks for during OSVs.

*Every member of the C-Suite should be able to reference the health center’s policies and procedures that ensure 340B compliance.*

3. Ensure adequate resources and attention on 340B compliance

As discussed above, ensuring compliance with 340B requirements requires substantial, on-going effort. This includes:

• Having a **team** in place to oversee the administrative aspects of the program. (See Appendix Eleven, and Section 2.D for sample job descriptions for 340B staff.)

• Providing this team with the resources necessary for them to stay informed about program developments, and to ensure compliance. These resources include, but are not limited to: training opportunities; outside auditor support; and legal support to review contracts.

4. Be alert and responsive to outside groups’ efforts to access 340B savings

As discussed above, a growing number of outside organizations are seeking to access the savings that health centers retain on some 340B drugs. To ensure the on-going sustainability of activities funded with 340B savings, the C-Suite should be on the look-out for such efforts, and be prepared to respond appropriately. As discussed below, this includes being able to demonstrate the value that these savings provide to underserved patients. See **Section 4.F** for more information.
5. **Be able to demonstrate how all 340B savings are used to increase access for underserved patients**

Health centers should be prepared to demonstrate the specific ways in which they use 340B savings to:

- Ensure that low-income patients can afford their medications, and
- Support activities that further their mission to expand access for underserved populations.

See **4.D** for information on appropriate uses of savings, and **4.E** for information on documenting how they are used.

6. **Ensure that all vendors you work with understand the unique aspects of 340B in the health center environment.**

As discussed in **Section 3.B.3**, health centers are a small part of the overall 340B program, and they are subject to unique requirements and challenges. *Therefore, health centers that seek to contract with outside groups to assist with their 340B programs (e.g., contract pharmacies, auditors, trainers) are strongly encouraged to ensure that the outside group has a thorough understanding of the unique nature of 340B in the health center environment.* Groups whose 340B experience is largely limited to other types of covered entities may lack the nuanced understanding needed to appropriately guide health centers in the 340B space.

7. **Align and integrate pharmacy services with your strategic goals and operational plans.**

As discussed in **Section 2.A**, 340B – and pharmacy services in general – lie at the intersection of three key goals: access, quality, and financial viability. For this reason, a key C-Suite responsibility is to ensure that pharmacy activities are integrated with the health center’s strategic plan and corporate-wide operations. This alignment will optimize the value that pharmacy services bring to your patients and organization.

Specifically, this alignment and integration involves:

- Incorporating pharmacy services into the health center’s board-approved strategic plan.
- Supporting the development of a system for measuring, monitoring, and reporting the performance of the pharmacy, and how it impacts other parts of your health center’s operations.
- Maintaining an overarching board-approved policy for the provision of pharmacy services (including participation in and compliance with the 340B Drug Pricing Program.) See **Appendix Six** for a sample.
- Supporting corporate-wide staff education to promote patient access and corporate compliance.
- Including consideration of pharmacy services in management planning and decision-making, e.g., new and expanded sites and services, hours of operation, personnel management.
- Supporting the development of internal and external communication plans to promote the health center’s pharmacy program.
- Considering the potential impact of the health center’s pharmacy across the health care delivery system in the development of partnerships and affiliations.
D. 340B Resources for the C-Suite

Apexus – the official source for HRSA-aligned training and TA around 340B – has some free resources that are designed for the C-Suite. These include:


- Sample job descriptions for two key non-clinical roles:
Chapter 3  ▪  The Basics of 340B

Chapter 3
The Basics of 340B

A. Background

1. What is the 340B Drug Pricing Program?

The 340B Drug Pricing Program (Program) provides eligible health care providers, such as Federally Qualified Health Centers (FQHCs), the ability to purchase outpatient drugs for its patients at significantly reduced costs (See Section 4.A for information on pricing, including the specific levels of required discounts.) By purchasing medications at a much lower cost, FQHCs can then pass the savings on to their patients through reduced drug prices, and/or can use any additional savings in support of the health center’s mission to expand access and improve health outcomes among medically underserved populations. The discounts provided in the Program are financed by the drug manufacturers, not the government.

2. The origins of the 340B Program

President George H.W. Bush signed Section 340B of the Public Health Service Act into law in 1992. Congress indicated at the time that its intention was for the program to enable eligible providers “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services”. (See H.R. Rep. No. 102-384(II), at 12 (1992).)

The creation of the 340B program provided significantly expanded health centers’ ability to provide their patients with access to affordable pharmaceuticals.

3. Recent growth in the 340B Program

For many years, the 340B Program was small and had little visibility. However, in recent years it has expanded noticeably, with program drug purchases tripling from 2005 to 2013. One reason for this expansion was that the Affordable Care Act expanded the list of provider types who were eligible to participate in the program. Other factors included an expansion in the use of “contract pharmacies” (see Chapter 11 for a discussion of contract pharmacies), better compliance with registration requirements, increases in the costs of drugs, and a growing awareness of the program

Due to recent increases in the total dollar value of drug discounts provided, drug manufacturers have been pushing for increased oversight and heightened emphasis on program integrity.

As discussed in Section 3.A.6, FQHCs account for only around 7% of all drug purchases under 340B. In contrast, hospitals account for approximately 80% of all 340B purchases. Given this breakdown, it is not surprising that most public attention on the 340B program focuses on hospitals.
4. The key players in the 340B Program

The key players in the 340B Program include:

**Health Resources and Services Administration (HRSA)** – The government agency that is responsible for oversight of the 340B Program. HRSA is part of the federal Department of Health and Human Services.

**Office of Pharmacy Affairs (OPA)** – The Office within HRSA that is responsible for administration and oversight of the 340B Program.

**Bureau of Primary Health Care (BPHC)** - The HRSA Bureau that oversees the Section 330 Health Center program. BPHC is not directly responsible for the 340B program, as this is OPA’s role. However, there are several critical areas of overlap between BPHC and OPA requirements, leading BPHC to become increasingly involved in 340B issues. See Section 3.B.1 for a discussion of the overlap between 330 and 340B, and how this distinguishes health centers from other types of 340B providers.

**Covered entity** – A healthcare organization that is eligible to participate in the 340B Program, per the statute at 42 U.S. Code §256b(a)(4). Besides FQHCs, other categories of covered entities include specific types of hospitals, and specialized clinics such as Black Lung and Tuberculosis clinics. See Section 3.A.5 for more information on the various types of covered entities. Throughout this Manual, “covered entities” may be referred to as “340B providers.”

**Participating manufacturer** – A drug manufacturer that participates in the 340B program. If a manufacturer wants its drugs to be covered by Medicaid, it must agree to participate in the 340B program, meaning that it will sell drugs at or below the ceiling price to covered entities.

**Contract pharmacy** – A pharmacy that contracts with a covered entity to dispense 340B drugs to the entity’s patients; contract pharmacies are either retail chains or independent pharmacies. This term is applicable to any situation where the pharmacy that is dispensing 340B medication is owned and operated by an entity other than the 340B covered entity, regardless of where the pharmacy is physically located — even if the physical location is within the walls of the covered entity. See Chapter 11 for a detailed discussion of contract pharmacies.

**In-House pharmacy** – A pharmacy that is owned by the covered entity; it may or may not be located in the same physical space as the health care providers. This term is applicable not only to pharmacies located in health center sites, but also to situations where the pharmacy is owned by the covered entity but situated as a stand-alone community pharmacy or located in any other physical location. See Section 8.A.2 for a detailed discussion of in-house pharmacies.

**Prime Vendor** – HRSA contractor that negotiates sub-ceiling prices and drug distribution arrangements on behalf of covered entities, and which also is charged with providing training and technical assistance on HRSA’s behalf to all 340B stakeholders. The Prime Vendor contract is currently held by Apexus, See Section 3.C.7 and Section 3.B.1 for more information on the Prime Vendor.

**Wholesale distributors** – An organization that purchases drugs from manufacturers and then sells them drugs to retail pharmacies and other entities. Distributors may work with multiple manufacturers.
Pharmacy Benefit Managers (PBMs) - An organization that administers prescription-drug programs for payers, such as private insurers and Medicare Part D plans. Their role is to manage drug formularies and seek savings from drug manufacturers in order to save the payers money. Some PBMs seek to share in the 340B savings by issuing contracts which reimburse the pharmacy at a rate below the community norms and, at times, will reimburse covered entities only at the actual 340B acquisition price.

Third Party Administrators (TPAs) - An organization responsible for ensuring that “diversion” of 340B medications does not occur (aka that 340B drugs are not provided to patients or for prescriptions that are not eligible for the program.) Most commonly, TPAs are utilized in contract pharmacy arrangements to determine which prescriptions are eligible to be filled with drugs purchased under 340B. TPAs act on behalf of the FQHC, and make their eligibility determinations based on the FQHC’s policies and procedures. (See Chapter 7 for information on which prescriptions are eligible.) TPAs should also provide transparent and auditable reporting whenever a 340B medication has been dispensed. The TPA uses an “accumulator” to determine when replenishment ordering should occur (see Section 10.B for more information) and may submit the 340B medication order to the drug wholesaler on the FQHC’s behalf (see 11.B.3.)

5. Which health care providers can participate in 340B? UPDATED

Under the statute, only nonprofit healthcare organizations that have certain Federal designations or receive funding from specific Federal programs are eligible to purchase discounted drugs through the 340B Program. These organizations are officially called “covered entities” (although this Manual often refers to them as 340B providers.) The categories of covered entities are listed at 42 U.S. Code §256b(a)(4), and include:

- Certain types of hospitals (e.g., DSH hospitals, Critical Access Hospitals, Children’s’ Hospitals)
- Federally Qualified Health Centers (FQHCs),
- Ryan White HIV/AIDS Program grantees,
- Certain types of specialized clinics, such as those treating hemophilia, Black Lung, STDs, and Tuberculosis

A list of all types of covered entities is available at https://www.hrsa.gov/opa/eligibility-and-registration/index.html

In policy discussions, covered entities are often grouped into two general categories — hospitals, and “grantees.” The term “grantees” refers to all covered entities that are not hospitals. It includes all FQHCs — even look-alikes, despite the fact that they do not receive Federal grants.

6. The relative size of various types of 340B providers NEW

In terms of the total number of organizations who participate in 340B, about half are hospitals and half are “grantees.” (See definition immediately above.) However, in terms of the dollar value of total 340B purchases, the split is very different, with hospitals accounting for roughly 80% of all purchases. Within the 20% of purchases made by “grantees”, approximately 7% are made by FQHCs, 7% are made by HIV grantees, and the remaining 6% is split among the specialized clinics.

Given this breakdown, it is not surprising that most public attention on the 340B program focuses on hospitals. Nonetheless, as discussed in Section 3.B, there are important distinctions between how 340B operates in the FQHC environment versus in a hospital. Health centers are well advised to pay particular attention to these distinctions.
B. How 340B is Different for Health Centers than Other 340B Providers

1. Intersections of 330 and 340B rules

While the general parameters of the 340B program may be similar for all types of covered entities (aka 340B providers), health centers encounter unique requirements and challenges for how 340B operates “on the ground.” This is because in addition to the 340B requirements, health centers must also meet all requirements outlined by BPHC and Section 330, and the 330 and 340B requirements often overlap in unique ways that do not apply to other types of covered entities. In addition, some aspects of the 340B program do not apply to health centers.

The following is a brief list of areas where 330 and 340B requirements overlap, creating special circumstances for health centers. Each of these areas of overlap will be discussed in detail later in this Manual.

- **Purchase price requirements:** BPHC requires all health centers that provide pharmaceutical services to pay no more than the 340B ceiling price for all drugs (except those for Medicaid patients.) See Section 3.C.1 for more info.

- **Sliding Fee requirements:** Section 330 requirements around using a sliding Fee Discount Schedule apply to pharmaceutical services. See Section 4.B.2 for more information.

- **OSVs:** During Operational Site Visits (OSVs), BPHC asks questions related to 340B. Failure to answer these questions appropriately can lead to a full 340B audit by OPA. See Section 13.C.4 and Appendix Two for more information.

- **Requirements re: use of 340B savings:** Section 330 statute requires health centers to reinvest any 340B savings into activities that promote the purpose of their HRSA/BPHC Scope of Project and advance their goal of providing care to medically underserved populations. See Section 4.D.1 for more info.

- **Interactions with PPS:** Being a Section 330 health center (either a grantee or Look-Alike) makes an organization eligible to be reimbursed by Medicaid under the FQHC Prospective Payment Systems (PPS.) Depending on how a health center’s Medicaid PPS is structured, it can create 340B issues involving both reimbursement and carve-in/ carve-out arrangements, particularly around clinic-administered drugs. See Section 9.G for more information.

- **Registration Windows:** Because OPA can use internal HRSA data systems (i.e., EHB) to verify health center sites’ eligibility for to participate in 340B, health centers may receive longer “windows” to register new sites on OPAIS, the OPA website. See Section 5.C.3 for more information.

2. General 340B requirements that do not apply to FQHCs

Yes. As stated in Section 3.A.6, hospitals account for approximately 80% of 340B purchases, while health center account for only 7%. As a result, it is not surprising that most discussion around 340B focuses hospitals.

There are some 340B requirements that apply to hospitals, but not to health centers. Therefore, health centers do not need to develop an in-depth knowledge of these issues. They include:

- The Group Purchasing Organization (“GPO”) exclusion

- The Orphan Drug Exclusion

- The requirement that all associated sites be reimbursable on the same Medicare Cost Report.
3. An important note when hiring outside groups for 340B support

As described above, health centers are a small part of the overall 340B program, and they are subject to unique requirements and challenges. Therefore, **health centers that seek to contract with outside groups to assist with their 340B programs (e.g., contract pharmacies, auditors, trainers) are strongly encouraged to ensure that the outside group has a thorough understanding of the unique nature of 340B in the health center environment.** Groups whose 340B experience is largely limited to hospitals or other types of covered entities may lack the nuanced understanding needed to appropriately guide health centers in the 340B space.

C. Operations

1. BPHC expectations re: prices paid for pharmaceuticals

   Every Notice of Award and Notice of Look-Alike Designation issued under the Health Center program contains the following standard term:

   “Consistent with Departmental guidance, HRSA grantees that purchase, are reimbursed or provide reimbursement to other entities for outpatient prescription drugs are expected to secure the best prices available for such products and to maximize results for the grantee organization and its patients. Eligible health care organizations/covered entities that enroll in the 340B Program must comply with all 340B Program requirements and will be subject to audit regarding 340B Program compliance. 340B Program requirements, including eligibility, can be found at [www.hrsa.gov/opa](http://www.hrsa.gov/opa).” (Emphasis added.)

   Thus, BPHC expects all health centers that provide pharmacy services to participate either in 340B, or in a similar program that provides the same or larger discounts.

   In addition, health centers should be aware that BPHC assesses compliance with 340B requirements as part of the Operational Site Visit. See Section 13.C.4 and Appendix Two for more information.

2. What drugs are available under 340B?

   Generally, the 340B Program covers the following outpatient drugs:

   - FDA-approved prescription drugs,
   - Over-the-counter drugs written on a prescription,
   - Biological products that can be dispensed only by a prescription (other than vaccines), and
   - FDA-approved insulin.

   Notably, vaccines are not covered under 340B. (However, the Prime Vendor, some state programs, and other group purchasing arrangements for FQHCs offer reduced prices on vaccines.)
3. Overview of key steps to operate a 340B program

The following is a very high-level overview of the steps involved in operating a 340B program. Each step will be discussed in detail later in this Manual, along with the need for on-going compliance monitoring at every step of the process.

4. How FQHCs access 340B-priced drugs

In order for an FQHC (or other covered entity) to purchase 340B-priced drugs, the Office of Pharmacy Affairs (OPA) requires that it must first be appropriately registered on the OPA database, called OPAIS. (See Section 5.A.1 for an overview of OPAIS.) The registration process differs by type of covered entity and delivery model (in-house versus contract pharmacy). In the case of FQHCs, registration on the OPA database is closely linked to the health center’s approved Scope of Project (Scope) in the HRSA Electronic Handbook (EHB). Registration is a multi-faceted, detailed and critical process, and timelines for registering FQHC delivery sites are subject to change – see Chapter 5 for a full discussion.

Once an FQHC registers its clinical sites and contract pharmacy sites on the OPAIS, each site (both clinical and contract pharmacy) must wait until its effective date before it can begin participating in 340B. The effective date generally occurs at the beginning of the next quarter following the quarter in which the health center completed the registration process. (See Chapter 5 for more information on the registration process and effective dates.)

Vendors from which covered entities purchase 340B drugs and devices verify that the provider is eligible for 340B by checking on OPAIS. Once eligibility is validated, the vendor ships the drugs to the appropriate pharmacy or clinical site, according to the instructions provided by the covered entity. This could be an in-house pharmacy that is owned and operated by the health center, or a contract pharmacy location. Regardless of where the drugs are shipped, the FQHC must always be the purchaser and responsible for payment and inventory oversight.
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5. Which prescriptions FQHCs can fill with 340B drugs

This issue is addressed in detail in Chapter 7, but the “short” answer is that at present 340B-purchased drugs may only be used for prescriptions that emanate from registered health center sites for the health centers’ patients, by eligible health center providers who are providing care that is within the health center’s scope of project. This is a critical and complex issue, so please see Chapter 7 for more information.

6. Two of the biggest compliance issues in 340B

The 340B statute explicitly prohibits two types of practices:

- Diversion – providing 340B-purchased drugs to individuals who are not patients of the FQHC; and
- Duplicate discounts – billing Medicaid for a 340B drug when the drug is subject to a Medicaid manufacturer rebate.

FQHCs must not engage in any practice that results in diversion or duplicate discounts. Diversion will be further discussed in Chapter 7 (Eligible Prescriptions), and duplicate discounts will be discussed in Chapter 9 (340B and Medicaid). In addition, both issues will be addressed in Chapter 13 (340B Compliance) and Chapter 14 (Tips for Avoiding Common Audit Findings.)

7. The Prime Vendor Program: Group Purchasing for 340B

The 340B statute requires HRSA to establish a Prime Vendor Program (PVP). The role of the PVP is to negotiate with pharmaceutical manufacturers and wholesalers on behalf of 340B providers to achieve prices that are below the ceiling price.

Participation in the PVP – including access to any sub-ceiling prices they negotiate (see Section 4.A.1 for a description of sub-ceiling prices) — is a free federal benefit available to all eligible 340B providers. However, these providers must register with the PVP in order to access the sub-ceiling pricing and a network of PVP authorized distributors. As of 2017, about 86 percent of all 340B providers were members of the Prime Vendor Program.

HRSA currently contracts with a company called Apexus to manage the PVP. Apexus PVP has contracts with over a hundred suppliers to offer sub-ceiling discounts on brand and generic 340B drugs, as well as non-340B products such as vaccines, diabetic meters, syringes, etc. Its purchasing power leverages billions in program purchases that benefit smaller covered entities, including FQHCs. Apexus reports that of October 2017, 88% of FQHCs enrolled in the 340B Program are members of the PVP. More information about the PVP can be found at www.340bpvp.com.

As discussed in Section 3.C.8, PVP/ Apexus is not the only 340B group purchasing program available to health centers. Please see the following section for another option.

Finally, as discussed in Section 3.D.1, Apexus also serves as the “official” provider of training and technical assistance that is “verified and aligned with HRSA.”
8. **340Better: Another 340B group purchase option**

Apexus’ Prime Vendor program is not the only 340B group purchasing program available to FQHCs. The Texas Association of Community Health Centers (TACHC) has been coordinating the [340Better pharmacy program](www.340Better.org) since 1999. This program works exclusively with FQHCs and is available free of charge to all FQHCs nationwide. Like the Prime Vendor, 340Better negotiates sub-ceiling prices on 340B drugs, and provides discounts on vaccines and non-pharmaceutical medical items. It is also a partner of Community Health Ventures’ Value in Purchasing program (CHV/VIP,) which is the only national group purchasing program endorsed by NACHC. For more information, go to [www.340Better.org](http://www.340Better.org).

Beyond Apexus and 340Better, NACHC is not aware of other 340B purchasing programs open to FQHCs. If there are other examples, please contact [regulatoryaffairs@nachc.org](mailto:regulatoryaffairs@nachc.org) and we will include this information in future editions of this Manual as appropriate.

D. **OPA’s Official Training and TA Resources around 340B**

1. **Apexus: OPA’s official source for 340B training and TA**

Apexus – the same group that runs the Prime Vendor Program – is also the official source for HRSA-aligned training and technical assistance around 340B. Per the OPA website, “HRSA and its contracted 340B Prime Vendor Program (PVP) are the only sources of information related to the 340B Program that are verified and aligned with HRSA.”

In this role, Apexus provides extensive educational and technical assistance to all 340B stakeholders. These resources – which are outlined in the following section – can be accessed via:

- Call Center: 888.340.BPVP (888.340.2787.) It also has a “live chat” function.
- Email: [ApexusAnswers@340bpvp.com](mailto:ApexusAnswers@340bpvp.com)

Also see Appendix One for a list of tools and other resources offered by Apexus.

2. **Training and TA Resources offered by Apexus**

Apexus offers the following resources free of charge to all 340B stakeholders:

- **FAQs**: [https://www.340bpvp.com/faqs/](https://www.340bpvp.com/faqs/) OPA has issued over 500 FAQs on 340B, and updates them regularly. Apexus communicates these FAQs through its website and through the Apexus Answers Call Center. We recommend using the “search” function to find what the topic you need. In reviewing the FAQs, please remember that the answer may be specific to a covered entity type (i.e. hospital) and may not be fully applicable to an FQHC. In such cases you can submit a request for an answer specific to your situation. Several key FAQs are referenced throughout this Manual.

- **340B University Live** – one to two day group trainings – see [https://www.340bpvp.com/education/340b-university/](https://www.340bpvp.com/education/340b-university/)

- In 2017, Apexus began offering 340B University sessions that are designed specifically for FQHCs in conjunction with the NACHC CHI.
• **340B University™ OnDemand** — [https://www.apexus.com/solutions/education/340b-u-ondemand](https://www.apexus.com/solutions/education/340b-u-ondemand) This is an online education program designed to support compliance and integrity for all 340B Program stakeholders. Topics include eligibility, registration, recertification, pricing, contract pharmacy, implementation, and audit preparedness.

• **Tools and templates** online such as sample policies and procedures tailored for FQHCs. Tools can be found at [https://www.340bpvp.com/education/340b-tools/](https://www.340bpvp.com/education/340b-tools/) Several of these tools are referenced throughout this Manual.

• **“Advanced 340B Operations Certificate Program”** – see [https://www.apexus.com/apexus-advanced-340b-certificate-program/#certified](https://www.apexus.com/apexus-advanced-340b-certificate-program/#certified) While there is a fee associated with this program, NACHC can provide a code to health centers and PCAs that reduces the fee by $100.

### E. For More Information

1. **Apexus**

   As discussed above, Apexus can be reached at:

   
   • Call Center: 888.340.BPVP (888.340.2787.) It also has a “live chat” function.
   
   • Email: ApexusAnswers@340bpvp.com

2. **340Better**

   The Texas Association of Community Health Centers (TACHC)’s 340Better Pharmacy Program is exclusively for FQHCs; it is also a partner of Community Health Ventures’ Value in Purchasing program (CHV/VIP,) which is the only national group purchasing program endorsed by NACHC.

   • 340Better’s website is [www.340Better.org](http://www.340Better.org)
   
   • TACHC’s office phone number is: (512) 329-5959
   
   • Email: 340Better@tachc.org

3. **Other Resources:**

   A summary of 340B resources available from both Apexus and OPA is available in [Appendix One](#).
A. Purchase Prices for 340B Drugs

1. How prices are set for 340B drugs

Under the law, participating manufacturers may charge no more than a “ceiling price” for 340B eligible drugs and devices provided to 340B providers. The ceiling price is determined by a formula, which varies depending on whether the drugs are generic or brand-name. (See Section 4.A.2 for the specific formulas.) Note that the ceiling price is the maximum amount that a manufacturer may charge a 340B provider for the drug itself; it may charge less. One reason why some 340B providers choose to purchase drugs through a group purchasing arrangement, such as the Prime Vendor or 340Better (see Sections 3.C.7 and 3.C.8), is that these organizations can often negotiate additional discounts (beyond the mandatory 340B discounts) from manufacturers. These discounts are called “sub-ceiling” discounts, and the final price for a drug that receives a sub-ceiling discount is the “sub-ceiling price.”

Also, note that distributors generally charge a fee for their services, which is added to the 340B price for the drugs. Therefore, the 340B price usually does not represent the full price that an FQHC pays for a drug.

Thus, the actual acquisition cost (AAC) for a 340B drug is calculated as:

- the 340B ceiling price (see below)
- minus any sub-ceiling discount
- plus any distributor fees

2. The formula for calculating 340B ceiling prices

Per the 340B statute, the ceiling price is defined as the lower of the following two options:

**Option One: AMP - URA:** Average Manufacturer Price (AMP) minus the Unit Rebate Amount (URA.) The URA consists of two parts:

- The minimum rebate percentage, which equals:
  - 23.1% of the AMP for most brand-name drugs
  - 13% of for generics
  PLUS
- An inflation penalty. This applies only if the “sticker price” of the drug has been increasing faster than inflation. While the inflation penalty previously applied only to brand-name drugs, in 2015 Congress expanded it to generic drugs.
In other words, Option One equals:

\[(\text{AMP}) - (\text{minimum rebate percentage}) - (\text{inflation penalty, if any})\].

**Option Two: Best Price:** The lowest price that any purchaser pays the manufacturer for the drug, factoring in all rebates, discounts, and other pricing adjustments. However, the statute contains a long list of exceptions to this “best price” requirement — for example, prices charged to other parts of the Federal government (e.g., Veterans Affairs, Indian Health Service) and state-run nursing homes are not considered.

3. **What is “penny pricing”? Which drugs does it apply to?**

   If a drug’s sticker price rises significantly faster than inflation, the inflation penalty could become large enough that the 340B pricing formula above yields a price that is less than zero. At the time of this Manual revision (winter 2018), manufacturers may charge one penny per unit for drugs for which the formula would result in a negative price. This policy is called “penny pricing.”

   It is important to note that OPA has requested input on alternatives to penny pricing. OPA finalized this policy in a regulation that was published in the final days of the Obama Administration, and was scheduled to go into effect early in the Trump Administration. However, the effective date has repeatedly been delayed by the Trump Administration. As of February 2018, media reports suggest that OPA will soon propose an alternative to “penny pricing.”

4. **Finding the ceiling price for a 340B drug**

   At the time of this Manual revision (February 2018), there is no easy way to determine the correct ceiling price for a drug purchased under 340B. This is because the AMP (a key factor in calculating ceiling prices) is considered proprietary information and is not available publicly. In 2010, Congress instructed OPA to establish a database with this information; however, that database has yet to become available. It is anticipated that this database will eventually become part of the larger OPAIS system (see Chapter 5).

5. **Factors that determine a drug’s Actual Acquisition Cost drug**

   In summary, a health center’s Actual Acquisition Cost (AAC) for a specific drug is determined as follows:

   • Start with the Average Manufacturer Price (AMP) for the specific quarter
   • Subtract the minimum rebate percentage (23.1% for brand drugs, 13% for generics)
   • Subtract the inflation penalty if applicable
   • If this calculation results in a price that is below zero, raise the price to one penny per unit.
   • Compare the results of this calculation above to the manufacturer’s “Best Price” for the drug; take the lower of the two amounts.
   • Subtract any sub-ceiling discounts.
   • Add distributor fees.
6. Why can prices vary for the same 340B drug?

There are many reasons why the price of a 340B drug may vary over time, as well as at a single point in time. These include:

- Manufacturers often change the AMP for a drug, which leads to changes in the 340B price on a quarterly basis.

- Different purchasing groups may be able to negotiate different sub-ceiling discounts. (See discussion of Apexus and 340Better in sections 3.C.7 and 3.C.8.)

- Different distributors charge different fees.

Nonetheless, the ceiling price for a specific drug should be consistent across all health centers (and other 340B providers) during any given quarter. If different health centers are being charged significantly different amounts for the same drug at the same time (more than can be accounted for by differences in sub-ceiling discounts and distributor fees), this suggests an error on how the ceiling price is being calculated for some of the health centers.

B. Charging patients for drugs purchased under 340B

1. Factors to consider when setting patient charges for 340B drugs

The 340B statute does not dictate how covered entities should charge patients for drugs purchased under 340B. Nonetheless, there are multiple factors that FQHCs should consider when determining how much to charge patients for drugs purchased under 340B. These include:

- Section 330 Sliding Fee Scale requirements and prohibitions

- Health Centers’ mission of providing affordable, accessible care to all, regardless of ability to pay

The following sections address each of these elements in detail.

2. How Section 330 Sliding Fee rules impact drug charges

As a reminder, Section 330 requirements around the Sliding Fee Discount Schedule (SFDS) state that:

- No patient shall be denied services due to an inability to pay.

- Uninsured and underinsured patients with incomes at or below 100% of the Federal Poverty Level (FPL) may be charged no more than a nominal fee for services;

- Uninsured and underinsured patients with incomes between 101% and 200% FPL must be charged for services based on a SFDS;

- Patients with incomes above 200% FPL are not eligible for discounts funded with Section 330 grant funds.

Note that HRSA/BPHC has stated that the SFDS requirements apply to the “service” part of the costs associated with providing a drug – namely, the dispensing costs. BPHC does not explicitly require FQHCs to apply the SFDS to the cost of the drugs themselves (called the “ingredient cost”), as they are considered supplies rather than ser-
vices. However, BPHC permits such discounts, and the law clearly states that health centers must ensure that no patient is denied services due to an inability to pay.

3. Underinsured patients qualify for the Sliding Fee Discounts

A patient is considered underinsured if the amount they would pay for a service with their insurance coverage is more than what they would be charged under the SFDS, based on their income. This can occur if an insured patient has a high deductible or copay. BPHC requires that all underinsured patients be charged based on the SFDS.

4. How the Health Center mission impacts 340B charges

The health center mission — to ensure affordable access to required services for underserved populations — indicates that health centers have a responsibility to ensure that SFDS-eligible patients are able to afford their prescriptions. For this reason, health centers should ensure that charges to SFDS-eligible patients for drugs purchased under 340B do not pose a financial barrier.

5. Must FQHCs charge SFDS patients exactly the 340B price?

Health centers are not restricted to charging the patient only their 340B purchase price; however, developing a SFDS is a delicate balance of affordability for the patient and financial viability of the program for the health center. To ensure affordability, health centers must ensure that the amount the patient is charged does not create a barrier to that patient accessing care - in this case prescription medication. To ensure financial viability of the program, it is both permissible and appropriate for the health center to recoup the costs associated with acquiring the drugs dispensed or administered to the patient, keeping in mind that costs associated with acquiring the drugs and devices may include more than the purchase price. Acquisition costs may include vendor fees as well as costs associated with stocking and maintaining adequate inventory.

In some cases, the 340B price of the drug may be so low (e.g., one penny) that it is appropriate to use a cost-plus pricing methodology to determine the ingredient cost. In other cases, the 340B price may be so high as to be unaffordable for a SFDS patient. In this case, the health center is expected to find a way to offset enough of that cost (e.g., through Patient Assistance Programs or other funding sources) to make the drug affordable. In addition, health centers are also expected to charge a fee to cover the costs of dispensing the drug (called a professional dispensing fee, or pdf.) As stated above, BPHC considers dispensing costs to be a service, and as such the SFDS must be applied to them.

6. Models for pricing 340B drugs for SFDS-eligible patients

While there are various models for pricing 340B drugs for SFDS patients, they all share one common element: they are designed to ensure that charges to SFDS-eligible patients for drugs purchased under 340B do not pose a financial barrier.

As stated above, it is permissible and appropriate for the health center to recoup the cost of acquiring the drugs, particularly in the case of drugs with relatively low 340B prices.
7. Different charges allowed at in-house versus contract pharmacies

Health centers are permitted to charge the SFDS-eligible patients different amounts for the same 340B drug depending on whether they purchase it at an in-house or contract pharmacy. Professional dispensing fees (PDF) can be significantly higher at contract pharmacies than in-house pharmacies, and health centers may adjust their charges to reflect these differences. Because of these higher fees, many contract pharmacy arrangements do not include generic drugs.

Also, some contract pharmacy arrangements are not able or willing to accommodate a SFDS. While it is possible to create SFDS groups at some contract pharmacies, a concise protocol must be created. The health center must work with the contract pharmacy to implement a clearly-defined procedure to indicate how a prescription will be categorized and identified to each respective group.

Though there is no requirement that all contract pharmacy arrangements provide a sliding fee, it is the health center's responsibility to ensure that the uninsured and underinsured patients below 200% FPL have access to affordable prescription medication. If this is not possible through a contract pharmacy, it must be achieved through another avenue.
C. Calculating 340B Savings

1. Are health centers required to calculate 340B savings?

At this time, there is no requirement for health centers (or other covered entities) to calculate the amount of savings that they receive under 340B.

2. Is there a standard method for calculating 340B savings?

No. At the time of this revision (winter 2018) there is no standard methodology for calculating 340B savings, or even general agreement across 340B providers on how to do so.

3. Some methodologies for calculating 340B savings

Given that there are currently no requirements around if or how 340B savings must be calculated, each health center should use a method that is appropriate for how its 340B program is structured and the data it has available.

To date, the most common way for health centers to calculate 340B savings is as the net margin after the sale of the 340B drugs. This is calculated as:

\[
\text{Total amount collected (insurance payment + co-pay or other patient payment)} - \text{Costs (including: drug acquisition costs; dispensing fees; administrative expenses for management and oversight of 340B program; and other fees such as to a TPA,)}
\]

Some health centers that use only 340B inventory (i.e., no open retail and no carve-out of Medicaid) use Pharmacy Net Income from their Monthly Profit and Loss Reports as a surrogate for the above calculation.

Alternatively, some 340B providers calculate savings as “GPO minus 340B”, meaning the difference between what they would have paid for the drugs if purchased under a standard GPO versus what they paid under 340B. However, many 340B providers do not have reliable data available on GPO pricing for the full range of drugs they purchased. Other groups calculate savings as “WAC minus 340B” or “AWP minus 340B”, but this can overstate 340B savings as both WAC and AWP can overstate how much a health center would actually pay in the absence of 340B.
Chapter 4 ▪ Prices, Charges, and Savings

D. Uses of 340B Savings

1. Does Federal law dictate how FQHCs must use their 340B savings?

Presently, the 340B statute does not specify how 340B providers should use savings resulting from their participation in 340B. However, the Section 330 statute — specifically Subsection 330(e)(5)(D) — requires that FQHCs must reinvest all 340B savings into activities that promote the purpose of their HRSA/BPHC Scope of Project and advance their mission of providing care to medically underserved populations.

2. The two general purposes for which 340B savings should be used

FQHCs should use their 340B savings for BOTH of the following purposes:

a. To ensure that low-income, uninsured and underinsured patients can afford their prescriptions. As discussed above (see Sections 4.B.2 and 4.B.3), FQHCs are expected to ensure that all uninsured and underinsured patients below 200% FPL have affordable access to drugs purchased under 340B.

b. To support specific programs that increase access for the health center’s general patient population: As previously stated, Congress’ intent in creating the 340B program was to enable safety net providers “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services”. Thus, the program’s purpose was not just to benefit the individual patients who receive drugs purchase under 340B, but to reduce health centers’ drug costs in order to free up funds for other activities that benefit their entire patient population. This is consistent with the requirement in Section 330(e)(5)(D) that requires all program income to be used for activities that further the objective of their BPHC-approved scope of project. Therefore, health centers may and should use 340B savings to support programs that benefit their overall patient population and advance their mission of increasing access to care for underserved populations.

3. Prohibited uses of 340B savings

Any use of savings that does not clearly promote the purpose of the health center project is not permissible, even if it benefits the patient population.

5. Examples of using 340B savings to benefit all patients

340B savings should be used to support activities that clearly expand access and improve outcomes for all patients. Here are some examples of how FQHCs use 340B savings to benefit their general patient population (as opposed to only those patients who receive 340B drugs):

- Providing opioid treatment services, including Medication-Assisted Treatment (MAT).
- Clinical pharmacy services such as: hepatitis C screening and management services; diabetes management services; anticoagulation management services; controlled substance stewardship; home visits for patients by a pharmacist-nurse team within 72 hours of hospital discharge.
- Establishing a pediatric obesity clinic
• **Care management services** such as: Care Management nurses, health coaches, social workers, case workers and patient resource specialists. Some of these services are provided in the FQHC, while others involve meeting patients in their homes, hospitals or nursing homes.

• **Making home visits** to homebound patients, including those who have recently been discharged from the hospital or a rehab facility, to help avoid readmissions.

• **Expanding access to dental services**, such as mobile dental vans that increase access to preventive services.

• **Underwriting sliding fee discounts on non-pharmaceutical services**: As previously noted, FQHCs are required to discount services to all patients with incomes below 200% FPL.

• **Helping patients access Patient Assistance Programs**: 340B savings help finance the software and staff needed to help patients access manufacturer Patient Assistance Program medications, allowing them access to expensive drugs they would otherwise go without.

• **Adding evening and weekend hours** so that patients who work during the day do not have to miss work to see the doctor.

• **Supporting community-based support for those with severe mental illness** including supported employment programs and peer support programs to help them re-engage with the community.

• **Facilitating pharmaceutical access for patients in remote areas**. For example, placing drug dispensing machines in very isolated communities; a “drug buggy” that drives around an FQHC’s entire 200-mile-wide rural service area each day to deliver pharmaceuticals to patients in remote areas.

• **Establishing Palliative Care programs**.

• **Updating technology and medical equipment**.

• **Supporting provider education programs** to attract and educate providers about working in underserved areas.

### E. Documenting How 340B Savings Are Used

#### 1. Considerations when documenting 340B savings

Health centers may want to create a brief document outlining how they use their 340B savings. This should include the following three elements:

• An explicit statement that you ensure that uninsured and underinsured patients with incomes below 200% FPL can afford their medications. Details on how much SFDS patients pay for their prescriptions may also be helpful.

• An explicit statement that you are required by statute - specifically, Section 330(e)(5)(D) of the Public Health Service Act — to reinvest all remaining savings into activities that:
  - Advance your mission of increasing access for the underserved,
  - Promoting the objectives of your HRSA/BPHC-approved health center project.
• A list of specific activities that benefit your general patient population that are funded with 340B savings. (See Section 4.D for a discussion of appropriate activities.)

2. Tool to help document how FQHCs use 340B savings


3. Addressing 340B savings in Policies and Procedures

Health centers can address 340B savings in their P&P’s with a general statement such as the following:

“X Health Center participates in the 340B Drug Pricing Program in order to expand access to affordable prescription medications for its eligible patients, and to generate savings to support expanded and enhanced services for the medically underserved patients in our service area.”

The P&P’s can also:

• Establish a consistent and accurate method of quantifying 340B savings;
• Define the services that are to be supported by 340B savings;
• Define a review panel and meeting interval to review 340B savings and subsequent allocation; and
• Outline a method to evaluate the quality and efficacy of services supported by 340B savings.

See Chapter 9 for more information on policies and procedures.

F. Other Considerations around 340B Savings

In recent years, a growing number of outside organizations — payers, contract pharmacies, PBMs, TPAs, etc. - have determined how to access the 340B savings intended to accrue to health centers and other 340B providers. This creates a challenging situation for health centers, as presently there is no statutory prohibition against their efforts.

There are many ways in which outside groups can structure their contracts with health centers such that they retain part (or all) of the 340B savings. Examples include:

• A third-party insurer determines that your health center is 340B eligible, and it reduces your reimbursement to the estimated 340B ceiling price.

• A retail pharmacy requests a sizeable percentage of the “spread” between the 340B purchase price and the insurance reimbursement, and/or a higher dispensing fee than they charge for non-340B drugs.

• A claims processor charges a higher fee for 340B drugs (more than is justified by higher administrative costs) on the grounds that your health center is paying less for these drugs.
• As of July 2017, CMS requires State Medicaid agencies to reimburse no more than the 340B ceiling price for 340B drugs covered under fee-for-service. While this requirement currently applies only to FFS, many states are actively seeking to impose the same reimbursement limits under Medicaid managed care. See Sections 9.D.2 and 9.D.3 for more info.

• State Medicaid agencies and/or managed care plans prohibit the use of 340B in contract pharmacies. This effectively eliminates the possibility of health centers without an in-house pharmacy retaining any 340B savings on drugs dispensed to Medicaid managed care patients.

1. **No statutory prohibition on outside groups accessing 340B savings**

At this time, the 340B statute does not prohibits outside groups from accessing 340B savings intended for safety net providers and their patients. While the Congressional Record is clear that the 340B program is intended to assist safety net providers to “stretch scarce Federal resources,” at the time of this Manual revision (February 2018), the statute does not explicitly prohibit the types of contracting arrangements described above. Therefore, health centers cannot reject these contracts on the grounds that they are illegal under 340B.

There is nothing in the 330 statute or HRSA policy documents that prohibits outside groups from seeking to access health centers’ 340B savings, or prohibits health centers from signing contracts that effectively transfer these savings to outside groups.

2. **Successful strategies for retaining 340B savings**

Some health centers and PCAs have successfully pushed back on outside groups that have sought to access their 340B savings. Examples of successful strategies have included:

• Demonstrating to the outside group how your FQHC uses the savings to benefit the general patient population, and the impact on the community if those savings are lost. (See Section 4.E.)

• Stating that the FQHC will withdraw from the contract unless more appropriate financial arrangements are offered.

• For Medicaid managed care, supporting state efforts to avoid duplicate discounts. (One reason why State Medicaid offices may seek to carve-out managed care is that it is an easy way to avoid duplicate discounts; therefore, helping the state implement other ways to achieve the same goal may be helpful. See Sections 9.A.6 and 9.A.7.)

• Enlisting the support of key policy and decision makers.

• Developing a process to evaluate potential vendor relationships (e.g. Request for Proposal/Services) in which vendors must submit a proposal to the health center for consideration. This will help determine which vendor is in better alignment with the goals and mission of the organization. This may also create an environment favorable to negotiations.

Ultimately, a health center faced with an outside organization that is seeking to take its 340B savings must carefully consider whether it wishes to continue the contractual relationship, and if so, what terms it is willing to accept.
Chapter 5
Registering on OPAIS

A. OPAIS

1. What is OPAIS?

OPAIS—the Office of Pharmacy Affairs Information System—is HRSA’s official repository of organizations participating in the 340B Program, including covered entities, contract pharmacies, and manufacturers. Managed by the Office of Pharmacy Affairs (OPA), OPAIS is publicly available and searchable, and is used by program stakeholders to confirm eligibility of providers and contract pharmacies, as well as their carve-in/carve-out status under fee-for-service Medicaid. For this reason, the information in the database must be accurate and up-to-date.

Officially launched in 2017, OPAIS replaced the former “OPA database.” All activities which were formerly conducted through the OPA database must now be done through OPAIS. This includes:

• registering sites and contract pharmacies,

• submitting “change requests” (to change information currently listed in OPAIS)

• annual recertification (see Chapter 6.)

2. What information is available through OPAIS?

Compared to the old OPA database, OPAIS is intended to be more user-friendly and provide easier access to a range of data about program participants. Public users can use OPAIS to obtain:

• Detailed information about all covered entities, contract pharmacies, and manufacturers

• The most current Medicaid Exclusion File (see Section 9.C.3)

• A list of all contract pharmacy arrangements for which the mandatory agreement has been filed permitting the use of 340B drugs for prescriptions reimbursed under Medicaid fee-for-service (see Section 11.B.5.)

In addition, OPAIS links to OPA’s official FAQs on the 340B program, available at https://www.hrsa.gov/opa/faqs/index.html
Eventually, it is expected that OPAIS will provide secure access to information about 340B ceiling prices. However, at the time of these revisions (winter 2018), this functionality has not yet been made available.

3. Accessing and navigating OPAIS

OPAIS is accessible at [https://340bopais.hrsa.gov/](https://340bopais.hrsa.gov/)

Detailed information on how to navigate OPAIS is available at [https://www.hrsa.gov/opa/340b-opais/index.html](https://www.hrsa.gov/opa/340b-opais/index.html)


4. The two FQHC staff members who can access OPAIS

Each FQHC’s record in OPAIS contains the name and contact information for two individuals for the FQHC:

- Authorizing Official (AO) – This person must be “fully authorized to legally bind the covered entity”. They should also have knowledge of the entity’s 340B operations. The AO is responsible for registration, recertification, profile updates, and attesting to compliance.

- Primary Contact (PC) — This should be a person other than the AO who will have knowledge of the 340B operations.
It is important to know who the AO and PC are for your health center, as:

- These are the only individuals whom OPA will reach out to with important information, such as when it is time to recertify (see Chapter 6).
- These are the only individuals who can initiate and/or approve changes to the FQHC’s OPAIS.

See Appendix Eleven for more information on AOs, PCs, and other non-clinical staff needed to operate a compliant and successful 340B program.

Therefore, it is very important that the name and contact information for the AO and PC be kept up-to-date on OPAIS. (See Chapter 6 for how to make changes.)

## B. Registration on OPAIS – Why and What

### 1. Why FQHCs must register on OPAIS

Per OPA, being appropriately registered on OPAIS and keeping that registration information up-to-date is a critical requirement for participating in 340B program.

According to OPA, all delivery and contract pharmacy sites must be registered on OPAIS — and have reached the effective date for eligibility — in order to participate in the 340B program. Any drugs that are dispensed or administered by at clinical sites or contract pharmacies that are not yet registered and effective on OPAIS are considered “diversion.”

Issues around appropriate registration (e.g., failure to register a site, failure to update information as required) are one of the major reasons for audit findings and mandatory repayments to manufacturers.

### 2. What must FQHCs register on OPAIS?

Per OPA, FQHCs (as well as other covered entities) must register on OPAIS database:

- each clinical service site in the health center’s Scope of Project as listed on Form 5B where prescriptions for 340B drugs will be written, or where 340B drugs will be administered
- each contract pharmacy location.

Each of these types of registrations are discussed separately below. Note that while in-house pharmacies are not included on this list, there are still special registration considerations that apply to them, as discussed in Section 5.B.6.
3. Registering clinical service sites

According to OPA, FQHCs must separately register each clinical service site listed on Form 5B where prescriptions will be written in order for those prescriptions to be eligible for 340B pricing. They must also register all Form 5B clinical sites where 340B drugs will be administered directly. (See Section 5.E.4 for a discussion of “other activities/locations” listed on Form 5C.)

As will be discussed in Section 5.B.8, each of these sites must be included in the health center’s Scope of Project (as listed in EHB) to be eligible to be registered in OPAIS, and to participate in 340B.

For each clinical site registered, the FQHC will be required to:

- list a “bill to” site – i.e., the site where the drugs purchased under 340B should be billed. (This is often the administrative site for the health center organization.)

- specify “ship to” location(s) – meaning the location(s) where the drugs purchased under 340B will be shipped. These may be clinical sites (when the 340B drugs are used in the center), in-house (aka FQHC-owned) pharmacies or contract pharmacies. In cases where patients from a clinical site may access 340B pricing at more than one location, multiple “ship to” locations may be listed.

- answer the following question:

  “Will the covered entity dispense 340B purchase medication to Medicaid patients AND subsequently bill Medicaid for those dispensed 340B drugs?”

This is a critical question, as answering it accurately is essential for compliance with the prohibition on “duplicate discounts” to the Medicaid program. Duplicate discounts will be discussed at length later in this Manual, starting with Section 9.A.5.

Note that at this time, health centers generally do not register sites listed on Form 5C on OPAIS. However, if a health center expects that a prescription will be written or a drug administered at a site that is not listed on Form 5B, it is imperative that this site be included in EHB on its Form 5C in order for those medications to be eligible for 340B, so that it can demonstrate that the prescription emanated from a registered site and the “other” site is under its BPHC-approved scope.

4. Registering contract pharmacy sites

FQHCs must also register the physical locations of all contract pharmacies where patients may access 340B-purchased drugs.

Contract pharmacy registration is completed during the same open enrollment windows discussed earlier in this chapter, and is not subject to the extended registration windows that OPA has recently made available to health centers’ clinical sites. (See Section 5.C.5.)

The following special considerations should be take into account when registering contract pharmacy sites.

- On or before the date the registration is submitted, the FQHC must have a fully-executed written contract in place with the contract pharmacy, as well as policies and procedures related to the FQHC’s oversight of the contract pharmacy.

- The pharmacy name, location address, and contact information in the contract must agree with the registration information.
Each specific pharmacy location dispensing 340B drugs must be separately listed in OPAIS.

The contract should indicate that it applies to all health center sites from which eligible prescriptions can emanate.

Note that special considerations apply when a contract pharmacy is bought by a new owner. See Section 5.E.1 for more information.

5. Linking contract pharmacy sites all appropriate clinical sites

Health centers with contract pharmacies that fill prescriptions emanating from more than one clinical site registered on OPAIS may register that contract pharmacy with a single clinical site, provided that both of the following conditions are met:

- All of the health center’s registered clinical sites are “associated” on OPAIS. Once the contract pharmacy is registered with one associated site, it will appear as a contract pharmacy on all associated sites in the OPAIS.

- The written contract with the contract pharmacy lists all clinical sites to which the contract applies.

It is important to remember that health centers may use the contract pharmacy for 340B only for sites included in the contract. OPAIS has contract pharmacy tabs visible on each of the associated 340B numbers, and the ability to add and terminate the contract pharmacy will be on each associated 340B ID number.

6. Registration considerations for in-house pharmacies

Unlike contract pharmacies, in-house pharmacies (meaning those that are owned by the health center, regardless of their physical location – see Section 8.A.1) are not required to be registered individually on OPAIS. However, there are still two considerations to keep in mind regarding in-house pharmacies, OPAIS, and 340B eligibility:

- In-house pharmacies may need to be listed as “ship-to” addresses for clinical sites.

- If 340B prescriptions are to be filled at a stand-alone in-house pharmacy (aka a FQHC-owned pharmacy not located within a clinical site), that pharmacy location must be included in the health center’s BPHC-approved Scope and appear as a site on Form 5B or an “other location” on Form 5C, as applicable, in EHB.

Also note that, as discussed in Section 8.A.2, pharmacy sites that are co-located with a FQHC clinical site but owned by a separate legal entity are considered contract pharmacy sites, and must be registered as such on OPAIS. In other words, it is ownership, rather than location, that determines whether a pharmacy site is considered a contract pharmacy.

7. “Associated” sites replace “parent” and “child” sites

Both the old OPA database and OPAIS consider a health center organization with multiple sites to be considered one organization. Under the old database, multi-site health center organizations were required to identify one site as the “parent” and the others as “child” sites.

OPAIS eliminates the parent/child terminology for health centers. (This terminology is still applied to hospitals.) Instead, separate sites of the same health center organization are “associated”, based on the fact that they share the same underlying grant number. Health centers should ensure that their sites are “associated” with each other by registering all the sites under the correct grant number.
8. The connection between BPHC Scope, EHB, & OPAIS

For FQHCs, 340B eligibility and OPAIS registration are closely linked to the health center’s approved Scope of Project (Scope) in the HRSA Electronic Handbook (EHB). Specifically:

• Pharmacy services must be included in the Health Center’s Scope and appear as a service on Form 5A in the Electronic Handbook in order for the Health Center to be eligible to participate in 340B.

• Each clinical site where prescriptions will be written must be in the Health Center’s Scope and appear as verified and operational on Form 5B in the EHB in order to be registered on the OPA database.

• Any “other location” where prescriptions may be generated must be registered on Form 5C in EHB to be 340B eligible

• If 340B prescriptions are to be filled at a stand-alone in-house pharmacy (aka a FQHC-owned pharmacy not located within a clinical site), that pharmacy location must be included in Scope and appear as a site on Form 5B in the EHB; however, it is not listed as a site in OPAIS.

• If the FQHC is using a contract pharmacy arrangement to provide its eligible patients with access to 340B medication (either exclusively or in addition to an in-house pharmacy) those arrangements do not appear in the EHB; however, each contract arrangement and all contract pharmacy sites must be registered in OPAIS.

C. Timelines for Registering on OPAIS

1. Standard registration timelines under OPAIS

In general, OPA only permits covered entities to register new clinical and contract pharmacy sites four times a year, during the first two weeks of each quarter. Sites that register successfully become eligible to start participating in 340B at the start of the following quarter, as shown below.

<table>
<thead>
<tr>
<th>Registration Period</th>
<th>Effective Date</th>
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It is important to note that prescriptions written at a newly-registered clinical site or dispensed at a newly-registered contract pharmacy site ARE NOT eligible to be filled with 340B purchased drugs at the time of registration. Eligibility only takes effect on the Effective Date.
2. Effective date for newly-registered sites

As indicated in the chart above, there is generally a three month gap between when a site is registered on OPAIS and its “effective date.” During that three-month period, the site is not permitted to participate in 340B. Only after the site is approved by OPA and reaches its Effective Date does it become eligible to participate in the Program. This is true even if the newly-registered site is associated with a Health Center organization which already has medical and pharmacy sites that are actively participating in 340B.

3. Current flexibility in registration timelines for FQHCs

In 2017, OPA began offering additional flexibility in the timelines for health centers to register new clinical sites. For several quarters in a row, OPA permitted health centers to register new clinical sites up until the first week of the third month of each quarter, and become effective on the first day of the following quarter. For example, OPA has allowed health centers to register new clinical sites through the first week of March, and to have those sites become effective on April 1.

OPA has been able to grant this flexibility because verifying the eligibility of new clinical sites is much easier for health centers than other types of covered entities. This is because health centers’ eligibility information is contained in EHB, and OPA can easily access EHB since they are in the same agency as BPHC.

It is important to note that there is no guarantee that OPA will continue to offer these extended registration timelines in the future. Therefore, health centers that will be opening new clinical sites are well-advised to monitor registration timelines and plan accordingly.

4. Registering new clinical sites during “extended windows”

Health centers who want to register a new clinical site outside of the four two-week windows described above should:

• Wait until the site is listed as “active” in EHB, then

• call Apexus for specific instructions (as the standard OPAIS registration system will not be available outside the standard periods.)

As noted above, there is no guarantee that OPA will continue to offer extended registration periods for health center clinical sites in the future, so health centers that plan to open new sites are well-advised to contact Apexus well in advance to obtain the latest information about timeframes.

5. No “extended registration” for contact pharmacies

The extended registration periods have applied only to clinical sites of health centers – not to contract pharmacy arrangements.
D. Process of Registering on OPAIS

1. Instructions for registering on OPAIS


2. Information needed to register a site on OPAIS

It is a good idea to have the following documents available before beginning the electronic registration process for either a clinical site or contract pharmacy.

- The Authorizing Official (AO) name, title, telephone number and email address.
- The Primary Contact (PC) name, title, telephone number, and email address – This should be a person other than the AO who will have knowledge of the 340B operations.
- Employer Identification Number (Tax Identification Number)
- Grant number/designation number per HRSA Electronic Handbook
- Address of Health Center(s) approved under the scope of the grant per EHB
- Medicaid billing number and/or NPI number (if entity will bill Medicaid for drugs purchased at 340B drug prices)
- Information on all contract pharmacy arrangements including:
  - Contract start date
  - DEA number of pharmacy
  - Contact information of pharmacy representative (name, title, telephone, and email address)
  - Correct address for each pharmacy location

3. What happens after a registration is submitted?

After the registration is complete, OPA will review the registration. Once the registration is processed and approved, the AO will receive a confirmation email from OPA. This receipt of the OPA approval email may range from a couple of days after registration until the end of the quarter in which the entity completed the registration. The registration effective date will be the first day of the following quarter. The newly-registered site may not participate in 340B prior to the effective date; doing so would constitute diversion, which is strictly prohibited.
4. The importance of the attestation

As part of the registration process, the Authorizing Official must sign an attestation that it will comply with Program requirements. **It is important to read this document thoroughly and ensure that your FQHC will be able to comply with all the statements before you submit this attestation, in particular because the Authorizing Official personally certifies to the truthfulness and accuracy of the statement and representations in the attestation.**

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**E. Special Circumstances**

1. **Contract pharmacy is purchased by a new owner**

In general (see exception below for Rite Aids that are purchased by Walgreens), if your contract pharmacy is purchased by a new owner, in general you must:

- terminate all existing sites in OPAIS, and
- register new ones, according to the timelines outlined in Section 5.C.1. Remember that you must have a signed, written contract in place with the new pharmacy prior to registering it.

These timelines generally lead to a minimum of three months of non-eligibility for the contract pharmacy site.
Apexus addresses this issue in FAQ ID: 1555, which was last updated in November 2017:

**Q:** If our contract pharmacy has been purchased by another pharmacy, do we need to update our records with OPA?

**A:** 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 the 340B database 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. Failure to report a change in ownership may result in a lapse in 340B access through the specific contract pharmacy. The covered entity must also terminate the contract pharmacy relationship established under the previous owners. To effectuate the termination, complete an online termination request: https://340bopais.hrsa.gov/ Failure to report a change in ownership may result in a lapse in 340B access through the specific contract pharmacy.

2. **Special note for Rite Aids purchased by Walgreens**

As of the winter of 2018, OPA is making exceptions to its regular registration timelines for Rite Aid sites that have been purchased by Walgreens, with the goal of minimizing the period of ineligibility resulting from the transition. **Health centers with one of these sites should contact Apexus immediately upon learning of the change of ownership**, to determine timelines and actions that will minimize the gap in eligibility.

At the time of these revisions, it was just announced that the remaining Rite Aids may be purchased by Albertsons. It is too soon to know if OPA will offer similar arrangements for these transitions, if they occur. Therefore, health centers with Rite Aids purchased by Albertsons should reach out to Apexus prior to the conversion to determine how to best minimize gaps in eligibility.

3. **Clinical service site relocates**

When a clinical service site that is currently registered on OPAIS moves to a new address, this can be handled via "change of address" request on OPAIS. (See Section 6.A. for how to make change requests.) It should not be necessary to terminate the site listed at the previous address and register the new address as a new site.

4. **Locations listed on Form 5C in EHB**

Some health centers provide services in locations that may not be listed as a specific service delivery site on Form 5B in the health center’s Scope of Project. Some examples might be clinical outreach initiatives, home visitation, and hospital rounds. To be in the health center’s Scope of Project, these other services must be listed on Form 5C. Note that at this time, health centers generally do not register other sites listed on Form 5C on OPAIS. However, if a health center expects that a prescription will be written or a drug administered at a site that is not listed on Form 5B, it is imperative that this site be included in EHB on its Form 5C in order for those medications to be eligible for 340B, so that it can demonstrate that the prescription emanated from an alternate delivery site that is approved in its BPHC-approved scope.
5. **Sub-recipients**

OPAIS will list sites that are sub-recipients of Federal grants, but seeking their own 340B identification numbers, separately from the parent entity.

6. **Organizations that are more than one type of covered entity**

Some health centers qualify as more than one type of covered entity (aka 340B-eligible provider) – e.g., in addition to being an FQHC, they may also be a HIV clinic, Family Planning Clinic, etc. See the following FAQ #1230 from Apexus for information on how these types of organizations should register on the OPA database issue.

F. **For More Information**


- For additional information and technical assistance with registration issues contact the 340B Prime Vendor at [ApexusAnswers@340bpvp.com](mailto:ApexusAnswers@340bpvp.com) or call Apexus at 1-888-340-2787. Also see their website dedicated to Database Technical Assistance, at [https://www.340bpvp.com/resource-center/faqs/database-technical-assistance](https://www.340bpvp.com/resource-center/faqs/database-technical-assistance)
Health centers’ interaction with OPAIS does not end once all clinical and contract pharmacy sites are registered. Rather, it is imperative that health centers ensure their data in OPAIS is kept current at all times, as incorrect information can lead to audit findings, mandatory repayments to manufacturers, and even a loss of 340B eligibility.

The first section of this chapter discusses the need and processes for keeping OPAIS records up-to-date in real time. The second section discusses “recertification” — the requirement for health centers to review and certify to the accuracy of their OPAIS records each year.

A. Changing and Updating Information in OPAIS

1. The importance of updating OPAIS in “real-time”

OPAIS should be updated immediately any time that there is a change in any of the information it contains. Updating OPAIS should not just be a once-a-year activity, done only during recertification.

As discussed in Section 5.A, OPAIS is the official source of information related to an entity’s participation in the program. Therefore, it is very important that the information contained in OPAIS be current and correct. Incorrect or outdated information in OPAIS can disrupt a health center’s eligibility for 340B pricing — leading to adverse findings during an audit, and required repayments to manufacturers.

2. Recent changes to process for updating OPAIS

With the launch of OPAIS in 2017, there were several changes to how “change requests” are handled. For example, some changes that formerly had to be done using a paper form can now be done on-line; also the Primary Contact (PC) can now initiate more change requests, although the Authorizing Official’s (AO) approval is still needed to formally submit the change.

3. More information on how to make changes in OPAIS

4. Hearing from OPA about the status of a change request

Apexus addresses this issue in its FAQ #1564, last updated on April 15, 2015:

Q: When can I expect to hear from HRSA about the status of a change request?

A: HRSA makes every effort to process change requests as soon as possible. Changes take approximately 10 business days to appear in the 340B database, but the actual timeframe 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.

5. Special Note about Changes to Medicaid Billing Status

One type of change request merits special attention — changes to the Medicaid carve-in/carve-out status for any registered site. (See Section 9.B and 9.C for further information.) Even after the A.O. has received an email indicating the request has been approved by OPA, the change will not immediately be reflected in the Medicaid Exclusion File (MEF), as the MEF is not updated automatically, but only on a periodic basis. Therefore, health centers are advised check the MEF regularly and NOT operationalize the change until it is reflected in the MEF.

B. Annual Recertification

To ensure accuracy, integrity and transparency, OPA requires every covered entity to “recertify” annually. The recertification process includes reviewing all the health center’s data in OPAIS, and then having the Authorizing Official attest that:

- all information in OPAIS is correct and up-to-date, and
- the health center will comply with all 340B requirements.

As discussed in Section 5.D.4, it is important to thoroughly read the attestation statement and ensure that your FQHC will be able to comply with all the statements and that the Authorizing Official can certify to their truthfulness and accuracy.

1. What needs to be recertified?

All clinical sites and all contract pharmacy sites must be recertified. (These are the same sites that were initially registered.) See Section 5.B.2 for a discussion of these sites. That includes checking all details, including but not limited to: addresses, ship-to information, bill-to information, Medicaid carve-in/out status, etc. FQHCs should review ALL the information for all their sites on OPAIS and compare this information against EHB, contract pharmacy data, wholesaler accounts, etc.

2. Why recertification is so important

There are two reasons why recertification is a very important element of participating in 340B:

- The 340B statute requires covered entities to recertify, and OPA requires that this recertification occur on an annual basis. Failure to complete the recertification within the specified timeframe will result in removal from the 340B Program for a minimum of 3 months.
The recertification process requires that the A.O. attest to health center’s compliance with all aspects of the 340B program, and the A.O. will be held accountable for any non-compliance that may occur.

In addition, recertification can also serve as a triggering event for an annual review of the health center’s entire 340B program, including policies, procedures, audit results, and reporting mechanisms.

3. When do health centers recertify? UPDATED

Each type or 340B provider (e.g., DSH hospital, FQHC, AIDS service provider) is designated a recertification period according to a schedule set by OPA. Each provider type does not always recertify at the same time each year. From 2015 through 2018, FQHCs have recertified in February – March, but there is no guarantee that this schedule will continue in future years.

4. How do FQHCs learn that when it’s time to recertify? NEW

OPA will email this information to the Authorizing Official (AO) and Primary Contact (PC) who are listed on the health center’s OPAIS record. (See Section 5.A.4.) This is one of several reasons why it is important to keep your AO and PC information up-to-date on OPAIS.

5. Where is information on how to recertify? NEW


6. Updating OPAIS to match EHB

As stated in the following FAQ issued by Apexus, during the recertification process, FQHC site names and addresses are supposed to be automatically updated to match what is in EHB. However, some FQHCs have found that changes they have made in EHB were not automatically carried over to the OPA database during the next recertification cycle. Therefore, FQHCs are well-advised to ensure that they proactively update OPAIS when the name and/or address of a clinical site changes. See Chapter Six for information on how to update OPAIS.

Note that per the FAQ below, when the OPA database is automatically updated based on changes in EHB, the Authorizing Official will be able to review any changes before they are official.

FAQ ID: 1463
Last Modified: 08/14/2014

Q: How is the HRSA Electronic Handbook system used in the 340B recertification process?

A: Section 330 health center grantees 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@hsa.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.
During recertification, FQHCs should review ALL the information for their sites on OPAIS and compare this information against EHB, contract pharmacy info, wholesaler accounts, etc.

7. **New sites cannot be registered during recertification**

No new registrations may be submitted as part of the recertification process. This prohibition applies to both clinical sites and contract pharmacy sites.

C. **For More Information**


- OPA has established an email address for recertification issues at [340b.recertification@hrsa.gov](mailto:340b.recertification@hrsa.gov)
Chapter 7
Which Prescriptions Are 340B-Eligible

A. General Information

According to the 340B statute, FQHCs (and other covered entities) may only provide 340B purchased drugs to individuals who are “patients” of the entity. As a result, policymakers often talk about the “patient definition” as the tool for determining eligibility for 340B drugs.

In practice, however, 340B eligibility determinations are made on a prescription-by-prescription basis, as opposed to a patient-by-patient basis. In other words, under current OPA guidance, the fact that an individual is clearly a FQHC patient does not mean that every prescription he or she receives is eligible to be filled with drugs purchased under 340B. Rather, each of that individual’s prescription must be separately evaluated against OPA standards to determine if may be filled with 340B drugs. Using 340B drugs to fill a prescription presented by a health center patient – but which does not meet OPA’s eligibility standards – is considered diversion

This chapter discusses current OPA guidelines around which prescriptions may be filled with 340B drugs, and how these guidelines apply to many different categories of prescriptions, including those written:

- in various locations
- by various providers
- at various points along the continuum of care (e.g., referrals to specialists, refills, hospital discharge prescriptions.)

Also, it is important to note that while OPA currently uses three criteria to determine which prescriptions are eligible (see Section 7.A.2), even these are subject to interpretation. Apexus attempts to further clarify the definition of eligible patient by expanding upon OPA interpretations and applying them to questions from covered entities. FQHCs will be best served by trying to adhere to OPA’s and Apexus’ understanding, while also recognizing that there currently is not clear guidance in all areas.

1. Why eligibility determinations are critical

If an FQHC uses a 340B-purchased drug to fill a prescription that does not meet the eligibility standards, this is considered diversion – which is strictly prohibited by the 340B statute.

Avoiding diversion – and documenting these efforts – is a critical part of an FQHC’s compliance responsibilities. All 340B providers (including FQHCs) are required to maintain purchasing and dispensing records to demonstrate that 340B drugs were provided only for eligible prescriptions. These records must be provided to OPA and manufacturer auditors upon request. More information about avoiding diversion is contained in Section 14.B.2.
2. **OPA’s current 3-part eligibility test**

1. The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual’s health care;

2. 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

3. 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 FQHC Look-Alike status has been provided to the entity.

An individual is **not** considered an FQHC ‘patient’ for purposes of 340B if health center does not maintain records or the responsibility of the patient’s care. Moreover, an individual is not a “patient” under 340B if the only health care services that the individual receives from the FQHC are pharmacy services (“the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting”).

This three-part test is outlined in the Federal Register, Vol 61, No. 207, October 24, 1996, p. 55156.

3. **Does where the prescription is generated matter?**

Yes, according to OPA, the service site where the drug was ordered/dispensed does matter. With the potential exception of prescriptions generated from patient referrals and/or hospital discharge prescriptions (see Sections 7.B.2 and 7.B.5, respectively), **only prescriptions written (or drugs dispensed) in clinical sites listed in OPAIS or in conjunction with other services listed as “in scope” on form 5C of the health center’s Scope of Project are eligible for 340B pricing**. As discussed in Section 5.B.8 a clinical site must be approved under the Health Center’s Scope of Project, and listed as active in EHB, in order for it to be registered in OPAIS. Examples of “other services” in scope that may result in eligible prescriptions include home visits, clinical outreach events, and hospital services that result in prescriptions for outpatient use.

4. **Does the provider make a difference?**

Yes, the provider writing the prescription (or dispensing a 340B drug) must meet **Part 2** of the three-part test outlined in Section 7.A.2:

“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;”

Currently, we would advise FQHCs to memorialize in memoranda of understanding even casual arrangements with providers who may prescribe 340B eligible prescriptions. Also see Section 7.B.9 for a discussion of providers who moonlight.
5. Does the type of service make a difference?

Yes, as indicated in the Part 3 of the three-part test listed in Section 7.A.2, in order for a prescription to be eligible to be filled with 340B-purchased drugs, it must result from a service which is consistent with the service or range of services for which Section 330 Health Center status (either grantee or look-alike designation) has been provided to the entity. In other words, the service must be “in scope.”

6. Frequency of visits to be considered a “patient”

There is no specific guidance to determine how frequently a patient must visit the health center in order to be considered eligible for prescriptions filled with 340B purchased inventory; therefore each health center should develop a policy consistent with the needs of its population.

Many health centers consider an individual to be an “active” patient if they have had a visit within the past two years. This policy:

- Is consistent with UDS requirements that patients be seen within the previous two-years to be counted as an unduplicated patient.

- Ensure that patients who require only annual physicals are not deemed “inactive” if — due to scheduling reasons — they go slightly longer than a year between physicals.

Another factor that health centers should consider is the frequency of visits recommended for patients with chronic disease.

B. Eligibility of specific types of prescriptions

1. Prescriptions for FQHC employees

An employment relationship alone is not sufficient for 340B eligibility. Health center employees are eligible for 340B only if they meet the definition of a “patient,” as described above. Consider the following questions to determine eligibility:

- Is the employee a patient of the FQHC?

- Is the prescription/dispense the result of a documented encounter with an eligible provider that occurred in a clinical site that is registered and eligible in the 340B database?
2. “Referral prescriptions” (e.g., those written by specialists)

The term “referral prescription” refers to a prescription written for an eligible FQHC patient (as defined under the 3-part test described in Section 7.A.2) that is written by a provider who is not directly employed by or under contract with the FQHC. For example, if the FQHC provider refers a patient to a specialist outside of the FQHC, and the specialist writes the patient a prescription, that prescription is called a “referral prescription.” The following question and answer from the Apexus website addresses patient referral prescriptions.

The following points of this response merit close attention:

• Responsibility for the care that generated the referral prescription must remain with the FQHC, and

• The FQHC’s written policies and procedures for 340B should address how referrals are managed.

Thus, when using 340B drugs to fill referral prescriptions for its patients, the FQHC must:

• Be able to provide documentation of:
  – the referral to the specialist,
  – a summary of the referral visit, including prescriptions ordered by the referring physician — or evidence of its unsuccessful efforts to obtain this summary; and
  – the health center PCP’s continued responsibility for the care of the patients.

• Ensure that its 340B Policy and Procedures address the health center’s established eligibility criteria for referral prescriptions and how the Health Center documents its responsibility for care provided in a referral situation.
3. FQHC providers should not re-write prescriptions from other providers

Health centers are strongly advised against having their providers rewrite prescriptions that were written by non-FQHC providers (e.g., specialists) for FQHC patients. This practice raises significant liability concerns. Health centers should consider having an official policy on this issue, in order to demonstrate that your health center has considered this issue and made an official determination of your position.

Peer Perspective

“The FQHC should ensure that its P&P Manual outlines specific steps for documenting the referral in the Electronic Health Record. The In-House Pharmacy must be able to document the referral in the chart and then note on the prescription that the referral documentation is available. It should be able to supply documentation on ED prescriptions and also Hospital Discharge prescriptions.”

4. How long is a referral to a specialist considered “active”?

As with the previous question, there is no specific guidance about how long a referral to a specialist considered is “active,” and therefore, that specialist prescriptions resulting from the referral can be filled with 340B drugs. Therefore, each health center should develop a policy that is consistent with its circumstances and the needs of its population.

When developing this policy, there are two parts to consider:

1. How long do patients have to act on the referral (aka see the specialist)? While there are no requirements in this area, many health centers have established a six-month window, as anything shorter might not accommodate scheduling barriers. If a patient does not see a specialist within 6 months of receiving the referral, a new referral is required if the resulting prescriptions are to be filled with 340B drugs.

2. Once the patient has the referral visit and a specialist prescription is deemed to be eligible based on the health center’s policy, how long does that prescription and its subsequent refills and renewals remain eligible? Again, there are no requirements in this area. However, a health center with a strong 340B compliance program recently provided the following input:

“Given the counsel of our auditing firm, our health center is adopting the position that as long as the health center PCP remains responsible for care and the specialty care is provided under that oversight, and the patient meets the definition of active, there is no need for repeat referrals or a schedule of required visits to the specialist (as this could be a financial and demographic burden for our patients). We have agreed however, that specialist prescription refills should be on an audit schedule to ensure the PCP is documenting knowledge of the continued specialty care and those meds.”
5. Hospital discharge prescriptions

The term “hospital discharge prescription” refers to a prescription written for an eligible FQHC patient (as defined under the 3-part test described in Section 7.A.2) that they receive upon being discharged from the hospital. These include prescriptions written upon discharge from both inpatient stays and the Emergency Department.

Guidance related to discharge prescriptions is contained in the following frequently asked question from the Apex-us website:

Thus, this FAQ does not clearly indicate whether hospital discharge prescriptions will qualify for 340B eligibility in an FQHC setting. **Hospital discharge prescriptions that are the result of a hospital visit 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 arguably are eligible.**

Health centers may provide services within their federally-approved scope of project which would be consistent with including a hospital discharge prescription as 340B-eligible. For example, assuming the arrangements meet other Section 330 requirements, the hospital ER may in fact, be the provider of after-hours coverage for the health center or the FQHC’s providers may “round” at a hospital to see their admitted patients both of which may generate a 340B-eligible prescription. Similarly, if upon discharge from a hospital emergency room an FQHC patient is provided a prescription for which the FQHC ultimately will be responsible, such as a prescription to control asthma after an acute episode has caused the patient to visit the ER, the prescription may be 340B eligible. See the FAQ below:
Thus, for a hospital discharge prescription to be eligible to be filled using 340B drugs:

- The individual must meet the definition of “eligible patient” of the FQHC.

- The FQHC should be able to explain why it is responsible for the use of the drug. (See examples in previous paragraph.)

- The FQHC should have auditable records that demonstrate its compliance with 340B program requirements.

Also, as with all scenarios, for a prescription to be filled with a 340B drug, the health center must consider whether the facts meaningfully comply with each part of the three-part eligibility test discussed in Section 7.A.2.

### 6. Refills of an existing prescription

If a health center patient was given a prescription with refills, these refills are eligible to be refilled with 340B drugs as long as the initial prescription was 340B-eligible. The “refill” would be a continuation of health care services provided by the FQHC. The FQHC should document the initial prescription for treatment in the patient’s medical record, and the “refill” would be part of the range of health care services provided.

### 7. Renewals  

When a health center patient requests that a prescription be renewed - i.e. to receive a new prescription that is identical to one that has previously been filled using 340B purchased drugs – “best practice” indicates that it should be treated as a new prescription for the purpose of determining 340B eligibility. The FQHC must consider whether the prescription still meets the 340B program definition for eligible prescriptions.

Thus, before using 340B drugs to fill a renewal script, the FQHC is advised to have policies and procedures that the health center’s responsibility for the care of the patient continues. These policies and procedures may include verification of the prescription in the EHR and periodic self-audits that include a sample of renewal prescriptions.

### 8. Drugs administered during an FQHC patient visit

FQHC providers often administer drugs during patient encounters. (These are often called clinic-administered or physician-administered drugs.) It is important to note that the same three-part eligibility test applies in the case of drugs administered during a patient-provider encounter as to drugs that a patient takes at home. Specifically: be 340B-eligible:

- the drug must be administered as part of a service that is consistent with the Health Center’s scope of project;

- the provider who administers the drug must be employed or under contract with the FQHC;

- the drug must be administered at a site that is registered on OPAIS, or in conjunction with other services listed as “in scope” on form 5C of the health center’s Scope of Project

9. Prescriptions Written by Providers who Moonlight

If a health center has one or more providers who “moonlight” - i.e., work for other health care organizations during the same period of time as the health center — special care must be taken. This is because the prescriptions that these providers write while working at the health center will be 340B-eligible (assuming they meet the other eligibility requirements), but those written while working for the other provider will not. For these providers, it is necessary to check the location where the prescription was written, in order to determine if it can be filled with 340B drugs.

From an organizational perspective it is recommended to establish a procedure requiring providers requests to be approved by the CMO and to provide written notification to the provider of his or her responsibility to assist in preventing ineligible prescriptions from being filled with 340B drugs (e.g., clearly identify when a prescription is generated through a non-FQHC moonlighting assignment.)

C. For More Information

As always, the official source of HRSA/OPA-aligned policy information is Apexus. Contact information is available at Section 3.D.1.

OPA’s “final guidelines regarding a definition of covered entity ‘patient’”, published in the Federal Register, Vol 61, No. 207/Thursday, October 24, 1996/Notices, p. 55156
Chapter 8
Models For Implementing 340B Pharmacy

A. Understanding and Evaluating Models

1. The two main categories of pharmacies from a 340B perspective

Pharmacies that are eligible to participate in 340B fall into one of two categories. There are different rules, benefits, and concerns for each category, so it is important to understand the distinction.

An in-house pharmacy, meaning that it is owned by the FQHC. An in-house pharmacy can be co-located with a clinical site, or be a stand-alone site. (See Section 8.A.2 for more information on in-house pharmacy sites.)

A contract pharmacy, meaning that the pharmacy is not owned by the FQHC. Contract pharmacies are generally located at sites that are physically separate from the FQHC; however, FQHCs occasionally arrange to have a contract pharmacy site co-located with one of their clinical sites. (See Section 8.A.5 and Chapter 11 for more information on contract pharmacy sites.)

Thus, for purposes of 340B compliance, whether a pharmacy site is considered in-house or contract is determined by who owns the pharmacy, not its physical location. Both in-house and contract pharmacies can be co-located with FQHC clinical sites, and they can both be at stand-alone sites.

Each model has its own advantages and challenges, and many FQHCs choose to use a combination. Which model a health center chooses will be based on a myriad of factors, some of which are suggested as considerations below.

2. What is an in-house (aka FQHC-owned) pharmacy?

Many health centers own and operate their own pharmacy. The health center owns the drugs, the pharmacy, and the pharmacy license. By owning its own pharmacy, a FQHC can keep all the 340B savings and have a pharmacist as an addition to its Health Center team.

The health center’s in-house pharmacy may be located within one or more of the health center’s clinical sites, or it may be a stand-alone site. If a health center implements a stand-alone in-house (aka FQHC-owned) pharmacy, the location must be added to the health center’s Scope of Project and appear as a site on Form 5B in HRSA’s Electronic Handbook (EHB). (See Section 5.B.8 for more information on this topic.)

In-house pharmacies can choose to either:

• Serve only patients who are eligible for 340B, or

• Have an “open door” (aka “open retail”) component, meaning that they serve members of the general public as well as their own patients.

Peer Perspective

“FQHCs can initiate in-house pharmacy with minimum cost. It is not cost prohibitive as is often portrayed in some webinars. With the right assistance, FQHCs can initiate in-house pharmacy for less than $20,000.”
3. What is an “open door” model for an in-house pharmacy?

All in-house pharmacies serve the health centers’ 340B-eligible patients. An “open door” model (also known as an "open retail model") refers to when an FQHC opens its in-house pharmacy to individuals who are not FQHC patients, and therefore may not be eligible for 340B.

Health centers that operate in-house pharmacies (whether located in a clinical site or stand-alone) must make a strategic decision about whether to operate these pharmacies as both a 340B pharmacy AND open door pharmacy.

There are several reasons that operating an open-door pharmacy may be of strategic value to the health center as well as the community. For example:

• If a health center’s in-house pharmacy is located in a community with limited pharmacy services, an open door pharmacy can increase pharmaceutical access for family and community members who are not health center patients.

• An open door pharmacy can be of value to the employees of an FQHC (and their families) by allowing them to pick up prescriptions during breaks or at lunch and not have to make another stop after work.

• An open door pharmacy can introduce new patients to the clinic when they fill their prescriptions.

4. Factors to consider when deciding whether to offer an “open door”

At a minimum, the following two factors should be considered when determining whether to adopt an “open door” model:

• Impact on operating margin: Including a open-door component in an in-house 340B pharmacy may bring value to the health center if a thorough business analysis indicates that it would positively contribute to the health center’s operating margin. If so, then this additional revenue could be used to further the health center’s mission.

• Operational complexity: Operating an in-house pharmacy with both 340B and open-door programs adds significant complexity to the health center’s compliance program. Most notably, the health center will need to maintain separate inventories (either physical or virtual – see 10.A.3) to distinguish between drugs purchased under 340B and those purchased outside the program. The health center must also have safeguards and internal audit measures in place to ensure 340B purchased drugs are not “diverted” to ineligible patients. Thus, a key factor in deciding whether to operate an open retail model is whether the FQHC is both able and willing to accommodate the operational complexities of dispensing both 340B and non-340B prescriptions. (In-house pharmacies that carve-out Medicaid will already have systems in place to deal with these complexities.)

• Increased audit risk: Because it adds complexity to a FQHC’s pharmacy program, operating an open door model may increase the chances of the FQHC’s 340B program being audited. It also poses an additional risk that the FQHC may be audited by the IRS to determine whether the open-door revenue is unrelated business income and therefore subject to Unrelated Business Income Tax (UBIT). The FQHC can mitigate its risk of being taxed on open-door revenue by linking that component of pharmacy business to its nonprofit mission to serve the community and its corporate policies and procedures.
5. What is a contract pharmacy?

A “contract pharmacy” is a pharmacy that is owned by an organization other than the health center. Contract pharmacies include both large retail chains, and independent community pharmacies. Contract pharmacies are generally located at a site that is separate from the FQHC; however, FQHC will occasionally arrange to have a contract pharmacy site co-located with one of its clinical sites.

Current OPA policy permits FQHCs and other covered entities to provide 340B drugs through one or more contract pharmacies. Contract pharmacies can be used alone or in combination with an in-house pharmacy. Often the contract pharmacy is more convenient for the patient, due to the pharmacy’s location and operating hours.

6. Special concerns with contract pharmacies

There are many special concerns involved with using a contract pharmacy. In fact, contract pharmacies are such a critical and complex issue that this Manual devotes an entire chapter to them — please see Chapter 11.

While these issues will be discussed in detail in that chapter, one key issue should be noted now: health centers retain full responsibility for their contract pharmacies’ compliance with all 340B requirements. Health centers using contract pharmacies must ensure a robust compliance framework is in place and that the health center has the capacity to monitor compliance within that framework, particularly around issues of diversion and duplicate discounts.

7. Factors to consider when choosing a model

When deciding whether to use an in-house pharmacy, one or more contract pharmacies, or a combination of both, at a minimum a FQHC should consider the following factors:

**Patient access:** How will each model impact FQHC patients’ ability to access 340B drugs? (e.g., convenience of hours, location, fees, wait times)

**Compliance responsibilities:** As previously stated, FQHCs that use a contract pharmacy model retain full responsibility for their contract pharmacies’ compliance with all 340B requirements. FQHCs should consider the effort involved in ensuring compliance under both models.

**Upfront and on-going costs:** Launching an in-house pharmacy involves an upfront financial investment (see text box in Section 8.A.2), which is generally not necessary under a contract pharmacy arrangement. However, under a contract pharmacy model, FQHCs will encounter on-going costs that are specific to the contract pharmacy, including dispensing and other fees, reducing the retained savings from the 340B program the FQHC could use in support of its mission.

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**Peer Perspective**

“Depending on your market, an FQHC owned and operated retail pharmacy may make a significant contribution to the financial viability of the health center, promote the image of the center as a community business, and even serve as a form of outreach in the community. The open retail pharmacy can connect people who may not have access to regular primary care to the health center as their medical home. The open retail model can be as simple a separate inventory in your on-site 340B pharmacy, or it may be as robust as a stand-alone local drug store. For an example of an FQHC made the strategic decision to open a “hometown” drug store complete with a soda fountain and homemade fudge go to:

https://www.facebook.com/carolinacommunitypharmacy/

http://www.indexjournal.com/lifestyles/taste/Sugar-Rush

“An in-house pharmacy has a big advantage in being able to better serve uninsured patients. Quite often, when uninsured patients go to the contract pharmacy, the cost of medication plus dispensing fee plus vendor fee brings prices above $20 very quickly and low-income uninsured patients don’t obtain their medication. With the in-house pharmacy, patients will obtain their medications whether they have funds or not.”
8. What is a “Bill to/Ship to” arrangement?

A “bill to/ship to” arrangement is when the bill for drugs that an FQHC purchases under 340B is sent to one address, but the drugs are sent directly to another location. For example, a health center with multiple sites will often have the bill sent to its central administrative office, but have the drugs shipped directly its pharmacy sites (which may be located at a different address.)

“Bill to/ship to” arrangements are always used in contract pharmacy arrangements, as it is the FQHC that purchases and pays for the drugs, even though the contract pharmacy dispenses them. (As discussed above, only organizations that qualify as covered entities and are registered on the OPA database are eligible to purchase drugs at 340B prices.) For more information on “bill to/ship to” arrangements under contract pharmacies, see Section 8.A.8.

B. Patients’ Right to Choose Pharmacy Provider

1. Must FQHC patients go to a pharmacy associated with the FQHC?

Health center patients are not required to use the health center’s in-house or contract pharmacies. In fact, the health center must inform the patient of his or her freedom to choose their own pharmacy provider. However, if the patient goes to a pharmacy that is not associated with the health center, they may be unable to have their prescription filled with drugs purchased under 340B, and may also be ineligible for any discounts that the health center offers.

2. Notifying patients of their right to choose any pharmacy

OPA has not issued guidance on how FQHCs (or other covered entities) should notify patients of their freedom to choose any pharmacy provider. Therefore, as discussed in Section 1C, this is a situation where different FQHCs take different approaches, and each FQHC should carefully evaluate the risks and effort involved with each approach before deciding which strategy they will use. For example, some health centers post a sign near the check-out desk alerting the patients (in all appropriate languages) of their freedom to choose a pharmacy provider. However, other FQHCs are concerned that some patients may not notice or understand the sign, so they have each patient sign a form indicating that they have been informed of the policy (similar to HIPAA.) In addition, some auditors may question whether a sign was actually posted at the time the patient received the prescription. Finally, other FQHCs ask new patients to indicate their preferred pharmacy on their intake form, and consider that action as meeting this requirement.

C. For More Information

For a more detailed discussion of models for implementing 340B pharmacy programs, please refer to:

Chapter 9
Medicaid and 340B

A. Introduction

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 programs 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.

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.
Chapter 9 • Medicaid and 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](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/clarificationmedicaidxclusion.pdf](http://www.hrsa.gov/opa/programrequirements/policyreleases/clarificationmedicaidxclusion.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](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

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.

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

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

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


- 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.
4. What is a physically separate inventory model?

In a physically separate inventory model, the drugs purchased under 340B are stored in a physically separate location from non-340B-purchased inventory. Drugs to be dispensed to 340B-eligible patients are purchased before the eligible prescriptions are filled.

Maintaining physically separate inventories can increase costs and inhibit cash flow, as they require having a “double” supply of each medicine on-hand. They also require significant additional space to store the larger inventory.

B. Replenishment Models

1. What is a virtual inventory – aka replenishment — model?

Under a “replenishment” or virtual inventory model, drugs are dispensed from a single physical inventory to both 340B eligible and non-340B eligible patients.

Rather than maintaining separate physical inventories, a “virtual” inventory is maintained electronically through the use of computerized tracking system or “accumulator”. Most covered entities hire software vendors and processors to provide these systems.

2. How a “replenishment” model works

In a physically separate inventory model, drugs are purchased using 340B pricing before the drug is dispensed to the patient. In a “replenishment” model, drugs are not characterized as 340B eligible until after the drug has been dispensed to the patient.

For instance, at the time a customer receives his or her drug at the contract pharmacy, it may not be apparent that the customer qualifies as a 340B eligible patient. Health centers often hire a Third Party Administrator (TPA) that uses specialized software to assist in identifying which prescriptions were 340B eligible after they were dispensed. A variety of data sources - such as patient lists, prescriber lists, lists of eligible sites, and patient encounter data — are used in this process.

The company matches the data from the health center to the pharmacy’s dispensing records. After the matching process, the company generates a report identifying the drugs dispensed to 340B eligible patients. The software (often called an “accumulator”) tracks the total number of each drug dispensed to 340B-eligible patients. Once the pharmacy has dispensed enough of a certain drug to equal an available package size, the health center may reorder that drug at the 340B price. Once drugs are received in inventory, these drugs are used to “replenish” the inventory that was dispensed, and they lose their identity as 340B drugs.

3. Must FQHCs use a TPA if they use a virtual inventory?

No, FQHCs are not required by OPA to hire a Third Party Administrator (TPA) to manage a virtual inventory. Some FQHCs with in-house pharmacies manage their own virtual inventories, and some contract pharmacies provide this function as part of their contract with the FQHC. As indicated in the text box, Apexus offers a tool to assist covered entities who manage their own virtual inventories to evaluate software options to manage this “split billing.”
C. For More Information

Apexus - the official source of OPA-endorsed policy information—has several FAQs and other resources on replenishment models. Contact information is available at Section 3.D.1.
Chapter 11  ▪  Contract Pharmacies

A. General Information

1. What is a contract pharmacy?

Health centers and other covered entities may choose to provide access to affordable medication to their 340B eligible patients by entering into a contract with an “outside” pharmacy – typically a pharmacy that is not owned or operated by the 340B covered entity. This outside pharmacy is called a contract pharmacy. Health centers may utilize multiple contract pharmacies to increase patient access to 340B drugs. It is important to note that a health center remains fully responsible for the compliance of all contract pharmacy sites that dispense drugs on its behalf.

2. Pros & cons of using a contract pharmacy

In conjunction with the issues discussed in Section 8.A.7, Health Centers should consider the following non-exhaustive list of pros and cons when deciding whether to use a contract pharmacy model (as opposed to an in-house model.)

Pros:

- Using contract pharmacies makes it easier for health centers to participate in 340B if they do not want or are unable to offer in-house pharmacy services, or if they want to supplement such services.

- Contract pharmacies may increase patient access to 340B drugs by partnering with pharmacies that may be more convenient for the patient.

- Relying exclusively on contract pharmacies eliminates the health center’s cost of operating an in-house pharmacy.

Cons:

- Compliance responsibilities are more complicated, as the FQHC is responsible for the activities of a separate organization(s).

- Relative to an in-house pharmacy model, using a contract pharmacy may result in higher costs and lower 340B savings for the health center, depending on how the contract with the pharmacy is structured.

- Also depending on how the contract is structured, patients may be charged higher fees when they get their drugs from a contract pharmacy compared to an in-house pharmacy.

- Using contract pharmacies appears to increase the likelihood that an FQHC will be audited (and the more contract pharmacy sites, the higher the chances of being audited).
3. Is there a limit on the number of contract pharmacy sites?

At this time, neither the 340B statute nor OPA limit the number of contract pharmacies that a FQHC (or other covered entity) may have. However, this was not always the case. Prior to 1996, a covered entity had to have an in-house pharmacy in order to participate in 340B. Starting in 1996, OPA began allowing covered entities without an in-house pharmacy to contract with a commercial pharmacy. Beginning in 2010, covered entities with in-house pharmacies were allowed to also provide 340B drugs to their eligible patients through contractual arrangements. Furthermore, covered entities were no longer restricted to one contract pharmacy and began contracting with multiple independent and chain pharmacies. Since that time, there has been a dramatic increase in the number of contract pharmacies participating in 340B, leading to increased oversight and heightened emphasis on program integrity.

4. How many contracts are needed?

According to the OPA website, FQHCs (emphasis added):

"must have a written contract in place with each specific pharmacy organization being used under a contract pharmacy arrangement, including a full listing of all pharmacy locations in that organization that may be utilized."

5. FQHCs are fully responsible contract pharmacies’ compliance

It is critical to keep in mind that use of a contract pharmacy arrangement does not lessen a FQHC’s duty to ensure compliance with the statute and OPA guidelines. Rather, health centers retain full responsibility for their contract pharmacies’ compliance with all 340B requirements.

For this reason, health centers using contract pharmacies must ensure a robust compliance framework is in place and that they have the capacity to monitor compliance within that framework. These compliance activities are discussed on the OPA website, and in Section 11.D. In addition, the first step in ensuring a compliant contract pharmacy model is to establish a well-written contract, as discussed in Section 11.C.

B. Operating a Contract Pharmacy Arrangement

1. How contract pharmacy arrangements operate

The health center pays a fee to the contract pharmacy for services the pharmacy performs. This may be a specified fee per transaction and may also include fees related to third-party administrators (TPAs.) The fee is negotiated between the health center and the pharmacy and is not governed by the 340B statute. See Section 11.C.4 for further discussion of fees.

It is important to carefully examine the terms of the proposed contract, including the fee structure. For example, health centers should avoid signing contracts which effectively transfer a significant part of the 340B benefit from the health center (whom Congress intended to receive the benefit) to the contract pharmacy.

A “ship to/bill to” arrangement may be used, in which the health center is responsible for purchasing 340B drugs from suppliers or manufacturers with instructions to ship the drugs directly to the contract pharmacy. The supplier or manufacturer will bill the health center for the cost of the drugs shipped.
In a physically separate inventory model (see Section 10.A.4), the health center will purchase 340B drugs and request the distributor to ship the drugs directly to the contract pharmacy. The contract pharmacy will then store the health center’s 340B-purchased drugs in a physically separate location from its own inventory. The contract pharmacy will take drugs from this inventory to dispense to the health center’s 340B eligible patients.

Most contract pharmacy arrangements operate under a “replenishment” or virtual inventory model. (See Section 10B.) In this model, the health center purchases 340B drugs and requests the distributor to ship the drugs directly to the contract pharmacy. The contract pharmacy then places the drugs into its own inventory to replace the drugs dispensed to 340B eligible patients.

The contract pharmacy must maintain a tracking system to identify which drugs taken from the inventory are dispensed to 340B eligible patients. Many health centers hire companies that use specialized software to identify which drugs dispensed to patients were eligible for 340B pricing. In some cases, a contract pharmacy may require the health center to use the pharmacy’s own software. Regardless of the arrangement, the health center bears the full responsibility for ensuring that 340B drugs are dispensed only to eligible patients.

2. Example of contract pharmacy arrangement with a TPA

• An FQHC signs a written contract with a contract pharmacy (often known as a Pharmacy Services Agreement) for the dispensing of 340B drugs.

• Both the FQHC and the contract pharmacy may contract with a Third Party Administrator (TPA) to facilitate data capture and reporting. There may also be an arrangement with a third-party to track inventory usage using specialized tracking software to prevent diversion and duplicate discounts. In our example we will use the term Virtual Inventory Manager (VIM) to denote the inventory tracking company. Note that the FQHC’s contract with the TPA or VIM does not take the place of a separate contract with the contract pharmacy.

• A patient purchases drugs from the contract pharmacy.
• Using an electronic routing device called a “switch”; the contract pharmacy sends a payment request (claim) for the drug sold to the TPA. The “switch” provides a secure portal for the transmission of patient information.

• The TPA verifies the appropriate insurer and based upon the policy terms, determines payment to the contract pharmacy for the drug. The TPA forwards the payment for the drug, via the switch, to the contract pharmacy. (As discussed below, the TPA may withhold its fees from the payment to the pharmacy.)

• On a periodic basis, the FQHC sends patient and provider information to the VIM.

• The contract pharmacy also uses the switch to transmit to the VIM records of all drugs it has dispensed.

• Using tracking software, the VIM matches data from the contract pharmacy files to the FQHC files. If a script meets eligibility criteria, the drug dispensed is eligible for 340B purposes.

• The VIM sends a report of the matches to the FQHC, TPA and the pharmacy. The report (“accumulation report”) is used by the FQHC to re-order or “replenish” the 340B eligible drugs dispensed by the contract pharmacy.
• The FQHC purchases the “replenishment” drugs using its own 340B purchasing account. In some instances, the contract pharmacy may order the drugs itself on behalf of the FQHC by using the FQHC’s 340B account. (See Section 11.B.3 for a discussion of which organization should place the actual order.) The invoice is sent to the FQHC for payment. (“Bill-to-FQHC/Ship-to-contract pharmacy, or “Bill-to/ Ship-to”)

• The drugs are shipped by the drug distributor directly to the contract pharmacy. The contract pharmacy places the shipment in its inventory. (“Ship-to”)

• The contract pharmacy, TPA, VIM and FQHC all receive a portion of monies collected from the sale of the drugs. The contract pharmacy receives its dispensing fees; the TPA and VIM receive their negotiated administrative fees; and the FQHC keeps the remaining collections.

• The FQHC will use the amount received to pay the 340B invoices. Any amount remaining (340B savings) can be used by the FQHC to provide other services to its patients.
3. Can vendors order or purchase 340B drugs for a FQHC? UPDATED

In this response, please note the important distinction between ordering and purchasing 340B drugs. While there has been some uncertainty about whether a TPA or contract pharmacy may order drugs on a FQHC’s behalf, it is clear that they may never purchase 340B drugs on their own accounts, even if they do so on a FQHC’s behalf.

**Ordering:** This is an example of an issue, discussed in Section 1C, where requirements are unclear. In the past, OPA informed some health center organizations that only an FQHC can order 340B drugs on behalf of its patients, and that TPAs and contract pharmacies may not do so, even if the drugs are ordered on the FQHC’s account and billed directly to the FQHC. However, at least one major pharmacy chain routinely orders 340B drugs on behalf of the covered entities with whom it contracts — and includes a provision requiring this arrangement in its standard contract — and this arrangement has yet to result in audit findings. In addition, documents distributed by 340B University suggest that vendors may submit replenishment orders directly to the distributor. Therefore, health centers are well-advised to consider risks and benefits of both approaches before choosing which to follow.

**Purchasing:** Regardless of which organization places the orders, it must be clear that it is the FQHC (or other covered entity) that purchases the 340B drugs. It is illegal for an organization who is not a covered entity to purchase drugs under the 340B program. For example, while a contract pharmacy might be permitted to order 340B drugs on behalf of the FQHC on the FQHC’s account, they are strictly prohibited from ordering 340B drugs on their own account.

4. Can vendors deduct fees directly from 340B revenues? UPDATED

This is another example of an issue, discussed in Section 1C, where requirements are unclear. In the past, OPA informed some health center organizations that contract pharmacies must forward the full amount that they collected for 340B drugs directly to the FQHC; the FQHC must then — in a separate transaction — pay the contract pharmacy and TPA their fees. However, many current contract pharmacies arrangements do not comply with this practice; rather, the pharmacy and TPA fees are deducted upfront before any proceeds are sent to the FQHC. To date, no audit findings have resulted from these upfront deductions. Nonetheless, it is recommended that FQHCs have contract pharmacies forward the full amount of collections to them, and to pay fees in a second, subsequent transaction.

5. Can contract pharmacies “carve in” Medicaid patients?

Please see Section 9.E. for a full discussion of this issue. In short, 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
- this three-way arrangement is in writing and has been submitted to HRSA/OPA.

OPA proposed a similar requirement for Medicaid managed care patients in the draft mega-guidance issued in August 2015, but this proposal was never finalized.
C. Elements of a Contract with a Contract Pharmacy

1. OPA's essential elements of a contract with a contract pharmacy

The FQHC and contract pharmacy must have in place a written contract which lists all health center sites and contract pharmacy locations that are part of the agreement.

OPA has provided a list of essential elements to address in contract pharmacy arrangements. These include:

(a) "The covered entity will purchase the drug, maintain title to the drug and assume responsibility for establishing its price, pursuant to the terms of an HHS grant (if applicable), and any applicable Federal, State and local laws. A “ship to, bill to” procedure is used in which the covered entity purchases the drug; the manufacturer/wholesaler must bill the covered entity for the drug that it purchased, but ships the drug directly to the contract pharmacy. ... In cases where a covered entity has more than one site, it may choose between having each site billed individually or designating a single billing address for all 340B drug purchases.” (See Section 8.A.8 for a discussion of “bill to/ship to” arrangements.)

(b) "The agreement will specify the responsibility of the parties to provide comprehensive pharmacy services (e.g., dispensing, recordkeeping, drug utilization review, formulary maintenance, patient profile, patient counseling, and medication therapy management services and other clinical pharmacy services)."

(c) "The covered entity will inform the patient of his or her freedom to choose a pharmacy provider. If the patient does not elect to use the contract pharmacy, the patient may obtain the prescription from the covered entity and then obtain the drug(s) from the pharmacy provider of his or her choice.”

“When a patient obtains a drug from a pharmacy other than the covered entity’s contract or the covered entity’s In-house pharmacy, the manufacturer is not required to offer this drug at the 340B price.” (See Section 8.B for a discussion of this issue.)

(d) "The contract pharmacy may provide other services to the covered entity or its patients at the option of the covered entity (e.g., home care, delivery, reimbursement services). Regardless of the services provided by the contract pharmacy, access to 340B pricing will always be restricted to patients of the covered entity.”

(e) "The contract pharmacy and the covered entity will adhere to all Federal, State, and local laws and requirements. Both the covered entity and the contract pharmacy are aware of the potential for civil or criminal penalties if either violates Federal or State law. [The Department reserves the right to take such action as may be appropriate if it determines that such a violation has occurred.]"

(f) "The contract pharmacy will provide the covered entity with reports consistent with customary business practices (e.g., quarterly billing statements, status reports of collections and receiving and dispensing records)."

Important Considerations in 340B Contract Pharmacy Arrangements

1. The covered entity is responsible for 340B compliance.
2. The covered entity and pharmacy must maintain auditable records.
3. Understand the terms of your contract and flow of the money. A covered entity can lose money on a contract pharmacy arrangement.
4. The use of contract pharmacies may trigger HRSA audits.
5. Medicaid fee-for-service prescriptions should not be included in arrangement unless the State has approved and notified HRSA.
6. Savings from the 340B Program inure to the covered entity; not to the contract pharmacy.
(g) “The contract pharmacy, with the assistance of the covered entity, will establish and maintain a tracking system suitable to prevent diversion of 340B drugs to individuals who are not patients of the covered entity. Customary business records may be used for this purpose. The covered entity will establish a process for periodic comparison of its prescribing records with the contract pharmacy’s dispensing records to detect potential irregularities....”

(h) “The covered entity and the contract pharmacy will develop a system to verify patient eligibility, as defined by HRSA guidelines. The system should be subject to modification in the event of change in such guidelines.

“Both parties agree that they will not resell or transfer a drug purchased at 340B prices to an individual who is not a patient of the covered entity.... The covered entity understands that it may be removed from the list of covered entities because of its participation in drug diversion and no longer be eligible for 340B pricing.”

(i) “Neither party will use drugs purchased under 340B to dispense Medicaid prescriptions, unless the covered entity, the contract pharmacy and the State Medicaid agency have established an arrangement to prevent duplicate discounts. Any such arrangement shall be reported to the OPA, HRSA, by the covered entity.” (See Chapter 9 for a discussion of Medicaid issues.)

(j) “The covered entity and the contract pharmacy will identify the necessary information for the covered entity to meet its ongoing responsibility of ensuring that the elements listed herein are being complied with and establish mechanisms to ensure availability of that information for periodic independent audits performed by the covered entity.”

(k) “Both parties understand that they are subject to audits by outside parties (by the Department and participating manufacturers) of records that directly pertain to the entity’s compliance with the drug resale or transfer prohibition and the prohibition against duplicate discounts.

“The contract pharmacy will assure 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. Such auditable records will be maintained for a period of time that complies with all applicable Federal, State and local requirements.”

(l) “Upon written request to the covered entity, a copy of the contract pharmacy service agreement will be provided to the Office of Pharmacy Affairs.

2. No OPA model for contract with contract pharmacy

OPA has not offered a model contract for FQHCs (or other covered entities) or use with contract pharmacies. However, in its March 10, 2010 Federal Register Notice, OPA included a non-exhaustive list of sample provisions for FQHCs and other covered entities to include in contracts with contract pharmacies. This list is contained in Appendix Four. Please note that, as OPA states in the Notice, these terms are:

“for illustrative purposes and are not intended to be comprehensive, exhaustive or required. They offer sample provisions for consideration, but are not intended to be used as the complete terms of the contract.”

When adopting any sample contract, FQHCs should ensure that their final contracts reflect all circumstances and requirements that are specific to their state, organization, and 340B program.
3. Sample contracts with contract pharmacies & TPAs

The Texas Association of Community Health Centers (TACHC) has two sample contracts that are used by participants in its 340B Better program: These are contracts:

- between a health center and its TPA (which TACHC calls a Pharmacy Benefit Administrator or PBA) which administers a replenishment model.

- Among a health center, TPA, and contract pharmacy

These contracts are much longer and more detailed than the standard contracts that contract pharmacies and TPAs offer to health centers and other covered entities, and they are specifically written to address the unique circumstances faced by health centers. These contracts have also been reviewed by both Apexus and legal counsel.

Appendix Five contains more information on both of these contracts, including:

- a summary of the issues they address,

- a description of the inter-related nature of both contracts, and

- how to access the full contracts from either TACHC’s 340B Better program or their PBA, 340Basics.

Remember that when adopting any sample contract, FQHCs should ensure that their final contracts reflect all circumstances and requirements that are specific to their state, organization, and 340B program.

At this time, NACHC is not aware of other sample contracts with contract pharmacies and TPAs which are both specific to FQHCs’ needs and requirements, and which the parties are willing to share. If there are other examples, please contact regulatoryaffairs@nachc.org and we will include this information in future editions of this Manual as appropriate.

4. Best practices re: fees paid to vendors

OPA does not have any specific requirements around the level or structure of fees to be paid by FQHCs to contract pharmacies or TPAs. Rather, these fees are negotiated between the FQHC and the vendor.

However, health centers are well-advised to ensure that the fee structures in their contracts are consistent with the Congressional intent behind the 340B program, which stated that the program’s benefits are to accrue to the covered entities. (See Section 3.A.2.) While contract pharmacies and TPAs should be appropriately reimbursed for their costs, fees structure which result in their retaining a significant share of the 340B savings are not consistent with this intent.

Peer Perspective

“This is extremely important for FQHCs. The majority of the contracts written today call for a percentage of the cost of drug to be paid to the 340B Vendor. The 340B Vendor has no money invested in the cost of the drug—the FQHC is paying for the drugs. On expensive medications this amounts to a sizable “fee” going to the vendor. FQHCs do not have to sign these contracts.”
For these reasons, “best practice” for FQHCs generally entails seeking to negotiate contracts in which:

- contract pharmacies receive a flat dispensing fee for each drug. (Note that flat fees may vary based on the drug, as some drugs involve higher dispensing costs than others.)

- TPAs are reimbursed on a per-transaction basis.

Thus, as a general rule, **FQHCs are strongly advised to avoid contracts in which the contract pharmacy or TPA keeps a percentage of the 340B revenues.** These structures can result in some of the benefits of the 340B program accruing directly to the contract pharmacy or TPA, particularly in the case of higher-cost drugs. However, see the following “Peer Perspective” text box for some additional complexities to consider.

**Peer Perspective**

“I agree 100% that FQHC’s should generally seek to avoid contracts which include sharing of a percentage of the 340B revenue. However, more and more pharmacies are moving toward a lower flat fee plus a percentage of the retail amount collected to protect potential lost margin on the higher priced specialty drugs, etc. The flat fees would require multiple tiers of pricing to manage to keep the pharmacy whole on the more expensive and higher margin drugs. Pharmacies are more likely to carve out these drugs from their 340B contracts if their fixed fees are not enough to cover what they would normally realize. Though not ideal, the flat fee plus a percentage of the amount collected could be reasonable if it is substantiated to represent the average the pharmacy would normally collect on non-340B claims and it is not directly tied to 340B benefit. Pharmacies should be willing to share their actual acquisition cost to justify the proposed percentage methodology for auditing purposes.”

5. **TPAs may not contract with a contract pharmacy on FQHC’s behalf**

No, FQHCs may not rely on their TPAs to contract with contract pharmacies on their behalf. Rather, in order for an FQHC to use a contract pharmacy, there must be a contract executed directly between the FQHC and the contract pharmacy. Note, however, that the T may assist the FQHC with the contracting process.
D. Ensuring Compliance of Contract Pharmacies

As stated in Section 11.A.5, FQHCs are fully responsible for their contract pharmacies’ compliance with all 340B requirements. OPA provides guidance to FQHCs (and other covered entities) on how to ensure this compliance on its website, in a section entitled “Five Requirements for 340B Compliance in Contract Pharmacy”. This section discusses both these OPA requirements, as well as Section 330 requirements that apply under the contract pharmacy model.

1. OPA’s requirements for contract pharmacy oversight

A well-written contract is only one element of ensuring compliance in contract pharmacy arrangements. On its web page on contract pharmacy oversight, OPA lists the following oversight activities and provides links to resources to each. The FQHC must:

1. Conduct independent annual audits and/or adequate oversight mechanism of its contract pharmacies; (see Sections 11.D.1 and 11.D.2)

2. Develop written 340B Program policies and procedures related to contract pharmacy oversight; (see Section 12.A.9)

3. Maintain auditable records at both the FQHC and contract pharmacy; (see Section 13.A.3)

4. Ensure that the written contract pharmacy agreement lists each contract pharmacy location individually;

5. Do not use contract pharmacy for 340B purposes until:
   – the contract has been finalized and signed; and
   – the contract has been registered on the OPA database (which may not be done until the contract has been signed by all parties – see Section 5.B.3); and
   – the effective date of the registration has been reached (see Section 5.C.1);

6. Ensure that 340B drugs are only provided to 340B eligible patients; (see Chapter 7 for a discussion of patient eligibility.)

7. Carve-out Medicaid at contract pharmacies or develop an alternative arrangement to work in collaboration with the state Medicaid agency to ensure duplicate discounts do not occur and report this to OPA; (see Chapter 9 for a discussion of Medicaid issues) and

8. Maintain accurate information in OPAIS, including FQHC contact information, contract pharmacy information, and Medicaid fee-for-service billing information. (See Chapter 6.)

Again, please see the OPA website for links to resources to assist in meeting each of these requirements.
2. Audit expectations re: contract pharmacies

As discussed in the Section 11.D, although it not explicitly required by statute, OPA currently expects all covered entities – including FQHCs - to conduct annual independent audits of each contract pharmacy location. As discussed in Section 13.B.3, the independent auditor should not have a financial interest in the contract pharmacy arrangement.

Apexus addresses these expectations in the following FAQ:

In addition, in the draft Program Guidance released in August 2015, OPA proposed:

• to make annual independent audits mandatory
• to require FQHCs (and other covered entities) to compare its 340B prescribing records with the contract pharmacy’s 340B dispensing records at least quarterly.

While this guidance was never finalized, FQHCs would be well advised to implement these, or similar, oversight measures.

3. Contract pharmacies must registered and recertified on OPAIS

Each contract pharmacy site must be separately registered in the OPAIS, and must be recertified annually. These issues are discussed at length in Chapter 5 and Chapter 6. In particular, please see Section 5.B.4, which outlines specific considerations related to registering contract pharmacy sites.

4. Checklist for self-auditing contract pharmacies

A sample checklist is contained in Appendix Eight, Self-Audit Tools.
E. For More Information

**Official OPA Guidance on Contract Pharmacies**

- OPA’s initial guidelines on contract pharmacy arrangements were published in March 2010 and are available at [http://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf](http://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf)

- OPA’s official webpage on “Contract Pharmacy Oversight” is at [http://www.hrsa.gov/opa/updates/contractpharmacy02052014.html](http://www.hrsa.gov/opa/updates/contractpharmacy02052014.html)


- OPA also has a general website on contract pharmacy services at [http://www.hrsa.gov/opa/implementation/contract/](http://www.hrsa.gov/opa/implementation/contract/)

**Other Resources on Contract Pharmacies**

- As previously discussed, the official source of OPA-aligned policy information is Apexus. Contact information is available at Section 3.D.1.

- An excellent resource for health centers considering their pharmacy options is *The Bridge to 340B Comprehensive Pharmacy Services Solutions in Underserved Populations* by Katheryne Richardson available at [http://www.hrsa.gov/opa/files/bridgeto340b.pdf](http://www.hrsa.gov/opa/files/bridgeto340b.pdf). This document provides a comprehensive discussion of different pharmacy strategies, worksheets to conduct needs assessments, and case studies reflecting the various options.
Chapter 12
Policies and Procedures (P&Ps)

A complete set of Policies and Procedures addresses much more than pharmacy operations. It reflects an overarching, Board-approved policy describing how the FQHC's pharmacy program is managed, its intent, how savings are used, how compliance is ensured, etc.

This chapter provides:

- A list of key issues that should be addressed in a P&P Manual
- Links to sample policies
- A checklist for evaluating your health center’s P&Ps.

A. Key Issues to address in P&Ps

This section outlines important issues that should be addressed in a health center’s Policy and Procedures manual for 340B. Sample language for many of these items is contained in the Board policy located in Appendix Six.

1. Purpose of 340B program

P&Ps should include a concise statement as to the purpose of the Policy and Procedures manual (P&P) and the FQHC’s participation in the 340B Program. One Health Center uses the following statement:

“X Health Center participates in the 340B Drug Pricing Program in order to expand access to affordable prescription medications for its eligible patients, and to generate savings to support expanded and enhanced services for the medically underserved patients in our service area.”
2. Using savings in a manner consistent with Congressional intent

As discussed in Section 4.E.5, NACHC recommends that P&Ps address the specific purposes for which 340B savings are used. Specifically the P&Ps should:

• Define the services that are to be supported by 340B savings;

and

• Outline a timeline and method to evaluate the quality and efficacy of services supported by 340B savings.

Please review Chapter Sections 4.D and 4.E carefully when determining the specific purposes for which you will use your 340B savings.

3. Definitions

The following terms should be defined, either in the body of the P&Ps or in an appendix

• Eligible patient

• Eligible prescriber

• Eligible location

• Scope of service

• Covered drugs. This definition should reflect OPA’s current definition of eligible patient (see Section 7.A.2) and should also establish the parameters for when referral prescriptions and or hospital discharge prescriptions to be eligible to be covered under 340B. See Section 7.B.2 and 7.B.5, respectively, for more information.

4. Policy for reviewing and revising P&Ps

The P&P should address:

• How often and when will the P&Ps be reviewed?

• What is the procedure for revising the P&Ps?

• How are changes approved, and how is this documented?

5. Staffing

The P&Ps should describe assigned staff responsibilities and role of oversight committee, if applicable. See Appendix Eleven for more information on recommended non-clinical staffing roles.
6. Policy Statements

The P&Ps should contain concise affirmative statements that the FQHC will comply with regulations and guidance pertaining to these areas:

- Compliance with 340B requirements.
- Accuracy of information in OPA database
- Eligibility for participation
- Compliance with prohibition against duplicate discounts and diversion
- Maintenance of auditable records
- Responsibilities of prescribers
- Patient Freedom of Choice
- Billing to Medicaid
- Systems and controls in place to ensure compliance.
- Self-audits
- Use of contract pharmacies
- Contract pharmacy oversight
- Contract pharmacy agreements
- Contract pharmacy locations
- Material breaches
- Violation reporting

7. Registration, Recertification, and Change Requests on OPAIS

The P&Ps should address procedures for

- registering
- recertifying, and
- making changes to the information contained in OPAIS database. This includes information on clinical sites, contract pharmacy sites, Authorizing Official, Primary Contact, Medicaid fee-for-service billing status, etc.

See Chapters 5 and 6 for information on registering, recertifying, and making changes on the OPA database.
8. Purchasing, Inventory Management, Dispensing

The P&Ps should:

- Describe procedures related to 340B purchasing, including supplier names and account numbers.
- Describe how 340B inventories are managed and tracked, including software used.
- Describe safeguards to ensure 340B drugs are only dispensed to eligible patients.
- Describe safeguards to protect against the possibility of duplicate discounts.

9. Contract Pharmacy

The P&Ps should:

- List all contract pharmacy agreements.
- List locations of all pharmacy sites under each contract.
- List all clinical sites served by each contract pharmacy site.
- Describe procedures (e.g., tracking software) used to prevent diversion.
- State whether the each contract pharmacy carves Medicaid in or out, for fee-for-service and managed care.
- For carve-in sites, describe procedures for avoiding the possibility of duplicate discounts.

10. Patient Freedom of Choice of Pharmacy Provider

The P&Ps should include a description of the FQHC’s procedures for ensuring that all patients are informed of their right to go to the pharmacy provider of their choice. See Section 8.B for more information.

11. Monitoring and Reporting

P&Ps should describe:

- frequency and types of audits they will undergo, including internal procedures used.
- how contract pharmacy oversight is provided, including independent external audits. (See Section 11.D.)
- how the FQHC defines “material breach.” (See Section 13.B.8)
- procedure for self-disclosing violations to OPA. (See Section 13.B.6.)
- how long the FQHC will maintain “auditable records”, including P&P manuals. (See Section 13.A.3.)
12. Ensuring affordability for SFDS-eligible patients

P&Ps should discuss how the health centers will ensure that low-income uninsured and underinsured patients (i.e., those eligible for the SFDS) are able to afford their medications. This discussion should address both ingredient costs and dispensing fees, at both in-house and contract pharmacies. See Section 4.B.2 for more on BPHC’s sliding fee requirements.

B. General information on P&Ps

1. Sample P&Ps

IMPORTANT: If choosing to use a sample policy and procedure manual as a guide, please ensure that the template is customized for your facility. Auditors often review a Health Center’s manual only to find blank spaces and information that does not accurately reflect the operations of the Health Center.

Sample P&P manuals are available as follows:

• Apexus offers a sample template for a “CHC 340B Comprehensive Policy and Procedures Manual.” This relatively brief document is available at https://docs.340bpvp.com/documents/public/resourcecenter/chc_policymanual.docx

• The Texas Association of Community Health Centers (TACHC), which has been coordinating the 340B pharmacy program for FQHCs since 1999 (see Section 3.C.8 for more information on 340Bbetter), has developed a detailed set of 340B P&Ps specifically for health centers. To access these P&Ps, contact Lynn Ford at the Texas Association of Community Health Centers (lford@TACHC.com) or go to the TACHC 340Bbetter website.

• Appendix Six contains a sample Board policy for 340B, which was provided by a health center that underwent a successful IRS audit. Note that this type of document must be accompanied by a Pharmacy Services Operations Manual that outlines detailed procedures for implementing the Board-approved policy.

• At this time, NACHC is not aware of other sample P&P Manuals that are specific to FQHCs, and which the parties are willing to share. If there are other examples, please contact cmeiman@nachc.org and we will include this information in future editions of this Manual as appropriate.

2. Checklist for evaluating a 340B P&Ps

Appendix Seven contains a checklist that can assist Health Centers in evaluating their 340B Policy and Procedures.

3. Do not destroy outdated P&P manuals

In the event of an audit, you may be asked to show the policies and procedures that were in effect at the time that a specific event occurred. Thus, you should keep P&P manuals for the same length of time as other “auditable records.” As discussed in Section 13.A.4, in the draft Mega-Guidance published in 2015, OPA proposed that FQHCs and other covered entities maintain auditable records for five years. While this guidance was never finalized, it indicates OPA’s expectations in this area.
Chapter 13
340B Compliance and Audits

FQHCs participating in the 340B Program have numerous responsibilities related to the Program in addition to avoiding diversion and duplicate discounts. These include, but are not limited to:

- keeping the OPA database information current,
- completing an annual recertification,
- meeting all eligibility requirements of the Program,
- documenting and maintaining written policies and procedures related to Program activities,
- conducting regular internal audits of Program activities,
- conducting ongoing oversight of contract pharmacy arrangements,
- providing current eligible prescriber lists and eligible locations to vendors,
- providing patient encounter data and related records to auditors when requested, and
- providing ongoing training to staff members involved in the 340B Program.

When subjected to a OPA audit, the auditors will consider the health center’s compliance with these responsibilities.

A. General Information on Audits:

1. Both OPA and manufacturers can audit FQHCs’ 340B programs

The statute permits both OPA and manufacturers to audit covered entities. Also, as discussed in Section 13.D.4, starting in 2017, manufacturers have begun hiring outside groups to conduct initial compliance checks (specifically around duplicate discounts) on their behalf.

In addition, HRSA’s Bureau of Primary Health Care (BPHC) now includes questions about 340B compliance as a standard part of its Operational Site Visit (OSV.) While this is not an official audit, FQHCs are well advised to ensure that they can respond appropriately to these questions, as failure to do so may trigger a full audit by HRSA OPA.

Finally, FQHCs should audit themselves on a regular basis.
Therefore, after some general information on audits, this chapter contains information on four types of audits:

- Self-audits
- HRSA OPA audits
- Questions about 340B included in all BPHC Operational Site Visits (OSVs) that could trigger an audit
- Manufacturer audits.

2. **340B audit requirements from OPA**

FQHCs must have safeguards to maintain compliance with Program rules and must keep “auditable records” (see Section 13.A.4) to verify compliance. It is the covered entity’s responsibility to inform OPA if it is no longer eligible for Program participation.

OPA has not established requirements around how or how often FQHCs (or other covered entities) should have their 340B programs externally audited, other than the expectation that the FQHC will perform annual independent audits of contract pharmacy arrangements. However, health centers with an “in-house” pharmacy would be well-advised to conduct an annual independent audit.

3. **What is meant by “auditable records”?**

A FQHC must maintain records demonstrating compliance with all 340B Program requirements for all of its sites, and all contract pharmacy locations which dispense 340B drugs. These supporting records must be made available to OPA at any time and to certain manufacturers if requested in an audit. While OPA has not clearly defined “auditable records”, at a minimum these records should include:

- Policies and Procedures (do not throw away old Policy and Procedures manuals after updating),
- copies of self-audits,
- copies of external 340B audits,
- contracts related to contract pharmacy 340B operations (e.g., contracts with the pharmacy itself; TPA contracts; virtual inventory tracking systems.) Note: do not throw away expired contracts
- pharmacy service agreements,
- vendor contracts
- patient records,
- invoices for 340B drugs purchased,
- reports of 340B drugs dispensed, and
- inventory reconciliations.

Refer to Appendix Nine for a listing of documents currently requested by OPA auditors for review.
4. How long should FQHCs keep auditable records?
OPA has not established a clear policy about how long a FQHC must maintain its auditable records. However, in the draft Guidance published in August 2015, OPA proposed requiring that FQHCs (and all other covered entities) keep these records for at least five years. While this proposal was not finalized, FQHCs are well-advised to keep their records for at least five years.

5. Factors that may increase FQHCs’ chances of a 340B audit
There is no official list of factors that increase an FQHC’s (or other covered entity’s) chances of being audited by OPA or a manufacturer. However, experience suggests that the following factors may affect the likelihood of being audited:

- **Size and complexity of the health center’s pharmacy program:** Larger, more complex programs appear more likely to be audited.
- **Number of contract pharmacies:** Covered entities with a large number of contract pharmacies appear more likely to be audited than those with a limited number.
- **Failure to respond in a timely manner to a manufacturer’s inquiry:** If a manufacturer does not think that it has received a timely response to an inquiry, OPA is more likely to pursue an audit and manufacturers will be more likely to seek authority to conduct its own audit. (See Section 13.D.3.)
- **Having an open door (“retail”) model pharmacy:** As discussed in Section 8.A.3, including an open door model adds significant complexity to a FQHC’s pharmacy program, potentially increasing its risk of being audited.
- **Negative finding(s) on a 340B-related issue during a BPHC Operational Site Visit:** See Appendix Two for a list of 340B-related questions that are asked as part of a BPHC Operational Site Visit.

6. Common audit findings, & how FQHCs can avoid them
This topic is addressed at length in Chapter 14. Also, see Appendix Nine for examples of common finding during self-audits.

7. Potential consequence of audit findings

- **Requirement to repay manufacturers:** The 340B statute states that covered entities will be liable to the manufacturers for diversion and duplicate discount violations. The amount owed to the manufacturer for the violation will be equal to the reduction in the price of the drug provided under its 340B pricing contract.

- **Posting on the OPA website:** As discussed in Section 13.C.3, once OPA reviews and approves a health center’s Corrective Action Plan (CAP), it will post a public notice on the 340B Program website to inform manufacturers regarding violations that have occurred. This notice will include findings of the 340B Program audit requiring possible repayment, and the FQHC’s contact information for manufacturers to utilize for questions.

- **Termination from the program.** OPA has the authority to terminate individual contract pharmacy sites, clinical sites, and entire organizations from the 340B program based on audit findings.
B. Self-Audits:

1. How can FQHCs self-audit?

A FQHC can use a variety of methods to self-audit its 340B Program. These include both:

- independent audits conducted by outside organizations (see Section 13.B.3) and
- internal audits conducted by FQHC staff (see Section 13.B.4)

Apexus 340B University™ website contains a compliance self-assessment tool for community health centers. See the bottom of the third column at https://www.340bpvp.com/education/340b-tools/. Also, refer to Appendix Eight for more self-audit tools that health centers may use, and Appendix Nine for examples of common finding during self-audits.

2. How often should FQHCs self-audit?

*FQHCs are well advised to perform some type of self-assessment each month, and more often if possible.* As mentioned above, see Appendix Eight for self-audit tools that health centers may use, and Appendix Nine for examples of common finding during self-audits. Also see Section 13.B.4 for information a brief discussion of internal audits.

3. What types of organizations may do our independent audits?

OPA has not established requirements around what types of external organizations may audit either in-house or contract pharmacies. (For example, there is no requirement that the auditor be a CPA.) However, FQHCs are well-advised to:

- Ensure that the entity which conducts the audits is completely independent from the program — aka, has no “skin in the game.” (For example, it is not advisable to have the PBM, VIM, or contract pharmacy audit a program in which they are participating.)
- Carefully examine all audit proposals, including the fees being proposed, before selecting an auditor.

To address both of these concerns, some health centers use a “peer audit” process, in which two health centers audit each other’s 340B program.
4. Should FQHCs have on-going internal audit procedures?

Absolutely. In addition to establishing a mechanism for regular, periodic independent audits, health centers are well-advised to have standard operating procedures that include on-going “audits” to identify and correct incidents of diversion or duplicate discount when they occur. Most health centers conduct this type of routine self-audit on at least a weekly or monthly basis. Some audit daily and require the employee who erred to make the correction. This serves as not only a compliance mechanism, but also a teaching tool. See Appendix Eight for self-audit tools, including a tool for “testing” the compliance of individual prescriptions.

5. What if we find a problem during a self-audit?

It is the FQHC’s responsibility to alert HRSA OPA to a “material” violation or breach. (See Section 13.B.8 for a discussion of how to define a “material” breach.) During the annual recertification process, the FQHC’s Authorizing Official attests to the fact that:

“the covered entity acknowledges its responsibility to contact HRSA as soon as reasonably possible if there is any material breach by the covered entity of any of the foregoing (points of 340B compliance).

According to OPA, a covered entity should self-disclose as soon as reasonably possible after a material violation. Currently there is no required self-disclosure process; however, as discussed below, there are recommended steps and tools.

6. What constitutes a “material” breach?

As previously discussed, HRSA/OPA requires FQHCs (and other covered entities) to report “material” breaches (aka violations) to HRSA OPA when identified during a self-audit. However, HRSA/OPA has no official definition of a “material” breach. Therefore, FQHCs are well-advised to:

• Develop a definition of what constitutes a “material” breach,

• Develop a process to determine when a breach qualifies as “material” under the FQHC’s documented definition, and

• Document this definition and process in their policies and procedures.

Apexus has developed a one-page tool to help covered entities to formulate internal policies defining a material breach, and the action to take when a material breach is identified. This “Defining Material Breach Documentation Tool” is available at https://docs.340bpvp.com/documents/public/resourcecenter/Establishing_Material_Breach_Threshold.pdf
7. Steps for self-disclosing a material breach

In situations where there is a material breach (as yet undefined by OPA – see Section 13.B.8), OPA has recommended the following steps in its September 2014 update (available at https://www.hrsa.gov/opa/updates/september-2014.html)

1. FQHC Reports Issue to OPA – including 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.
   (See Section 13.B.7 for information about a tool to assist with self-disclosure.)

2. FQHC Works with Manufacturer
   - The FQHC and the manufacturer work out any necessary financial remedy in good faith. (See Section 13.A.6 for a discussion of repayments.)

3. OPA Reviews Self-Disclosure, including:
   - violation information;
   - CAP, ensuring that it fully addresses issues causing the violation;
   - repayment plan and/or completion of plan; and
   - completion of contact to all affected manufacturers.
   - NOTE: HRSA staff will follow-up with the FQHC Authorizing Official if any of the requested information is missing from the self-disclosure.

4. OPA Closes Self-Disclosure
   - When all criteria under Step #3 are met, the FQHC receives written communication from OPA that the matter is closed.
8. **Apexus tool for self-disclosure**

Apexus has worked with OPA, covered entities, and manufacturers to develop a suggested tool for the self-disclosure process. The self-disclosure tool includes a sample letter to OPA, a tool for assessing materiality of a violation, a sample letter to manufacturers, a format for summarizing non-compliance, and a template for a corrective action plan.

C. **HRSA OPA Audits**

1. **Increases in OPA audit activity**

HRSA OPA audits began in 2012 and as of November 2017, OPA had completed over 700 audits. **OPA audit activity is expected to keep increasing each year.** At present, OPA’s audits are conducted by an outside contractor, as opposed to OPA staff.

2. **Issues that OPA focuses on during audits**

OPA’s completed audits have tended to focus on:

- the accuracy of information in OPAIS,
- drug diversion,
- duplicate discounts, and
- oversight of contract pharmacies.

As of December 2017, FQHCs have had a higher rate of adverse audit findings than other types of covered entities (75% versus 70%). Also, see **Appendix Nine** for a list of documents that OPA auditors request during audits.

3. **What to expect in a OPA audit**

The information in this section was taken from the following OPA website: [http://www.hrsa.gov/opa/programintegrity/index.html](http://www.hrsa.gov/opa/programintegrity/index.html)

Before the audit begins:

- The FQHC selected for audit will receive an engagement letter explaining what to expect and how to appropriately prepare.
- Auditors will conduct an introductory teleconference with the FQHC to request and obtain specified documents, including policies, procedures and internal controls.
- Auditors will work with the FQHC to schedule an opening meeting with the FQHC management to discuss expectation for the onsite audit.
- Auditors will request data be provided prior to the onsite visit via a secure site.
While the auditors are onsite:

- Auditors obtain and review select 340B Program data and internal controls.

- Audit procedures include, at a minimum:
  
  - review of relevant policies and procedures and how they are operationalized;
  
  - verification of internal controls to prevent diversion and duplicate discounts, including OPA Medicaid Exclusion File designations, and accuracy of FQHC’s 340B database record;
  
  - review of 340B Program compliance at FQHC sites and contract pharmacies; and
  
  - testing of 340B drug transaction records on a sample basis.

- If the onsite audit takes place at the administrative offices, the auditor may request to visit a registered health center.

- Auditors collect the facts throughout the audit but are not authorized to summarize any findings to the FQHC. Their report to OPA will contain the facts as they understand it and must undergo OPA review. Additionally, any auditor statements made during the audit are not considered final and are subject to change.

After the audit:

- Auditors forward a preliminary report to OPA for review.

- OPA reviews the preliminary report, drafts a Final Report and issues the report to the FQHC, with a request for a corrective action plan (CAP), if applicable.

- After OPA issues a Final Report, the FQHC has 30 calendar days from the date of the OPA Final Report to review findings noted in the OPA Final Report, and to review OPA’s request for a CAP related to the findings noted.

- If the FQHC agrees with the Final Report, it must submit a CAP to OPA within 60 calendar days for OPA’s approval.

- If the FQHC disagrees with the Final Report, it must notify OPA in writing within 30 calendar days with appropriate supporting documentation of its disagreement. OPA reviews the FQHC’s response and, if appropriate, may reissue the Final Report if changes are made based on documentation submitted.

- If the FQHC fails to submit a CAP, it may be removed from the 340B Program.

- Once an audit report is finalized by OPA, the findings and any associated corrective action will be summarized on the OPA public website.

- In addition, once OPA reviews and approves a CAP, it will post a public notice on the 340B Program website to inform manufacturers regarding violations that have occurred. This notice will include findings of the 340B Program audit requiring possible repayment, and the FQHC’s contact information for manufacturers to utilize for questions.
• OPA closes out the audit once the FQHC attests that all repayment is resolved (if necessary) and that the CAP has been fully implemented.

• FQHCs whose findings involve repayment will be subject to another audit in a year.

4. **BPHC Operational Site Visits assess 340B compliance**

Yes. Starting in late 2014, questions regarding 340B compliance have been a standard part of all Health Center Operational Site Visits (OSVs) coordinated by HRSA's Bureau of Primary Health Care (BPHC). HRSA OPA stated that:

“Starting in Fiscal Year 2015, grantees that participate in the 340B program and are scheduled for a HRSA site visit will be asked to demonstrate compliance with the 340B program. While the primary focus of the site visit remains on the HRSA grant, several basic questions will serve as an important reminder for grantees of the importance of 340B compliance, as well as a potential trigger for further investigation by the Office of Pharmacy Affairs (OPA).…

“In general, covered entities should be able to efficiently and effectively prevent compliance issues and identify any material breach; propose a plan for periodic assessment and continuous monitoring; and outline a clear method to monitor contract pharmacies to maintain compliance with program requirements. Successful covered entities have also routinely identified annual policy review date, entity contact person, and clarified an internal 340B communication/education strategy.

**The specific questions related to 340B that are asked during an OSV are listed Appendix Two.** Note that these questions are expected to stay the same when BPHC introduces the revised OSV Guide based on the new Compliance Manual.
5. **OPA suggestions for preparing for OSV questions on 340B**

The information in this section was taken from the HRSA website below:


“... HRSA recommends that each covered entity establish and document criterion that demonstrates compliance for the following requirements as outlined below.

- “Be prepared to share your organization’s 340B policies, procedures, and other related documents in order to document they address the following:
  - Patient Definition
  - Individuals provided access to 340B drugs purchased by the covered entity have an established relationship with the patient as documented by the covered entities maintaining records of that individual’s healthcare.
  - Individuals provided access to 340B drugs purchased by the covered entity have received healthcare services from a healthcare professional who is either employed by the covered entity or under contractual or other arrangements (e.g., referral for consultation) such that responsibility for care provided remains with the covered entity; i.e., 340B prescriptions are only made available that receive services that are either provided directly by the covered entity/or through formal written referral arrangements.
  - 340B drugs purchased/dispensed by the covered entity to such individuals are consistent with the service or range of services for which grant funding was approved.
- “Duplicate Discount
  - The covered entity has the ability to prevent duplicate discounts for patients covered under Medicaid and who receive a 340B drug.
- “Contract Pharmacy
  - If the covered entity dispenses 340B drugs to patients through a contract pharmacy services model the covered entity should be prepared to provide the following:
    - The written contract between the covered entity and the contract pharmacy.
    - Policies, procedures, and/or other documents as to how the contract pharmacy will prevent diversion.
    - Policies, procedures and/or other documents as to how the contract pharmacy will prevent duplicate discounts.
    - How the covered entity provides oversight (e.g., annual audit or other mechanism) of the 340B drugs dispensed by the contract pharmacy.”
D. Manufacturer Audits

1. When can a manufacturer audit an FQHC?

A drug manufacturer participating in 340B has the right to audit records of a Health Center organization, its child sites, and its contract pharmacies to ensure that duplicate discounts and diversion have not occurred. The manufacturer must first obtain approval from OPA to conduct such an audit. The manufacturer must show reasonable cause to believe the FQHC is not complying with the rules.

Here is the process the manufacturers are expected to follow:

- The manufacturer should first notify the FQHC if it believes a violation has occurred. The manufacturer should work with the FQHC in good faith to resolve any issues.

- If the manufacturer cannot resolve the matter through good faith negotiations, the manufacturer may submit its “reasonable cause” evidence and its audit work plan to OPA, along with supporting documentation of its attempt to resolve the matter with the FQHC.

- OPA will review the documentation and audit work plan to determine if the manufacturer may proceed with its audit.

- The manufacturer will provide audit results to the FQHC as well as OPA.

2. Manufacturers using outside contractors to look for violations

In 2017, several manufacturers contracted with a group named Kalderos to research potential instances of duplicate discounts among many types of 340B covered entities. Legally, health centers are not required to respond to information requests from organizations such as Kalderos. However, given that Kalderos demonstrated that it was working on behalf of drug manufacturers – and that these manufacturers have the right to audit covered entities – health centers are well advised to respond promptly to these inquiries.

3. Responding to a letter from a manufacturer

If a FQHC receives a letter from a manufacturer asking about its 340B practices, the FQHC is well-advised to engage its legal counsel and respond promptly, and in good faith. Failure to respond promptly, and in a “good faith” manner, could increase the likelihood that OPA will determine that there is “reasonable cause” to suspect that the FQHC has violated 340B rules, and approve the manufacturer’s request to audit the FQHC.
E. For More Information

The OPA website contains detailed information and guidance on 340B Program compliance. This is in the form of program updates, policy releases, and Federal Register guidance.

The following Program Updates – available at http://www.hrsa.gov/opa/updates/programupdates.html - are of particular relevance to health centers.

• 08/17/2017 OPA Monthly Update - August 2017
• 01/06/2017 OPA Monthly Update - January 2017
• 12/15/2016 HRSA OPA Manufacturer Update
• 08/12/2016 Contract Pharmacy: Important Tips
• 04/15/2016 340B Pricing System: Manufacturers 340B Database Verification and Other Updates
• 02/12/2016 The Importance of Establishing and Following 340B Program Policies and Procedures
• 01/08/2016 340B Audits: News to Use in 2016
• 12/17/2015 340B Price Unavailability: How to Report to HRSA
• 11/20/2015 340B Peer-to-Peer Program and Best Practices
• 10/09/2015 The Medicaid Exclusion File: Important Clarifications
• 08/17/2015 340B Resources


• 2014-1 Clarification of Use of the Medicaid Exclusion File
• 2012-1.1 Clarification of HRSA audits of 340B Covered Entities
• 2011-3 Clarification of Manufacturer Audits of 340B Covered Entities
• 2011-2 Clarification of Penny Pricing Policy
• 2011-1.1 Clarification of Non-Discrimination Policy
Federal Register notices concerning the 340B Program may be found at: [https://www.hrsa.gov/opa/program-requirements/federal-register-notices/index.html](https://www.hrsa.gov/opa/program-requirements/federal-register-notices/index.html). They include:

- 09/29/2017 Ceiling Price and **Manufacturer Civil Monetary Penalties** Final Rule; Further delay of the Effective Date
- 08/12/2016 340B Drug Pricing Program; **Administrative Dispute Resolution**
- 07/24/2012 Notice Regarding Section 340B of the Public Health Service Act **Registration Period**
- 03/05/2010 Final Notice Regarding 340B Drug Pricing Program: **Contract Pharmacy Services**
- 03/15/2000 Notice Regarding the Section 340B Drug Pricing Program – Program Guidance Clarification (Duplicate Discounts)
- 03/15/2000 Notice Regarding the Section 340B Drug Pricing Program – **Program Guidance Clarification**
- 02/09/2000 Notice Regarding **HRSA Grant Requirement** – Participation in 340B Drug Pricing Program
- 12/12/1996 Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 **Patient and Entity Eligibility**

Also, as previously discussed, the official source of HRSA-aligned policy information is Apexus. Contact information is available at Section 3.D.1.
Chapter 14  
Tips for Avoiding Common 340B Audit Findings

A. General Information

As stated previously, the most common audit findings for FQHCs have involved:

- Incorrect OPA 340B database records
- Diversion
- Duplicate discounts
- Inadequate oversight of contract pharmacy

This chapter starts with some general tips for avoiding audit findings; it then addresses each area of common findings, providing examples of specific audit findings and tips for avoiding them.

1. General tips for avoiding common audit findings

- Develop and maintain comprehensive policies and procedures that clearly describe the compliance framework, processes in place to support compliance, individuals responsible, and how the health center uses its savings from the 340B Program. The Board of Directors should approve an over-arching policy that provides the framework for department specific procedures. See Chapter 12 for more information on Policies and Procedures, and Appendix Seven for a checklist to assist in evaluating a Health Center’s 340B Policy and Procedures Manual.

- Develop corporate-wide training programs to ensure all health center staff understand the purpose of the 340B Program and are knowledgeable about the health centers policies and procedures.

- Conduct regular self-audits. Self-audits are discussed in Section 13.B, and a self-audit tool and other resources are located at Appendix Eight.

- Develop and document a definition of what constitutes a “material” breach, and the action that the FQHC will take when a material breach is identified. (See Section 13.B.8 for more information on “material” breach.”) To assist with the process, Apexus has prepared a “Defining Material Breach Documentation Tool” which is available at https://docs.340bpvp.com/documents/public/resourcecenter/Establishing_Material_Breach_Threshold.pdf

- Ensure that you have staff specifically assigned to cover all key clinical and non-clinical tasks associated with operating a compliant 340B program. See Appendix Eleven for a list of non-clinical roles and responsibilities.
B. Tips for Specific Compliance Areas

1. Incorrect OPAIS Records

   • Examples of specific findings have included:
     – incorrect name for FQHC
     – not all clinical sites are listed on the database
     – contract pharmacy was registered without having a written contract in place
     – incorrect contract pharmacy address.

   • Potential strategies for avoiding these findings:
     – Pay close attention to requirements and timelines around registration and recertification.
     – Regularly check information in OPAIS for accuracy and completeness as part of self-audit process.

   • Resources
     – Chapter 5 and Chapter 6 of this Manual, which address registration and recertification on OPAIS, respectively.
     – Federal Register dated 7/24/2012 regarding the Registration Period. Available at: https://www.hrsa.gov/opa/program-requirements/federal-register-notices/index.html

2. Diversion

Diversion is a frequent OPA audit finding, especially in contract pharmacy settings. Often diversion is the result of improper matching of the entity’s patient data to the contract pharmacy’s dispensing records.

   • Examples of specific findings have included:
     – 340B drug dispensed at a contract or in-house pharmacy for a prescription written by an ineligible provider
     – 340B drug dispensed for a prescription written at an ineligible site.
     – 340B drug dispensed for a referral prescription for which the FQHC did not demonstrate that it retained responsibility for care.

   • Strategies for avoiding these findings:
     – Ensure that the “filters” or “tables” used in matching data files contain not only patient and drug information, but also eligible provider lists and encounter site locations.
     – Ensure that lists of eligible providers prescribing medications are kept current by updating at least monthly. If an outdated prescriber listing includes a provider who is no longer associated with the FQHC, the potential for diversion is increased. Be sure to archive monthly provider listings as the credentialing staff may only have a “live” version. This will assist in determining provider eligibility during audits.
– Always include encounter site locations in the matching process. Except for eligible prescriptions generated from patient referrals and/or hospital discharge prescriptions (see Sections 7.B.2 and 7.B.5, respectively), only prescriptions written in 340B registered locations are eligible for 340B pricing. Sometimes a provider may work in more than one office location. Only prescriptions originating from eligible providers in sites registered on the OPA database are 340B eligible. For this reason, the location of service is important when matching data files.

– Discuss your strategies for avoiding diversion in your Policies and Procedures. Do not throw away old Policy and Procedure manuals after updating, as you might be asked to produce the policies that were previously in effect.

• Resources

– Chapter 7 of this Manual, which addresses the definition of an eligible patient, as well as referral prescriptions, hospital outpatient prescriptions, and refills/ renewals of 340B-eligible prescriptions

3. Duplicate Discounts

• Examples of specific findings have included:
  – Contract pharmacy treating Medicaid patient dispense as 340B eligible due to incorrect PCN/BIN identifiers in its filters.
  – Contract pharmacy treating Medicaid patient dispense as 340B eligible due to patient type being incorrect in FQHC patient database.
  – FQHC billing Medicaid contrary to information included in Medicaid Exclusion File (e.g., stating that they carve out when registering, but then filling prescriptions for Medicaid patients with 340B drugs.)
  – incorrect or incomplete NPI or Medicaid billing numbers

• Potential strategies for avoiding these findings:
  – If your pharmacy is carving in for Medicaid fee-for-service patients, ensure that you are listed correctly on the Medicaid Exclusion File. (See Section 9.C.1.)
  – Include both your Medicaid Provider Numbers and NPI numbers in the Medicaid Exclusion File.
  – Include MPN/NPI in the Medicaid Exclusion File for all states that are billed and follow the state billing policies of all states that are billed by your entity (not just the one in which you are located.)
  – Do not use a contract pharmacy to dispense to Medicaid FFS patients, unless you have a written agreement with the pharmacy and the state Medicaid agency as to how duplicate discounts will be avoided.
  – Discuss your strategies for avoiding duplicate discounts in your Policies and Procedures. Do not throw away old Policy and Procedures manuals after updating, as you might be asked to produce the policies that were previously in effect.
• Resources
  – Chapter 9 of this Manual, which addresses the intersection of Medicaid and 340B, including information on avoiding duplicate discounts.

4. Inadequate oversight of contract pharmacies

• Examples of specific findings have included:
  – Contract pharmacy was registered without having a written contract in place
  – Entity did not provide contract pharmacy oversight
  – 340B drug dispensed at a contract pharmacy for a prescription written at an ineligible site by an ineligible provider, not supported by responsibility of care
  – Contract pharmacy was billing Medicaid without notification to OPA
  – No documentation of oversight activities

• Potential strategies for avoiding these findings:
  – Discuss your strategies for overseeing contract pharmacies in your Policies and Procedures. Do not throw away old Policy and Procedures manuals after updating, as you might be asked to produce the policies that were in effect at a point in the past.

  Peer Perspective
  “My experience over a number of years has shown that the greatest problem with contract pharmacy arrangements is that the 340B entity does not understand the monthly statements—does not have a grasp of understanding that monthly statements need to clearly show what has been dispensed, what has been ordered for replenishment, how much money has been collected, how much are the dispensing fees, and how much are the Vendor fees. FQHCs are not in compliance if they do not understand the statements.”

• Resources
  – Chapter 11 of this Manual, which addresses oversight of contract pharmacies.
  – Federal Register Notice dated 03/05/2010 regarding Contract Pharmacy Services. Available at: https://www.hrsa.gov/opa/program-requirements/federal-register-notices/index.html
Appendix One  
HRSA & APEXUS 340B Resources

### A. General Resources

<table>
<thead>
<tr>
<th>Resource</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>340B University™ (Apexus)</strong></td>
<td>Web-based education through:</td>
</tr>
<tr>
<td></td>
<td>• 340B Tools</td>
</tr>
<tr>
<td></td>
<td>• 340B University™ On Demand</td>
</tr>
<tr>
<td><strong>Office of Pharmacy Affairs Information System (OPAIS)</strong></td>
<td>Searchable database of covered entities, child sites, contract pharmacies,</td>
</tr>
<tr>
<td><a href="https://340bopais.hrsa.gov/">https://340bopais.hrsa.gov/</a></td>
<td>and manufacturers</td>
</tr>
<tr>
<td></td>
<td>On-line registration, recertification, and change requests</td>
</tr>
<tr>
<td></td>
<td>Reports (link to Medicaid Exclusion File)</td>
</tr>
<tr>
<td><strong>Apexus Answers</strong></td>
<td>Call center for assistance with 340B questions by phone call, email, or chat.</td>
</tr>
<tr>
<td></td>
<td>888-340-2787</td>
</tr>
<tr>
<td></td>
<td>Email: <a href="mailto:ApexusAnswers@340bpvp.com">ApexusAnswers@340bpvp.com</a></td>
</tr>
<tr>
<td></td>
<td>Monday – Friday 8 a.m. to 5 p.m. (Central)</td>
</tr>
<tr>
<td><strong>Health Resources and Services Administration</strong></td>
<td>Audit process</td>
</tr>
<tr>
<td><strong>Office of Pharmacy Affairs (OPA)</strong></td>
<td>General information on 340B Program</td>
</tr>
<tr>
<td></td>
<td>Links to 340B database</td>
</tr>
<tr>
<td><strong>OPAIS User Guides</strong></td>
<td>User guides for registration, recertification, and changes to OPA 340B</td>
</tr>
<tr>
<td><strong>Prime Vendor Program (PVP/Apexus)</strong></td>
<td>Contracting and distribution for covered entities</td>
</tr>
<tr>
<td></td>
<td>888-340-2787</td>
</tr>
<tr>
<td><strong>PVP Resource Center</strong></td>
<td>Frequently asked 340B questions and answers</td>
</tr>
</tbody>
</table>
B. Specific Tools Available on Apexus Website


- Defining Material Breach Documentation Tool
- 340B Independent Audit RFP Checklist
- HRSA Notification Template - 340B Price Unavailable
- Use of 340B Savings
- 340B Acronym Guide
- 340B Glossary of Terms
- Self-Disclosure to HRSA and Manufacturer template
- 340B Compliance: For the C-Suite
- HRSA Recertification Attestation Language
- 340B Compliance and the Controlled Substance Ordering System (CSOS)
- Split-Billing Decision Checklist
- 340B Manager and Coordinator Job Description Template
- 340B Analyst Job Description Template
- Checklist for Covered Entity Contract Pharmacy Carve-In Request
- Mapping the 340B Drug Operations Environment ([Word](https://www.google.com) or [Excel](https://www.google.com))
- Policy and Procedure Self-Audit Tool
- Contract Pharmacy Self Audit Tools
  - Contract Pharmacy Eligibility
  - Prevention of Duplicate Discounts
  - Prevention of Diversion
- Establishing a Compliant Consignment Inventory Program
- Dashboard Best Practices for Covered Entities
- HRSA Audits of Entities
- CHC Self Audit Tools
  - CHC Eligibility
  - Prevention Duplicate Discounts
  - Prevention of Diversion
- CHC Sample 340B Policy and Procedure Manual - [Updated](https://www.google.com)
- CHC 340B Compliance Self-Assessment Policy
- CHC 340B Compliance Self-Assessment Data and Transactions
Appendix Two

340B Questions Asked During BPHC Operational Site Visits

As of Summer 2015

1. Does the health center participate in the 340B drug pricing program? (if NO, the remaining questions are not required)

2. Does the health center have written 340B policies, procedures, or other related documents? (if NO, proceed to question 4)

3. If YES to #2, do the policies, procedures or other related documents address the following areas to assure that the individuals provided access to 340B drugs purchased by the health center meet all of the following?
   
   a) The health center has an established relationship with the individual, as documented by the health center maintaining records of the individual’s health care;

   b) The individual receives health care services from a health care professional who is either employed by the health center or under contractual or other arrangements (e.g. referral for consultation) such that responsibility for care provided remains with the health centers; i.e. 340B prescriptions are only made available to those who receive services that are either provided directly by the health center (Form 5A Column I or II) and/or through formal written referral arrangements (Form 5A Column III) consistent with approved scope of project; and

   c) The prevention of duplicate discounts for patients covered under Medicaid?

4. Does the health center dispense 340B drugs to patients through a contract pharmacy services model? If YES, please verify the following:
   
   a) Does a written contract exist between the health center and contract pharmacy(ies)?

   b) Does the health center have within its contract or in written Policies and procedures how the contract pharmacy will ensure against diversion?

   c) Does the health center have, within its contract or in its written policies and procedures, a process that reflects how the contract pharmacy will ensure against duplicate discounts?

5. Does the health center attest that it provides oversight (e.g. annual audit or other mechanism) of the 340B drugs dispensed by the contract pharmacy(ies)?
Appendix Three: Congressional Inquiry Letter to 340B Providers

The following letter was sent by the Energy and Commerce Committee of the U.S. House of Representatives to a health center in upstate New York. An identical letter was sent to 18 other 340B providers, including 3 other health centers. All the letters and responses can be found on the Energy and Commerce Committee website.

Letter to Dr. Singleton

Page 1

The Energy and Commerce Committee of the U.S. House of Representatives is interested in learning about the experience of health centers and their patients in relation to the 340B Drug Pricing Program. We are concerned that the program may be misused or abused in ways that undermine its intent and初衷.

We would appreciate your assistance in providing detailed information about the experiences of your health center and your patients under the 340B Drug Pricing Program. This information will help us understand whether the program is being used to benefit the patients and providers as intended.

We are particularly interested in hearing about any situations where the 340B Drug Pricing Program has led to

1. Financial benefits for patients or providers
2. Inappropriate use of 340B drugs by health centers or providers
3. Any other issues that may affect the integrity of the program

Please provide your responses by the close of business on [insert date]. We would also be grateful if you could provide any relevant documentation or evidence to support your responses.

Sincerely,

[Signature]

Chairman

Committee on Energy and Commerce

The Honorable Frank Pallone, Jr.
Ranking Member

The Honorable Greg Walden

Chairman

Subcommittee on Oversight and Investigation

Letter to Dr. Singleton

Page 2

Thank you for your prompt attention to this matter. If you have any questions regarding this letter or the 340B Drug Pricing Program, please contact Benjamin Shulman, Deputy Director, or Hana Marchi, Director of Health Care and Antitrust, at 202-225-6912.


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Appendix Four
OPA’s Suggested Provisions for Contracts with Contract Pharmacies

The following language is excerpted from HRSA’s Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services published in the Federal Register Vol. 75, No. 43 / Friday, March 5, 2010. (Emphasis added.)

“The following suggested contract provisions are included for illustrative purposes and are not intended to be comprehensive, exhaustive or required. They offer sample provisions for consideration, but are not intended to be used as the complete terms of the contract. Given the variances among many jurisdictions and among the numerous types of covered entities, HRSA has decided at this time not to include a complete model contract in this notice.

1. “The covered entity owns covered drugs and arranges to be billed directly for such drugs. The pharmacy will compare all shipments received to the orders and inform the covered entity of any discrepancy within five (5) business days of receipt. The covered entity will make timely payments for such drugs delivered to the pharmacy.”

2. “The covered entity will verify, using the contract pharmacy’s (readily retrievable) customary business records, that a tracking system exists which will ensure that drugs purchased under the 340B Drug Pricing Program are not diverted to individuals who are not patients of the covered entity. Such records can include: Prescription files, velocity reports, and records of ordering and receipt. These records will be maintained for the period of time required by State law and regulations.”

3. “Prior to the contract pharmacy providing pharmacy services pursuant to this agreement, the covered entity will have the opportunity, upon reasonable notice and during business hours, to examine the tracking system. For example, such a tracking system may include quarterly sample comparisons of eligible patient prescriptions to the dispensing records and a six (6) month comparison of 340B drug purchasing and dispensing records as is routinely done in other reconciliation procedures. The contract pharmacy will permit the covered entity or its duly authorized representatives to have reasonable access to contract pharmacy’s facilities and records during the term of this agreement in order to make periodic checks regarding the efficacy of such tracking systems. The contract pharmacy agrees to make any and all adjustments to the tracking system which the covered entity advises are reasonably necessary to prevent diversion of covered drugs to individuals who are not patients of the covered entity.”

4. “The pharmacy will dispense covered drugs only in the following circumstances:

   (a) Upon presentation of a prescription bearing the covered entity’s name, the eligible patient’s name, a designation that the patient is an eligible patient of the covered entity, and the signature of a legally qualified health care provider affiliated with the covered entity; or
(b) receipt of a prescription ordered by telephone or other means of electronic transmission that is permitted by State or local law on behalf of an eligible patient by a legally qualified health care provider affiliated with the covered entity who states that the prescription is for an eligible patient. The covered entity will furnish a list to the pharmacy of all such qualified health care prescribers and will update the list of prescribers to reflect any changes. If a contract pharmacy is found to have violated the drug diversion prohibition, the contract pharmacy will pay the covered entity the amount of the discount in question so that the covered entity can reimburse the manufacturer.”
Appendix Five
Finding Sample Contracts for TPAs and Contract Pharmacies

The Texas Association of Community Health Centers (TACHC) has developed a program with 340Basics (a Third Party Administrator – also referred to as a Pharmacy Benefit Administrator (PBA)) to help FQHCs contract with retail pharmacies. To assist FQHCs in implementing this program, they have developed two agreements:

- A 340B Prescription Drug Administrative Services Agreement – between the FQHC and TPA
- A Pharmacy Services Agreement – between the FQHC, TPA, and contract pharmacy.

(See below for information on how to access these detailed documents.)

These two documents, which are described in detail below, outline the relationship between the FQHC, 340Basics and a contracted retail pharmacy. These agreements cannot operate without the other agreement in place; they cannot be separated from each other. The two agreements are inter-related, if there are changes to one, a respective change needs to be made the other.

These two agreements have been reviewed by both Apexus and legal counsel, are highly detailed, and address a range of FQHC-specific issues. They are much more detailed and reflective of FQHCs’ unique needs/requirements than the standard contracts that pharmacies typically offer FQHCs.

At this time, NACHC is not aware of other sample contracts with contract pharmacies or TPAs which are both specific to FQHCs, and which the parties are willing to share. If there are other examples, please contact regulatoryaffairs@nachc.org and we will include this information in future editions of this Manual as appropriate.

A. Agreement between FQHC and TPA

The TACHC/340Better agreement outlines the relationship between the FQHC and the TPA, including:

- Outlines in detail the responsibilities of the TPA:
  - Outside third party, no conflict of interest in dispensing
  - Claims processing
  - Pharmacy plan design, review and management
  - Obtaining and maintaining 340B pricing
  - Communication with contracted retail pharmacy
  - Reporting of claims data (audit trail designed by auditors)
  - Coordination of ordering of replenishment stock for contracted retail pharmacies
  - Maintenance and reporting of inventory at contracted retail pharmacies
  - Software to coordinate ordering, reporting, invoicing, etc.
– Extensive audit-ready downloadable reporting
– Electronic maintenance of patient data including additions and deletions
– Electronic record keeping of claims data, patient eligibility file, dispensed drugs, participating contracted retail pharmacies and authorized providers for 7 years
– Manage and grow the network of contracted retail pharmacies
– Supervision and enforcement of all subcontractor agreements
– Fiduciary responsibility
– Compensated via a flat-fee administration fee per prescription as payment for service (no percentage fees)
– Liability insurance

• Outlines in detail the responsibilities of the FQHC:
  – Must be eligible for 340B
  – Contract with a wholesaler to supply the delivery of the 340B drugs
  – Forward and maintain pertinent patient and provider information to the TPA
  – Utilize the Pharmacy Services Agreement
  – Timely payment to wholesaler, TPA and contracted retail pharmacy

• Mutual responsibilities for both the TPA and the FQHC:
  – Confidentiality of all information
  – Follow HIPAA guidelines
  – Warrants no staff has been debarred from federal health care programs or convicted of a federal felony

B. Agreement among FQHC, TPA, and Contract Pharmacy

This agreement outlines the relationship between the FQHC, the TPA and each contracted retail pharmacy, including:

• Outlines in detail the responsibilities of the TPA:
  – True-Ups tracked and reconciled

• Outlines in detail the responsibilities of the FQHC:
  – Ultimate responsibility for pricing and 340B program
  – Decide the 340B formulary, co-pay schedule and pharmacy plan
  – Register contracted retail pharmacies with HRSA’s Office of Pharmacy Affairs (OPA)
  – Order and pay for 340B drugs from wholesaler with shipment to contracted retail pharmacies

• Outlines in detail the responsibilities of the contracted retail pharmacy:
  – Utilize inventory tracking system provided by TPA
  – Transmit claims electronically
  – Reconcile all 340B deliveries received
- Dispense 340B drugs written by FQHC providers to only FQHC patients
- **Charge patient co-pay “lesser of” either 340B or Usual and Customary** (U&C) as generated/tracked by TPA
- Claim submittal at 340B drug’s NDC 11
- Forward 100% of third-party payments to FQHC

- Mutual responsibilities for both the TPA, the FQHC and the contracted retail pharmacy:
  - Confidentiality of all information
  - Follow HIPAA guidelines
  - Warrants no staff has been debarred from federal health care programs or convicted of a federal felony

**C. How to access these sample agreements**

For a complete copy of the two agreements outlined above, contact:

- **Lynn Ford** at the Texas Association of Community Health Centers (TACHC) or
- **Colleen DiClaudio** at 340Basics.

Also, additional information is available at the [340Basics website](http://340Basics.com) or the [TACHC 340Better website](http://TACHC340Better.com).
Please note the following important notes:

- **This document is only a general Board policy. Health Centers must also have a detailed set of procedures** for implementing this policy. (See the reference to “Procedures” at the end of the Policy. See Chapter 11 and Appendix Seven for more information on detailed P&Ps.

- Section One of this policy is only relevant to health centers who operate an “open door retail” model. If your health center does not offer open retail, Section I of this policy should be deleted in its entirety. See Section 8.A.3 of this Manual for information on open retail models.

- As with all sample policies and procedures, **this document must be adapted to reflect the unique situation of your health center.** Please do not simply “copy and paste” this document into your P&Ps.

**Title:** Provision of Pharmacy Services

**Category:** Pharmacy Services

**Effective Date:**

**Policy:**

In support of its mission to promote access to affordable high-quality primary care services and improve the health of the communities served, X Health Center (XHC) provides pharmacy services that are available to both medical patients of XHC and the community at large.

XHC pharmacies are duly licensed and operated in compliance with all local, state, and federal laws and regulations.

Core services available to all patients include dispensing of prescription medications, patient and family counseling, health education, and medication therapy management (MTM) to achieve both optimal clinical outcomes and cost effectiveness.

The Director of Pharmacy Services will administer a robust quality assurance and improvement program and report to the Corporate Quality Improvement Committee.
SECTION I: 
PHARMACY SERVICES FOR THE GENERAL PUBLIC 
(SERVICES PROVIDED TO INDIVIDUALS WHO ARE NOT MEDICAL PATIENTS OF XHC) 

Editor’s Note: As discussed above, the entire Section One should be deleted for health centers that do not operate an “open door retail” model: 

Under Section 330 of the Public Health Service Act pharmacy services are a required service for community health centers. X Health Center provides pharmacy services to the general public in order to promote access to affordable prescription medication for all residents of the communities served. Policies specific to services provided to the general public (individuals who are a pharmacy patient only) include: 

• Prescriptions dispensed for individuals not qualifying as a patient as defined by the 340B Drug Discount Program will be filled using alternate inventory purchased at a non-340B price. 

• The general public may be eligible for discounted pricing as long as such discounts are not in violation of third party payer agreements or in violation of local, state, or federal regulations. 

• The general public will be eligible for all available services (with the exception of 340B discount pricing) including patient counseling, health education, and MTM 

SECTION II: 
340B DISCOUNT DRUG PRICING PROGRAM 
(SERVICES AVAILABLE TO MEDICAL PATIENTS OF XHC) 

BACKGROUND ON THE 340B DISCOUNT DRUG PRICING PROGRAM: 

Section 340B of the Public Health Service Act requires drug manufacturers participating in the Medicaid Drug Rebate Program to sign an agreement with the Secretary of Health and Human Services. This agreement limits the price manufacturers may charge certain covered entities for covered outpatient drugs. The resulting program is called the 340B Program. The program is administered by the Office of Pharmacy Affairs (OPA), a part of the federal Health Resources and Services Administration/Department of Health and Human Services. 

Upon registration on the OPA database as a participant in the 340B Program, entities agree to abide by specific statutory requirements and prohibitions. 

POLICIES SPECIFIC TO 340B PHARMACY SERVICES: 

X Health Center participates in the 340B Drug Pricing Program in order to expand access to affordable prescription medications for its eligible patients, and to generate savings to support expanded and enhanced services for the medically underserved patients in our service area. 

As a participant in the 340B Drug Pricing Program, X Health Center (XHC) policies are: 

• XHC uses any savings generated from 340B in accordance with 340B Program intent 

• XHC meets all 340B Program eligibility requirements. 
  – XHC listing as a covered entity in the Office of Pharmacy Affairs (OPA) Database covered entity listing is complete, accurate, and correct. 
  – XHC receives a grant or designation consistent with that conferring 340B eligibility.
• XHC complies with all requirements and restrictions of Section 340B of the Public Health Service Act and any accompanying regulations or guidelines including, but not limited to, the prohibition against duplicate discounts/rebates under Medicaid, and the prohibition against transferring drugs purchased under 340B to anyone other than a patient of the entity. [REFERENCE: The Section 340B statute, 340B Guidelines, 340B Policy Releases]

• XHC maintains auditable records demonstrating compliance with the 340B requirement described in the preceding bullet.

• XHC identifies eligible prescriptions to be those in which: a.) the prescribing provider is employed or under contractual or other arrangements with XHC; b.) the individual receives a health care service (within the scope of grant/designation for which 340B status was conferred) from this professional such that the responsibility for care remains with the health center; and c.) XHC maintains records of the individual’s health care.

• XHC “carves-out” Medicaid from 340B eligibility and maintains information consistent to this in the OPA Medicaid Exclusion Database. (Editor’s note: Medicaid. If your health center carves in, this bullet must be adjusted accordingly. You must also have P&Ps in place to prevent duplicate discounts.  See Chapter 9 for more information.)

• XHC has systems/mechanisms and internal controls in place to reasonably ensure ongoing compliance with all 340B requirements.

• XHC conducts routine compliance audits under the direction of the Director of Pharmacy Services. Audit results are reported to the Corporate Compliance Officer.

• XHC provides comprehensive orientation to the 340B program for new pharmacy staff and conducts regular and ongoing updates and continuing education.

• XHC conducts corporate wide training on the 340B program to maximize the value to patients served at all medical sites.

• XHC has procedures in place to protect the patient’s right to use the pharmacy of their choice.

• XHC may choose to uses contract pharmacy services, in which case the contract pharmacy arrangement is performed in accordance with OPA requirements and guidelines including, but not limited to:
  – XHC obtains sufficient information from the contractor to ensure compliance with applicable policy and legal requirements, and XHC has utilized an appropriate methodology to ensure compliance including an annual independent audit of the contract pharmacy arrangement.

• XHC acknowledges its responsibility to contact OPA as soon as reasonably possible if there is any change in 340B eligibility or material breach by the XHC of any of the foregoing policies.

• XHC acknowledges that if there is a breach of the 340B requirements, XHC may be liable to the manufacturer of the covered outpatient drug that is the subject of the violation, and depending upon the circumstances, may be subject to the payment of interest and/or removal from the list of eligible 340B entities.
XHC elects to receive information about the 340B Program from trusted sources, including, but not limited to:

- The Office of Pharmacy Affairs (OPA)
- The 340B Prime Vendor Program, managed by Apexus

Any OPA contractors

**Scope:**

These policies apply to all XHC pharmacy services in which pharmaceuticals purchased under the 340B Drug Pricing Program are dispensed and/or administered.

**Responsible Persons:**

The following XHC Staff are engaged with 340B program compliance.

A. Chief Executive Officer
   - Responsible as the principal officer in charge for the compliance and administration of the program
   - Responsible for attesting to the compliance of the program in form of recertification

B. Chief Financial Officer
   - Responsible for financial management and allocation of savings to support the non-profit mission of XHC

C. Chief Pharmacy Officer/Director of Pharmacy
   - Accountable agent for 340B compliance
   - Agent of the CEO responsible to administer the 340B program to fully implement and optimize appropriate savings and ensure current policy statements and procedures are in place to maintain program compliance

D. Corporate Compliance Officer or Director of Internal Audit
   - Collaborates with the Director of Pharmacy Services on the internal audit plan of the compliance of the 340B program
   - Includes information on compliance with the 340B program requirements as part of quarterly compliance report to the XHC Board of Directors.

E. Chief IT Officer/Pharmacy Informatics Person
   - Support the Pharmacy software selection of tracking software to manage the 340B program
   - Define process and access to data for compliant identification of eligible patients
   - Archive the data so as to be available to auditors when audited

**Procedures:**

Detailed procedures supporting this policy are outlined in the Pharmacy Services Operations Manual.

- Board Approval: Date
- Board Approved Revision: Date
- Board Review/no revisions: Date
- Date of Next Scheduled Board Review: Date
Appendix Seven

Checklist for Evaluating Policies and Procedures

The following checklist, based on the information in Chapter 12, can assist in evaluating a Health Center's 340B Policy and Procedures Manual.

<table>
<thead>
<tr>
<th>Recommended Information</th>
<th>P&amp;P Page Number</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Purpose</strong></td>
<td></td>
</tr>
<tr>
<td>Provide concise statement as to the purpose of:</td>
<td></td>
</tr>
<tr>
<td>• the Policy and Procedures manual (P&amp;P) and</td>
<td></td>
</tr>
<tr>
<td>• the health center's participation in the 340B</td>
<td></td>
</tr>
<tr>
<td>Program</td>
<td></td>
</tr>
<tr>
<td><strong>Definitions</strong> - may be in body of P&amp;P, or in an</td>
<td></td>
</tr>
<tr>
<td>appendix. Define the following terms:</td>
<td></td>
</tr>
<tr>
<td>• Eligible patient</td>
<td></td>
</tr>
<tr>
<td>• Eligible prescriber</td>
<td></td>
</tr>
<tr>
<td>• Eligible location</td>
<td></td>
</tr>
<tr>
<td>• Scope of service</td>
<td></td>
</tr>
<tr>
<td>• Covered drugs</td>
<td></td>
</tr>
<tr>
<td><strong>Sites and addresses:</strong> List or otherwise reference</td>
<td></td>
</tr>
<tr>
<td>all sites and addresses to which this policy applies</td>
<td></td>
</tr>
<tr>
<td><strong>Review and Revisions of P&amp;P:</strong> Lay out the policy</td>
<td></td>
</tr>
<tr>
<td>around:</td>
<td></td>
</tr>
<tr>
<td>• Frequency of review</td>
<td></td>
</tr>
<tr>
<td>• Procedure for revisions</td>
<td></td>
</tr>
<tr>
<td>• Approval of revisions</td>
<td></td>
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<tr>
<td><strong>Background:</strong> Provide a concise overview of the</td>
<td></td>
</tr>
<tr>
<td>340B program. See example in the sample Board-</td>
<td></td>
</tr>
<tr>
<td>level policy in Appendix Six.</td>
<td></td>
</tr>
<tr>
<td><strong>Statements of Compliance</strong> Include concise</td>
<td></td>
</tr>
<tr>
<td>affirmative statements that the entity will comply</td>
<td></td>
</tr>
<tr>
<td>with regulations and guidance pertaining to these</td>
<td></td>
</tr>
<tr>
<td>bulleted areas.</td>
<td></td>
</tr>
<tr>
<td>• Use of 340B savings</td>
<td></td>
</tr>
<tr>
<td>• Compliance with 340B requirements.</td>
<td></td>
</tr>
<tr>
<td>• Accuracy of information in OPA database</td>
<td></td>
</tr>
<tr>
<td>• Eligibility for participation</td>
<td></td>
</tr>
<tr>
<td>• Compliance with prohibition against duplicate</td>
<td></td>
</tr>
<tr>
<td>discounts and diversion</td>
<td></td>
</tr>
<tr>
<td>• Maintenance of auditable records</td>
<td></td>
</tr>
<tr>
<td>• Responsibilities of prescribers</td>
<td></td>
</tr>
<tr>
<td>• Patient Freedom of Choice</td>
<td></td>
</tr>
<tr>
<td>• Billing to Medicaid</td>
<td></td>
</tr>
<tr>
<td>• Systems and controls in place to ensure compliance.</td>
<td></td>
</tr>
<tr>
<td>• Self-audits</td>
<td></td>
</tr>
<tr>
<td>• Use of contract pharmacies</td>
<td></td>
</tr>
<tr>
<td>• Contract pharmacy oversight</td>
<td></td>
</tr>
<tr>
<td>• Contract pharmacy agreements</td>
<td></td>
</tr>
<tr>
<td>• Contract pharmacy locations</td>
<td></td>
</tr>
<tr>
<td>• Material breaches</td>
<td></td>
</tr>
<tr>
<td>• Reporting violations</td>
<td></td>
</tr>
<tr>
<td><strong>Recommended Information</strong></td>
<td><strong>P&amp;P Page Number</strong></td>
</tr>
<tr>
<td>-----------------------------</td>
<td>---------------------</td>
</tr>
<tr>
<td><strong>Staffing</strong></td>
<td></td>
</tr>
<tr>
<td>Describe all 340B staff positions and their responsibilities. (See Appendix Eleven)</td>
<td></td>
</tr>
<tr>
<td><strong>Registration, Recertification, and Change Requests on OPAIS</strong></td>
<td></td>
</tr>
<tr>
<td>Describe responsible staff and procedures for:</td>
<td></td>
</tr>
<tr>
<td>• Registration</td>
<td></td>
</tr>
<tr>
<td>• Recertification</td>
<td></td>
</tr>
<tr>
<td>• Making changes on OPAIS</td>
<td></td>
</tr>
<tr>
<td>See Chapters 5 &amp; 6</td>
<td></td>
</tr>
<tr>
<td><strong>Purchasing, Inventory Management, Dispensing</strong></td>
<td></td>
</tr>
<tr>
<td>Describe:</td>
<td></td>
</tr>
<tr>
<td>• procedures related to 340B purchasing, including supplier names and account numbers.</td>
<td></td>
</tr>
<tr>
<td>• how 340B inventories are managed and tracked, including software used.</td>
<td></td>
</tr>
<tr>
<td>• safeguards to ensure 340B drugs are only dispensed to eligible patients.</td>
<td></td>
</tr>
<tr>
<td><strong>Contract Pharmacy</strong></td>
<td></td>
</tr>
<tr>
<td>• List all contract pharmacy agreements.</td>
<td></td>
</tr>
<tr>
<td>• List locations of pharmacies under contract.</td>
<td></td>
</tr>
<tr>
<td>• List all sites served by contract pharmacy.</td>
<td></td>
</tr>
<tr>
<td>• Describe tracking software used to prevent diversion.</td>
<td></td>
</tr>
<tr>
<td>• Describe policy around Medicaid participation (carve-in/out)</td>
<td></td>
</tr>
<tr>
<td>• Describe how contract pharmacy oversight is provided, including independent external audits.</td>
<td></td>
</tr>
<tr>
<td><strong>Monitoring and Reporting</strong></td>
<td></td>
</tr>
<tr>
<td>• Describe frequency and types of audits, including internal procedures used.</td>
<td></td>
</tr>
<tr>
<td>• Describe how contract pharmacy oversight is provided, including independent external audits. (See above)</td>
<td></td>
</tr>
<tr>
<td>• How the FQHC defines “material breach.” (See Section 13.B.8)</td>
<td></td>
</tr>
<tr>
<td>• procedure for self-disclosing violations to OPA. (See Section 13.B.6.)</td>
<td></td>
</tr>
<tr>
<td>• how long the FQHC will maintain “auditable records”, including P&amp;P manuals. (See Section 13.A.3.)</td>
<td></td>
</tr>
<tr>
<td><strong>Sliding Fee Scales</strong></td>
<td></td>
</tr>
<tr>
<td>• Discuss how the health center ensures that low-income uninsured and underinsured patients (i.e., those eligible for the SFDS) are able to afford their medications.</td>
<td></td>
</tr>
<tr>
<td>• This discussion should address both ingredient costs and dispensing fees, at both in-house and contract pharmacies.</td>
<td></td>
</tr>
<tr>
<td>See Section 4.B.2 for more on BPHC’s sliding fee requirements.</td>
<td></td>
</tr>
<tr>
<td><strong>340B Savings</strong></td>
<td></td>
</tr>
<tr>
<td>• Define the services that are to be supported by 340B savings; and</td>
<td></td>
</tr>
<tr>
<td>• Outline a timeline and method to evaluate the quality and efficacy of services supported by 340B savings..</td>
<td></td>
</tr>
<tr>
<td>See Section 4.E.5 for more on P&amp;P’s around 340B savings.</td>
<td></td>
</tr>
</tbody>
</table>
Appendix Eight
Self-Audit Tools

This appendix contains tools that may be used by a health center in testing its compliance with the 340B Program guidelines. In addition to the checklists and audit guidance included in this appendix, additional audit tools are available through 340B University™.

340B University™ (APEXUS)
Apexus serves as the exclusive contractor for the 340B Drug Pricing Program. It is a verified source of 340B information with educational services including 340B University, 340B Tools, and other information on demand and webinar offerings.

340B University™ OnDemand
This is an online education program designed to support compliance and integrity for all 340B Program stakeholders. Topics include eligibility, registration, recertification, pricing, contract pharmacy, implementation, and audit preparedness.

340B University™ Tool Guide
“A Summary of Tools and Resources”
This guide provides a link to the most recent version of 340B University™ tools, as well as a short description of each tool.

Vendors
“340B Compliance Self-Assessment: Vendors”
This tool provides a series of questions which the entity can use to assess compliance by contract pharmacy vendors.

Material Breach
This is a one page tool that can be used to formulate internal policies defining a material breach and the action to take when a material breach is identified.

Self-Assessment Policy
“340B Compliance Self-Assessment: Policy – A Quick Self-Assessment for Community Health Center Leaders”
This tool provides a series of questions which the entity can use to assess compliance by Community Health Centers.
**Self-Audit Process**


This tool provides a sample internal audit process for community health leaders to conduct self-audits of their 340B Program operations.

**Use of 340B Savings**

“340B Benefits and the Use of 340B Savings Documentation Tool”


This tool provides guidance in documenting the use of 340B savings.

**Self-Audit Tools**

The following pages contain tools that can be used in conducting self-audits of the 340B Program.

- Checklist for Review of the 340B Program
- Checklist for Review of Contract Pharmacy Agreement
- Example of Individual Prescription Testing
### Checklist for Review of 340B Program

In addition to this checklist, complete Policy and Procedures manual checklist and Contract Pharmacy checklist.

<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Who are the key employees associated with the 340B Program?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Authorizing Official</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Primary Contact</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 340B Coordinator</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 340B Drug Purchasing Agent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Contract Pharmacy Contacts</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Internal Auditor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the OPA 340B database contain accurate information regarding the Authorizing Official, Primary Contact, and Contract Pharmacy contacts?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have key employees received initial training on the 340B Program and its requirements?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Who received the training?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• When was the training?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• What was the form of training?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do key employees receive on-going training on the 340B Program and its requirements?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Who received the training?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• When was the training?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• What was the form of training?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How often are self-audits of the 340B Program conducted?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• When was the last self-audit?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Was there a written report of findings?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Who received the report?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• What corrective action taken to correct any issues identified?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are in house physical inventories used?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• If drugs are used for non-340B eligible patients, are there two separate physical inventories?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• What safeguards are in place to ensure that the 340B inventory is only used for eligible patients?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>What types of contract pharmacy oversight activities take place?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• What reports are received monthly?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Are reconciliations performed of 340B drugs ordered to 340B drugs dispensed?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do self-audits test for the following:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Accurate information in OPA database</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Parent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Child sites</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Contract pharmacies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Medicaid carve-in/carve-out election</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Registration dates</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Diversion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Patient eligibility</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Prescriber eligibility</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Location eligibility</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Duplicate Discounts</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Medicaid compliant billing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Information in Medicaid Exclusion File</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Billing of Medicaid and Medicaid MCO patients</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• In-house pharmacy inventories</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Reconciliation of beginning inventory to ending</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Steps to prevent diversion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Support for 340B replenishment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Contract Pharmacy Arrangements</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Compliance with Medicaid billing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Patient eligibility</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Prescriber eligibility</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Location eligibility</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Support for 340B replenishment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are auditable records maintained for a minimum of 5 years?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Copies of self-audits</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Copies of external 340B audits</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Pharmacy Service Agreements</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Patient records</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Invoices for 340B drugs purchased</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Reports of 340B drugs dispensed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Inventory reconciliations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Policy and Procedures manual</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Checklist for Review of Contract Pharmacy Agreement

<table>
<thead>
<tr>
<th>Audit Step</th>
<th>Audit Response</th>
<th>Comments</th>
<th>Common Issues</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Obtain a copy of the 340B OPA database registration page for the FQHC</td>
<td>Can be found at:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Obtain copy of Pharmacy Services Agreement(s) (i.e. contract pharmacy agreement)</td>
<td>There must be a written contract between the covered entity and the contracted pharmacy.</td>
<td></td>
<td>Cannot locate contract</td>
</tr>
<tr>
<td>3. Compare database information to contract as follows:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. Is signed contract date on or before the date of the OPA database registration date?</td>
<td>A pharmacy cannot be registered until the contract is fully executed.</td>
<td></td>
<td>Missing signatures Missing dates</td>
</tr>
<tr>
<td>b. Do the pharmacy name, location address, and contact information per the contract agree with the OPA database?</td>
<td>Demographic information and contact information on OPA website must agree to contract.</td>
<td></td>
<td>Does not agree</td>
</tr>
<tr>
<td>c. Does the contract list each specific pharmacy location address that is included in the 340B Program?</td>
<td>Contract must list all CHC locations that will be issuing prescriptions for filling at that pharmacy site.</td>
<td></td>
<td>Out of date contract New pharmacy location not added to contract</td>
</tr>
<tr>
<td>d. Is each specific pharmacy location address dispensing 340B drugs under the contract registered separately in the OPA database as a contract pharmacy?</td>
<td>Each pharmacy location must be registered separately.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>e. Is each health center location (parent and child sites) whose patients can use the specific contract pharmacy listed in the pharmacy contract?</td>
<td>The contract must contain listing of all health center sites whose patients can use the contract pharmacy.</td>
<td></td>
<td>Contract not updated for new health center site</td>
</tr>
<tr>
<td>f. Is contract pharmacy listed under parent site on the OPA database if all patients of the health center sites may utilize the pharmacy?</td>
<td>All contract pharmacy locations must be listed under the parent entity in order for ALL child site patients to use the pharmacy. If the pharmacy is listed under the child site only, only patients of that child site may use the contract pharmacy.</td>
<td></td>
<td>Location may be listed only under child site</td>
</tr>
<tr>
<td>g. Is the pharmacy location (ship-to address) accurately listed in the OPA database?</td>
<td>The “ship to” address must be the physical location of the pharmacy.</td>
<td></td>
<td>P.O. Box used rather than street address</td>
</tr>
<tr>
<td>h. If contract pharmacy is no longer used, is it listed as terminated in the OPA database?</td>
<td>If a contract pharmacy is terminated, OPA must be notified and the termination date will be noted in the OPA database.</td>
<td></td>
<td>Pharmacy no longer used but not terminated in database</td>
</tr>
<tr>
<td>4. Are the following essential elements addressed in the contract?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a. Covered entity (CE) owns drugs and is billed directly for drugs. (Ship to, bill to)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. Contract outlines responsibilities of parties to provide comprehensive pharmacy services.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Patient will be informed of freedom to choose pharmacy provider.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d. Regardless of services provided, access to 340B pricing is only to eligible patients.</td>
<td></td>
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</tr>
<tr>
<td>e. Both parties will adhere to Federal, State, and local laws.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>f. Pharmacy must provide reports consistent with customary business practices.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>g. Contract pharmacy will establish and maintain tracking system.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>h. Both parties will develop system to verify patient eligibility.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>i. 340B drugs will not be dispensed to Medicaid patients without agreement with State Medicaid agency.</td>
<td></td>
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</tr>
<tr>
<td>j. Documentation must be available for independent audits.</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>k. Both parties understand they are subject to audits by outside parties.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>l. Contract pharmacy services agreement will be provided to OPA if requested.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix Eight ▪ Self-Audit Tools

Example of Individual Prescription Testing under Virtual Inventory Model

Procedures:
1. Obtain listing of 340B drug invoices by supplier (one month).
2. Select 1 invoice from each supplier for further testing.
3. Select 1 drug NDC from the invoice.
4. For each NDC number selected, obtain Pharmacy Processor/Software Accumulator records that support purchase.
5. Select 3 patient dispenses on Processor/Accumulator report to support NDC purchase.
6. Test patient dispense information to patient medical record using template below.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Process</td>
<td>Capture RX</td>
<td>From Processor Virtual Inventory Records</td>
</tr>
<tr>
<td>Name of Patient</td>
<td>Patient</td>
<td>Drug</td>
</tr>
<tr>
<td>West Town CHC</td>
<td>Jane Doe</td>
<td>Naxitam cap 40 mg</td>
</tr>
<tr>
<td>East Valley CHC</td>
<td>John Smith</td>
<td>Naxitam cap 40 mg</td>
</tr>
<tr>
<td>Mid Town CHC</td>
<td>Sally Brown</td>
<td>Naxitam cap 40 mg</td>
</tr>
</tbody>
</table>

Further research needed:
Sally Brown - Prescription dispensed was a refill; however, all refills per original prescription had been used. No evidence in medical record of new prescription written.
Appendix Nine
OPA Auditor Document Request List - FY 2018

The following is the list of documents that are being requested in advance as part of a HRSA Audit in 2018. Note that health centers are expected to provide a listing of all 340B drug orders or prescriptions issued for the most recent six-month period.

1. **Policies and procedures**
   
   A. CE registration/recertification and ensuring that the 340B database is up-to-date
   
   B. Description of procurement process (including contract pharmacy, if applicable)
   
   C. Prevention of GPO violations (applies only to DSH, PED & CAN)
   
   D. Definition of covered outpatient drugs, including any exclusions
   
   E. CE’s process for conducting oversight of its contract pharmacy(ies)
   
   F. How the CE accounts for 340B inventory or replenishment/accumulation (including NDC matching), if applicable
   
   G. Prevention of diversion at CE and contract pharmacy – Process for confirming the following: site eligibility location, referral/responsibility of care remained with CE, medical/patient health record, patient eligibility (including status change), provider eligibility (relationship), consistent with the scope of grant (if applicable / non-hospital)
   
   H. Mechanism to prevent duplicate discounts at CE, off-site outpatient facilities, and contract pharmacies with details explaining carve-in or carve-out status
   
   I. When and how CE would self-disclose and CE’s definition of non-compliance material breach

2. **Most recently filed (and applicable) Medicare cost report and trial balance documentation.**

3. **340B Universe:** 340B Drug Orders or Prescriptions (include in-house and contract pharmacies). A listing of all 340B drug orders or prescriptions issued during the most recent 6-month period – preferably in Excel format or another electronic format. The following data elements should be included:

   A. Unique identifying number – this is likely the RX number, but can be any number you assign that will allow tracking through your system to retrieve all information associated with the order
   
   B. The drug/product name/NDC
   
   C. The acquisition price
   
   D. The type of account the drug was purchased through and the associated 340B ID number E. The quantity issued
   
   F. The patient id number
G. The payer (All payers including Medicaid)

H. The date of the order and date it was dispensed or administered

I. The ordering provider

J. The location/site 340B drug was administered/ordered/prescribed

K. Whether the drug was dispensed/or used, reversed, or returned to stock

**Description of the 340B Universe:**

The CE should include a narrative describing the methodology, by which the data was gathered, and any limitations or exclusions (e.g. whether reversed transactions, or any other elements, were excluded or other 340B orders or dispenses, were direct purchases included or other purchasing mechanisms).

A sample of prescriptions will be selected for testing while the audit team is on site. For the selected items, individual records will need to be available in either electronic or paper format. If electronic health records are utilized, please provide an individual with system knowledge to navigate the EHR. Scans of hardcopies of selected documents may be requested to be uploaded to the NIH Secure Site.

4. CEs should be prepared to show the auditor proof of employment, contract, or credentialing for providers during the audit.

5. A listing of CE’s wholesalers and 340B drug purchase orders made between dates of selected time frame, including price paid

6. A listing of contract pharmacies utilized, and the current contracts that:
   a) individually identify each registered contract pharmacy location utilized and/or registered; and
   b) identify all or each covered entity location(s) utilizing the contract pharmacy.

7. A copy of any self-disclosures made to the Office of Pharmacy Affairs since the beginning of the audit timeframe.

8. A listing of all accounts used to purchase drugs for the parent and off-site outpatient facilities, which includes locations dispensing or distributing 340B drugs and a description of the applicable pricing (340B, GPO, WAC, CSOS, Other).

9. A listing of all clinics and locations where health care services are provided to individuals for which the CE deems itself responsible for the health care services provided purposes of meeting 340B eligibility.

10. A listing of all Medicaid billing numbers and NPI numbers utilized to bill Medicaid for 340B drugs (include out-of-state Medicaid billing numbers and the state associated with that number, if applicable).

11. Provide Notice of Grant Award (NGA) or subgrantee documentation.
Appendix Ten  ▪  Common Internal Audit Findings

Incorrect 340B database record

- Often covered entities are unable to locate copy of contract signed by both parties.

Incorrect 340B database record

- Contract pharmacy is not registered correctly

Incorrect 340B database record

- All eligible locations are not listed in the contract.

Incorrect 340B database record

- Contract was not executed before the pharmacy registration date in the OPA database.

Incorrect 340B database record

- Contract pharmacy address is incorrect in OPA database.

Individual Dispense Testing

- Prescriptions were generated in ineligible locations.

Individual Dispense Testing

- Unable to locate support in FQHC medical record for 340B replenishment drugs purchased by contract pharmacy
Several staffing positions are needed to effectively manage the non-clinical aspects of the 340B Program. With the exception of the Authorizing Official and Primary Contact (which should be separate individuals), job responsibilities could be shared among staff members.

A. **340B Coordinator**

Responsibilities of this position (which may be shared among more than one individual) include:

- coordination of the 340B Program,
- policy and procedure development and maintenance,
- education and training,
- registration/recertification/and changes to OPA database,
- self-audits,
- external audit coordination,
- 340B contract management,
- oversight of contract pharmacies,
- maintenance of provider lists and filters used in tracking systems,
- reporting, and
- purchasing/inventory oversight.

340B University™ provides a comprehensive job description for this position. If using this job description, ensure that it is customized for the FQHC’s operations.


B. **Authorizing Official for OPA/OPAIS**

The Authorizing Official (AO) is typically the Chief Executive Officer, Chief Financial Officer, or Director of Pharmacy. This must be a person with the authority to approve or sign contracts for the 340B Program. This individual's name and contact information is registered on OPAIS database. The AO must annually attest to the accuracy and completeness of data maintained in OPAIS, and will receive email notifications from OPA regarding changes and due dates for recertification.
C. **Primary Contact for OPA/OPAIS**

The Primary Contact (PC) can be any designated representative of the covered entity. This person works closely with the AO to keep him/her informed of Program requirements. The PC’s name and contact information is registered on OPAIS. The PC will receive email notifications from HRSA regarding changes and due dates for recertification.

D. **Internal Auditor**

The responsibilities of this position (which may be shared by 340B Coordinator) include:

- performing sample and targeted audits,
- documenting findings and preparing reports, and
- working with external auditors.

E. **Finance Staff**

Finance Department staff must be able to fully understand all items on monthly billing statements—what was dispensed, what was ordered to replace, what was paid in dispensing fees and vendor fees.