

# A Pharmacy's Guide to 340B Contract Pharmacy Services Best Practices

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### Acknowledgement

This Guide is the result of a collaboration between members of a NCPA workgroup that assumed the mission to document industry best practices for pharmacies interested in participating in the 340B Drug Discount Program. The workgroup was comprised of a multi-disciplinary team made up of representatives from NCPA member pharmacies, NCPA leadership, and practice experts in the 340B community. This Guide is intended to represent the combined learnings of individuals and organizations that have participated in the 340B program. The authors have attempted to be as complete and thorough as possible in the discussion of the various topics of this Guide. The 340B best practices workgroup endorses this guide and encourages pharmacies to work with appropriate legal representation when considering the topics and recommendations contained herein.

NCPA would like to thank Alan J. Arville, Member, Epstein Becker & Green, P.C., and Robert Judge, Partner, 340B Advisors, who made substantial contributions to the development of this Guide.

### Overview

The Public Health Services 340B drug discount Program (the “340B Program”) was passed by Congress in 1992 and requires drug manufacturers to provide outpatient drugs to eligible health care organizations at significantly reduced prices. The intent of the 340B program is to reduce outpatient drug costs for health care providers that serve high volumes of poor, uninsured, and underinsured patients, so these providers can better serve them. Over time, Congress has expanded the numbers and types of institutions that can access 340B program prices to include children’s hospitals, rural referral centers, critical access hospitals and certain cancer hospitals in addition to the original 13 categories of safety-net providers who could participate in this program. Today, there are approximately 17,000 health care facilities eligible to participate in the 340B program, enabling them to stretch scarce resources, reach more eligible patients, and to provide more comprehensive services.

While the 340B program accommodates many dispensing arrangements for program participants, retail pharmacies became eligible to serve Covered Entities as contract pharmacies in 1996. The ability for retail pharmacies to be involved in the 340B program was expanded further in 2010 when Covered Entities were granted the ability to establish agreements with multiple pharmacies to meet their 340B dispensing requirements. Over time as safety-net participation in the 340B Program has increased and as greater numbers of retail pharmacies have entered into agreements with Covered Entities to become contracted 340B pharmacies, safety-net facilities have been able to offer their eligible patients a greater number of locations to receive their medications, while expanding on the services they provide for our neediest citizens.

This Guide attempts to meet the goal of assisting member pharmacies with establishing the policies and procedures, and best practices associated with supporting Covered Entities that participate in the 340B program. The sections contained herein discuss the major elements that organizations interested in contracted pharmacy agreements should consider in order to manage the programmatic, financial, and legal risks associated with performing as 340B contract pharmacies. The information provided is intended to serve as a tool to make it easier for pharmacies to successfully support Covered Entities that participate in the 340B program.

The development of this Guide is the result of collaboration and participation of the members of a NCPA workgroup that assumed the mission of creating industry best practices for 340B contract pharmacy participation. The workgroup was comprised of a multi-disciplinary team made up of representatives from NCPA member pharmacies, NCPA leadership, and practice experts in the 340B community. The Guide recommends best practices for pharmacies to support Covered Entities that participate in the 340B program. NCPA recommends pharmacies use the best practices as a guide for establishing 340B contract pharmacy programs with Covered Entities.

The information is intended as a general guide for pharmacies that wish to participate as contract pharmacies to 340B-eligible Covered Entities, and is not intended nor should it be construed in

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any way as legal advice. Pharmacies should seek legal or other professional advice before acting or relying on any of the content. The Guide is not intended to be comprehensive. The Guide will be maintained and updated as regulatory, policies, or business practices require.

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## Introduction to the 340B program

The 340B program was created by the enactment of Public Law 102-585, the Veterans Health Care Act of 1992, which is codified as Section 340B of the Public Health Service Act. The program is governed under two federal statutes, Section 340B of the Public Health Service Act<sup>1</sup> and Section 1927 of the Social Security Act<sup>2</sup> and is named for the section of the statute under which it was established.

As a result of Medicaid reform, which Congress enacted in 1990 when it created the Medicaid Drug Rebate Program, pharmaceutical manufacturers were required to provide rebates to states for medication purchases based on the drug's Average Manufacturer Price (AMP) and its best price, or the lowest price for a drug that a pharmaceutical manufacturer made available in the private sector, as a condition of having their products covered by Medicaid.<sup>3</sup> An unintended consequence of this law was that pharmaceutical manufacturers had a disincentive to continue to offer deep discounts on drugs to other purchasers, since by so doing it could result in a lower AMP and best price, which would lower the price paid by Medicaid.<sup>4</sup> Consequently prices paid for drugs by public sector and non-profit safety-net facilities, began to increase.<sup>5</sup> After Congressional hearings concluded that manufacturer exclusion of these voluntary discounts was having a negative impact on prices for some of these safety-net facilities, Congress established the 340B program as an amendment to the Veterans Health Care Act of 1992.<sup>6</sup> The program is administered by the federal Office of Pharmacy Affairs (OPA), which falls under the Health Resources and Services Administration (HRSA).

Congress intended for the 340B program to be used to benefit specific safety-net facilities and their patients, with the goal of assisting facilities by reducing their pharmaceutical expenses. As stated in official legislative reports at the time, savings on drug prices would enable these providers to improve financial stability and position providers to stretch scarce dollars to serve vulnerable patients.<sup>7</sup> These services may include providing a reduced price of pharmaceuticals for patients, expanding services to patients, and/or providing services to more patients.

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<sup>1</sup> Public Health Service Act, 42 U.S.C. § 256b.

<sup>2</sup> Social Security Act, 42 U.S.C. § 1396r-8.

<sup>3</sup> GAO, Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement, GAO (Washington, D.C.: Sep. 2011) at page 1.

<sup>4</sup> H.R. Rep. No 102-384 (II), at 10-11 (1992).

<sup>5</sup> Veterans Health Care Act of 1992, Pub. L. No. 102-585 § 602, 106 Stat. 4943, 4967-4971 (1992).

<sup>6</sup> Veterans Health Care Act of 1992, Pub. L. No. 102-585, §§ 601-03, 106 Stat. 4943 (1992).

<sup>7</sup> H.R. Rep. 102-384(II), at 12.

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Drugs purchased under the 340B Program are exempt from the Medicaid best-price agreements. This exemption allows eligible safety-net entities to negotiate and purchase drugs at rates at or below the Medicaid ceiling price. The result of these lower prices enables safety-net facilities to use these savings to offer more services to the patients in their community, and thereby stretch scarce health care dollars.

Medication available to be purchased at 340B program prices is independent of a patient's insurance status or financial resources. Provided patient eligibility standards are met, medications dispensed to both insured and uninsured patients can be purchased using 340B program prices and no financial means test is required. This fact has helped to inspire broad use of the 340B program by safety-net facilities, as the revenue generated from insured patients has been used to fund the healthcare mission of safety-net facilities, and is consistent with the legislative intent of the 340B program.<sup>8</sup> This trend has been tacitly endorsed by HRSA, which elaborated on the program's purpose, by explaining "[if providers] were not able to access resources freed by the drug discount when they...bill private health insurance, their programs would receive no assistance from the enactment of the section 340B and there would be no incentive for them" to enroll or remain in the program.<sup>9</sup>

### 340B Covered Entity Eligibility

Only nonprofit health care organizations that have certain federal designations or receive funding from specific federal programs are eligible to participate in the 340B program. Sixteen categories of eligible institutions have been established since the original Section 340B statute was created. These "Covered Entities" include: six categories of hospitals, four categories of health centers, five categories of specialized clinics, and entities which receive Ryan HIV/AIDS Program Grants.<sup>10,11</sup>

Hospitals eligible to participate in the 340B program include:

- Disproportionate share hospitals (DSHs);
- Free-standing children's hospitals;

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<sup>8</sup> Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55,156 (Oct. 24, 1996), at <http://hrsa.gov/opa/programrequirements/Federalregisternotices/patientandentityeligibility102496.pdf>.

<sup>9</sup> HRSA, Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program. Established by Section 340B of the Public Health Service Act (2005), available at [www.hrsa.gov/hemophiliatreatment/340Bmanual.htm](http://www.hrsa.gov/hemophiliatreatment/340Bmanual.htm).

<sup>10</sup> Public Health Service Act § 340B, 42 U.S.C. § 256B (2013).

<sup>11</sup> U.S. Department of Health and Human Services, Health Resources and Services Administration, Fiscal Year 2014 Justifications for Estimates for Appropriation Committees.

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- Cancer hospitals exempt from the Medicare prospective payment system;
- Sole community hospitals (SCHs);
- Rural referral centers (RRCs); and
- Critical access hospitals (CAHs).

Health centers eligible to participate in the 340B program include:

- Federally qualified health centers (FQHCs);
- FQHC look-alikes;
- Native Hawaiian health centers; and
- Tribal and urban Indian clinics.

Specialized clinics eligible to participate in the 340B program include:

- Black lung clinics;
- Hemophilia treatment centers;
- Title X family planning clinics;
- Sexually transmitted disease clinics; and
- Tuberculosis clinics.

Ryan HIV/AIDS Program Grantees eligible to participate in the 340B program include:

- State-operated AIDS drug assistance programs; and
- Ryan White CARE Act Part A, Part B, and Part C programs.

To participate in the 340B program, Covered Entities must meet eligibility criteria (for certain hospitals), and register during a quarterly registration period with the Office of Pharmacy Affairs (OPA) by completing and submitting enrollment information. Covered Entities can download these forms from OPA's website under <http://www.hrsa.gov/opa> by selecting "legal resources." Once OPA verifies eligibility, Covered Entities can begin to participate in the 340B Program at the start of the next quarter.

### **340B Program Prohibitions**

In order for a Covered Entity to participate in the 340B program, it must comply with various statutory requirements related to the program, including several that are intended to ensure that only eligible patients receive access to 340B-priced medications and that rebates for 340B-priced medications are prevented.

#### *Prohibition against Drug Diversion*

The anti-diversion requirements of the 340B program prohibit the resale or transfer (e.g., dispensing) of 340B outpatient drugs to individuals who are not

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considered “patients” of a 340B Covered Entity (i.e., individuals who do not meet the program’s guidelines on patient eligibility requirements). Reselling or otherwise transferring a 340B drug to a person who is not a patient of the Covered Entity, to an entity that is not officially “a part of” the 340B Covered Entity, or for excluded services (e.g., inpatient) is commonly referred to as drug diversion.<sup>12</sup>

The 340B program defines prohibited diversion as dispensing or administering 340B drugs to one of the following:

- “non-patients” of the Covered Entity;
- ineligible facilities within the same facility; or
- excluded services of the Covered Entity.<sup>13</sup>

Although not necessarily diversion on its face, the use of 340B product in “mixed-use” settings (where both inpatients and outpatients may receive drugs, such as an Emergency Room or oncology clinic), relationships and drug distribution within a health care system in which some entities are 340B Covered Entities and some are not, and distribution of drugs to employees who are part of a hospital owned/operated insurance plan represent a few (but certainly not all) examples of activities that can create a risk of diversion if appropriate controls are not in place.

Although OPA does not require physically separate drug inventories, Covered Entities must maintain separate purchasing and dispensing tracking systems that provide a clear audit trail that indicates which drugs have been purchased for and dispensed to both categories of patients (inpatients and outpatients). Indeed, OPA requires that each Covered Entity keep track of drugs purchased and dispensed using the product’s National Drug Code (NDC), which is a unique identifier, so that it is possible to audit with certainty compliance with the program’s anti-diversion and group purchasing organization (GPO) exclusion rules.<sup>14</sup> In most cases, OPA recommends Covered Entities use a product’s 11-digit NDC for ease of administration and integrity of the program.

### *Prohibition against Double Dipping on Medicaid Rebates*

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<sup>12</sup> Integrating Pharmacy Operations and Compliance, Part 2: The 340B Program, Health Care Compliance Association, Matthew D. Vogelien and Jennifer L. Hobbs (June 2010).

<sup>13</sup> 58 Federal Register 68922 et. seq. (Dec, 29, 1993).

<sup>14</sup> Statutory Prohibition on Group Purchasing Organization Participation, Health Resources and Services Administration, 340B Drug Pricing Program Notice Release No. 2013-1, Department of Health & Human Services (Feb.7, 2013).

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A second prohibition in the 340B program relates to Medicaid reimbursement and requires that Covered Entities track which program is paying for the medication to maintain compliance with the 340B program.

Federal and state Medicaid laws governing billing and reimbursement of 340B drugs have a significant financial and administrative impact on 340B providers. The 340B statute protects pharmaceutical manufacturers from giving a 340B discount and a Medicaid rebate on the same drug.<sup>15</sup> Under the 340B program, drug manufacturers provide front-end discounts to Covered Entities, meaning that the Covered Entity receives a discount at the outset when it purchases the drug. The amount of this discount is comparable to the discount that is required in the Medicaid Drug Rebate Program. While pharmaceutical manufacturers participate in both the 340B Drug discount program and the Medicaid Drug Rebate Program, they are only required to provide a single discount on a given medication to a Medicaid patient. If a state seeks a Medicaid rebate on the same unit of drug that the manufacturer sold to a Covered Entity for a Medicaid patient at a discounted price under the 340B program, “double dipping” can occur.<sup>16</sup> Under this scenario, the manufacturer, in essence, will have provided two price concessions for the same drug.

For this reason, the 340B program governs how a Covered Entity may seek reimbursement from a state Medicaid program for 340B drugs provided to Medicaid beneficiaries.<sup>17</sup> The program’s double dipping prohibition places obligations on both the Covered Entity and the state to ensure that, with respect to 340B drugs dispensed to Medicaid beneficiaries, the manufacturer incurs either the 340B discount at the time of the Covered Entity’s purchase or a later Medicaid rebate to the state, but not both.

In 1993, when the original 340B legislation was enacted, HRSA issued guidance intended to protect manufacturers from duplicate discounts.<sup>18</sup> The guidance, which directed states to exclude 340B claims from rebate requests and Covered Entities to bill Medicaid at Actual Acquisition Cost (“AAC”), eventually proved unworkable for both states and Covered Entities. As a result, in 2000, HRSA issued new guidance directing Covered Entities to instead refer to State Medicaid agencies’ policies for applicable billing policies. .<sup>19</sup> This guidance has yet to be

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15 Public Health Service Act, 42 U.S.C. §256b(a)(5)(A), Social Security Act, 42 U.S.C. §1396r-8(a)(5)(C).

16 Understanding the 340B Program: A Primer for Health Centers, National Association of Community Health Centers (May 2011).

17 Medicaid Exclusion/Duplicate Discount Prohibition, Health Resources and Services Administration, Department of Health & Human Services, <http://www.hrsa.gov/opa/programrequirements/medicaidexclusion/> (Aug. 2013).

18 58 Federal Register at 34058, Vol. 58, No. 119 I (June 23, 1993).

19 51 Federal Register, Vol. 65, No. 51 at 13983 (Mar. 15, 2000).

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widely deployed, as many states have not created 340B-specific reimbursement rules or instead require Covered Entities to bill Medicaid at their 340B AAC.

OPA requires Covered Entities that bill Medicaid for drugs purchased through the 340B program to provide their outpatient pharmacy Medicaid provider number during the initial 340B program enrollment process if they intend to bill Medicaid for drugs purchased under the 340B program.<sup>20</sup> When done properly, Medicaid agencies use the Covered Entity's billing numbers, the Medicaid Exclusion file, and the discounted price actually billed by the Covered Entity to identify the pharmacy claims submitted by 340B pharmacies, and then to exclude those claims from the Medicaid rebate program.

The statutory prohibition against double discounts on rebates is limited solely to claims filled for Medicaid beneficiaries. If a patient of a 340B Covered Entity has prescription drug coverage – whether private or Medicare – the Covered Entity may be entitled to bill the insurer and, depending on the amount of reimbursement, may receive the benefit of the difference between the entity's discounted 340B cost to acquire the drug and the insurer's payment amount. Some manufacturers have inserted provisions within their agreements with pharmacy benefit managers (PBMs) to exclude 340B paid claims from their rebate submissions. The industry is only beginning to establish provisions to assist PBMs with supporting this requirement.<sup>21</sup>

There are currently no published guidelines specifically addressing the relationship between Medicaid Managed Care Organizations (“MCO Medicaid”) and 340B program claims. Apexus has stated that as long as medications purchased under the 340B program are not subject to a rebate claim by the state Medicaid agency, the 340B program does not specify whether 340B medications may be provided to a MCO Medicaid beneficiary.<sup>22</sup>

Ultimately, Covered Entities are required to ensure that drugs purchased under the 340B Program are not subject to a rebate claim by the state Medicaid agency. Thus, the distinction between fee-for-service and Medicaid Managed Care claims is of critical importance for Covered Entities and contract pharmacies, since some states may be submitting rebate requests for 340B MCO Medicaid claims unbeknownst to the Covered Entity and the contract pharmacy. State Medicaid billing practices vary widely so Covered Entities and contract pharmacies are advised to work closely with their state Medicaid agency on this issue. At the

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<sup>20</sup> 59 Federal Register 25110 et. seq. (May 13, 1994).

<sup>21</sup> 340B Information Exchange Reference Guide, National Council for Prescription Drug Programs, [http://www.ncdpd.org/pdf/340B\\_Information\\_Exchange\\_Reference%20Guide\\_v1.0.pdf](http://www.ncdpd.org/pdf/340B_Information_Exchange_Reference%20Guide_v1.0.pdf).

<sup>22</sup> Apexus 340B Prime Vendor Program, Frequently Asked Questions, Policy/Implementation: Purchasing, Inventory and Reimbursement.

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very least, contract pharmacies should discuss these issues with Covered Entities to ensure that all parties have the same understanding of state and federal rules as they apply to the arrangement's use of 340B drugs for MCO Medicaid beneficiaries.

### *Prohibition on Group Purchasing Organization Participation*

Certain hospitals and their off-site outpatient clinic sites that are registered on the OPA 340B database as participating in the 340B program are subject to a statutory prohibition against obtaining covered outpatient drugs through a group purchasing organization (GPO). Disproportionate share hospitals (DSH), children's hospitals, and free-standing cancer hospitals participating in the 340B program are subject to a provision of the enabling statute which states that in order to participate in the 340B program these entities may not "obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement."<sup>23</sup> Organizations that are not part of the Covered Entity are not subject to the GPO prohibition; however, the Covered Entity is still prohibited from having organizations purchase covered outpatient drugs through a GPO on its behalf or otherwise receive covered outpatient drugs purchased through a GPO.

Compliance with the GPO prohibition is an eligibility requirement for certain categories of Covered Entities. Upon registration for the 340B program, an authorizing official of a DSH, children's hospital, or free-standing cancer hospital must sign an acknowledgement of this statutory requirement.<sup>24</sup> The Covered Entity must also attest to compliance with the GPO prohibition during the 340B annual recertification process. This requirement is reviewed during HRSA 340B Program audits.<sup>25</sup> It is HRSA's longstanding position that a Covered Entity enrolled in the 340B program subject to the GPO prohibition and listed on the OPA 340B database may not use a GPO for covered outpatient drugs at any point in time. Covered Entities may establish an outpatient non-GPO (i.e., Non-340B) account to create a compliant method for obtaining covered outpatient drugs for non-340B eligible outpatients or for situations where 340B drugs are not available (e.g., if the hospital elects to carve-out Medicaid or has 340B ineligible patients in mixed-use areas).<sup>26</sup>

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<sup>23</sup> Statutory Prohibition on Group Purchasing Organization Participation, Health Resources and Services Administration, 340B Drug Pricing Program Notice Release No. 2013-1, Department of Health & Human Services (Feb. 7, 2013).

<sup>24</sup> *Id.*

<sup>25</sup> *Id.*

<sup>26</sup> *Id.*

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### Patient Eligibility

HRSA has defined a Covered Entity “patient” through a Federal Register notice available on OPA’s website<sup>27</sup> and through informal guidance. The current patient definition guidelines establish a three-part test that individuals must meet to become eligible for medications to be purchased at the 340B Program price:

- The Covered Entity has established a relationship with the individual, such that the Covered Entity maintains records of the individual's health care;
- The individual receives health care services from a health care professional who is either employed by the Covered Entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the Covered Entity; and
- The individual receives a health care service or range of services from the Covered Entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.<sup>28</sup>

Importantly, an individual is not considered a patient of a Covered Entity for purposes of the 340B program if the only health care service received by the individual from the Covered Entity is the dispensing of a drug or drugs for subsequent self-administration or administration in a home setting. As a result, only patients who receive care through eligible 340B program institutions or from affiliated departments or clinics that administer their 340B programs using either in-house pharmacies or contracted 340B retail pharmacies may be eligible for 340B program pricing for their medications. HRSA published proposed changes to the 340B definition of patient in 2007;<sup>29</sup> however, those changes have yet to be adopted. HRSA has indicated it plans to withdraw the 2007 proposed definition and replace it with a new proposed definition, which is expected to be published in 2014.<sup>30</sup>

The penalty for failing to comply with the program’s anti-diversion provision is forfeiture of the discounts back to the manufacturer. Where the violation is known and intentional, Covered Entities may be required to pay interest on the discounts that they refund. Finally, if the violation is systematic and egregious as

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<sup>27</sup> 61 Federal Register 55156 et. seq. (October 24, 1996).

<sup>28</sup> *Id.*

<sup>29</sup> 78 Federal Register 1544 et seq. (January 12, 2007).

<sup>30</sup> 340B Drug Pricing Program: Important Benefit, Important Responsibility, <http://www.hrsa.gov/opa/update.html>

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well as knowing and intentional, a Covered Entity may be disqualified from participation in the program for a reasonable time, to be determined by HRSA.<sup>31</sup>

### Audits

HRSA and manufacturers have the right to audit the records of Covered Entities to protect against diversion and “duplicate discounts.”<sup>32</sup> In fact, in late 2011 and 2012, as a result of investigations by the General Accounting Office and Office of the Inspector General that evaluated the 340B program, and due to manufacturer and Congressional pressures, HRSA has begun to audit Covered Entity 340B programs focusing on contract pharmacy arrangements and Covered Entity eligibility. The results of HRSA’s audits have revealed limited instances involving (i) diversion and duplicate discounts; (ii) outpatient facility eligibility; (iii) prescriber relationships; and (iv) and GPO exclusions.<sup>33</sup>

## Contract Pharmacy Overview

How does a drug prescription written by a provider for a patient become eligible to receive 340B pricing in a contract pharmacy? What responsibilities does a contract pharmacy have in the delivery of 340B-priced medications to an eligible patient? How does a pharmacy become a contract pharmacy? These and other questions are critical to any pharmacy that enters into a contract pharmacy relationship with a Covered Entity. While the specific duties of a Covered Entity’s contract pharmacy program may vary, there are several elements that are common to all.

The 340B program has experienced tremendous growth since HRSA issued the first guidelines in 1993. Of significant value to Covered Entities and their patients was the introduction of contract pharmacies in 1996.<sup>34</sup> This resulted after many Covered Entities that wanted to participate in the 340B program complained that they were unable to do so because of lack of access to an in-house pharmacy or lack of resources to develop one. As a result, HRSA published guidelines that authorized a Covered Entity to enter into a single contract pharmacy relationship to meet the dispensing needs of a Covered Entity site. If a contract pharmacy had multiple locations, the Covered Entity site could

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<sup>31</sup> *Id.*

<sup>32</sup> 61 Federal Register 65406 et seq. (Dec. 12, 1996).

<sup>33</sup> Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement, General Accounting Office, [www.gao.gov/products/GAO-11-836](http://www.gao.gov/products/GAO-11-836) and State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs – June 2011, Office of the Inspector General, [www.oig.hhs.gov/oei/reports/oei-05-09-00321.pdf](http://www.oig.hhs.gov/oei/reports/oei-05-09-00321.pdf)

<sup>34</sup> 61 Federal Register 43549 et seq. (Aug. 23, 1996).

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select only one as its contract pharmacy location to dispense 340B covered drugs to eligible patients of the Covered Entity. The guidelines stipulated requirements obligating the Covered Entity and contract pharmacy to comply with numerous safeguards intended to protect against diversion and duplicate discounts. Notably, HRSA took the position that its 1996 guidelines did not create a new right, but rather, as a matter of State agency law, Covered Entities had the right to contract with retail pharmacies to act as their agents for the purpose of dispensing 340B drugs.<sup>35</sup>

HRSA provided an exception to its single contract pharmacy arrangement in 2001 when it established the Alternative Methods Demonstration Projects (AMDP) program, which provided a limited exception to this general rule. Under the AMDP program, Covered Entities could apply and receive approval from HRSA to pursue alternatives to contracting with a single pharmacy. These alternative models included: “(1) the use of multiple contract pharmacy service sites, (2) the utilization of a contract pharmacy to supplement in-house pharmacy services, and/or (3) the development of a network of 340B covered entities.”<sup>36</sup> The intent was to allow community health centers and other 340B safety-net providers to develop new ways to improve access to 340B prescription drugs for their patients.

Based on the success of the AMDPs, and the urging of safety-net providers who wished to utilize alternatives to the single entity site/single pharmacy location contract pharmacy model to provide broader access to medications purchased at 340B Program prices, HRSA expanded Covered Entities' ability to create networks of contracted pharmacies for their 340B programs with guidelines authorizing “multiple contract pharmacy arrangements” in March 2010.<sup>37</sup> In the final guidelines, HRSA provided a list of essential elements that must be addressed in contract pharmacy arrangements and sample model contract terms.<sup>38</sup> These essential elements will be described further in the Section of this Guide entitled “Contract Pharmacy Services Agreements.”

Under HRSA's multiple contract pharmacy guidance, Covered Entities may establish agreements either through multiple contracts with individual pharmacies or through a single contract with a chain pharmacy that identifies the specific pharmacy locations that will support the Covered Entity's 340B program. Covered Entities may enter into arrangements with contract pharmacies to supplement pharmacy services that the Covered Entity itself

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<sup>35</sup> 61 Federal Register at 43550 (Aug. 23, 1996).

<sup>36</sup> 72 Federal Register 1540-1543 (Friday, January 12, 2007)

<sup>37</sup> 75 Federal Register 10272, et. seq. (Mar. 5, 2010).

<sup>38</sup> 75 Federal Register 10277, et. seq. (Mar. 5, 2010).

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provides to patients of the Covered Entity.<sup>39</sup> HRSA, however, refused to incorporate Covered Entity network arrangements (i.e., arrangements involving a network of more than one Covered Entity) into the expanded types of allowable contractual arrangements because of ongoing concerns about the ability of such arrangements to maintain program integrity.

Creating a contractual relationship with a local pharmacy or pharmacies may be attractive to many Covered Entities primarily because the start-up costs are relatively minimal. The option expands access for patients of the Covered Entity by providing multiple pharmacy locations that may be used to dispense a patient's 340B-eligible medications. Furthermore, it may eliminate the need for infrastructure improvements or build-out costs for the Covered Entity, including the need to hire pharmacists and may require less support staffing. However, depending on how inventory is managed for the Covered Entity, this arrangement may still involve considerable expense when purchasing the initial drug stock for patients. Services performed by the pharmacy are usually reimbursed at an agreed-upon dispensing fee paid per prescription by the Covered Entity to the pharmacy.

The ability to incorporate multiple pharmacies into a 340B contract pharmacy network has only been available for a brief period. While it has delivered benefits in terms of expanded access to and participation in 340B program prices for Covered Entities and their patients, it has introduced many new challenges for pharmacies, including operational complexity, non-standard program management requirements, increased program costs, and additional audits from HRSA, manufacturers, and PBMs. Yet, a well-managed contract pharmacy arrangement can address these additional complexities while delivering value to the Covered Entity and its contract pharmacy partners. In addition to the essential elements of a contract pharmacy arrangement referenced above, an overview of contract obligations of parties to a contract pharmacy arrangement can be found in the "Contract Pharmacy Services Agreements" of this Guide.

The 340B statute does not contain language that directs Covered Entities on how their 340B programs should operate or how drugs are to be delivered to eligible patients. It only mandates certain requirements and prohibitions. As a result, so long as Covered Entities adhere to the statute's limitations, they have several options available to them for setting up their 340B programs, including using sample closets, managing physician dispensing systems, using their own in-house pharmacies or establishing multiple contract pharmacy arrangements. Since HRSA issued guidance establishing multiple contract pharmacy arrangements in

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<sup>39</sup> 75 Federal Register 10275, et. seq. (Mar. 5, 2010).

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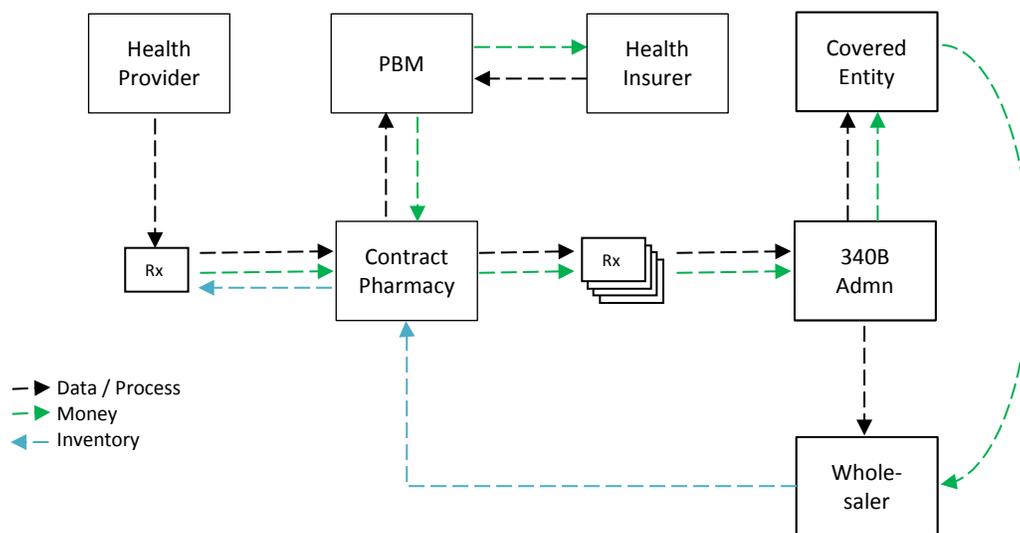
2010, the number of contract pharmacy arrangements has increased significantly. As these arrangements enable Covered Entities to expand the care they provide to vulnerable patient populations, the use of contract pharmacies has greatly expanded both the reach and complexity of the 340B program.

While there is more than one method for a Covered Entity to establish its 340B contract pharmacy arrangement, increasingly the industry is evolving to a method that includes four types of participants, or functions. Each has a specific purpose and coordinates actions with those of the other participants or functions in order to complete a 340B transaction. A typical 340B contract pharmacy program includes:

- Covered Entities, which act as the 340B program sponsors and are responsible for ensuring their programs are compliant with HRSA guidelines and statutory requirements;
- Contract pharmacies, which dispense 340B prescriptions to eligible patients on behalf of Covered Entities;
- Pharmaceutical wholesalers, which process, ship and bill for 340B inventory orders placed by Covered Entity's or their surrogates; and
- 340B Administrators, third party vendors that are typically contracted to Covered Entities to assist them with managing their 340B program;

A 340B transaction generally follows a process similar to the one described below.

**Figure 1: Typical 340B Contract Pharmacy Process Flow**



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1. A prescription is presented by a patient to a participating 340B contract pharmacy.
2. The pharmacy processes the prescription and adjudicates it to the appropriate payor(s) for the claim. After processing, the prescription is filled and dispensed to the patient.
3. At defined periods, dispensed prescriptions are evaluated for inclusion in the Covered Entity's 340B program. This can be done by the Covered Entity or contract pharmacy. In some instances, a Covered Entity may use a 340B Administrator to perform this operation. Responsibility for decisions made regarding 340B eligibility remains with the Covered Entity.
4. Prescriptions that are "carved-in" to the Covered Entity's 340B program are recorded and reconciled, meaning that revenues associated with the carved-in prescription are remitted to the Covered Entity from the contract pharmacy. Pharmacies either retain or are paid a dispense fee for the dispensing service related to the prescription.
5. When a full package size quantity is used (based on the product's 11-digit NDC), the Covered Entity (or its 340B Administrator) orders replenishment inventory for the contract pharmacy. Orders are replenished using a "bill to/ship to" process where replacement product ships to the contract pharmacy and the invoice is sent to the Covered Entity for payment. It is important to note that in most cases OPA recommends replenishment using the product's 11-digit NDC. In cases where 11-digit replenishment is not available, but the 9-digit NDC product is available, the Covered Entity is responsible for maintaining records of the product replenishment.
6. The Covered Entity is responsible for ensuring adequate documentation demonstrating that only eligible patients receive 340B drugs and that there is no double dipping on Medicaid rebates. Contract pharmacies are required to coordinate their records with the Covered Entity to demonstrate compliance with the 340B program.

The time for which a 340B prescription is perfected (meaning the pharmacy has had its inventory replenished and received a dispense fee, while the Covered Entity has recovered the amounts collected for claims from pharmacies and paid the pharmaceutical wholesaler for the 340B inventory) varies and is dependent

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on the timing of replenishment. Replenishment usually occurs after all the content of the dispensed NDC package size has been used for a 340B eligible prescription.

### Contract Pharmacy Requirements and Obligations

In contrast to a typical prescription that is dispensed in a retail pharmacy and paid for by a combination of the patient's insurer and any copayment or co-insurance amount, a prescription qualifies as a 340B eligible prescription based on the relationship between the Covered Entity, prescriber, patient and the contract pharmacy. In order for a prescription to be treated as a 340B qualifying prescription, a Covered Entity must be eligible to participate in the 340B program and must be registered with OPA. Only prescriptions written by eligible providers for qualifying outpatient encounters are eligible to be purchased using 340B Program prices. In addition, the qualifying 340B prescription must be filled at a pharmacy that is identified and registered on the OPA website as a contract pharmacy of the Covered Entity.

When establishing a contract pharmacy relationship, the Covered Entity is required to execute a contract with a pharmacy(ies) to provide pharmacy services. The Covered Entity purchases and owns all 340B inventory drugs, or uses its contract with wholesalers and manufacturers to replenish inventory used by the contract pharmacy for drugs dispensed to 340B-eligible patients. To the extent permitted by applicable law, the contract pharmacy (or the Covered Entity's 340B Administrator) may place orders on behalf of the Covered Entity, but the Covered Entity always pays for the drugs using the 340B cost of goods from the wholesaler. Replenished inventory is usually sent from the drug wholesaler directly to the pharmacy with the invoice for replenished inventory sent to the Covered Entity under a "ship-to/bill-to" arrangement with the pharmaceutical wholesaler. As referenced above, special guidelines apply to contracted pharmacy arrangements, and Covered Entities are responsible for ensuring that these will be met.<sup>40</sup>

The contract pharmacy must be licensed by the appropriate state Board of Pharmacy to dispense medications and should be qualified to administer the pharmacy services required of the Covered Entity. In return for the services it provides, the Covered Entity will typically pay a dispensing fee to the contract pharmacy.

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<sup>40</sup> 75 Federal Register 10277, et. seq. (Mar. 5, 2010).

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Since the contract pharmacy remains responsible for ensuring it manages and operates its pharmacy, it must be certain that its contract pharmacy relationship with the Covered Entity is fiscally sound. Elements to consider should include an understanding of the contract pharmacy’s overall financial position for business it transacts today, to include revenue and gross margin, whether the anticipated business relationship with the Covered Entity will result in new or additional business, or whether it will simply be transitioning its business to the Covered Entity. It should also factor in any additional costs it may incur by operating as a contract pharmacy. Such costs may include: additional pharmacy staff, start-up inventory, inventory carrying costs, lost financial incentives on its wholesaler agreements due to reduced direct purchases, etc. This topic will be explored in greater detail in “Contract Pharmacy Best Practices” Section of the Guide.

**Table 1: Contract Pharmacy – Pros & Cons**

<b>Strengths</b>	<b>Challenges</b>
<ul style="list-style-type: none"><li>• Opportunity for increased pharmacy volume and revenue</li><li>• Predictable, competitive margin on claims generated by major health care provider in community</li><li>• Opportunity to provide additional access to specific patients, particularly those with complex disease states</li><li>• Leverage the pharmacy’s skills and capabilities and/or build additional capabilities</li><li>• Partnership with largest healthcare brand in the pharmacy’s community</li><li>• Competitively positions pharmacy to develop collaborative arrangements with healthcare providers</li><li>• Lower operating costs, specifically in terms of working capital</li><li>• Programs to serve a broader community of patients (including underserved patients)</li></ul>	<ul style="list-style-type: none"><li>• Additional capital for inventory loaned to Covered Entity before replenishment takes place</li><li>• Understanding of operating and reporting requirements and costs</li><li>• Impact on existing book of business: will the 340B program result in additional patients or will it churn existing business?</li><li>• Business impact if required to wait for replenishment or have slow moving products (true-up)</li><li>• Potential impact on wholesaler purchases, and purchase guarantees or tiered buying discounts</li><li>• OPA and/or HRSA audit compliance: records demonstrate regulatory compliance (against diversion and double dipping of Medicaid rebates)</li><li>• 3<sup>rd</sup> party payor contract compliance and potential that audits may reverse claims and/or recover for overpayment</li></ul>

### The Role of 340B Administrators

Because of the complexity that can result from establishing a network of retail pharmacies that are contracted to provide 340B contract pharmacy services to Covered Entities, and managing the Covered Entity's inventory tracking systems, a new type of service provider has emerged to assist Covered Entities with managing their 340B programs. These businesses are commonly referred to as 340B Administrators, or 340B PBMs.

340B Administrators are not defined in the 340B statute, nor are they addressed in HRSA guidelines. Instead, these organizations arose organically and came into being because of the complexity inherent in administering contract pharmacy relationships across multiple pharmacies with a variety of third party payor agreements, wholesaler agreements, and patient populations. 340B Administrators contract with Covered Entities to help build their pharmacy networks and administer the management of their 340B programs, performing the following types of responsibilities:

- Work with Covered Entities to identify and select pharmacies to be included in the Covered Entity's contract pharmacy network;
- Determine which pharmacy claims are eligible to participate in the Covered Entity's 340B program;
- Track and accumulate inventory used by contract pharmacies for 340B claims, and replenish this inventory by initiating orders to wholesalers on behalf of Covered Entities;
- Reconcile and recover third party payments to pharmacies and coordinate the invoicing of Covered Entities and payments to contract pharmacies for dispensing services; and
- Prepare reports to Covered Entities and pharmacies necessary to accurately track the program's performance and ensure audit compliance.

While Covered Entities are increasingly using 340B Administrators to manage their 340B programs, Covered Entities retain responsibility to HRSA and manufacturers for the integrity and compliance of their programs. Contract pharmacies often find that when they engage in a 340B program, they must coordinate with both the Covered Entity and the 340B Administrator to ensure program performance.

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### Types of 340B Administrators

For the most part, 340B Administrators can be grouped into one of three categories:

- **Split Billing Software Companies.** 340B split billing companies are commonly software providers that target hospitals with solutions that manage the complexities of using Group Purchasing Organization program pricing for an institution's in-house needs, and 340B purchases for outpatient use in their outpatient pharmacies. These organizations are increasingly important given recent HRSA guidelines concerning compliance with GPO exclusion requirements for certain Covered Entities.
- **Chain & Independent Pharmacies.** Both national chain pharmacies and some independent pharmacies with sufficient resources and focus have entered the market to offer administration services. These institutions have developed the capability to provide both contract pharmacy programs and administrative capabilities for 340B institutions and typically offer their services exclusively to their stores (they do not include other pharmacies). These organizations have realized success working with Covered Entities who require a large, consistent pharmacy footprint for their 340B program.
- **Independent 340B Administrators.** These are pure-play contract pharmacy 340B Administrators who act as the program's coordinator for the Covered Entity. They contract across all pharmacy types and usually do not own any contract pharmacies. This group represents a common type of 340B service provider and is realizing success by its ability to organize a variety of participating contract pharmacies and through their perceived independence.

### 340B Administrator Services

The 340B program places special requirements on a Covered Entity for it to remain compliant with the 340B statute and HRSA guidelines. In general, when a Covered Entity contracts with a 340B Administrator, the 340B Administrator may perform some or all of the following four basic services:

- **340B prescription eligibility.** An important component of the 340B program is that each prescription that is written by a healthcare provider must be assessed for eligibility to receive 340B pricing. The 340B program is not member-based so much as it is prescription-based. 340B

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Administrators accumulate records of prescriptions that have been dispensed by the Covered Entity's contract pharmacies and evaluate each to establish whether a pharmacy claim is eligible to be included in the Covered Entity's 340B program. To do this, the Administrator matches dispensing records from the contract pharmacy with patient eligibility data supplied by the Covered Entity.

- **Accumulate and replenish 340B inventory.** Once a claim has been adjudged to be 340B eligible, the 340B Administrator carves the claim into a file where it tracks and accumulates a record of the units that were dispensed. Not all eligible claims are necessarily carved-in to a Covered Entity's 340B program. 340B Administrators sometimes apply a financial test to a claim to determine whether a Covered Entity will make or lose money if it is included in their 340B program. Based on this evaluation, some but not all eligible claims may become carved-in 340B claims. Accumulation is done, in most cases, using the medication's 11-digit NDC. Once accumulation has tallied to the medication's package size, it is eligible to be replenished. On behalf of the Covered Entity the 340B Administrator will initiate a replenishment order with the specific 340B wholesaler used by the Covered Entity. Inventory that is replenished will ship to the contract pharmacy to replace the inventory that had been "loaned" by the pharmacy to the Covered Entity for the 340B prescriptions that were dispensed. The invoice for this replenished stock is sent by the wholesaler to the Covered Entity for payment. Covered Entities are responsible for payment of all 340B products ordered by the 340B Administrator on its behalf.
- **Reconciliation of claim payment.** At discrete periods, the 340B Administrator reconciles and recovers all funds collected by the pharmacy related to claims carved into the 340B program. This includes payments received from third party payers, co-payments collected from patients and any monies collected from uninsured individuals who receive 340B-priced prescriptions. From these monies, the contract pharmacy is paid a dispensing fee for the contract pharmacy services provided by the pharmacy for the Covered Entity, which is calculated by the 340B Administrator. The difference between the monies that have been collected by the pharmacy for 340B claims and the dispensing fee that is paid to the pharmacy is remitted by the 340B Administrator to the Covered Entity which uses this amount to pay for the 340B invoices received from the 340B wholesaler. Any monies remaining after payment to the drug wholesaler may be used by the Covered Entity to

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support its health care mission.

- **Reporting and audits.** HRSA requires that the Covered Entity be responsible for validating the integrity of its program and to ensure that no 340B-priced medication is dispensed to an ineligible patient or receives a rebate by a state Medicaid agency. To assist the Covered Entity with ensuring it meets this responsibility, 340B Administrators may be responsible to the Covered Entity for maintaining, preparing and producing the necessary records for the Covered Entity to validate its program. By doing so, when and if a Covered Entity is audited by HRSA or a manufacturer, it can produce records demonstrating how claims were carved into its 340B program and that no double dipping on Medicaid rebates has occurred.

On behalf of the Covered Entity, the key role of the 340B Administrator is to facilitate the coordination of activities between the Covered Entity and contract pharmacies. 340B Administrators help establish and manage the network of retail pharmacies used by the Covered Entity for its 340B program and ensure only eligible prescriptions are included into the program. They track and manage the inventory loaned by the contract pharmacy to the Covered Entity's program that has been dispensed for 340B-eligible prescriptions. They ensure all revenues are appropriately accounted for, collected and allocated to the Covered Entity so inventory can be replenished to the contract pharmacy, and that parties are paid for the services rendered. Finally, they provide audit-ready records that document the integrity of the Covered Entity's program.

The 340B program is complex and the mechanisms required to build, manage, track, and report requires a considerable investment of time and money. There is much more that can be said about 340B Administrators and the various services that each provides to perform the 340B duties required by Covered Entities, but this overview covers the duties that are common to all.

### Contract Pharmacy Business Process

In contrast to a typical prescription that is dispensed in a retail pharmacy and paid for by the patient's insurer, 340B prescription eligibility is determined by the relationship between the Covered Entity, prescriber, patient and the contract pharmacy. In order to access 340B program prices, a Covered Entity must be eligible to participate in the 340B program and must be registered with OPA. 340B Drugs may only be dispensed pursuant to prescriptions written by eligible providers for qualifying outpatient encounters. The qualifying 340B prescription

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must be filled at a pharmacy that is identified as a contract pharmacy of the Covered Entity and registered with the Office of Pharmacy Affairs.

As referenced previously, in order for a retail pharmacy to participate in a Covered Entity's 340B program, it must execute an agreement with the Covered Entity and be registered by the Covered Entity with the Office of Pharmacy Affairs. Pharmacies can elect to maintain a separate physical inventory of 340B-priced goods, or use a method referred to as "virtual inventory" control where the pharmacy dispenses from its inventory and is later replenished by the Covered Entity. This method is commonly used by contract pharmacies and Covered Entities today. Under this arrangement, a pharmacy will typically receive a fixed fee per dispensed drug for the contract pharmacy services it provides on behalf of the Covered Entity.

By participating as a contract pharmacy, the retail pharmacy acts as an extension of the Covered Entity in that it collects third party payments and patient co-payments for prescriptions it dispenses to 340B-eligible patients, and remits these amounts to the Covered Entity in return for a dispense fee and replenished inventory from the Covered Entity.

For the contract pharmacy, it is imperative that it establish an acceptable dispense fee and timely reconciliation of payment and inventory replenishment in order to ensure a successful contract pharmacy 340B program.

### Contract Pharmacy Services Agreements

As previously discussed in this Guide, HRSA issued new guidance on March 5th, 2010, that, effective April 5th, 2010, permitted Covered Entities to contract with multiple outside pharmacies.<sup>41</sup> In addition to allowing Covered Entities to utilize multiple contract pharmacy arrangements, the March 5th, 2010 guidance clarified the requirements of contract pharmacy arrangements. For one, HRSA's guidance requires the Covered Entity to have a formal written agreement, typically referred to as the "contract pharmacy services agreement," with the contract pharmacy.<sup>42</sup> HRSA's guidance did not address the role of the 340B Administrators, which are now commonly utilized by Covered Entities to help them administer the 340B contract pharmacy relationship. The Covered Entity and the contract pharmacy will likely need to also enter into a separate agreement with the 340B Administrator. In some cases, the Covered Entity, contract pharmacy and 340B Administrator may enter into a "3-Party" contract to minimize the number of contracts. In order to comply with HRSA's guidance,

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<sup>41</sup> 75 Fed. Reg. 10272-10279 (Mar. 5, 2010).

<sup>42</sup> 75 Fed. Reg. 10277 (Mar. 5, 2010).

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the Covered Entity and the contract pharmacy need to be parties to the same formal written agreement (i.e., it would not be sufficient for the Covered Entity and contract pharmacy to each contract with a 340B Administrator, but not with each other).

Whether the parties enter into one or more contracts, it is essential for the contract pharmacy to ensure that the terms of the contract pharmacy agreement(s) are thoroughly reviewed from a legal compliance, operational, and business standpoint. The contract needs to specifically set forth the actual procedures that the parties will follow for handling funds, workflow, and management of drug inventory. Increasingly, 340B Administrators are building 340B contract pharmacy networks and marketing those networks to Covered Entities. To this end, 340B Administrators may utilize a model contract with the pharmacies which can hinder the ability of the pharmacy to directly negotiate specific terms and conditions between the Covered Entity and contract pharmacy. Since each contract pharmacy arrangement is unique, contract pharmacies should be wary of such one-size-fits all contract pharmacy services agreement. NCPA recommends that its members seek legal counsel competent in the 340B Program to ensure that the contract pharmacy agreement protect the member's legal interests and is compliant with applicable law.

### HRSA's Essential Elements

HRSA's March 5th, 2010 guidance provided a list of essential elements that must be addressed in contract pharmacy agreements. To the extent the parties utilize a 340B Administrator, the contractual provisions need to be carefully drafted to take into account the 340B Administrator's responsibilities.

- **“Ship to, Bill to”.** The contract pharmacy arrangement must address the “ship to, bill to” process pursuant to which the Covered Entity purchases the 340B drug, and the manufacturer/wholesaler ships the drug directly to the contract pharmacy.<sup>43</sup>

NOTE: HRSA's March 5th, 2010 guidance contemplated that the covered entity, as the purchaser of the 340B drugs, would maintain the title of the 340B drug until it is dispensed to a patient.<sup>44</sup> The guidance, however, did not address “replenishment models,” pursuant to which the contract pharmacy dispenses 340B drugs from its own drug inventory which are then replenished by the Covered Entity. Contract pharmacies that utilize a “replenishment” model should engage legal counsel to

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<sup>43</sup> 75 Fed. Reg. 10277 (Mar. 5, 2010).

<sup>44</sup> *Id.*

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ensure that HRSA's essential elements are addressed in a manner that is both consistent with the actual contract pharmacy model and compliant with the 340B program.

- **Comprehensive Pharmacy Services.** The contract pharmacy services agreement must specify that the contract pharmacy will provide “comprehensive pharmacy services.” HRSA's guidance includes the following examples: “dispensing, recordkeeping, drug utilization review, formulary maintenance, patient profile, patient counseling, and medication therapy management services and other clinical pharmacy services.”<sup>45</sup>
- **Patient Choice.** The Covered Entity must inform patients that they are free to choose a pharmacy provider of their choice.<sup>46</sup>
- **Other Services.** HRSA's guidance is clear that the pharmacy may provide other services to the Covered Entity or its patients (e.g., home care, delivery, and reimbursement services) provided that 340B pricing is only available for covered drugs dispensed to eligible patients.<sup>47</sup>
- **Compliance with Law.** The Covered Entity and the contract pharmacy will adhere to federal, state, and local laws.<sup>48</sup>
- **Contract Pharmacy Reports.** The contract pharmacy must provide the Covered Entity with reports that are consistent with standard business practice (e.g., quarterly billing statements, status reports of collections and receiving and dispensing records).<sup>49</sup>

NOTE: In practice, if the parties utilize a 340B Administrator, the 340B Administrator may provide services to create and transmit such reports to both the Covered Entity and the contract pharmacy. The contract pharmacy services agreement should clearly identify the entity that will provide this function.

- **Tracking System/Verify Patient Eligibility.** The contract pharmacy and Covered Entity must work together to establish and maintain a tracking system sufficient to prevent diversion and verify patient

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<sup>45</sup> 75 Fed. Reg. 10277-10278 (Mar. 5, 2010).

<sup>46</sup> 75 Fed. Reg. 10278 (Mar.5, 2010).

<sup>47</sup> *Id.*

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*

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eligibility. The Covered Entity is required to establish a process for periodic comparison of its prescribing records with the contract pharmacy's dispensing records to detect potential irregularities. Furthermore, the parties must agree that they will not resell or transfer a 340B drug to an individual that is not a patient of the Covered Entity.<sup>50</sup>

NOTE: Although HRSA has made it clear that the Covered Entity is ultimately responsible for ensuring that the contract pharmacy arrangement is compliant with 340B program requirements, the 340B Administrator may play an essential role in establishing and maintaining the tracking system. Under such circumstances, it would be appropriate for the contract pharmacy services agreement to address the 340B Administrator's responsibility with respect to the tracking system.

- **Medicaid Duplicate Discounts Prohibited.** The 340B drugs must not be used to fill Medicaid prescriptions, unless the Covered Entity, the contract pharmacy and the applicable State Medicaid agency have established an arrangement to prevent duplicate discounts that is reported by the Covered Entity to the Office of Pharmacy Affairs of HRSA.<sup>51</sup>

NOTE: The process for preventing Medicaid duplicate discounts depends upon the policy of the Medicaid agency of the applicable state. The prohibition against Medicaid duplicate discounts is commonly addressed by "carving out" Medicaid patients from the contract pharmacy arrangement (i.e., the contract pharmacy would not dispense 340B drugs to Medicaid patients). However, certain states may require that the Contract Pharmacy "carve-in" Medicaid prescriptions.

HRSA has not issued a policy or other formal guidance specifying whether Covered Entities have a responsibility to prevent duplicate discounts for 340B-purchased drugs reimbursed by Medicaid managed care organizations. However, the U.S. Department of Health and Human Services, Office of Inspector General noted in a report on contract pharmacy arrangements that the risk of duplicate discounts could be applicable to MCO Medicaid as with traditional fee-for-service Medicaid in States where drug manufacturers are paying rebates on drugs dispensed through MCO Medicaid. To add to the complexity, the OIG report noted that certain 340B Administrators reported that the information needed to accurately identify MCO Medicaid prescriptions is

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<sup>50</sup> *Id.*

<sup>51</sup> 42 U.S.C 256b(a)(5)(A)(i)

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not readily available.<sup>52</sup> Therefore, with the assistance of legal counsel, contract pharmacies should contact their state Medicaid agencies on this issue to seek direction on how the state would like contract pharmacies and Covered Entities to handle MCO Medicaid claims in order for the state to meet its obligations to remove 340B MCO Medicaid claims from their rebate requests.

- **Independent and Self-Audits.** The Covered Entity and contract pharmacy must identify information that is necessary for the Covered Entity to evaluate whether the program is in compliance. HRSA's guidance indicates that it is the expectation of HRSA that Covered Entities will fulfill their obligation to ensure ongoing compliance by the utilization of independent audits.<sup>53</sup> The contract pharmacy must make the necessary information available for use for independent audits and/or self-audits performed by the Covered Entity.<sup>54</sup>

NOTE: In order for the audit to be truly "independent," the Covered Entity should use an outside consultant to perform the audit and not the 340B Administrator. On February 5, 2014, the HRSA issued a letter to 340B covered entities ("Covered Entities") stressing that Covered Entities must exercise "vigilant oversight" of their contract pharmacy arrangements to ensure compliance with the 340B Program requirements to prevent diversion and duplicate discounts and "if HRSA finds a covered entity providing no oversight of its contract pharmacy arrangements, this is a violation of program requirements and HRSA will no longer permit the participation of that contract pharmacy arrangement."<sup>55</sup> Thus, contract pharmacies should proactively coordinate and support Covered Entity oversight and audit activities.

- **HRSA and Manufacturer Audits.** The Covered Entity and contract pharmacy are subject to outside audits by HRSA and drug manufacturers of records that pertain to compliance with the restrictions against diversion and Medicaid duplicate discounts. The contract pharmacy must ensure that all pertinent reimbursement accounts and dispensing records maintained by the pharmacy are 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

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<sup>52</sup> HHS OIG, Memorandum Report: Contract Pharmacy Arrangements in the 340B Program, Page 4 (Feb. 5, 2014).

<sup>53</sup> 75 Fed. Reg. 10274 (Mar. 5, 2010).

<sup>54</sup> *Id.* at 10278.

<sup>55</sup> Letter to 340B Covered Entities from CDR Krista Pedley, Director, Office of Pharmacy Affairs, Feb. 5, 2014.

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auditable records will be maintained for a period of time that complies with all applicable Federal, State, and local requirements.<sup>56</sup>

- **Contract Available to OPA.** A copy of the contract must be provided to the OPA upon written request.<sup>57</sup>

### Key Legal Compliance Concerns

**Diversion/Medicaid Duplicate Discounts.** HRSA's guidance clearly states that the Covered Entity is ultimately responsible for ensuring that the contract pharmacy arrangement is compliant with all aspects of the 340B program. This includes ensuring that 340B drugs are only dispensed to "eligible patients" and are not resold and that manufacturers are not subjected to duplicate discounts by selling drugs subject to a state Medicaid rebate at the 340B price.<sup>58</sup>

**Orphan Drugs.** The Affordable Care Act and the Medicare and Medicaid Extenders Act of 2010 expanded the categories of Covered Entities to include critical access hospitals, free-standing cancer hospitals, sole community hospitals and rural referral centers. For these categories of Covered Entities only, drugs designated by the Food and Drug Administration as drugs "for a rare disease or condition" ("Orphan Drugs") are excluded from covered outpatient drugs subject to mandatory 340B pricing requirements (the "Orphan Drug Exclusion"). Other Covered Entities, such as disproportionate share hospitals, are not subject to the Orphan Drug Exclusion.<sup>59</sup>

In 2013, HRSA published a final rule clarifying how it would implement the exclusion provision for Orphan Drugs under the 340B Program.<sup>60</sup> HRSA's rule limited this provision only to those Orphan Drugs that are "transferred, prescribed, sold, or otherwise used for any medically-accepted indication other than treating the rare disease or condition" for which the drug was designated orphan status. This rule was subsequently challenged in federal district court by the Pharmaceutical Researchers and Manufacturers of America (PhRMA) who claimed that HRSA had overstepped its authority since it did not possess the requisite statutory authority to implement such a rule. The court ruled in PhRMA's favor and vacated HRSA's rule.<sup>61</sup>

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<sup>56</sup> 75 Fed. Reg. 10274 (Mar. 5, 2010).

<sup>57</sup> *Id.*

<sup>58</sup> 75 Fed. Reg. 10274-10275 (Mar. 5, 2010).

<sup>59</sup> 42 U.S.C 256b(e).

<sup>60</sup> 78 Federal Register 44016 et. seq. (July 23, 2013).

<sup>61</sup> *Pharmaceutical Research and Manufacturers of America v. US Department of Health and Human Services* (HHS), Civil Action No. 13-1501, May 23, 2014.

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As a result of the district court's decision, HRSA recently announced they are considering their options to appeal the court's decision as well as issue guidance allowing the purchase of drugs not used for orphan purposes.<sup>62</sup> HRSA also has been planning to issue a comprehensive proposed rule, known as the "Mega Rule," that addresses such issues as eligibility, patient definition and contract pharmacy. In light of the court's decision, HRSA is currently assessing the implications on future rulemaking.

**Anti-Kickback Law.** HRSA's guidance provides that contract pharmacies and Covered Entities need to take into consideration the provisions of the federal anti-kickback statute when negotiating and entering into contract pharmacy arrangements. The federal anti-kickback law prohibits the exchange (or offer to exchange) of anything of value in an effort to induce (or reward) the referral of federal health care program business (e.g. Medicare and Medicaid patients).<sup>63</sup> Violators of the federal anti-kickback statute are subject to civil and criminal penalties. In addition to the federal anti-kickback law, contract pharmacy arrangements also need to comply with state anti-kickback and fee-splitting laws.

The federal anti-kickback law is very broad and prohibits not only remuneration intended to induce referrals of patients, but also remuneration intended to induce the purchasing, leasing, ordering, or arranging for any good, facility, service or item paid for by a federal health care program. The Department of Health and Human Services' Office of Inspector General has promulgated safe harbor regulations that define practices that are not subject to the federal anti-kickback law because such practices would be unlikely to result in fraud or abuse.<sup>64</sup> Financial arrangements that do not comply with one or more of the safe harbors are not per se illegal. Rather, being outside the safe harbor requires a closer examination of all the facts and circumstances surrounding the transaction with an emphasis on its underlying intent.

To minimize the risk of a violation of the federal anti-kickback law, the parties should ensure that the contract pharmacy's compensation is consistent with fair market value for the services actually rendered by the pharmacy. For example, a contract pharmacy could potentially violate the federal anti-kickback statute if it provided the Covered Entity contract pharmacy services at below fair market value to exchange for the referral of Medicaid fee-for-service patients.<sup>65</sup>

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<sup>62</sup> Orphan Drug Exclusions, Health Resources Services Administration, <http://www.hrsa.gov/opa/programrequirements/orphandrugexclusion/index.html>, June 18, 2014

<sup>63</sup> See 42 U.S.C. § 1320a-7b.

<sup>64</sup> See 42 U.S.C. § 1320a-7b(b)(3); 42 C.F.R. § 1001.952.

<sup>65</sup> 61 Fed. Reg. at 43556 (Aug. 23, 1996).

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**HIPAA.** Contract pharmacy arrangements typically require that Covered Entities, contract pharmacies, and, if applicable, 340B Administrators, use and disclose “individually identifiable health information” in connection with the treatment of patients, the reimbursement for pharmacy services, and the verification of patient eligibility. Therefore, Covered Entities and contract pharmacies will need to ensure that the contract pharmacy arrangement complies with HIPAA/HITECH laws and regulations governing the privacy and security of “protected health information” (“PHI”).<sup>66</sup>

Covered Entities and contract pharmacies are typically both “covered entities” as defined by HIPAA privacy rules. As “covered entities” under HIPAA, Covered Entities and contract pharmacies may disclose PHI to each other for certain purposes expressly permitted under the HIPAA privacy rules, including the treatment of patients.<sup>67</sup> 340B Administrators, however, are not “covered entities” under HIPAA and, in order to receive PHI, may need to qualify as a “business associate” of the Covered Entity and contract pharmacy. Depending on the nature of the services provided by the 340B Administrator, the Covered Entity, or both the Covered Entity and the contract pharmacy, may need to enter into a HIPAA/HITECH compliant business associate agreement with the 340B Administrator. It is important for contract pharmacies to seek the advice of legal counsel to determine whether a business associate agreement is necessary.

### Operational and Financial Considerations

In order to minimize any disruptions to pharmacy operations caused by the contract pharmacy arrangement, the contract pharmacy should consider the following issues:

**Replenishment.** Covered Entities and contract pharmacies that utilize a replenishment model may ensure the contract pharmacy services agreement specifies the timing and process for replenishment. Under a “virtual inventory” system, which is commonly used for contract pharmacy arrangements, replenishment occurs when a non-340B drug is initially dispensed to a patient whose prescription is eligible for 340B Program prices, and the Covered Entity later replaces the non-340B dispensed drug with 340B priced inventory. Although the replaced inventory is purchased at 340B prices, the title of such drug products passes to the pharmacy upon delivery.

**Periodic “True-Up.”** The contract may set forth the process for the periodic reconciliation or “true-up” of drug inventory and the true-up of drug inventory

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<sup>66</sup> See 45 C.F.R. Parts 160, 162, and 164.

<sup>67</sup> 42 C.F.R. 164.502.

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after the contract pharmacy services agreement expires or is terminated. The true-up process is necessary to address situations where the contract pharmacy's inventory dispensed pursuant to the 340B program cannot be timely replenished by the Covered Entity. This includes situations such as drug shortages, or where drugs are discontinued or classified as "slow moving" drugs. "Slow moving" drugs include drugs that are dispensed by the pharmacy but have not reached the package size necessary to trigger replenishment by the Covered Entity. The agreement may specify the maximum time period that can pass before a 340B drug is classified as "slow moving." The process for resolving the problem of discontinued drugs or "slow moving" drugs may involve establishing a methodology to determine an amount that the Covered Entity will pay to the contract pharmacy to make it whole for the un-replenished drug.

**Formulary.** There is no designated formulary for the 340B program. However, the Covered Entity and contract pharmacy may determine that only certain drugs or categories of drugs will be covered by the contract pharmacy arrangement. Such determinations are typically based on economic or operational issues. The contract pharmacy may desire to be involved in establishing the formulary. Examples of categories of drugs that are sometimes excluded from the 340B formulary are multi-source generic drugs, drugs reimbursable under Medicare Part B, controlled substances, and specialty drugs. To avoid any confusion as to the types of drugs covered by the contract pharmacy arrangement, the contract pharmacy services agreement should clearly set forth the 340B drug formulary.

**Third Party Reimbursement and Co-Payments.** The contract may specify how and when third party payments and co-payments received, or anticipated to be received, by the contract pharmacy are submitted to the Covered Entity or 340B Administrator. The process may involve the 340B Administrator obtaining claims data at the switch or from the retail pharmacy system. Typically, the Covered Entity or the 340B Administrator will then invoice the contract pharmacy the anticipated third party reimbursement and co-payments received after deducting the applicable dispensing fee. If claims information is obtained from the switch, the 340B Administrator, contract pharmacy and the switch will likely need to enter into a separate agreement to provide the 340B Administrator access to such data.

**Dispensing Fees.** The contract pharmacy's dispensing fee should be clearly set forth in the contract pharmacy services agreement. For a successful contract pharmacy arrangement, it is critical that the amount of the dispensing fee result in a "win-win" for both the contract pharmacy and the Covered Entity. The parties may consider including a mechanism in the contract pharmacy services agreement that requires the parties to periodically review and, if necessary, adjust

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the dispensing fee, to ensure that the anticipated financial outcomes of the 340B program are met.

Contract pharmacies are often paid a flat dispensing fee for each 340B transaction, but other compensation models have been utilized. For example, the arrangement may utilize “tiered-pricing” in which a different dispensing fee may apply, depending on the particular drug, or a percentage-based compensation model. HRSA has recognized that the dispensing fee is a private transaction to be negotiated by the parties, which provides Covered Entities and contract pharmacies some flexibility in establishing the dispensing fee. However, the OIG has expressed that percentage compensation arrangements, depending on the particular facts, may be problematic under the federal anti-kickback statute because they provide financial incentives that may encourage overutilization of items and services and may increase program costs.<sup>68</sup> It is recommended that contract pharmacies that are considering a dispensing fee structured in a manner other than a flat fee engage health care legal counsel to ensure 340B and federal and state anti-kickback law compliance.

**Reports from the Covered Entity.** In addition to the reports to be provided by the contract pharmacy to the Covered Entity, the contract pharmacy services agreement may address reports that the contract pharmacy needs from the Covered Entity. The contract pharmacy will likely need the Covered Entity or 340B Administrator to provide it reports that demonstrate which dispensing transactions are classified as 340B covered transactions in order to verify the dispensing fees owed to the contract pharmacy. The agreement should describe the content of such reports and how and when the reports will be provided to the contract pharmacy.

### Contractual Provisions to Consider

**Wholesaler.** The contract pharmacy services agreement should designate the particular wholesaler from which 340B drugs will be purchased or clearly specify how such wholesaler will be selected.

**Third-Party Payor Clawbacks.** The contract pharmacy and Covered Entity should consider that third-party payors may retroactively reverse claims after reimbursement and co-payments have already been provided by the contract pharmacy to the Covered Entity. For example, such claim reversal may result from a third party payor audit. The contract pharmacy should consider the methodology for reconciliation to address third-party payor reversals in the contract.

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<sup>68</sup> OIG Advisory Opinion No. 98-1, (Mar. 19, 1998).

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**Reclassification / True-ups.** It is critical for the retail pharmacy to be invoiced amounts that are predictable so that it has a low impact on retail pharmacy work flow. Therefore, it is generally a good policy to set forth a maximum period of time in which the Covered Entity and the 340B vendor may retroactively correct or reclassify claims as 340B covered transaction.

**Ability to Suspend Services.** Since there is not an exact science to establishing contract pharmacy arrangements, the Covered Entity and contract pharmacy may consider including a provision in the contract pharmacy services agreement that allows either party to suspend the contract pharmacy arrangement by providing advanced notice within a reasonable time frame if the anticipated objectives of the arrangement are not being met.

**Change of Law Provision.** The 340B program is under intense congressional scrutiny and HRSA is expected to issue comprehensive regulations at some point in 2014. Since changes to the 340B program will almost certainly occur over the next few years, the contract pharmacy services agreement may include a strong “change of law” provision that requires the parties to amend the contract as required by new laws and regulations. In addition, the “change of law” provision may allow the parties to terminate the agreement in the event new laws or regulations have a material economic impact on the arrangement.

**Other Terms and Conditions.** Of course, the parties to a contract pharmacy services arrangement should include other non-340B specific provisions typically included in service contracts as appropriate, including, but not limited to, provisions addressing term and termination, insurance, confidentiality, dispute resolution, assignment, and other additional pharmacy services.

### Avoiding Pitfalls and Disputes

The key facet for a successful 340B contract pharmacy arrangement is collaboration between the Covered Entity, contract pharmacy, and, if applicable, 340B Administrator to ensure a “win-win” situation for all the parties involved. Such collaboration requires open lines of communication between competent representatives of the parties. Systems should be in place to ensure such open communication, such as periodic phone calls among key members and a clear escalation process to address problems as they arise. The following are other items that the pharmacy should consider prior to entering into the contract pharmacy services agreement:

**Cost of doing business.** Understand the pharmacy's operating costs. A pharmacy should determine its monthly operating expense and evaluate this amount on a per claim basis. Also, the pharmacy should determine its cost to

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dispense a prescription so it can ensure that the financial arrangement established with the Covered Entity is fiscally sound.

**Ensure established financial systems.** Most financial systems account for revenue and costs of goods to establish operating or gross margin. The pharmacy should discuss any additional accounting methods that will be required to account for payables to the Covered Entity and the receipt of the dispensing fee for services provided.

**Reconcile inventory.** In addition to relying on reports provided by the Covered Entity and/or its 340B Administrator to track utilization, the pharmacy should ensure that it can audit inventory used in the 340B program including inventory dispensed, replenished, owed, and aged. This will enable the contract pharmacy to validate the records supplied by the Covered Entity or 340B Administrator and any replenishment orders.

**340B eligibility and claim carve-in.** Most 340B programs use different criteria to establish patient eligibility and to evaluate claims for inclusion in the Covered Entity's 340B program. Pharmacies should ensure that they understand this criteria and the methods used to "carve-in" 340B eligible claims. They should ensure that they have access to data necessary to independently evaluate the classification of 340B claims.

### Contract Pharmacy Agreement Checklist

- Are the Covered Entity and the Contract Pharmacy in direct contractual privity (i.e., parties to the same contract)?
- Are all of HRSA's essential elements covered by the contract pharmacy services agreement?
- Do the operational procedures set forth in the contract pharmacy services agreement accurately reflect the actual arrangement?
- Can the contract pharmacy adopt the operational procedures with minimal impact on the pharmacy's standard workflow and drug inventory management?
- Are the contract pharmacy's responsibilities under the contract pharmacy services agreement appropriate (e.g., the contract pharmacy should not be responsible for preventing diversion if it is "blind" as to which patient prescriptions are eligible to be purchased at 340B program prices)?

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- Has the contract pharmacy conducted any due diligence on the proposed 340B Administrator? Does the 340B Administrator have a reputation for dealing with contract pharmacies fairly and providing good customer service?
- Will the contract pharmacy, Covered Entity, and 340B Administrator establish a team with representatives from each party that will meet regularly to review various aspects of the contract pharmacy arrangement?

### Essential Contract Pharmacy Practices

One of the critical success factors of a successful 340B program for a Covered Entity is to have an effective and well developed pharmacy network. How well these networks perform is impacted by the relationship the Covered Entity establishes with its pharmacies and staff. This is true for both Covered Entity owned-and-operated in-house pharmacies, as well as contract pharmacy arrangements.

It follows then, that a successful 340B program requires a thoughtful approach to pharmacy selection. Pharmacies that support a Covered Entity's 340B program have the potential to significantly impact the program's success, which can also substantially affect the pharmacy's operations and performance. It is imperative that both the Covered Entity and pharmacy understand that the program's success is intertwined with how well the interests of these organizations are aligned. The parties must approach the 340B program as a relationship that will be long-term and commit to cultivating an arrangement that serves the interests of both parties and the patients that use their services.

Since supporting a Covered Entity's 340B program may impact participating pharmacies in different ways, it is important to note that there is not a one-size fits all contract, process, or dispensing rate that is suitable for all pharmacy partners. It is important, also, for Covered Entities to recognize this, as it may be entirely appropriate for various pharmacies to partner with a Covered Entity under different contract terms and at different rates. Working with a 340B Administrator that is willing to develop a solution that is tailored to fit the needs of the particular Covered Entity and contract pharmacy is an important determinant of program success.

From a Covered Entity's perspective, successful relationships with its contract pharmacy(ies) include the following elements:

**Location.** Because the 340B statute prohibits Covered Entities from mandating that 340B-eligible patients use only the Covered Entity's contract pharmacies, it is important to select pharmacies that are proximal to where the Covered Entity's

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patients reside. As a consequence, pharmacy location is critical to the Covered Entity. A successful contract pharmacy will be conveniently located relative to the Covered Entity and its patients, and have operating hours that are convenient. The pharmacy should be staffed with employees that can communicate in the language of the Covered Entity's patients and possess the ability to distribute drug information in these languages.

**Inventory.** Whether using 340B inventory that is purchased in advance of a dispensing event, or inventory that is replenished by the Covered Entity at defined replenishment points, the pharmacy should ensure it possesses sufficient inventory of drugs the Covered Entity will require on its formulary to meet the needs of the Covered Entity's patients. Pharmacies should also ensure that they maintain sufficient supply of over-the-counter (OTC) drugs and medical supplies to meet the needs of the Covered Entity's patients and possess the ability to order special items on request.

**Participation in Third Party payer networks.** Pharmacies that support a Covered Entity's 340B program should be able to participate in the various insurance plans for the Covered Entity's patient population. The contract pharmacy should also be able to carve-out certain claims from third party payor networks as directed by the Covered Entity.

**Collaboration with care management initiatives.** Some Covered Entities may require adherence to Covered Entity guidelines pertaining to patient education on drug therapy or sharing information on patient medication compliance. The contract pharmacy should ensure that it has the staff and resources to provide these services, if required.

**Program compliance.** This includes compliance with all Covered Entity policies and procedures related to their 340B program. These include: (a) ensuring that there is no diversion of drugs bought by the Covered Entity at the 340B program price to other than Covered Entity patients; and (b) working with Medicaid to ensure that there is no opportunity for potential duplicate discount / rebates.

**Coordination.** Regularly scheduled meetings between contract pharmacy(ies) and Covered Entity management to ensure continuity of care and feedback on the program as it relates to the Covered Entity, its pharmacies, and overall patient access to the 340B program.

As a pharmacy becomes confident it can address the 340B needs of the Covered Entity, it must also ensure that it can satisfactorily address items that are critical

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to its ability to create a long-term and mutually satisfying 340B contract pharmacy program with the Covered Entity. The following are some of the key items to consider as pharmacies evaluate participating as contract pharmacies for a Covered Entity's 340B program:

### Cost to dispense

Any pharmacy that participates as a contract pharmacy in support of a Covered Entity's 340B program must understand its operating overhead and the margin it is receiving today for the prescriptions it dispenses. This is because, as opposed to a typical retail pharmacy where margin is based on the difference between the payment it receives for the prescriptions it dispenses and the cost of goods it pays to its wholesaler, the 340B contract pharmacy is paid a dispensing fee per transaction. Any pharmacy seeking to participate as a Covered Entity contract pharmacy should understand what it costs to dispense a prescription so it can ensure that it recovers these costs as a 340B contract pharmacy. It should also understand its margin profile related to its book of business so that it can ensure that this profile is maintained or improved upon (since participation as a 340B contract pharmacy includes additional program overhead). The pharmacy should consider periodic review of its dispensing fee as the pharmacy's costs may change over time. Without this, the pharmacy may struggle, and this may cause the Covered Entity's 340B program to struggle, too. Left unchecked, an unsatisfactory financial relationship for the contract pharmacy may cause it to leave the 340B program or close its doors.

In addition, any additional services or programs required by the Covered Entity to be provided by the contract pharmacy may be recognized as a compensable cost, since such services may further enhance the value proposition to the Covered Entity and the patients who take advantage of the 340B program.

### Compensation

While understanding a pharmacy's cost to dispense is important to ensure that it covers its costs when supporting a Covered Entity's 340B program, the pharmacy should also understand how it will receive payment from the Covered Entity for 340B eligible claims. Will the pharmacy be paid a flat dispense fee, or a percent of the difference between the third-party paid amount and the 340B acquisition cost? Will all eligible 340B claims be included into the Covered Entity's program, or will only those claims that offer a financial benefit to the Covered Entity be included?

The answers to these questions are important. For example, a pharmacy should consider the appropriate dispense fee if the only claims that are carved-in to the Covered Entity's 340B program are those where there is a financial benefit to the

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Covered Entity, since the carved-in claims will likely be the same claims that the pharmacy earns its margin on from third-party payers. In effect, the pharmacy would be left with lower margin products in its third party payor program while ceding the higher margin products to the Covered Entity in return for a dispense fee. In contrast, if all eligible claims are included in the Covered Entity's program, the pharmacy may be able to receive a lower dispense fee on every claim, since the dispense fee may be higher than the gross margin dollars it receives on its generic products.

Understanding the structure of payment is important to ensure that the pharmacy understands how the program will impact its operations. At a minimum, pharmacies will want to ensure they have evaluated the dollar margin impact through the 340B contract pharmacy arrangement with the Covered Entity.

### Understand third party payor agreements

It is important for contract pharmacies to understand their contracts with third party payors to identify any requirements or limitations concerning involvement with the 340B program. Since pharmacies maintain the contractual relationship with payors for prescriptions dispensed to patients with covered benefits, and are therefore responsible to payors for any violation of these agreements -- regardless of the agreement a pharmacy may have with a Covered Entity for contract pharmacy services -- it is incumbent on the pharmacy to ensure that any 340B requirement in these agreements is adhered to so as to not compromise the pharmacy's relationship with its third party payors. If a pharmacy experiences difficulties with a third party payer due to dispensing as a 340B contract pharmacy, this could impact the services it is required to provide to the Covered Entity.

It is important that any action taken by a third party payor for claims that are included in the Covered Entity's 340B program receive consideration in the event of a third party audit or other action taken that affects the pharmacy's performance or claims included in the Covered Entity's program.

### Virtual replenishment

Inventory controls are important in any 340B program, but especially for Covered Entities that work with contract pharmacies. Covered Entities can ensure appropriate inventory controls by having a separate inventory for the 340B-purchased drugs. Though OPA has not expressed any particular method, Apexus has provided that this can be accomplished by keeping either a separate

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physical inventory or a virtual inventory (replenishment system).<sup>69</sup> With a virtual inventory, initial dispensing of 340B medications is completed from the pharmacy's existing stock, but the pharmacy is able to designate each prescription as 340B through a software or other system, creating a 340B inventory-utilization record. The Covered Entity replenishes these drugs to the pharmacy by purchasing them at a 340B price and the drugs become part of the 340B inventory purchased by the Covered Entity.

The use of virtual inventory in a 340B program requires planning by the Covered Entity and its contract pharmacies. Because a pharmacy "loans" its inventory to the Covered Entity for prescriptions that are carved-in to a 340B program, it must calculate the time it will require before the "loaned" inventory is replenished by the Covered Entity. A Covered Entity must replenish with the same 11-digit NDC that was dispensed, or maintain records of the product replenishment where only the 9-digit NDC product is available.<sup>70</sup>

Depending on the dispensing velocity of the NDCs used for Covered Entity claims, a pharmacy may have to wait for a period of time before the replenished inventory is available. This can affect the pharmacy's working capital since it may require new inventory in advance of when the replenishment inventory is available. Because virtual replenishment is not typically synchronized with orders placed by the pharmacy for its non-340B inventory, deliveries can be lumpy and can lead to inventory swelling in the pharmacy. Irregular inventory levels can be the single largest challenge for pharmacies that serve as contract pharmacies.

Pharmacies should ensure they have adequate terms in place with the Covered Entity (of its 340B Administrator) that address the frequency of replenishment (daily, weekly, bi-weekly, etc.), and options to make the pharmacy whole for expensive and/or slow-moving inventory.

### Working capital impact

When implementing a 340B program, Covered Entities can ensure appropriate inventory controls by maintaining either separate physical inventories at their contract pharmacies or by deploying a virtual inventory replenishment system. The overwhelming majority of contract pharmacy arrangements today are deployed using virtual inventory replenishment. Under this arrangement, the pharmacy is required to maintain the initial starting inventory from its own stock. This inventory is loaned to the Covered Entity until such time utilized inventory reaches the NDC's package size so it can be replenished, or is trued-up.

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<sup>69</sup> 340B University Notes, 340B Replenishment, pp 47-48, 340B Prime Vendor Program (PVP).

<sup>70</sup> Apexus 340B Prime Vendor Program, Frequently Asked Questions, Policy / Implementation: Purchasing, Inventory and Reimbursement.

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Depending on the size of the Covered Entity with whom it works; the number of other pharmacies that participate as contract pharmacies for the Covered Entity; the number of patients who take advantage of the Covered Entity's 340B program; the velocity of medications being dispensed by the contract pharmacy; and other relevant factors, the starting inventory loaned to the Covered Entity can be substantial. Contract pharmacies should understand the potential "inventory float" it will be making to the Covered Entity and ensure the costs of doing so are factored into their fees.

### True-up timeframe and rate

Depending on the patient mix, therapies prescribed, and the velocity of 340B prescriptions dispensed, contract pharmacies will need to understand how slow moving items will be replenished. The industry manages this through a system called "true-ups."

A true-up refers to how a pharmacy will be compensated when it has not sold through a complete package size to generate a replenishment order for a product within a defined period of time. These occurrences are usually treated as reversals of the 340B claim, whereby the claim and associated inventory is removed from the Covered Entity's 340B Program and the pharmacy is compensated by the Covered Entity for the cost of the inventory that had been carved into the 340B program. True-up timeframes are negotiated between the contract pharmacy and the Covered Entity (or its 340B Administrator). Typically these timeframes can range from 90-180 days depending on the parties involved. The greater the time between when a prescription is first dispensed and when the NDC has sold through its package size, the greater the amount of pharmacy cash that will be tied-up in the form of unpaid inventory that the pharmacy has loaned to the Covered Entity.

The contract pharmacy will want to negotiate with the Covered Entity, or its 340B Administrator, the time that will be allowed to pass before a drug is trueed-up, the intervals between true-up periods, and how the reimbursement will be calculated for the trueed-up inventory. If not fully understood and carefully managed, true-ups can create a challenge for pharmacies if they must wait long periods between when the drug is first dispensed and when inventory is replenished.

### Impact on non-340B business with wholesaler

Replenishment of loaned inventory to a contract pharmacy by a Covered Entity is made by the Covered Entity's pharmaceutical wholesaler. Covered Entities can have pharmacy networks that use different wholesalers (based on the preferences of the pharmacies). Having the Covered Entity use the wholesalers

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preferred by its contract pharmacies ensures a more integrated program and minimizes situations where dispensed drugs cannot be replenished due to differences in wholesaler product lines.

Because replenishment to a contract pharmacy is made from a Covered Entity's 340B purchases on its wholesaler account, participating as a Covered Entity's contract pharmacy may impact the pharmacy's total purchases through the account it maintains with its drug wholesaler. When a contract pharmacy's business shifts to the 340B program, this business now "belongs" to the Covered Entity and not to the pharmacy. This could have a resulting impact on tiered pricing or other rebate incentives the pharmacy has with its wholesaler and should be evaluated by the prospective contract pharmacy, as an increase in the cost of inventory for non-340B sales may be an unintended consequence of the pharmacy's involvement as a contract pharmacy for a Covered Entity's 340B program.

Pharmaceutical wholesalers handle shifts in business differently. Oftentimes, a contract pharmacy may not understand the impact of a 340B wholesaler program on its purchase agreement with its wholesaler until after the program has launched, when it may be too late to address. Contract pharmacies should understand where they are performing on their wholesaler agreement and take protective actions where appropriate. It is advisable to discuss participation in a Covered Entity's 340B program with the pharmacy's wholesaler in advance of launching its program to discuss potential issues and alternatives.

### New patient opportunities v. cannibalization of existing patient base?

A prospective contract pharmacy should understand the patient composition of the Covered Entity's 340B program to identify whether the pharmacy will serve new patients, or net additions, or whether it will be transitioning existing patients to the Covered Entity's 340B program. Whether a contract pharmacy will see new or additional patients could be a function of: (a) how aggressively the Covered Entity promotes its 340B program to patients; (b) the number of sites the Covered Entity will include in its 340B program; and (c) the number of pharmacies that will serve as contract pharmacies to the Covered Entity. Answers to these questions will allow the pharmacy to assess the business potential related to a 340B program opportunity.

### Pharmacy audit protection

A Covered Entity is fully responsible for its registered outpatient facilities' compliance with all 340B program requirements. The Covered Entity is also responsible for all contract pharmacy arrangements listed on the 340B database and with ensuring that it regularly reviews performance.

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Audits of 340B Covered Entities may be performed by HRSA or manufacturers, and include the Covered Entities' outpatient facilities and their contract pharmacies. In addition, pharmacies may be subject to internal audits conducted by the Covered Entity. Pharmacies need to ensure that they can support the audit requirements of the Covered Entity. This usually includes providing records sufficient to demonstrate 340B prescription eligibility and replenishment so that there is no diversion at the claim level and the ability to demonstrate appropriate actions on Medicaid claims (accurately recording a claim as carved-in or out of the Covered Entity's 340B program).

Contract pharmacies should be in a constant state of audit readiness. The pharmacy's compliance personnel should review relevant 340B audit requirements (including HRSA audit guidelines and the audit provisions contained in the contract pharmacy services agreement), and its process for maintaining dispensing data and reimbursement accounts with respect to 340B drugs. Contract pharmacies should discuss in advance with Covered Entity representatives what the contract pharmacy is expected to provide in the event of an audit. Although the 340B Administrator (if applicable) may be responsible for maintaining a tracking system and generating dispensing reports, the contract pharmacy should ensure it has a method to access and produce relevant 340B dispensing data (separate from its non-340B operations) without relying on the 340B Administrator. In the event of a manufacturer audit, the contract pharmacy would need to be able to produce dispensing data specific to the manufacturer's drugs.

In addition to supporting the audit requirements of the 340B program, pharmacies and Covered Entities should agree on how 340B claims will be addressed in the event of a third party payor audit. Should a pharmacy audit result in a claim reversal such that the pharmacy is required to pay monies back to the third party payor, the Covered Entity and contract pharmacy should consider a method to make the pharmacy whole, since third party reimbursements for carved-in 340B claims are remitted to the Covered Entity.

### 340B flag for third party payment consideration

While Covered Entities often serve indigent and underserved patients, it is not uncommon for an eligible patient to be covered by a commercial insurer, Medicare Part D plan or other form of non-Medicaid or "free care" payment. There are no direct restrictions or mandates in law related to how 340B medications can be used for these plans, including no prohibition on duplicate discounts. However, there are often agreements in place between manufacturers and payors that include or exclude claims for 340B medications from amounts, utilization or both from rebate or other performance initiative calculations. The

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technical consequence of these agreements is that a payor/PBM must identify claims for 340B medications to properly complete their rebate submission to the manufacturer.

In July 2011, the National Council for Prescription Drug Programs (NCPDP), the ANSI-accredited standards body that governs information exchanges related to medications, supplies, and services within the healthcare system, published results from its 340B Workgroup and established the NCPDP 340B Information Exchange Reference Guide. This publication intended to “meet the industry needs for electronic communication between trading partners of an individual prescription or prescription claim’s status under the 340B drug pricing program.”<sup>71</sup> The goal was to establish standards by which pharmacies could identify prescriptions that have been dispensed using drugs purchased at the 340B Program price so that these claims could be appropriately identified for carve-out from Medicaid claim rebate submissions, as well as to respond to PBM and manufacturer requirements to carve-out duplicate discounts on claims submitted for commercial rebate.

This standard included instructions on how pharmacy billing software should be written to allow identification of claims when 340B drugs are dispensed, both at the point of sale and retrospectively. As PBMs cannot easily distinguish claims filled with 340B drugs, some manufacturers have declined to pay rebates on any drugs dispensed by Covered Entities so as to avoid a potential duplicate discount. The standard nominally intended to allow PBMs to identify non-340B claims for which they might claim the customary commercial rebate. The guide contained instructions for pharmacies and Covered Entities to identify 340B claims processed at the point of sale, or retrospectively after the drug has been dispensed. According to this standard, pharmacies may transmit NCPDP Submission Clarification Code (420-DK) in the Claim Segment of a Claim Billing (B1) transaction for a point-of-sale transaction or Information Reporting (N1) transaction for retrospective transactions to identify a claim as a 340B transaction.<sup>72</sup> Adoption of this standard is still evolving. As states explore options to ensure accuracy of their Medicaid rebates, it is a potential option to ensure the integrity of the 340B program’s prohibition against duplicate discounts.

While the standard for identifying 340B claims is developing, pharmacies are advised to remain up to date on the NCPDP standards and determine whether their participating pharmacy agreements require the pharmacy to identify 340B

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<sup>71</sup> NCPDP 340B Information Exchange Reference Guide, National Council for Prescription Drug Programs, July 2011.

<sup>72</sup> *Id.* at 20.

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claims or implement any other particular process for submitting 340B claims. Pharmacies should seek legal counsel and should direct their pharmacy services administrative organizations to contact the pharmacy prior to agreeing to any process for identifying and submitting 340B claims.

### Before Getting Started

#### What to find out from a Covered Entity before proceeding

Before proceeding with a Covered Entity, a pharmacy will want to ensure that it understands the Covered Entity's 340B program objectives and how it will participate. By ensuring that the pharmacy has a clear understanding of the Covered Entities objectives for its 340B program and the expectations it has for the contract pharmacy's performance, parties will ensure a smoother program and avoid the potential for surprises. When meeting with the Covered Entity, the pharmacy will want to understand:

**The 340B program opportunity.** The pharmacy should understand the expected number of 340B patients whose prescriptions may be eligible to be purchased using 340B program prices that the pharmacy would potentially serve, as well as the total number of pharmacies that will participate as contract pharmacies for the Covered Entity. This information is important since the pharmacy must assess whether the relationship with the Covered Entity presents the opportunity for the pharmacy to serve new patients or whether it will simply transition its current customer base into the Covered Entity's 340B program.

**The Covered Entity's plan for patient awareness and outreach.** Since patients cannot be required to use an entity's 340B program, the pharmacy should discuss how the Covered Entity will educate patients about its 340B program and the pharmacies that are available. The pharmacy should be prepared to discuss ways that it may assist the Covered Entity in reaching out to patients in the community.

**Audit roles and responsibilities.** Because HRSA requires that the Covered Entity be responsible for validating the integrity of its program, pharmacies will want to clarify the responsibility it will have in the event of an audit from a third-party payer, manufacturer, or HRSA. Clearly identifying what the pharmacy will be responsible for producing in the event of an audit, and the actions that the Covered Entity (or its 340B Administrator) will take in the event an audit will allow the pharmacy to understand risk, scope out responsibilities and plan its resources more effectively.

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### What to find out from the Contract Pharmacy Administrator

If a Covered Entity will use a 340B Administrator to help manage its 340B program, the pharmacy will want to ensure it gains a full understanding of the methodology the Administrator will use to ensure program compliance and the eligibility, reconciliation, replenishment, and reporting functions of the contract pharmacy operation. Specifically, the pharmacy will want to understand:

**How 340B claims are established.** A key consideration for a pharmacy is how 340B claim eligibility will be established. The pharmacy will need to find out from the 340B Administrator whether it will be required to process a claim to the Administrator or whether claims will be evaluated and carved into the Covered Entity's 340B independent of any additional actions required by the contract pharmacy.

Many 340B Administrators determine a claim's eligibility for the 340B program retrospectively, after it has been approved by a payor and dispensed to the patient. This is accomplished when the 340B Administrator pulls dispensing data from a pharmacy's switch provider. Pharmacies have little or no additional action required after they dispense the medication. However, the pharmacy must authorize its switch to release claim data to the 340B Administrator so an eligibility assessment can be made. The pharmacy's claim data allows the Administrator to see all data associated with a claim, including patient, drug NDC, quantity dispensed, third party paid amount and copay values. The Administrator uses this data to establish eligibility and to accumulate and track quantities for replenishment.

There are a number of 340B Administrators available to Covered Entities and their contract pharmacies to help manage a 340B program. They offer a range of services and use different processing techniques to perform their services. Some 340B Administrators require the contract pharmacy to perform additional actions, such as perform coordination of benefit processing, or pre-adjudication processing of a prescription, before it can be established as eligible for the 340B price. Others require software to be installed on the pharmacy system so data can be captured and transmitted to the 340B Administrator or Covered Entity for evaluation. If a Covered Entity uses a 340B Administrator to help manage its 340B program, participating contract pharmacies will want to understand all additional activities they will be required to undertake in order to establish a prescription as eligible for the Covered Entity's 340B Program. In cases where an Administrator does not use switch data to reconcile a dispensed claim against a Covered Entity's patient data, it can have a significant impact on the pharmacy's workflow and resources.

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**Replenishment process and cycle times.** Most 340B Administrators that use virtual inventory replenishment models require that the pharmacy dispense drugs from its own inventory. Only after enough volume of a drug that matches its package size (in most cases, an 11-digit NDC match<sup>73</sup>) has been dispensed to patients whose prescriptions are eligible to be purchased using 340B program prices will it be replenished. Pharmacies need to understand the criteria used by the 340B Administrator for accumulating volume for replenishment; the frequency with which replenishment will occur once replenishment status has been achieved; how manufacturer shortages, out of stock or product discontinuances will be managed; as well as the method, timing and payment amount that will be used to “true-up” a pharmacy’s inventory for slow moving, discontinued product or end of contract situations.

**Frequency and scope of reports.** Just as a Covered Entity requires the 340B Administrator to produce reports that track performance and provide an audit trail for claims carved into a 340B program, pharmacies require information to assist them with tracking performance, liabilities, and inventories used. Pharmacies should ensure they receive detailed descriptions of the reports that the Administrator uses and the frequency with which they will be made available. Pharmacies should understand whether they will have access to online reports and the ability to perform ad hoc queries to assist them with their business management requirements. Copies of all reports should be made available. The pharmacy should also seek a commitment of resources from the 340B Administrator that will be available to assist with any performance or supply related issues associated with the 340B program.

**Opportunity assessment.** The pharmacy should work with the 340B Administrator to understand the total 340B program opportunity and the number of pharmacies that will serve as contract pharmacies for the Covered Entity. The 340B Administrator should be able to tell the pharmacy what the anticipated target volume will be at the levels committed to the Covered Entity as well as the outreach programs that will be used to drive utilization. The pharmacy should discuss collaboration opportunities and ways in which it can help increase utilization of the program.

### What the Covered Entity should find out from the Contract Pharmacy

Just as a pharmacy should ensure a solid understanding of the Covered Entity’s 340B program and the responsibilities the pharmacy will be expected to

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<sup>73</sup> Apexus 340B Prime Vendor Program, Frequently Asked Questions, Policy / Implementation: Purchasing, Inventory and Reimbursement.

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undertake, the pharmacy should expect that a well-run program will seek information about and the capabilities of the contracted pharmacy.

**e-Prescribing.** In seeking a compliant and efficient way to ensure prescriptions are delivered to a contract pharmacy, a Covered Entity may want to seek information about a pharmacy's ability to support e-prescribing. While growing in popularity, the ACA has made federal money available to assist safety-net providers to implement electronic medical record and e-prescribing platforms. With this capability in place a Covered Entity can significantly reduce the potential for drug diversion within the 340B program.

**Data sharing capacity.** A Covered Entity may seek information about a pharmacy's ability to support HL7 standards of interoperability. With HL7 pharmacies and Covered Entities may have a better opportunity to share information through the Covered Entity's electronic medical record system. Using data interchange and making use of queuing functions, prescribers and their agents can access pharmacy dispensing records during patient encounters to evaluate dispensing information and gaps in care during a patient office visit.

**Wholesale distributor.** Covered Entities must ensure that they have 340B wholesaler agreements with each of the pharmaceutical distributors that will be used to support the entity's contract pharmacy network. While a Covered Entity may seek to identify contract pharmacies that use the same wholesaler that the Covered Entity uses, they are not limited to this as many wholesalers now allow their client to contract with more than one wholesaler. Covered Entities can therefore build a network of contract pharmacies with different wholesalers (based on the preferences of the pharmacies).

**340B limitations in third party payor agreements.** As more and more third party payors are being impacted on their rebate submissions to manufacturers, there is an increasing trend towards contract language that requires 340B claims to be identified by the pharmacy, or contracted at a different network rate. There are no restrictions against this in the 340B statute. It is important that Covered Entities require their contract pharmacy partners to check their contracts for 340B-specific language or limitations.

It is important for contract pharmacies to evaluate their third-party agreements for language that may impact their performance as a 340B contract pharmacy so that it operate in a way that does not compromise the pharmacy with the third-party payor. Being mindful of any limitations or requirements at the beginning of a contract pharmacy relationship is important especially in case the pharmacy is audited later.

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### Conclusion

Stretching resources, serving underserved patients, and improving services is the principal benefit a Covered Entity that participates in the 340B Program can realize. As key partners to safety-net providers, pharmacies can play a critical role in enabling them to realize these benefits, but it requires that both the Covered Entity and its contract pharmacies have aligned goals and objectives. When achieved, retail pharmacies may become partners in the delivery of quality health care to a Covered Entity's patients. By so doing, retail pharmacies may also extend the services they provide to other important areas, such as assisting patients to participate in manufacturer Patient Assistance Programs, delivering medication therapy management, helping providers determine gaps in care, offer adherence management, or provide other services that can strengthen the quality of care patients in the health care safety-net receive.

This Guide was intended to provide pharmacies with an understanding of the 340B program, the various models that are available to support contracted pharmacy arrangements with Covered Entities, and a summary of the considerations and best practices used in support of a contract pharmacy relationship. For Covered Entities, the creation and maintenance of an infrastructure that will facilitate access to care for the neediest in our communities cannot be achieved without the active participation of a contract pharmacy network. For the community pharmacy, participation in a Covered Entity's 340B network offers the potential to serve new patients while collaborating with the most important health care providers in our communities.

Participation in a 340B contract pharmacy network will open opportunities for pharmacies to integrate themselves into the provider's medical home, which may become increasingly important as health care transforms under the Patient Protection and Affordable Care Act. A thoughtful and strategically managed contract pharmacy network creates a long-term meaningful relationship between the Covered Entity and its contract pharmacy.

### Frequently Asked Questions

**Q1. What is 340B?**

**A1.** The 340B Drug Pricing Program helps reduce outpatient drug costs for health care providers that serve high volumes of poor, uninsured, and underinsured patients in qualified safety-net organizations. There are sixteen categories of eligible safety-net institutions that are eligible to participate in 340B Program. Only nonprofit health care organizations that have certain federal designations or receive funding from specific federal programs are eligible to participate. These “Covered Entities” include: six categories of hospitals, four categories of health centers, five categories of specialized clinics, and entities which receive Ryan HIV/AIDS Program Grants. HRSA guidance allows these organizations to contract with retail pharmacies to dispense 340B medications.

**Q2. What is the financial impact of participating in a 340B Program?**

**A2.** The financial impact to a pharmacy that participates as a contract pharmacy for a Covered Entity's 340B program depends on multiple factors, including the prescription volume that comes from the Covered Entity and the dispensing fee it receives, as well as the working capital and operating costs that are required to provide these services. While the 340B Program enables safety-net providers to purchase medication at significantly reduced prices and provide expanded services to their patients, pharmacies that participate in a Covered Entities 340B program should understand their operating costs for providing services and ensure that their dispensing fees are sufficient to provide dispensing services.

**Q3. Can a covered entity use 340B drugs for patients with private insurance?**

**A3.** Yes, provided the individual is a qualifying patient of the Covered Entity.

**Q4. Can drugs purchased under the 340B program be used with Medicare Part D?**

**A4.** Yes. Nothing in the Medicare Modernization Act or 340B statutes or guidelines prevents drugs purchased under the 340B pricing program from being used to fill Medicare Part D prescriptions provided the patient's prescription is 340B eligible. This includes prescriptions filled during the coverage gap (aka donut hole). Covered Entities that intend to use 340B drugs to fill dual eligible prescriptions must notify OPA and provide their Medicaid provider number or NPI which is used to ensure that duplicate discounts are not paid on Medicaid claims. A March 15, 2000 340B program guidance from HRSA advised Covered Entities to refer to their respective Medicaid State agency drug reimbursement guidelines for applicable billing limits for prescriptions filled using 340B drugs.<sup>74</sup>

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<sup>74</sup> 51 Federal Register, Vol. 65, No. 51 at 13983 (Mar. 15, 2000).

**Q5. Will a 340B program disrupt my pharmacy operations, add additional burdens on my staff, or inconvenience regular customers?**

**A5.** A properly run 340B program should require little additional staff resources (other than that required to fulfill and dispense medications). The amount of resources required (whether as personnel, capital, or space) will depend on the type of 340B program implemented by the Covered Entity. Virtually all 340B contract pharmacy arrangements require a modest investment in working capital and bookkeeping resources to track and manage the inventory and third party payments for the Covered Entity.

**Q6. What is the difference between dispensing a non-340B drug and a 340B drug? What do I do differently than when I dispense non-340B drugs?**

**A6.** Generally, the duties performed by a pharmacy are the same for 340B and non-340B drugs. Once a prescription is presented, the pharmacist or technician will perform all the duties typically associated with dispensing a prescription, including using standard NCPDP transaction codes and adjudication requirements through any third party insurance. As a result, serving 340B patients is as seamless as filling prescriptions for any customer using an insurance card.

**Q7. What inventory will I use to fill 340B prescriptions?**

**A7.** Most contract pharmacy arrangements use a virtual inventory system since it eliminates the need for the pharmacy to manage a separate physical 340B inventory. Under a virtual inventory system, pharmacies fill prescriptions from their existing stock and manage their inventory as they always do. The Covered Entity (or its 340B Administrator) keeps track of the quantities of medications dispensed to 340B patients, and replenishes the pharmacy's stock, as needed.

**Q8. How often will my stock be replenished for medications that I have dispensed to 340B patients?**

**A8.** Replenishment typically takes place after the full bottle amount of the 11-digit NDC package size has been dispensed to 340B patients. In cases where 11-digit replenishment is not available, but the 9-digit NDC product is available, the Covered Entity is responsible for maintaining records of the product replenishment.

**Q9. How will I be certain to have enough 340B medication in stock?**

**A9.** There is no need to change the way the pharmacy manages its inventory. The Covered Entity (or its 340B Administrator) should keep track of medications dispensed to 340B patients, and replenishes the pharmacy's stock as needed.

**Q10. How will I know when 340B medications have been ordered to replenish my stock?**

**A10.** Pharmacies should request to receive periodic reports showing the quantities of inventory that have been accumulated for a Covered Entity's 340B program. Reports should include

information tracking inventory dispensed and accrued for replenishment, the inventory that has been replenished, and the inventory that is outside the acceptable replenishment window and therefore available for “true-up.” Pharmacies should also expect to receive notification of when replenishment orders will be placed so they can validate the replenishment order and authorize replenishment.

**Q11. Are 340B and non-340B stock interchangeable if the medications are therapeutically equivalent?**

**A11.** If Covered Entity's 340B program requires separate inventory, then the contracted pharmacy will need to ensure that such inventories are not mixed. If a Covered Entity's 340B program uses a virtual inventory system, then the contract pharmacy will never have 340B inventory within its establishment as all inventory used to fill 340B prescriptions will be from the pharmacy's own inventory, which will subsequently be replenished by the Covered Entity after the full bottle amount for the NDC package size has been dispensed. Substitutions for therapeutically equivalent medications are prohibited and 340B drugs must be replenished with the same drugs with the same 11-digit NDC 11, unless the product is backordered, recalled or discontinued. In most cases OPA recommends 11-to-11 digit NDC replenishment for ease of administration and integrity of the program. In cases where 11 digit replenishment is not available, but the 9 digit NDC product is available, the entity is responsible for maintaining records of the product replenishment.

**Q12. Who determines a Contract Pharmacy's dispensing fee?**

**A12.** Typically, the Covered Entity, or its 340B Administrator working in conjunction with the Covered Entity, will work with the pharmacy to determine a dispensing fee for the contract pharmacy. For a successful contract pharmacy arrangement, it is critical that the amount of the dispensing fee result in a “win-win” for both the contract pharmacy and the Covered Entity. The pharmacy should understand its cost to dispense and gross margin objectives so it can establish an informed financial arrangement with the Covered Entity.

**Q13. How do I know who is eligible for the program?**

**A13.** Covered Entities are responsible for ensuring that prescriptions for patients are eligible to be purchased at 340B Program prices. The contract pharmacy and Covered Entity must work together to establish and maintain a tracking system sufficient to prevent diversion and verify patient eligibility. The Covered Entity is required to establish a process for periodic comparison of its prescribing records with the contract pharmacy's dispensing records to detect potential irregularities.

**Q14. How does a pharmacy register to become a contract pharmacy?**

**A14.** Covered Entities that elect to utilize contract pharmacy arrangements are required to register each contract pharmacy with the Office of Pharmacy Affairs (OPA). Covered entities must complete an online registration form during a two-week window that is available at the start

of every quarter to associate each new contracted pharmacy with the Covered Entity. Once registration is complete the pharmacy can start processing 340B eligible prescriptions beginning the first day of the subsequent quarter. Because the opportunity to sign on as a Covered Entity's contract pharmacy is limited to four times each year, contract pharmacies should allow themselves sufficient time to negotiate terms with the Covered Entity (or its 340B Administrator) before the quarterly window opens for Covered Entities to register their new contract pharmacies.

A contract pharmacy is ineligible to be utilized by a Covered Entity until it is approved by OPA and listed in the 340B database. All contract pharmacies must be listed in the OPA's 340B database (located at <http://opanet.hrsa.gov/OPA/>) using their correct names and addresses. Drug manufacturers and drug wholesalers will not make drug shipments to pharmacies that do not match the legal description and location listed in the 340B database.

**Q15. Are 340B Covered Entities required to contract with a retail pharmacy?**

A15. No. Covered Entities are free to choose how they will provide 340B pharmacy services to their patients, subject to federal and state law. Options available to Covered Entities include contracting with a retail pharmacy, providing in-house pharmacy services, using sample closets, providing in-clinic physician administration of drugs to patients, as well as other alternatives.

**Q16. If our contract pharmacy has been purchased by another pharmacy, do we need to update our records with OPA?**

A16. OPA requires that the entity register the new contract pharmacy. The Covered Entity will be required to update its record with OPA and notify them that the contract pharmacy has been purchased by another pharmacy, so the continuity of contract pharmacy services is not disrupted in the OPA Database. To ensure the process proceeds expeditiously, the "Covered Entity Authorizing Official" for the organization should submit the change. If it is submitted by another individual, the change may be delayed and may hamper the Covered Entity's ability to purchase 340B drugs until the matter is resolved. Covered Entities can update contract pharmacy records online at: <http://opanet.hrsa.gov/OPA/CRPublicSearch.aspx>. Covered Entities are notified by OPA when updates have been completed. For all properly completed forms, which do not raise any questions for follow-up, changes can be expected to be made to the OPA database within two weeks of submission.

**Q17. When registering a pharmacy on the OPA database is it necessary to identify all pharmacy locations or all Covered Entity sites that will be served by the pharmacy?**

A17. Covered Entities are required to identify all the pharmacy locations eligible to dispense drugs to patients of the Covered Entity, as well as all Covered Entity sites that will use each of the contracted pharmacies.

**Q18. If a pharmacy uses a repackager at a separate address from the contract pharmacy to process 340B prescriptions must the Covered Entity register the repackager on the OPA database?**

A18. The Covered Entity is not required to register it as a contract pharmacy as long as the following conditions are met: (1) the Covered Entity retains ownership and title to the 340B drugs; (2) the Covered Entity will not sell its 340B drugs to the repackager; (3) The repackager will not dispense 340B drugs; and (4) based on those specific circumstances, and the fact that the repackager is not a pharmacy, will not dispense drugs and is not listed as a “ship to” address for the covered entity, OPA does not require the repackager to register as a contract pharmacy.

**Q19. Who is authorized to sign the Online Contract Pharmacy Registration Form for the 340B Program?**

A19. The printed Contract Pharmacy Registration Form which is produced at the end of the online contract pharmacy registration process must be signed by a responsible and accountable representative of each organization (Covered Entity and pharmacy). For the Covered Entity, the representative may be the President or an administrator (CEO, COO, CFO, etc.). For the pharmacy, the representative may be the owner, President, manager or an administrator (CEO, COO, CFO, etc.). In some instances, the same representative may sign on behalf of the Covered Entity and the pharmacy. In such instances, the person signing the form must be authorized, in the capacity for which each signature is given, and provide an explanation for why a single person has signed the form on behalf of the covered entity and the pharmacy.

**Q20. What is OPA's policy on the effective dates for contract pharmacy?**

A20. Effective October 1, 2012, the registration period for 340B program registration of contract pharmacies is limited to the following: October 1 – October 15 for an effective start date of January 1; January 1 – January 15 for an effective start date of April 1; April 1 – April 15 for an effective start date of July 1; and July 1 – July 15 for an effective start date of October 1. In situations where the 15th falls on a Saturday, Sunday, or Federal holiday, the deadline will be the next business day. The contract pharmacy registration process is not complete unless the registration form has been completed in its entirety and the original, signed copy is received by OPA. Signed contract pharmacy registration forms are due to OPA within 15 days from the time online registration was completed. Incomplete packages will not be considered.

OPA will not post a retroactive date for any contract pharmacy arrangement; as such, the date that the organization submitted paperwork should not be presumed the effective date.

For more information on what constitutes a complete package, visit the OPA Web site at [www.hrsa.gov/opa](http://www.hrsa.gov/opa). Do not begin the Contract Pharmacy arrangement prior to its posting and effective date shown on the OPA web-based database. Any entity or child site must first be registered in the OPA database, and then a contract pharmacy may be added to it.

**Q21. How can a pharmacy find out the contract pharmacy effective date?**

A21. The OPA sends an email notification that gives the effective date of the arrangement to the Covered Entity and the contracted pharmacy. Do not assume that the date that the organization submitted paperwork is the effective date.

**Q22. Can a Covered Entity have pharmaceutical transaction(s) reclassified, after the fact, assuming they were purchased and then used for 340B eligible patients?**

A22. Reclassification of past purchases is not advised for the following reasons:<sup>75</sup>

- It can be a potential audit trigger for a manufacturer. Manufacturers look for alterations in purchasing activity to identify entities to audit. A large or unusual spike in 340B purchases (resulting from reclassification of claims) is an example of what manufacturers would be looking for to identify entities potentially out of compliance.
- OPA policy does not support reclassification of claims. If an entity didn't fully implement 340B, the manufacturer is under no obligation to honor the reclassifications, so the likelihood that an entity would actually receive the 340B chargebacks is small. Many times the processes the vendors use to reclassify claims is not fully transparent to the manufacturer. OPA developed this standard response to provide more clarification:
- Going back in time to reclassify claims (especially when it is not transparent to the manufacturer) could force the manufacturer to set new pricing calculations, which potentially impact many other calculations beyond 340B. This is really the butterfly effect here: one entity's reclassification could end up impacting countless other transactions, imparting excessive administrative work on the part of the manufacturer. In order for the manufacturers to close their books, they can't be repeatedly going back in time and resetting calculations.

**Q23. Does the 340B Program savings generated from a contract pharmacy relationship belong to the contract pharmacy, the entity, or both?**

A23. Unless otherwise specified, all 340B Program savings belong to the 340B Covered Entity. The intent of the 340B Program is to help covered entities stretch scarce federal resources. Pharmacies should establish their dispense fee for the services they provide to the Covered Entity in support of their 340B and ensure that such fees are included in the service agreement it establishes with the Covered Entity.

**Q24. In a 340B contract pharmacy relationship, does reimbursement from payors, associated with 340B claims, belong to the Covered Entity and the contract pharmacy receives a fee for its service?**

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<sup>75</sup> Apexus 340B University, Frequently Asked Questions, Policy/Implementation: Purchasing, Inventory and Reimbursement; [https://docs.340bpvp.com/documents/public/resourcecenter/faq/FAQs\\_PolicyImplementation\\_Purchasing\\_Inventory\\_Reimbursement.pdf](https://docs.340bpvp.com/documents/public/resourcecenter/faq/FAQs_PolicyImplementation_Purchasing_Inventory_Reimbursement.pdf)

A24. Yes. 340B drugs (and associated reimbursement from payors) belong to the Covered Entity. In most circumstances the contract pharmacy receives a fee for its services. While the Covered Entity and contract pharmacy determine/negotiate payment terms of a 340B contract, there is currently no written guidance on the revenue disposition or sequence of payment collection between Covered Entities and their contract pharmacies.

**Q25. Can a 340B entity use a contract pharmacy's third party payor contracts, or does the entity need its own contracts?**

A25. Covered Entities must meet the legal requirements of the 340B program (patient definition, no duplicate discounts, auditable records, etc.). So long as those requirements are met, along with all other applicable requirements under Federal, State, and local law, whether or not a Covered Entity chooses to use a pharmacy's third party payor contracts is not a 340B statutory or policy issue; this is a private business decision between the Covered Entity, third party payor, and the contract pharmacy. Pharmacies may want to review their third party payor agreements and obtain competent legal advice before proceeding as it may impact their decision (i.e., the state law regarding agency, individual insurance contract language addressing this issue, etc.). Of note: Any reimbursement under Medicaid must be compliant with Federal and State law. In addition, any payment under Medicaid for drugs purchased under 340B must be completed in a way that prevents a Medicaid rebate claim (i.e., duplicate discount.)

**Q26. What information is available about contract pharmacy dispensing fees?**

A26. Dispensing fees are negotiated between the contract pharmacy and the 340B Covered Entity. These fees are based upon a variety of variables including the part of the country in which the Covered Entity is located and the services that the pharmacy provides. There is no federally mandated maximum or minimum dispensing fee, nor is there a standard dispensing fee required for 340B prescriptions. Pharmacies should understand their business mix and gross margins that they receive today as well as their dispensing costs before agreeing to a dispense fee. Pharmacies may also refer to NCPA resources to understand more about dispensing fees, such as:

- NCPA Digest Sponsored by Cardinal Health (members only) <http://www.ncpanet.org/membership/benefits/ncpa-digest-sponsored-by-cardinal-health>
- NCPA Ownership Academy (members only) <http://www.ncpanet.org/ownership>

**Q27. Is it appropriate for a contract pharmacy dispensing fee to be paid based on a percent of the sales price?**

A27. The 340B statute does not directly address dispensing fees paid on a percent of the sales price. If a Covered Entity wishes to engage in this practice, the pharmacy should obtain

competent legal counsel to ensure the fee structure meets 340B guidelines and is consistent with federal and state fraud and abuse laws. The Covered Entity will also want to ensure that such arrangements are consistent with any grant requirements applicable to the Covered Entity. Pharmacies should carefully review the final contract pharmacy guidelines published at 75 Fed. Reg. 10272 (March 5, 2010).

**Q28. Can a contract pharmacy take its dispensing fees from the third party payor reimbursement BEFORE paying the Covered Entity, the third party payor reimbursement?**

A28. HRSA has emphasized that the Covered Entity is ultimately responsible for 340B compliance. The services that will be provided to the Covered Entity's patients by the contract pharmacy and how the pharmacy will be paid will be key parts of contract pharmacy negotiations. However, the following considerations may be useful to help a pharmacy determine when it will receive dispensing fees:

- There is not written guidance for exactly how the pharmacy(ies) and Covered Entity should handle the transfer of the dispensing fees.
- OPA has verbally recommended that the contract pharmacy(ies)' collections be first transferred to the Covered Entity, and then the Covered Entity would pay the pharmacy its dispensing fees. This recommendation supports a very transparent (and auditable) mechanism to show that:
  - the Covered Entity paid for and received collections for the 340B drugs, and
  - the pharmacy was paid only a fee for dispensing and other services provided under the contract.
- Pharmacies should seek consultation with competent legal counsel to ensure that other legal requirements are not violated (e.g., Medicare/Medicaid anti-kickback statutes, state fee-splitting laws, etc.).

**Q29. How will the 340B dispense fee contribute to the pharmacy's business?**

A29. Understanding a pharmacy's margin profile is an important consideration for any pharmacy seeking to participate as a 340B contract pharmacy. Pharmacies should know their Ingredient Margin for brand and generic products that they dispense today. Pharmacies should also understand their cost to dispense per prescription. A pharmacy's net margin will be the difference between its ingredient margin and operating expense, divided by the number of prescriptions dispensed. Knowing the fiscal health of the pharmacy today will position the pharmacy for a more informed discussion with the Covered Entity about dispense fees.

**Q30. Does involvement as a Covered Entity's contract pharmacy for their 340B program mean the pharmacy will grow its business volume?**

A30. Understanding whether the pharmacy will be capturing additional business by participating as a contract pharmacy or simply churning its book to replace contract pharmacy dispense fees for ingredient margin is a key consideration. If the pharmacy is churning its book, then it will need to consider the trade-off of margin from its current book to the dispense fee it will receive as a replacement. For pharmacies that participate on a 100% 340B carve in program, such an arrangement can be attractive. If the pharmacy will be onboarding new business, it will need to ensure it has evaluated its operating capacity to accommodate additional business, including headcount, supplies, inventory, cash, etc.

**Q31. Can a Covered Entity be selective about which prescriptions to include in its 340B program, including Schedule II drugs?**

A31. Other than Medicaid claims, the 340B statute does not directly address how eligible claims participate in a Covered Entity's 340B program. A Covered Entity has flexibility in establishing which products to include in its formulary and how eligible claims are carved into its 340B program. This applies to Schedule II controlled substances. If a Covered Entity elects to use Schedule II drugs for patients in its 340B program, it must ensure that its contract pharmacies hold current DEA licenses. Pharmacies should obtain competent legal counsel to ensure the method to establish eligible claims that are carved into a Covered Entity's 340B program is consistent with OPA guidance.

**Q32. How will my 340B sales impact my relationship with my wholesaler?**

A32. Because replenishment to a contract pharmacy is made from a Covered Entity's 340B purchases on its wholesaler account, involvement in a Covered Entity's 340B program may impact the pharmacy's total purchases through the account it maintains with its drug wholesaler. This could have a resulting impact on tiered pricing or other rebate incentives the pharmacy has with its wholesaler and should be evaluated by the prospective contract pharmacy. Contract pharmacies should understand where they are performing on their wholesaler agreement and take protective actions where appropriate. It is advisable to discuss participating in a Covered Entity's 340B program with the pharmacy's wholesaler in advance of launching its program to discuss potential issues and alternatives.