

# 340B INFORMATION EXCHANGE

## ***REFERENCE GUIDE***

### ***Version 2.0***

The NCPDP *340B Information Exchange Reference Guide* was developed 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.

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# 340B INFORMATION EXCHANGE REFERENCE GUIDE

Version 2.0

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# 1. INTRODUCTION

The 340B program is administered by the Health Resources & Services Administration.

The NCPDP *340B Information Exchange Reference Guide* is intended to provide background and a practical framework related to identification of 340B Drug Pricing Program transaction data for Section 340B stakeholders and trading partners throughout the industry as they utilize NCPDP standards.

If you have any questions regarding the availability or content of the NCPDP *340B Information Exchange Reference Guide* see [www.ncdp.org](http://www.ncdp.org) or contact the Council office at (480) 477-1000 or via e-mail at [ncdp@ncdp.org](mailto:ncdp@ncdp.org).

## 1.1 DOCUMENT SCOPE

This document contains situations, questions, answers and other information related to Section 340B's interaction with existing NCPDP standards. Users of this document should consult the NCPDP documents listed below for further information and clarification.

### ***TELECOMMUNICATION STANDARD***

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The Telecommunication Standard was developed to provide a standard format for the electronic submission of third party drug claims. The development of the standard was to accommodate the eligibility verification process at the point-of-sale and to provide a consistent format for electronic claims processing. Unless otherwise noted, references in this document refer to Telecommunication Standard Version D.0.

### ***BATCH STANDARD***

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This document supports the business need to support the same functionality as the NCPDP Telecommunication Standard Implementation Guide, except in a batch environment.

### ***EDITORIAL DOCUMENT***

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This document contains clarifications, corrections, examples, and questions/answers that were obtained after the publication of the NCPDP Telecommunication Standard Implementation Guide. It must be used as a reference between official publications of the implementation guide. This document may be updated as often as quarterly and new versions should be downloaded. It is available from the public and members only sections of the NCPDP website.

### ***DATA DICTIONARY***

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Full reference to all fields and values (contained within or reference to the *External Code List*) used in the NCPDP standard with examples.

### ***EXTERNAL CODE LIST***

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Full reference to values used in the NCPDP standards.

The NCPDP *External Code List* (ECL) values and descriptions are applicable to each specified ECL publication date. Since the NCPDP ECL may be updated on a quarterly basis, more current ECL publications may reflect additions, deletions and/or modifications to those values and descriptions in this document.

### ***STANDARDS MATRIX***

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This document contains charts that list the versions of the Standards and Implementation Guides approved or under consideration by NCPDP, with reference to the Data Dictionary and External Code List documents appropriate for use.

These documents are available to NCPDP members in the “Members” section of the website at [www.ncdp.org](http://www.ncdp.org). Non-members may obtain the documents with membership; please see [www.ncdp.org](http://www.ncdp.org) or contact the NCPDP office at 480-477-1000, or via e-mail at [ncdp@ncdp.org](mailto:ncdp@ncdp.org).

## 2. BACKGROUND

The 340B Task Group was formed in Work Group 9 Government Programs in 2009. This task group develops recommendations on the use of existing standards or future enhancements to standards that will serve the needs of trading partners involved in the 340B federal pricing program. In July 2011, the 340B Information Exchange Reference Guide Version 1.0 was published. The guide was designed to educate trading partners on the use of the Telecommunication Standard Implementation Guide in specific business cases related to Section 340B. In October 2016 and April 2017, NCPDP hosted Stakeholder Action Group (SAG) meetings to identify the current and future issues around 340B Drug Pricing Program data transparency and program integrity. In follow-up to the data obtained at those SAG meetings and the current industry guidance, the task group has updated the Information Exchange Reference Guide. The task group will continue to meet and update the guide as needed.

### 2.1 340B DRUG PRICING PROGRAM OVERVIEW

See section [Participants](#) for more information about entities described below.

“Section 340B” or “340B” refers to a portion of the Public Health Service Act of 1992 and Public Law 102-585. Section 340B obligates participating drug manufacturers to offer discounted prices for almost all products to select federal grantees and hospitals known as Covered Entities. Congress established the 340B program “to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”<sup>1</sup> The federal agency charged with administering 340B, called the Health Resources and Services Administration (HRSA), Office of Pharmacy Affairs (OPA) described the purpose of the program as follows:

*The purpose of the 340B program is to lower the cost of acquiring covered outpatient drugs for selected health care providers so that they can stretch their resources in order to serve more patients or improve services. Additional program resources are generated if drug acquisition costs are lowered but revenue from grants or health insurance reimbursements are maintained or not reduced as much as the 340B discounts.<sup>2</sup>*

The Section 340B price is determined by a complex formula based on variables defined under the Centers for Medicare and Medicaid Services (CMS) Medicaid Drug Rebate Program (MDRP). Discounts available through the Section 340B program are often substantial and, as a result, provide Covered Entities with both the opportunity to utilize the purchase price cost savings and revenue opportunities, due to reimbursement rates above the 340B purchase price, from their pharmacy program to further their safety-net mission.

Section 340B drugs are purchased by a Covered Entity for the exclusive use of a Covered Entity’s Eligible Patients in an outpatient setting. The definition of an Eligible Patient is established by HRSA’s Office of Pharmacy Affairs.

Covered Entities are required to ensure compliance with Section 340B’s requirement to restrict dispensing drugs purchased under Section 340B to Eligible Patients.

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<sup>1</sup> H.R. Rep. No. 102-384, pt. II, at 12 (1992)

<sup>2</sup> <https://www.hrsa.gov/opa/index.html>

## **2.2 SECTION 340B AND MEDICAID**

Drug manufacturers that have signed a National Drug Rebate Agreement with CMS are often referred to as “participating manufacturers.” These manufacturers are obligated to pay a rebate to state Medicaid agencies for covered outpatient drugs dispensed to the state’s Medicaid enrollees (both Fee for Service (FFS) and Medicaid Managed Care Organization (MMCO)). However, manufacturers are protected from paying rebates on drugs that were sold to Covered Entities at the 340B discounted price. This is known as a “duplicate discount” and is prohibited by law.<sup>3</sup> Each state Medicaid agency has a methodology for how they will identify 340B drug claims for exclusion from the manufacturer invoices. Stakeholders should obtain and become familiar with the 340B policies from each state based on the Medicaid patients they serve. The state Medicaid 340B policies provide direction to stakeholders regarding how 340B drugs will be reimbursed (for FFS claims) and also how 340B drug claims will be identified for the purpose of avoiding duplicate discounts.

### **2.2.1 MEDICAID ‘CARVE-IN’ FEE FOR SERVICE**

Upon enrollment in the 340B Program, Covered Entities must determine whether they will use 340B drugs for their Medicaid patients (carve-in) or whether they will purchase drugs for their FFS Medicaid patients through other mechanisms (carve-out). Carve-in signifies a 340B Covered Entity will utilize 340B purchased medications for their FFS Medicaid patients for prescriptions filled at their on-site pharmacies, and/or medications administered in their clinics by their physicians.

How 340B drugs should be billed and reimbursed by state Medicaid agencies is a matter of state policy. The Medicaid Program Covered Outpatient Drug rule<sup>4</sup> requires states to address the reimbursement for Section 340B drugs in their state plans. Many states choose to pay ‘carve-in’ claims at the Covered Entity’s Section 340B acquisition cost plus a professional dispensing fee<sup>5</sup>.

### **2.2.2 MEDICAID MANAGED CARE**

Medicaid MCO drug claims with a date of service on or after 3/23/2010 became eligible for a Medicaid rebate under the Patient Protection and Affordable Care Act of 2010.<sup>6</sup> Therefore, each Medicaid MCO operating in a state is required to report the drug claim encounters for the Medicaid MCO enrollees to the state Medicaid agency for inclusion in the state’s quarterly Medicaid rebate invoices. Under the Medicaid and CHIP Managed Care Final Rule<sup>7</sup> published in April of 2016, Medicaid MCOs are required to exclude 340B drug claims from the drug encounters they report to the state for the purpose of avoiding duplicate discounts. Some states have communicated 340B policies in which they indicate they are using the Medicaid Exclusion File for both FFS and Medicaid MCO claims. (For example, the Covered Entity’s carve-in decision is being used for both FFS and Medicaid MCO patients.) Other states are requiring Covered Entities to assign claim level identifiers on all 340B drugs dispensed to both FFS and Medicaid MCO enrollees. A few states have created their own “State Level Covered Entity Carve-In list” for the purpose of avoiding the duplicate discounts.

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<sup>3</sup> 42 U.S.C. § 256b(a)(5)(A)(i); 42 U.S.C. § 1396r-8(j)(1)

<sup>4</sup> *Federal Register* Vol. 81 No 20 pp.5170-5357 February 1, 2016

<sup>5</sup> <https://www.medicare.gov/medicaid/prescription-drugs/state-prescription-drug-resources/drug-reimbursement-information/index.html>

<sup>6</sup> <https://www.congress.gov/bill/111th-congress/house-bill/3590>

<sup>7</sup> <https://www.medicare.gov/medicaid/managed-care/guidance/final-rule/index.html>

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## **2.3 SECTION 340B AND OTHER PAYERS**

While Covered Entities often serve the indigent and low-income, 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. The statutory Medicaid duplicate discount prohibition does not apply to Medicare Part D, commercial and other payment sources. However, there are often agreements in place between manufacturers and payers that include or exclude claims for Section 340B drugs from amounts, utilization or both from rebate or other performance initiative calculations. The technical consequence of these agreements is a payer/processor must identify claims for Section 340B drugs to properly complete their rebate submission to the manufacturer.

## **2.4 IMPLEMENTATION**

To date, there has been limited implementation of standard or reliable methods by which a payer/processor could identify claims for Section 340B drugs. While the framework to identify these transactions was created by NCPDP, and described in this guide, there remains a lack of adoption across stakeholders and lines of business concerning the need for and the methods by which claims for Section 340B drugs are identified. For Medicaid lines of business, as described above, there are clear requirements on stakeholders to ensure duplicate discounts do not occur and varied methods of compliance due in part to a lack of complete federal guidance on this topic. For non-Medicaid lines of business, any identification of claims for Section 340B drugs would be controlled by trading partner agreement as the statutory and regulatory prohibitions against duplicate discounts do not apply. Where NCPDP standards are not limited to Medicaid, the identification methods for Section 340B drugs and other guidance in this document are intended to support trading partners in all lines of business.

Beyond compliance with duplicate discount prohibitions, claim level identification of Section 340B drugs may be required by trading partners to comply with commercial contracts. For example, rebate agreements between payers and manufacturers may treat Section 340B purchased drugs differently from non-340B purchases. Where such identification is required by trading partner agreement, the methods described in this document will permit trading partners to conclusively determine claims for Section 340B drugs and execute their obligations under trading partner agreement as they relate to Section 340B drugs. Absent claim level identification, trading partners risk being too exclusionary or too inclusive in their adherence to contractual obligations as they relate to Section 340B drugs.

### 3. BUSINESS ENVIRONMENT

The NCPDP Telecommunication Standard Implementation Guide addresses the data format and content, the transmission protocol, and other appropriate telecommunication requirements between trading partners – most often a pharmacy and a payer/processor. Since 1993, with the implementation of Section 340B of the Public Health Service Act of 1992, select federal grantees have had access to statutory discounts when purchasing pharmaceuticals that are provided by participating drug manufacturers. Occasionally, based on trading partner agreements or prevailing law, there is a need for a payer/processor to identify claims for drugs purchased pursuant to Section 340B for their internal use or downstream reporting to manufacturers, government entities or other industry stakeholders.

#### 3.1 OBJECTIVES

The NCPDP *340B Information Exchange Reference Guide* is intended to provide clear guidance to the industry on how trading partners will exchange information related to Section 340B while utilizing the NCPDP Telecommunication Standard Implementation Guide. This document seeks to provide guidance in the following areas:

- Identification of the relevant parties in a Section 340B environment.
- Education on the varying inventory and business models for Section 340B drugs and their impact on the Telecommunication Standard Implementation Guide.
- Clarification on Section 340B procurement by a Covered Entity and how they impact claim scenarios.

#### 3.2 PARTICIPANTS

Section 340B(a)(4) of the Public Health Service Act specifies which Covered Entities are eligible to participate in the 340B Drug Program. Covered Entity eligibility can be confirmed on the 340B Office of Pharmacy Affairs Information System available at <https://340bopais.hrsa.gov/>

- Covered Entity: An organization authorized to purchase drugs under the rights granted pursuant to Section 340B of the Public Health Service Act of 1992. Covered Entities apply and are designated as such by the Office of Pharmacy Affairs within HRSA. Covered Entities may include but are not limited to:
  - Disproportionate Share Hospitals
  - Federally Qualified Health Centers
  - Community Health Centers
  - Comprehensive Hemophilia Treatment Centers
  - Family Planning Clinics
  - Ryan White Care Act funded clinics
  - Children’s Hospitals
  - Critical Access Hospitals
  - Rural Referral Centers
  - Free-standing Cancer Hospitals
  - Sole Community Hospitals

- Entity-owned Retail Pharmacy: A retail pharmacy owned by the Covered Entity and operated in a location registered with OPA, and as such, is permitted to dispense Section 340B drugs to eligible patients of the Covered Entity.
- Contract Pharmacy: A pharmacy under written contract with a Covered Entity, and registered with OPA as such, to service Eligible Patients of Covered Entity and to dispense Section 340B drugs to such persons based on the criteria established by the Covered Entity.
- Administrator: An intermediary software and service provider under contract with the Covered Entity and Contract Pharmacy to provide administrative services related to Section 340B usually including eligible prescription identification, drug procurement, financial reconciliation and auditing.
- Manufacturer: Manufacturers that participate in the MDRP, are required under the 340B statute to enter into an agreement with the Secretary under which the manufacturer must agree to charge a price that will not exceed the amount determined under statute (ceiling price) when selling covered outpatient drugs to eligible 340B Covered Entities for outpatient use.
- Payer/Processor: An entity responsible for administering the pharmacy benefit of individuals and groups that has often contracted with pharmacies and manufacturers for certain services and preferred pricing.
- State Medicaid Program: A health initiative managed by a state government that works in conjunction with the federal Medicaid program. State Medicaid programs use federal funding along with funding from the respective state to provide needed health services for eligible individuals.

### **3.3 COMMON 340B BUSINESS MODELS**

The 340B business models and relationships among participants can vary greatly from Covered Entity to Covered Entity. This section describes some of the most common arrangements in practice today.

#### **3.3.1 COVERED ENTITY OWNED**

Many Covered Entities, especially larger ones, own their own pharmacies either within, adjacent or proximate to their main facility or campus. These pharmacies often operate like retail community pharmacies or outpatient hospital clinic pharmacies but can take many forms. Within these pharmacies can be both Section 340B drugs and non-Section 340B drugs. In this model, the Covered Entity would hold a contract with various payer/processors that cover the lives of its patient-customers.

#### **3.3.2 CONTRACT PHARMACY**

Under the Contract Pharmacy model, the Covered Entity engages one or more Contract Pharmacies to provide services to its Eligible Patients using Section 340B drugs. Most often these are local retail/community pharmacies, but any mail, clinic, specialty, other or even pharmacies of unaffiliated Covered Entities could be a Contract Pharmacy. Under this model the Contract Pharmacy services its 'normal' patients who have no affiliation with the Covered Entity using non-Section 340B drugs. For this reason, contract pharmacies primarily use a virtual inventory model to report their 340B transactions. For Eligible Patients of the Covered Entity, and subject to the Covered Entity's rules, the Contract Pharmacy may dispense drugs purchased under

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Section 340B. In this model the Contract Pharmacy holds contracts with various payer/processors that cover the lives of its patient-customers, including those of a Covered Entity. HRSA has indicated that Contract Pharmacies cannot dispense Section 340B drugs to Medicaid FFS patients unless there is a documented tri-party arrangement among the Contract Pharmacy, Covered Entity and the state Medicaid agency for the purpose of avoiding duplicate discounts. Arrangements of this type must be reported to HRSA/OPA<sup>8</sup>. Many state 340B policies require Contract Pharmacies to carve out claims for their FFS enrollees.

### **3.3.3 CONTRACT PHARMACY ADMINISTRATOR**

The Covered Entity and Contract Pharmacy may each delegate a portion of their responsibilities to an Administrator that holds contracts with both the Contract Pharmacy and Covered Entity. The Administrator is most often charged with implementing the prescription/patient eligibility rules of the Covered Entity against prescriptions filled by the Contract Pharmacy ensuring Section 340B drugs are only dispensed to Eligible Patients. The Administrator will often manage the procurement as well as financial impacts of the 340B program for both the Covered Entity and Contract Pharmacy. In this model the Contract Pharmacy holds contracts with various payer/processors that cover the lives of its patient-customers, including those of a Covered Entity.

## **3.4 INVENTORY**

Inventory methods of Section 340B drugs selected in one of the above models may have a direct impact on when the party holding a contract with a payer/processor is able to determine whether a pharmacy is utilizing Section 340B drugs. There are two basic inventory methods employed by the industry, physical and virtual.

### **3.4.1 PHYSICAL INVENTORY**

Any of the pharmacy models detailed in section [Common 340B Business Models](#) may elect to utilize a physically segregated inventory of Section 340B drugs and non-Section 340B drugs. The Section 340B drugs can only be dispensed to Eligible Patients of the Covered Entity that holds title to the Section 340B drugs. Strategies to ensure integrity of this inventory method often involve separate storage areas but also item marking (e.g., stickers) to facilitate use of the proper items and return to the proper inventory location after use. Using this method will mean the person or machine dispensing a prescription must be aware of the eligibility rules of the Covered Entity that holds title to a Section 340B drug prior to providing service as such knowledge would be a prerequisite to selecting an item from one inventory versus another.

### **3.4.2 VIRTUAL INVENTORY**

Any of the pharmacy models detailed in section [Common 340B Business Models](#) may elect to utilize a virtually segregated inventory of Section 340B drugs and non-Section 340B drugs. This inventory method may also be referred to as a 'retrospective' (sometimes known as 'virtual' or 'replenishment') model. When utilizing this method, the pharmacy only has one type of inventory, almost always non-Section 340B inventory, on its premises and will always dispense from whatever inventory it has on its premises. This non-Section 340B inventory may also be referred to as a 'neutral', 'WAC' or 'retail' inventory. At some point after a dispensing event has completed, a determination is made (usually by the pharmacy using split billing software or an

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<sup>8</sup> <https://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf>

inventory management vendor) that a specific dispensing meets the eligibility rules of a Covered Entity and is eligible for Section 340B drugs through such Covered Entity. Using this inventory method almost always means the person or machine dispensing a prescription has no knowledge of whether Section 340B drugs or non-Section 340B drugs are being dispensed.

Once a sufficient quantity has been dispensed, a Covered Entity may purchase the drug at the discounted 340B price and have it delivered to the pharmacy. This order of 340B-purchased drugs replaces or “replenishes” the non-340B purchased drugs originally dispensed on behalf of the Covered Entity.

The time between a 340B dispense and subsequent replenishment order varies greatly based on several operational factors and can be as brief as same day or as long as never. Examples of factors contributing to delayed ordering may include; having a low volume of eligible patients for a given medication (slow accumulations), delayed testing to allow for returns of prescriptions filled but not picked up, or product not being available to order due to shortages. An example of the replenishment process is depicted in [Appendix Inventory Replenishment Process](#).

### **3.4.3 COMBINATION**

Pharmacies may have both physical and virtual inventories at the same pharmacy for the same Covered Entity at the same time. Some examples that cause this would be special order of slow-moving items for known Eligible Patients, items that must be ordered through restricted Risk Evaluation and Mitigation Strategies (REMS) channels, return-to-stock of already replenished items or wholesaler/manufacturer shipping errors.

## **3.5 REBATES AND 340B DUPLICATE DISCOUNTS**

The MDRP includes CMS, state Medicaid agencies, and participating drug manufacturers. The program, in existence since 1991, helps offset the federal and state costs of outpatient prescription drugs dispensed to Medicaid patients. Subsequent references to “states” may include their third party MDRP invoicing vendor, where applicable. At a basic level, each state submits a quarterly invoice to each participating manufacturer reflecting the statutory rebate amount due for all units of a covered drug that were dispensed to a Medicaid patient in the invoice period. Manufacturers remit rebate payments directly to each state. Within the Medicaid state agency rebate process, the industry encounters a common scenario, referred to as “duplicate discounts”. Duplicate discounts occur when manufacturers pay Medicaid rebates on drugs sold to a 340B Covered Entity at an already discounted 340B price. The duplicate discount paid on a Medicaid claim is prohibited by statute as described in [Section 340B and Medicaid](#).

Manufacturers and payers may enter into free-market rebate contracts for non-MDRP rebate arrangements. These free-market contracts may stipulate a treatment of 340B drugs (i.e., exclusion). In such a case, any rebate paid on a claim for drugs purchased at a 340B price may be in excess of the manufacturer’s contractual expectations. While not a “duplicate discount” prohibited by statute, the financial effect is similar. Conversely, in the same free-market case any denial of rebate by a manufacturer on a claim for drugs purchased at a 340B price may be to the financial detriment of the payer.

Identification of the claims for Section 340B drugs is the first step in the effort to prevent duplicate discounts. Please reference section [Identification of Data Elements](#) for additional detail regarding the identification methods for 340B claims.

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### 3.5.1 MEDICAID EXCLUSION FILE

On a quarterly basis, HRSA requires Covered Entities that bill Medicaid to make a decision regarding their intent to dispense 340B discounted drugs to Medicaid patients, also known as “carving-in.” Carve-in entities must inform HRSA by reporting their Medicaid Provider number and/or National Provider Identifier (NPI) used to bill Medicaid so their information will be listed on the Medicaid Exclusion File.<sup>9</sup> Many states reference the quarterly Medicaid Exclusion file to exclude all claims from the carve-in Covered Entities from manufacturer rebate invoices. (This is known as an “entity level” exclusion methodology.)

There currently is no such exclusion file available to identify Covered Entities that carve-in MMCO claims although several states utilize the Medicaid Exclusion File for their MMCO claims as well.<sup>10</sup> In these states, a Covered Entity is effectively required to make a decision at the provider identifier level as to whether Section 340B drugs will be used for both Medicaid FFS and MMCO claims. Covered Entities may have multiple provider identifiers and/or multiple dispensing sites each with different provider identifiers. A Covered Entity may, subject to state policy, make a different election concerning the use of Section 340B drugs for each unique provider identifier as the Medicaid Exclusion File is provider identifier specific for the applicable period.

Although HRSA has indicated the Medicaid Exclusion File should only be used for FFS, many states continue to use the Medicaid Exclusion File to remove 340B claims from both FFS and MCO to avoid duplicate discounts. Therefore, prior to a Covered Entity listing themselves on the Medicaid Exclusion File, they should review the state 340B policy(s) for each state in their market and ensure they understand how their carve-in election will be used by the state(s) for the purpose of identifying 340B claims.

The Medicaid Exclusion File has been published since the early 1990s and pre-dates the implementation of the NPI in 2008. After the implementation of the NPI, the Medicaid Exclusion File was enhanced to include NPIs but the Medicaid Exclusion File will contain NPIs and/or Medicaid Provider identifiers for Covered Entities that carve-in Medicaid FFS claims. Covered Entities are required by HRSA to report their decision to carve-in Medicaid FFS claims and are required to accurately report their provider identifiers to prevent duplicate discounts. In addition, manufacturers should be cautious in referencing the Medicaid Exclusion File because states use it in different ways. NCPDP recommends Covered Entities provide their NPIs to HRSA when reporting a 340B carve-in. Where NCPDP claims to a Medicaid agency will always include an NPI, including the NPI on the Medicaid Exclusion File permits the best opportunity for trading partners to match claims to the Medicaid Exclusion File.

Manufacturers are permitted to dispute a state’s rebate invoice and engage a State in a review of specific claims when the manufacturer suspects an error or duplicate discount. This process is largely manual and conducted via person-to-person communication. To the extent available, states should provide manufacturers both the NPI and Medicaid Provider identifier of a provider when distributing supporting claims level data to manufacturers in the dispute process.

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<sup>9</sup> <https://www.hrsa.gov/opa/program-requirements/medicaid-exclusion/index.html>

<sup>10</sup> <https://oig.hhs.gov/oei/reports/oei-05-14-00430.pdf>

### 3.5.2 EXAMPLE SCENARIOS THAT RESULT IN A DUPLICATE DISCOUNT

- **Provider Reporting Error** – A Covered Entity is not appropriately listed on the HRSA Medicaid Exclusion File for a specific date of service. If a Covered Entity did not accurately report their Medicaid Provider ID and/or NPI in a timely manner and was not listed on the Medicaid Exclusion File when using Section 340B drugs during the applicable period for Medicaid FFS claims, a state Medicaid Agency that references the Medicaid Exclusion File could inadvertently include claims for rebate invoices. In this case, a duplicate discount would occur when the manufacturer pays the rebate on that claim.
- **Claim Submission Error** – The Covered Entity or their Contract Pharmacy did not submit the appropriate claim level data elements to a Medicaid MCO or Medicaid FFS when dispensing a Section 340B drug, as required by the state Medicaid Agency’s 340B identification policies. Without the 340B claim level identifiers, the state Medicaid Agency has no way to know whether a specific claim should be included or excluded from the manufacturer’s invoice. Should the state Medicaid agency include a claim for a Section 340B drug in its rebate invoice and the manufacturer pays the rebate, a duplicate discount occurs.
- **Claim Reporting Error** – State Medicaid Agencies and Medicaid MCOs may use intermediaries or contractors to implement their programs. Any use of 340B claim level identifiers by a Covered Entity or Contract Pharmacy to prevent duplicate discounts is only effective if the party submitting the rebate invoices to manufacturers is able to properly exclude claims for Section 340B drugs from such invoices. This requires all contractors and intermediaries involved in delivering claims data to the party submitting invoices to either forward 340B claim level identifiers or exclude claims with such identifiers from further transmission. Should an intermediary fail to forward 340B identifiers received on a claim for Section 340B drugs or exclude such a claim from its transmission to the party submitting rebate invoices, the state Medicaid agency may submit an invoice for rebate on such a claim, and if the manufacturer pays the rebate, a duplicate discount occurs.

Should any trading partner identify a duplicate discount issue, they should work with impacted manufacturers and state Medicaid Agencies to remedy the duplicate discount scenario in accordance with HRSA guidance.

## 4. BUSINESS FUNCTIONS

This section will detail the specific cases for submitting the Section 340B information when required by contract between a pharmacy and payer/processor trading partner.

### 4.1 340B DETERMINATION

The determination to use Section 340B drugs or not use Section 340B drugs for a specific dispensing will be made based on a variety of data inputs. Covered Entities, or their contracted service providers, will make the determination of whether to use Section 340B drugs using data that is specific to a single dispensing. Depending on the inventory model used by the Covered Entity, or their contracted service providers, this determination may take place at the point-of-service (prior to dispensing) or retrospectively (post-dispensing). Generally, those determinations fall into four categories:

1. **Section 340B Eligible.** Does the dispensing qualify under the Section 340B eligibility requirements for determining patient eligibility to use Section 340B drugs? These eligibility rules will vary based on the type of Covered Entity (i.e., Disproportionate Share Hospitals have different requirements from Community Health Center grantees).
2. **Governmental or Contractual Requirements.** Are there external restrictions on the use of Section 340B drugs? Many states have imposed restrictions on the use of Section 340B drugs in Medicaid and/or Medicaid Managed Care to prevent duplicate discounts which would preclude use of Section 340B drugs in situations that would otherwise be eligible. For example, in Medicaid FFS, a Covered Entity may, subject to state policy, bill for Section 340B drugs but must report its NPI(s) or Medicaid Provider ID(s) used to bill Section 340B drugs to HRSA in advance. HRSA publishes the Medicaid Exclusion File quarterly which lists the Covered Entities and associated identifiers submitting claims for Section 340B drugs to FFS Medicaid. Covered Entity/identifier combinations not listed on the Medicaid Exclusion File for the applicable date of service cannot bill Section 340B drugs to Medicaid FFS.
3. **Internal Operational Procedures.** Does the dispensing qualify under a Covered Entity's program procedures? Beyond eligibility in one and two above, a Covered Entity, together with their contracted service providers, will frequently further restrict the universe of dispensings where Section 340B drugs are used. These limitations are often operational (i.e., not using Schedule II drugs due to ordering and recordkeeping requirements) and financial (i.e., not using drugs that would fall below a certain savings threshold). Such limitations can be specific enough to apply only to a single day, patient, drug, prescriber, pharmacy, etc.
4. **External Operational Limitations.** Are there any external impediments to purchasing a Section 340B drug? Despite a Covered Entity's qualification to purchase a Section 340B drug and a desire to do so, the drug may not be available for purchase. This unavailability could be as simple as an out-of-stock situation at the wholesaler where the Covered Entity holds a 340B account or a credit limitation that precludes further purchases by the Covered Entity. More commonly, this situation impacts retrospective procurement when a product is discontinued – either by the wholesaler or manufacturer – or the Covered Entity has not accumulated enough 340B eligible dispensings to procure a Section 340B drug.



The list of determination criteria above is designed to provide an overview of the potential variables used by Covered Entities and their contracted service providers in making a 340B determination. This list is not meant to be all-inclusive nor is every element applicable to every situation.

The processes used by a Covered Entity to determine whether Section 340B drugs will be used are prerequisites to any exchange of information concerning Section 340B drugs and, if applicable, associated pricing.

#### 4.1.1 CHANGES TO DETERMINATION

From time to time a Covered Entity or their contracted service provider may change the 340B determination with respect to a particular claim based on the receipt of new information. Changes could cause previously ineligible claims to be determined eligible for Section 340B drugs or previously eligible claims to be determined ineligible for Section 340B drugs. Based on the timing of the re-determination and the Covered Entity's processes, it will be necessary to review what actions, if any, had been taken based on the prior determination and take appropriate action to negate those actions and substitute with actions based on the new determination.

### 4.2 IDENTIFICATION DATA ELEMENTS

NCPDP has developed multiple identifiers that can be used in connection with the exchange of information related to Section 340B. Generally, information pertaining to Section 340B is conveyed using a Submission Clarification Code (420-DK), a Basis of Cost Determination (423-DN) or a Basis of Reimbursement Determination (522-FM).

#### 4.2.1 SUBMISSION CLARIFICATION CODE (420-DK)

A claim is identified as being for a Section 340B drug through the use of the Submission Clarification Code (420-DK) field in the Claim Segment of a Claim Billing or Information Reporting transaction. The field can contain multiple repetitions to indicate a myriad of situations related to the specific claim being billed. To indicate a claim is billing for Section 340B drugs, the value of 20 is used.

Field Name/Number	Value	Description
Submission Clarification Code (420-DK)	20	340B - Indicates that, prior to providing service, the pharmacy has determined the product being billed is purchased pursuant to rights available under Section 340B of the Public Health Act of 1992 including sub-ceiling purchases authorized by Section 340B (a)(10) and those made through the Prime Vendor Program (Section 340B(a)(8)).

In NCPDP *Telecommunication Standard Version F.2* and higher, the Submission Clarification Code (420-DK) 340B value has been moved to a new field – Submission Type Code (D17-K8) and assigned a new value, AA. This guide is based on NCPDP *Telecommunication Standard Version D.0* so the only reference used throughout the guide will be to the Submission Clarification Code (420-DK). The use of the Submission Type Code (D17-K8) value of AA beginning in NCPDP *Telecommunication Standard Version F2* will be identical to the current use of the Submission Clarification Code (420-DK) value of 20.

## 4.2.2 BASIS OF COST DETERMINATION (423-DN)

A claim is identified as being billed at a Section 340B price through the use of the Basis of Cost Determination (423-DN) field in the Pricing Segment of a Claim Billing transaction. Use of value 08 in the Basis of Cost Determination field indicates the Ingredient Cost Submitted (409-D9) field is the Section 340B price of the product and quantity billed. This value has specific limitations on the situations under which trading partners may use this value.

Field Name/Number	Value	Description
Basis of Cost Determination (423-DN)	08	340B/Disproportionate Share Pricing/Public Health Service: Price available under Section 340B of the Public Health Service Act of 1992 including sub-ceiling purchases authorized by Section 340B (a)(10) and those made through the Prime Vendor Program (Section 340B(a)(8)). Applicable only to submissions for Medicaid and other state or federal programs when required by law or regulation and when the payer and/or processor has communicated a unique RxIIN or unique RxIIN/RxPCN combination to distinguish these from other lines of business that do not meet the requirement.

For compound claims, the Section 340B price of each ingredient can be identified using value 08 in the Compound Ingredient Basis of Cost Determination (490-UE) field and the corresponding Section 340B price of the compound ingredient submitted in the Compound Ingredient Drug Cost (449-EE) field within the Compound Segment. The resulting final preparation may only use value 08 in the Basis of Cost Determination (423-DN) field if all ingredients are billed at the Section 340B price within the Compound Segment. For purposes of clarity, other references in this guide to the Basis of Cost Determination (423-DN) are not meant to address compounds unless specifically noted.

## 4.2.3 BASIS OF REIMBURSEMENT DETERMINATION (522-FM)

In contrast to the Submission Clarification Code (420-DK) and the Basis of Cost Determination (423-DN) which are submitted by a pharmacy to a payer/processor, the Basis of Reimbursement Determination (522-FM) is returned by the payer/processor in the Response Pricing Segment. The Basis of Reimbursement Determination field will contain a code that identifies how the Ingredient Cost Paid (506-F6) field was calculated. Value 12 is used for the Section 340B price as described below:

Field Name/Number	Value	Description
Basis of Reimbursement Determination (522-FM)	12	340B/Disproportionate Share/Public Health Service Pricing  Price available under Section 340B of the Public Health Service Act of 1992 including sub-ceiling purchases authorized by Section 340B(a)(10) and those made through the Prime Vendor Program (Section 340B(a)(8)). Applicable only to submissions for Medicaid and other state or federal programs when required by law or regulation and when the payer and/or processor has communicated a unique RxIIN or

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		unique RxIIN/RxPCN combination to distinguish these from other lines of business that do not meet the requirement.
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#### **4.2.4 COMBINATIONS OF IDENTIFIERS**

The identification elements for a Section 340B drug, the Submission Clarification Code (420-DK) value of 20, and a Section 340B price, the Basis of Cost Determination (423-DN) value of 08, are mutually exclusive. Either data element will only be used, subject to the limitations of the NCPDP Telecommunication Standard, based on trading partner agreement. The use of either field to identify a claim as 340B should be identified in the payer sheet and if not identified for that purpose may contain other values.

Similarly, the Basis of Reimbursement Determination (522-FM) value of 12 will only be returned by the payer/processor based on trading partner agreement subject to the limitations of the NCPDP Telecommunication Standard. This value exclusively describes the Ingredient Cost Paid (506-F6).

While it would be a normal business case for a claim submitted with a Section 340B price in the Ingredient Cost Submitted (509-F9) and a Basis of Cost Determination (423-DN) value of 08 to have the Ingredient Cost Paid (506-F6) also equal the Section 340B price and be paired with a Basis of Reimbursement Determination (522-FM) value of 12, there is no requirement of the NCPDP Telecommunication Standard to price claims using this methodology where the submission and response are mirrored.

### **4.3 340B DETERMINATION MADE PRIOR TO SERVICE**

When a Covered Entity, through its pharmacy or contracted pharmacy, makes the determination that a claim is being billed for Section 340B drugs prior to providing service, usually when using a physical inventory of Section 340B drugs, it may convey this information in real-time to a payer/processor in a Claim Billing (B1) transaction. Specifically, the pharmacy may, based on trading partner agreement:

- Include the Submission Clarification Code (420-DK) value of 20 to identify the claim is being billed for a Section 340B drug and/or
- Include the Section 340B price for the product/quantity billed in the Ingredient Cost Submitted (409-D9) field and indicate such using Basis of Cost Determination (423-DN) value of 08.

### **4.4 340B DETERMINATION MADE POST-SERVICE**

When the determination is made retrospectively that a claim previously billed and paid utilized Section 340B drugs, usually involving a virtual inventory replenishment system, it is too late to identify the drug as a Section 340B drug or the price as a Section 340B price on a real-time claim transaction. Depending on business needs and applicable contractual requirements, this information may be able to be exchanged between trading partners. While these methods exist to accommodate the identification of a retrospective 340B transaction, they have not been widely adopted in the industry due to a variety of issues, nor have they been thoroughly tested to be utilized for this purpose. Some of the available methods include the following.

#### **4.4.1 340B INFORMATION REPORTING TRANSACTION**

If the business need is to identify for the payer/processor whether Section 340B drugs were used in connection with a paid claim and the determination is made post-service, the pharmacy, or their agent, may submit an Information Reporting (N1) transaction to the payer/processor subsequent to service to essentially attach the 340B value of 20 to the Submission Clarification Code (420-DK) for the paid claim after the fact. More information on the structure of this transaction can be found in Appendix I of the NCPDP *Telecommunication Standard Implementation Guide Version D.6* and higher. For purposes of clarity, and to distinguish comments made here from other uses of the Information Reporting (N1) transaction, this document refers to an N1 designed to convey 340B identification as a '340B-N1'.

Under this scenario, the pharmacy will submit two transactions to the payer/processor at different times. At the point of service, in the normal course of business, a claim transaction is submitted with no Section 340B information. At a subsequent time, a 340B-N1 is submitted with the Section 340B Submission Clarification Code (420-DK) included. With both transactions, the payer/processor can effectively identify those claims from pharmacies that are for Section 340B drugs and those that are not for Section 340B drugs.

Once the payer/processor receives the 340B-N1, this information can be passed to subsequent trading partners like health plans, state Medicaid agencies, manufacturers or rebate aggregators through other NCPDP standards such as the Post Adjudication Standard and the Manufacturer Rebate Standard based on the trading partner agreements between the payer/processor and any such organization.

The 340B-N1 solves the business need to identify whether Section 340B drugs were used in connection with a specific claim. This can be useful to the payer/processor and its trading partners to comply with the duplicate discount prohibition and meet other contractual requirements concerning the inclusion or exclusion of Section 340B drugs from rebates and other reporting processes. In business cases like complying with the duplicate discount prohibition where the 340B determination needs to be passed from the Covered Entity to the state Medicaid Agency's MDRP invoicing processor, it is necessary that all intermediate trading partners have the ability to accept the information conveyed by the 340B-N1 and exchange it with the next party. While having this information can be useful to intermediate trading partners, unless all trading partners in the sequence are able to support this incremental process to pass the information to the ultimate destination, the 340B-N1 is not an effective solution for the business need.

##### **4.4.1.1 RXIIN/RXPCN ROUTING**

A 340B-N1 should always be submitted to the RxIIN<sup>11</sup>/RxPCN combination of the original claim transaction or Claim Rebill (B3) transaction.

#### **4.4.2 340B BATCH FILE**

If the business need is to identify whether Section 340B drugs were used in connection with a paid claim to a party other than the payer/processor, a batch file can be used. NCPDP does not have a standard for the exchange of this information but, in general, the file must contain records to uniquely identify each claim and an indicator of whether Section 340B drugs were used. The NCPDP 340B Task Group determined there was not sufficient industry demand for a standard file layout.

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<sup>11</sup> Formerly RxBIN

A 340B batch file solves the business need to identify whether Section 340B drugs were used in connection with a specific claim but, unlike the 340B-N1, it directly connects the 340B determination source (i.e., the Covered Entity) with the ultimate receiver (i.e., state Medicaid rebate processor) avoiding the need for all intermediate trading partners to develop processes to capture and relay this information.

The State of Oregon has developed a file layout that is in use for trading partners in that state.<sup>12</sup>

### **4.4.3 CONSIDERATIONS IN EXCHANGING 340B INFORMATION POST-SERVICE**

The following situations apply to each of the methods described in sections [340B Information Reporting Transaction to 340B Batch File](#).

#### **4.4.3.1 REVERSAL AND REBILLING**

If the business need is to identify whether Section 340B drugs were used in connection with a paid claim when the determination is made post-service, reversing and rebilling the transaction to include the Submission Clarification Code (420-DK) value of 20 is not compliant. The NCPDP External Code List defines the Submission Clarification Code (420-DK) value of 20 to be limited to those situations where the determination is made “prior to providing service”. Therefore, any use of the value for retrospective determinations would not meet the situational criteria for the value.

If the business need is to change the pricing of a claim (i.e., to 340B acquisition cost) of a paid claim when the determination is made post-service, reversing and rebilling the transaction to reprice the claim using a different price, including the Basis of Cost Determination (423-DN) value of 08 is permitted. However, there are risks associated with reversing and rebilling transactions that trading partners should address such as, time limitations on reversals and claim billing, application of DUR and other utilization management edits.

#### **4.4.3.2 REPLENISHMENT TIMING**

Depending on the volume of the pharmacy, frequency of use of a specific drug, frequency of replenishment, accounting methods, and other factors, the time between the B1 transaction and a corresponding 340B-N1 transaction could be as short as same-day and as long as infinity, but most of the time within ninety days of the original claim transaction.

#### **4.4.3.3 WHEN A CLAIM “BECOMES” 340B**

In the virtual inventory replenishment model, the initial claim is for a prescription filled with non-Section 340B drugs. At a later time, the prescription is determined to be eligible for Section 340B drugs based upon business rules provided to the pharmacy or 340B Administrator by the Covered Entity. There is currently no standard method in use to identify or communicate this subsequent determination of a dispensed claim as being filled with Section 340B drugs to all stakeholders.

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<sup>12</sup> As of the date of publication, the document is available at: <http://www.oregon.gov/oha/HSD/OHP/Pages/Policy-Pharmacy.aspx>  
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#### **4.4.3.4 WHEN TO SUBMIT A 340B-N1**

When required by trading partner agreement, the 340B-N1 transaction should be submitted to a payer/processor after the claim becomes filled with Section 340B drugs as described in section [When a Claim “Becomes” 340B](#). After such occurs, it is expected the 340B-N1 be submitted within 30 days.

#### **4.4.3.5 HISTORICAL 340B CLAIMS**

Trading partners are encouraged to document in their contracts the expected “look back” timeframe for the purpose of reporting claims later identified as having been filled with Section 340B drugs due to the use of the replenishment model. For example, perhaps a trading partner contract with a start date of 1/1/18 could contain language to require the Covered Entity to report any claims with a Date of Service on or after 1/1/16 be reported with the 340B indicators after the drug was replenished with Section 340B drugs. Trading partners should also specify whether the “look back” period is based on either the contract start date or the claim date of service. Trading partners should also consider this when determining run out clauses.

## 5. BEST PRACTICES AND KNOWN LIMITATIONS

### **5.1 UNIQUE RXIIN<sup>13</sup> AND RXPCN FOR MEDICAID AND AIDS DRUG ASSISTANCE PROGRAMS (ADAP)**

As described in section [340B Determination](#), the determination of whether to use Section 340B drugs often includes a review of the payer type. Most commonly, in order to comply with the duplicate discount prohibitions of Section 340B, it is imperative that a patient's coverage be conclusively identifiable as Medicaid, including Medicaid Managed Care or an ADAP. A best practice recommendation is for state Medicaid Agencies and/or their contracted Medicaid MCOs as well as ADAPs to utilize a unique combination of RxIIN and RxPCN for their Medicaid or ADAP members. Such a clear segmentation of members permits a Covered Entity, or their contracted service provider, to properly submit claims for Section 340B drugs for these members or carve-out the claims from use of Section 340B drugs as may be applicable to the specific circumstance. The requirement for unique RxIIN and RxPCN combinations has existed in the Medicare Part D and ADAP business lines for several years.

Implementation of a unique RxIIN and RxPCN does create challenges for the payer/processor community due to costs of segmenting these members and issuing/printing cards as well as potential member/patient disruption caused by the inability to use probabilistic matching and intelligent routing when a submitted claim is not an exact match to the submitted RxIIN and RxPCN but can be conclusively tied to the member.

### **5.2 SUBMISSION TYPE CODE (D17-K8)**

As described in section [Submission Clarification Code \(420-DK\)](#), the Submission Clarification Code (420-DK) value of 20 has been sunset in future versions of the NCPDP Telecommunication Standard. Beginning in NCPDP *Telecommunication Standard Version F.2*, the business need to communicate the situation conveyed by Submission Clarification Code (420-DK) value of 20 will be moved to a new field, Submission Type Code (D17-K8). The Submission Type Code (D17-K8) value of AA carries the same definition as the current Submission Clarification Code (420-DK) value of 20. All trading partners, particularly governmental trading partners, that specifically reference Submission Clarification Code (420-DK) value 20 in their guidance, procedures, regulations or other requirements documentation must update these documents prior to implementation of *Telecommunication Standard Version F.2*.

### **5.3 DISPUTE DATA EXCHANGE**

Disputes between manufacturers and state Medicaid agencies (or their contractors) often involve an exchange of claim level data to support a state's rebate invoice. Manufacturers and states may utilize the Medicaid Exclusion File as a tool to validate the appropriateness of rebate invoicing. As described in section [Medicaid Exclusion File](#), this file contains Provider NPIs and/or Medicaid Provider IDs. Claims from providers to the state will always contain an NPI. NCPDP recommends, to the extent available, any claims level data provided to the manufacturer or agent by a state should contain both the NPI and Medicaid Provider ID associated to a claim, so the manufacturer may compare to the Medicaid Exclusion File. Refer to the Medicaid Drug Rebate Program Hot Topics/Best Practices for additional information<sup>14</sup>.

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<sup>13</sup> Formerly RxBIN

<sup>14</sup> [Medicaid Drug Rebate Program Hot Topics/Best Practices](#)

## **5.4 DATA EXCHANGE LIMITATIONS**

### **5.4.1 340B-N1 AND 340B BATCH FILE**

The 340B-N1 and the 340B Batch File are each designed to solve the business need to identify whether Section 340B drugs were used on a claim. Both the 340B-N1 and 340B Batch File are mechanisms to report information about a previously filed claim but are not themselves claim transactions and therefore do not contain pricing fields. More specifically, none of the pricing segment fields needed to convey 340B pricing are available for use in either the 340B-N1 request or response.

### **5.4.2 REAL-TIME CLAIM AND VIRTUAL INVENTORY**

The most common inventory method used by the industry is the virtual model described in section [Virtual Inventory](#). When this method is used, dispensing occurs from a non-Section 340B inventory and claims are adjudicated at the time of dispensing. Subsequent to dispensing, the 340B Determination process described in section [340B Determination](#) occurs to classify previous dispensing activity as eligible for Section 340B drugs. The 340B Determination process often relies on the availability of data from the Covered Entity, wholesaler/manufacturer and pharmacy and is most often performed by the Administrator. The time lag between adjudication and the 340B determination can be shorter than a day but is frequently days or weeks due to availability of needed data and program integrity controls such as (i) a time lag to ensure a prescription is delivered to a patient, (ii) manual research to validate records supporting 340B eligibility and (iii) internal audit procedures. Additionally, determination that a claim is eligible for Section 340B drugs is an input to the replenishment process but not indicative that the replenishment process was successful. The time lag between determination that a claim is eligible for Section 340B drugs and when a replenishment order is ultimately received could be days or weeks but potentially years later. It is also possible that replenishment never occurs despite a desire by the Covered Entity, Contract Pharmacy and Administrator for such to occur (i.e., product is discontinued).

For these general reasons, it is impossible for a Covered Entity or Contract Pharmacy that utilizes a virtual inventory to use the Section 340B identifiers at the point-of-service in a real-time claim. To be able to accurately include Section 340B identifiers on the claim would require the submitter to have the ability to capture information that will only become known in the future. To that end, once replenishment occurs all the needed information is known and one of the retrospective methods described in section [340B Determination Made Post-Service](#) can be used to convey the use of a Section 340B drug.



## 6. FREQUENTLY ASKED QUESTIONS

This section addresses some of the most common questions from the industry about the interaction of Section 340B with NCPDP standards. New questions will be addressed by the Work Group 9 Government Programs 340B task group for potential future inclusion in this document.

### 6.1 PHARMACY 340B IDENTIFICATION METHODS

As described earlier, pharmacies may use different business models, inventory methods, accounting policies and other procedures that affect their ability to identify Section 340B claims and at what time. Questions in this section are related to the differences, expectations and conclusions surrounding such variations.

#### 6.1.1 WILL ALL OF A CONTRACT PHARMACY'S CLAIMS BE FOR SECTION 340B DRUGS?

It is possible, but highly unlikely, that all of a contract pharmacy's claims will be for Section 340B drugs. Section 340B does not cover all drugs and does not cover medical supplies commonly found in pharmacies and covered under most pharmacy benefits like diabetic testing supplies, vaccines, syringes, valved holding chambers, etc. While there is nothing prohibiting a pharmacy from servicing only the Eligible Patients of the 340B Covered Entity and dispensing only Section 340B drugs, such would be rare in practice. Additionally, as described in section [340 Determination](#), claims eligible under law for Section 340B drugs may not result in Section 340B drugs being used.

#### 6.1.2 WILL ALL OF AN ELIGIBLE PATIENT'S OUTPATIENT CLAIMS BE FOR SECTION 340B DRUGS?

Being an Eligible 340B Patient who receives drugs from a 340B Covered Entity or contract pharmacy does not necessarily mean the Eligible Patient will receive Section 340B drugs. Eligibility alone does not mean the Covered Entity or Contract Pharmacy purchased Section 340B drugs and dispensed them to the Eligible Patient. The determination process described in section [340B Determination](#) would separately apply to each dispensing of a drug.

#### 6.1.3 HOW DOES A PAYER/PROCESSOR COMMUNICATE THEIR SUPPORTED METHODS OF SECTION 340B CLAIM IDENTIFICATION?

If a payer/processor supports any or all of the identification data elements described in section [Identification Data Elements](#) on either a claim or 340B-N1 transaction, the applicable transaction type(s) and applicable situations should be described in the Payer Sheet. If a Payer/Processor or other entity (i.e., state) supports a batch file similar to what is described in section [340B Batch File](#), file format and delivery specifications should be communicated to trading partners per agreement.

#### 6.1.4 HOW DOES A PAYER/PROCESSOR DETERMINE THEIR SUPPORTED METHODS OF SECTION 340B CLAIM IDENTIFICATION?

A payer/processor must determine its business need for 340B claim identification and support an appropriate method or methods that will permit achieving such goals. As described in sections [340B Determination Made Prior To Service](#) and [340B Determination Made Post-Service](#), multiple methods of 340B claim identification exist to support varying business cases and each method may or may not be appropriate

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for all situations or trading partners. It is unlikely that a payer/processor with a business need to identify claims for Section 340B drugs would be able to rely on data elements used in a claim transaction for more than the scenarios described in section [340B Determination Made Prior To Service](#).

### **6.1.5 CAN A PHARMACY SUPPORT ONLY ONE METHOD OF SECTION 340B CLAIM IDENTIFICATION?**

Yes. The methods are designed to be used independently of each other depending on a pharmacy's customary business practices. A pharmacy is only expected to support one method at a given time and only one method should be used on any one claim.

As described in later sections of this document there are limitations to each method, so a pharmacy is not restricted from implementing both if required for its business needs.

## **6.2 PARTIAL SECTION 340B CLAIMS**

While most claims involving Section 340B drugs will be entirely for Section 340B drugs, it is possible that only a portion of an Eligible Patient's prescription is filled with Section 340B drugs, especially when a pharmacy is using a virtual inventory model. Questions in this section are related to the differences, expectations and conclusions surrounding such partial Section 340B situations.

### **6.2.1 WHEN WILL A SINGLE CLAIM BE FOR BOTH SECTION 340B DRUGS AND NON-SECTION 340B DRUGS?**

In a physical inventory model, a prescription for an Eligible Patient could be filled partially with drugs from the Section 340B inventory and partially with drugs from the non-Section 340B inventory for such reasons as inventory shortage, short-dated merchandise, or for unknown reasons. In the virtual inventory model, replenishments customarily occur only when the quantity of units dispensed to Eligible Patients has exceeded the number of units in one selling unit (e.g., 100 tablet bottle). In practice, it would be rare for a pharmacy to always dispense in multiples of the selling unit or in fractions of the selling unit that always add up to one unit. Therefore, with each replenishment there may be a portion of one or more claims for each drug that are not able to be fully replenished, with the remaining units rolling over to the next replenishment cycle for potential future replenishment. At the time after the first partial replenishment, but before any potential future replenishment, the claim has been filled with both Section 340B drugs and non-Section 340B drugs.

#### **6.2.1.1 REPORTING A PARTIAL SECTION 340B CLAIM WHEN THE DETERMINATION IS MADE PRIOR TO SERVICE**

When a pharmacy is able to make the Section 340B determination prior to service, usually when using a physical inventory, and concludes a prescription is going to be filled partially with Section 340B drugs and partially with non-Section 340B drugs it is advisable that the pharmacy endeavor through subsequent wholesaler/manufacturer orders to get the transaction to 100% Section 340B or 100% non-Section 340B internally. There is no method in a claim transaction to indicate that only part of a claim is for Section 340B drugs.

If internal inventory reconciliation is not possible to get a claim to 100% Section 340B drugs or 100% non-Section 340B drugs, the 340B-N1 may be used as described in the next section.

### **6.2.1.2 REPORTING A PARTIAL SECTION 340B CLAIM WHEN THE DETERMINATION IS MADE POST-SERVICE**

When a pharmacy has determined only a portion of a paid claim has become filled with Section 340B drugs, a 340B-N1 is submitted to the payer/processor with a Quantity Dispensed (442-E7) equal to the total number of billing units that have become Section 340B drugs. The quantity in Quantity Dispensed (442-E7) must always be less than or equal to the quantity in Quantity Dispensed (442-E7) on the original claim.

### **6.2.2 IS IT POSSIBLE TO HAVE MULTIPLE PARTIAL REPLENISHMENTS ON A SINGLE CLAIM?**

Yes. Depending on the accounting and replenishment methods of the Covered Entity, or their agent, it is possible that multiple partial replenishments will occur and be related to the same claim.

#### **Example:**

A new drug is purchased in bottles of 100 tablets. A pharmacy dispenses from its non-Section 340B inventory a total of six prescriptions for 30 tablets each in the month of January. At the end of the month it is concluded that five of the six prescriptions were for Eligible Patients. A bottle of 100 tablets is then purchased at the Section 340B price to replenish the non-Section 340B inventory. At this time, the Covered Entity, which uses a first-in-first-out accounting system, determines the first three prescriptions for Eligible Patients are now 30 tablets of Section 340B drugs and the fourth is 20 tablets of non-Section 340B drugs and 10 tablets of Section 340B drugs. The fifth prescription is still 30 tablets of non-Section 340B drugs.

In February, the pharmacy again dispenses six prescriptions for the same drug of 30 tablets each. At the end of the month again five prescriptions are identified to be for Section 340B drugs. The beginning number of units determined eligible for Section 340B drugs but not yet replenished is 50. The new number of units determined to be eligible is 150, so the total number eligible for replenishment is 200, or two bottles. At the end of February, the remaining 20 non-Section 340B tablets from January's fourth eligible prescription, the 30 tablets from January's fifth eligible prescription and all 30 of each of February's five eligible prescriptions are determined to be for Section 340B drugs.

Assuming the payer/processor of January's fourth eligible prescription was entitled to receive Section 340B information by trading partner agreement, the pharmacy would send two separate 340B-N1 transactions. The first 340B-N1 transaction, sent sometime in February, would have a quantity dispensed in Quantity Dispensed (442-E7) equal to 10. After receiving the second replenishment, the pharmacy would reverse its original 340B-N1 by submitting an Information Reporting Reversal (N2) and submit a revised 340B-N1 transaction with a quantity dispensed in Quantity Dispensed (442-E7) of 30.

### **6.2.2.1 CAN MULTIPLE 340B-N1 TRANSACTIONS BE SUBMITTED THAT ARE ASSOCIATED TO THE SAME B1 TRANSACTIONS?**

No. If there are multiple partial replenishments, each accepted 340B-N1 must be reversed and then a new cumulative 340B-N1 submitted like in the example above. Alternatively, if supported, an Information Reporting Rebill (N3) transaction could be used to reverse and replace the 340B-N1 in a single transaction.

### **6.2.3 IS IT POSSIBLE TO RECEIVE A 340B-N1 TRANSACTION WHERE THE QUANTITY DISPENSED IS LESS THAN THAT OF THE ORIGINAL CLAIM AND NOT RECEIVE ANY FURTHER 340B-N1S?**

Yes. Once a payer/processor has received a 340B-N1 associated to a paid claim transaction, it can conclude only that the Covered Entity has determined the prescription to be eligible for Section 340B drugs and that the quantity dispensed indicated in the received 340B-N1 was determined by the Covered Entity to be Section 340B drugs. The Covered Entity is not obligated to make all Section 340B eligible prescriptions filled with Section 340B drugs. While most transactions will, in final state, be for either non-Section 340B drugs or Section 340B drugs in their entirety, it is not uncommon for eligible prescriptions not to become filled with Section 340B drugs due to the inability to replenish (i.e., out of stock, discontinued, recalled, NDC change) or Covered Entity policy (i.e., only replenish prescriptions less than 90 days old).

### **6.2.4 HOW IS QUANTITY DISPENSED (442-E7) COMPLETED ON A 340B-N1?**

The quantity dispensed in a 340B-N1 transaction will always be the total number of billing units that have been determined to be filled with Section 340B drugs and will always be both greater than zero and less than or equal to the quantity dispensed of the associated claim transaction.

### **6.2.5 IS IT POSSIBLE TO RECEIVE A VALID 340B-N1 TRANSACTION WHERE THE QUANTITY DISPENSED IS GREATER THAN THAT OF THE ORIGINAL CLAIM?**

No. If this occurs the payer/processor should reject the 340B-N1 by using NCPDP Reject Code "E7" (Missing/Invalid Quantity Dispensed). Payer/Processors are also encouraged to use appropriate free text fields to convey to the pharmacy or submitter that the submitted quantity exceeds the original quantity. The same would apply to an Information Reporting Rebill (N3) in this situation.

### **6.2.6 HOW ARE COMPOUNDS THAT ARE PREPARED IN PART WITH SECTION 340B DRUGS AND IN-PART WITH NON-SECTION 340B DRUGS HANDLED?**

Using the method of determination prior to providing service, there is no method in a claim transaction to convey to the payer/processor that only a portion of a compound is utilizing Section 340B drugs.

Using the post-service method of determination, the 340B-N1 will have the Compound Segment completed with the Compound Ingredient Quantity (448-ED) of each Section 340B drug. The non-Section 340B drugs in the compound are omitted from the Compound Segment. One would complete Compound Ingredient Quantity (448-ED) in similar fashion to completing Quantity Dispensed (442-E7) as described above where it only contains the units that are for Section 340B drugs. It is possible for a given ingredient to have a number of units in Compound Ingredient Quantity (448-ED) on the 340B-N1 that are less than the number of units reported for that drug in the associated claim in Compound Ingredient Quantity (448-ED). If only one ingredient in the compound is a Section 340B drug, the Compound Segment of the 340B-N1 will only contain one ingredient. Quantity Dispensed (442-E7) in the Claim Segment of a 340B-N1 for a compound will always contain the total quantity dispensed identical to the associated claim, the submitter is not expected to determine the pro-rata portion of the entire compound dosage form quantity that is considered a Section 340B drug.

## **6.3 SECTION 340B PRICING**

The solutions described in this guide to identify claims for Section 340B drugs are independent of the Section 340B acquisition cost. Questions in this section are related to the differences, expectations and conclusions surrounding the exchange of Section 340B pricing transaction data.

### **6.3.1 DOES BASIS OF COST DETERMINATION (423-DN) VALUE OF 08 MEAN A CLAIM IS FOR A SECTION 340B DRUG?**

No. Basis of Cost Determination (423-DN) value 08 (340B Disproportionate Share Pricing) has an explicit link to the Ingredient Cost Submitted (409-D9) and not necessarily to the acquisition cost of the product being billed. While most business uses of Basis of Cost Determination (423-DN) value 08 in the request Pricing Segment would be related to Section 340B drugs, there is no direct link in the NCPDP Telecommunication Standard between the dollar amounts in the Pricing Segment and the type of product being billed.

### **6.3.2 CAN A PAYER/PROCESSOR REQUIRE BASIS OF COST DETERMINATION (423-DN) VALUE OF 08 ON ALL CLAIMS FOR SECTION 340B DRUGS?**

A pharmacy must only use a Basis of Cost Determination (423-DN) value of 08 when submitting a Section 340B cost in the Ingredient Cost Submitted Field (409-D9). If a pharmacy is not submitting a Section 340B cost in the Ingredient Cost Submitted field (409-D9) a payer/processor cannot require, and a pharmacy cannot submit, a Basis of Cost Determination (423-DN) value of 08.

*340B/Disproportionate Share Pricing/Public Health Service  
Price available under Section 340B of the Public Health Service Act of 1992 including sub-ceiling purchases authorized by Section 340B (a)(10) and those made through the Prime Vendor Program (Section 340B(a)(8)). Applicable only to submissions for Medicaid and other state or federal programs when required by law or regulation and when the payer and/or processor has communicated a unique RxIIN or unique RxIIN/RxPCN combination to distinguish these from other lines of business that do not meet the requirement.*

### **6.3.3 CAN A PAYER/PROCESSOR REQUIRE SUBMISSION OF THE SECTION 340B ACQUISITION COST ON A CLAIM TRANSACTION?**

The standard allows for 340B acquisition cost to be submitted as noted by the Basis of Cost Determination (423-DN) value of 08 in the following situation:

*340B/Disproportionate Share Pricing/Public Health Service  
Price available under Section 340B of the Public Health Service Act of 1992 including sub-ceiling purchases authorized by Section 340B (a)(10) and those made through the Prime Vendor Program (Section 340B(a)(8)). Applicable only to submissions for Medicaid and other state or federal programs when required by law or regulation and when the payer and/or processor has communicated a unique RxIIN or unique RxIIN/RxPCN combination to distinguish these from other lines of business that do not meet the requirement.*

In many cases it is impossible at the point of a claim submission to know that Section 340B drugs will be used and therefore pharmacies would be unable to submit the 340B acquisition cost. Trading partners are encouraged to keep this in mind when developing their agreements. Please refer to sections [Inventory](#) and [340B Determination](#) for more information on operating models.

#### **6.3.4 MUST A SECTION 340B COST BE SUBMITTED IN THE PRICING SEGMENT WHEN USING SUBMISSION CLARIFICATION CODE (420-DK) VALUE 20?**

See section [Combinations of Identifiers](#).

#### **6.3.5 IS THERE A WAY TO SUBMIT SECTION 340B ACQUISITION COST ON A 340B-N1 TRANSACTION?**

No. There is no Pricing Segment on a 340B-N1 transaction.

#### **6.3.6 IS THERE A WAY FOR A PAYER/PROCESSOR TO REPRICE A PREVIOUSLY PAID CLAIM IN THE RESPONSE TO A 340B-N1 TRANSACTION?**

No. There is no Pricing Segment in the response to a 340B-N1 transaction.

### **6.4 340B-N1 MATCHING ISSUES**

When a payer/processor receives a 340B-N1 it must match it to an underlying paid claim. Questions in this section are related to the differences, expectations and conclusions surrounding such matching.

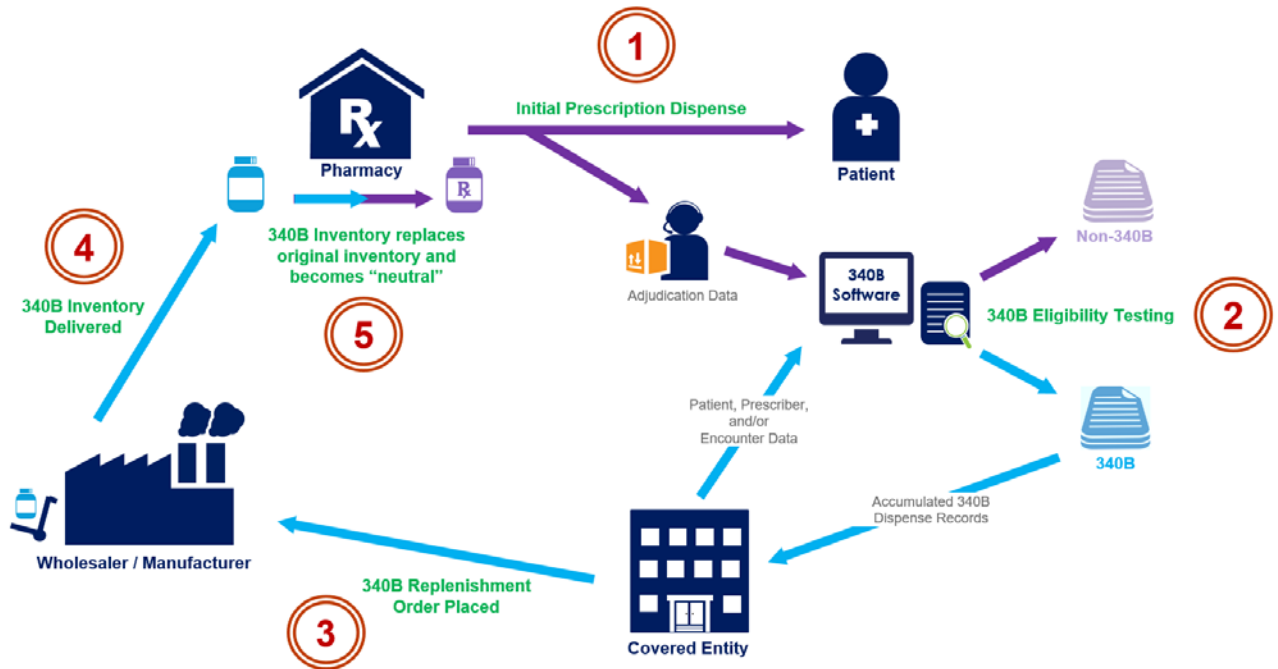
#### **6.4.1 HOW DOES A PAYER/PROCESSOR RESPOND IF IT RECEIVES A 340B-N1 THAT CANNOT BE MAPPED TO A PAID CLAIM?**

The payer/processor will reject the 340B-N1 using NCPDP Reject Code 607 (Information Reporting (N1/N3) Transaction Cannot Be Matched To A Claim (B1/B3)).

#### **6.4.2 IF THE ASSOCIATED PAID CLAIM WAS A PARTIAL AND COMPLETION FILL, HOW WOULD A PHARMACY SUBMIT?**

If a pharmacy has partially filled the prescription, and submitted both a partial and completion claim transaction, it must also submit a partial and completion 340B-N1 transaction. If the pharmacy initially submitted a claim for a partial fill but never completed the partial fill, the pharmacy will submit a 340B-N1 just indicating the partial fill dispensing status.

## 7. APPENDIX A. INVENTORY REPLENISHMENT PROCESS



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## 8. APPENDIX B. HISTORY OF 340B INFORMATION EXCHANGE REFERENCE GUIDE CHANGES

### 8.1 VERSION 1.0

Initial release of the guide.

### 8.2 VERSION 2.0

Section 1	Introduction (modified)
Section 2	Background (modified)
Section 2.1	340B Drug Pricing Program Overview (modified)
Section 2.2	Section 340B and Medicaid (modified)
Section 2.2.1	Medicaid “Carve-In” Fee for Service (modified)
Section 2.2.2	Medicaid Managed Care (modified)
Section 2.3	Section 340B and Other Payers (renamed from Section 340B In Commercial Insurance)
Section 3.1	Objectives (modified)
Section 3.2	Participants (modified)
Section 3.3	Common 340B Business Models (renamed from Common Business Models)
Section 3.3.2	Contract Pharmacy (modified)
Section 3.4.2	Virtual Inventory (modified)
Section 3.4.3	Combination (modified)
Section 3.5	Rebates and Duplicate Discounts ( <b>New</b> )
Section 3.5.1	Medicaid Exclusion File ( <b>New</b> )
Section 3.5.2	Example Scenarios that result in a Duplicate Discount ( <b>New</b> )
Section 4.	Business Functions was reorganized
Section 4.1	340B Determination ( <b>New</b> )
Section 4.1.1	Changes to Determination ( <b>New</b> )
Section 4.2	Identification of Data Elements (modified)
Section 4.2.1	Submission Clarification Code (modified)
Section 4.2.2	Basis of Cost Determination (423-DN) ( <b>New</b> )
Section 4.2.3	Basis of Reimbursement Determination ( <b>New</b> )
Section 4.2.4	Combination of Identifiers ( <b>New</b> )
Section 4.3	340B Determination Made Prior to Service (modified)
Section 4.4	340B Determination Made Post-Service (modified)
Section 4.4.1	340B Information Reporting Transaction (modified)
Section 4.4.2	340B Batch File ( <b>New</b> )
Section 4.4.3	Reversal and Rebilling ( <b>New</b> )
Section 4.4.3.3	When a Claim “Becomes” 340B (modified)
Section 4.4.3.4	When to Submit a 340B-N1 (modified)
Section 4.4.3.5	Historical 340B Claims (modified)
Section 5.	Best Practices and Known Limitations ( <b>New</b> )
Section 5.1	Unique RxIIN and RxPCN for Medicaid and ADAP ( <b>New</b> )

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- Section 5.2 Submission Type Code (D17-K8) **(New)**
- Section 5.3 Dispute Data Exchange **(New)**
- Section 5.4 Data Exchange Limitations **(New)**
- Section 5.4.1 340B-Nx and 340B Batch File **(New)**
- Section 5.4.2 Real Time B1 and Virtual Inventory **(New)**
  
- Section 6 Frequently Asked Questions (Formerly Section 5)
- Section 6.1 Pharmacy 340B Identification Methods (renamed from Identification Methods)
- Section 6.1.1 Will all of a contract pharmacy's claims be for Section 340B Drugs? (modified)
- Section 6.1.2 Will all of an eligible patient's outpatient claims be for Section 340B drugs? (modified)
- Section 6.1.3 How does a payer/processor communicate their supported methods of Section 340B claim identification? (modified)
- Section 6.1.4 How does a payer/processor determine their supported methods of Section 340B claim identification? (modified)
- Section 6.32 Can a payer/processor require Basis of Cost Determination (423-DN) value of 08 on all claims for Section 340B drugs? (modified)
- Section 6.3.3 Can a payer/processor require submission of the Section 340B acquisition cost on a B1 transaction? (modified)
- Section 6.3.4 Must a Section 340B cost be submitted in the Pricing Segment when using Submission Clarification Code (420-DK) value 20? (modified)
- Section 6.3.5 Is there a way to submit Section 340B acquisition cost on a 340B-N1 transaction? (modified)
  
- Appendix A. Inventory Replenishment Process **(New)**