

340B INFORMATION EXCHANGE

REFERENCE GUIDE VERSION 1.0

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.

July 2011

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340B Information Exchange Reference Guide

Version 1.0

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**Published by:
National Council for Prescription Drug Programs**

**Publication History:
Version 1.0 July 2011
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1. INTRODUCTION

The NCPDP *340B Information Exchange Reference Guide* is intended to provide practical guidelines related to Section 340B for software developers and trading partners throughout the industry as they implement NCPDP standards to ensure a consistent implementation.

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

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.

BATCH STANDARD

The NCPDP Batch Format provides practical guidelines and ensures consistent implementation throughout the industry of a file submission standard to be used between pharmacies and processors, or pharmacies, switches, and processors. The batch file is to be submitted in a non-real-time mode.

EDITORIAL DOCUMENT

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

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

Full reference to values used in the NCPDP standard.

STANDARDS MATRIX

This document contains a high-level overview of the latest version/release and/or the most commonly used of those standards and implementation guides, as well as NCPDP's Data Dictionary

and External Code List. Additionally, this document provides version/release/publication reference charts for approved and draft NCPDP standards/implementation guides.

These documents are available to NCPDP members in the "Members" section of the website at www.ncdp.org. Non-members may purchase the documents with membership; please see www.ncdp.org or contact the NCPDP office at 480-477-1000, or via Internet e-mail at ncdp@ncdp.org.

2. BACKGROUND

An NCPDP sponsored 340B focus group was held at the Council office on October, 23, 2009 with 24 participants from various sectors of the industry within and outside of the NCPDP membership attending. Conclusions of the focus group were that industry standardization and educational outreach should be explored in the following areas:

- Identification of claims filled with drugs purchased pursuant to Section 340B on a claim transaction by the pharmacy to a payer/processor.
- Identification of the 'site of origin' to aid covered entities and/or trading partners to make the 340B-eligible determination at the pharmacy.
- Reporting of TrOOP reductions to Part D processors by TrOOP excluded entities (largely Health Resources and Services Administration (HRSA) grantees).

In November 2009, the 340B and Related Issues Task Group was formed in Work Group 9 Government Programs with the following charge:

"Develop recommendations on use of existing standards or future enhancements to standards that will serve the needs of trading partners involved in the 340B federal pricing program. Provide a forum for discussion and education on the various issues related to 340B federal pricing program."

Since its formation, the Task Group has met regularly to discuss and execute its goals; the first is to identify a 340B purchased drug at the individual claim level. The values and use cases to accomplish this goal, using two different methods, were first included in the *Telecommunication Standard Implementation Guide Version D.6* (published December 2010) and the June 2010 *External Code List*. While this *340B Information Exchange Reference Guide* in no way modifies or supersedes the *Telecommunication Standard Implementation Guide*, it is designed to educate trading partners on the use of the *Telecommunication Standard Implementation Guide* in specific business cases related to Section 340B.

2.1 BASIC SECTION 340B 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, in its most basic sense, obligates participating drug manufacturers to offer discounted prices 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."¹ The federal agency charged with administering 340B, called the Health Resources and Services Administration, 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.²

The Section 340B price is determined by a complex formula that is based on the Average Manufacturer Price less a discount, adjusted for inflation, or the manufacturer's 'Best Price'. Discounts available through the Section 340B program are often substantial and, as a result, provide Covered Entities with both the

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

² HRSA, Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Service Act (July 2005), <http://www.hrsa.gov/hemophiliatreatment/340Bmanual.htm>.
Version 1.0

July 2011

OFFICIAL RELEASE

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opportunity to utilize the cost savings and revenue opportunities 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 set by each Covered Entity within the guidelines established by the Health Resources and Services Administration (HRSA)'s Office of Pharmacy Affairs (OPA). The most basic Eligible Patient definition is someone who receives medical care from the Covered Entity. The definitions and requirements are complex and ever-evolving so their inclusion in this document is not necessary.

Covered Entities are required to ensure compliance with Section 340B's requirement to restrict drugs purchased under Section 340B to their Eligible Patients. Should a Section 340B drug be dispensed in error to someone who is not a Covered Entity's Eligible Patient it is considered Diversion. When Diversion occurs the Covered Entity is required to refund the discount obtained through Section 340B to the manufacturer who provided the discount.

2.2 SECTION 340B AND MEDICAID

Section 340B explicitly requires Covered Entities not to seek payment for Section 340B drugs from a fee-for-service Medicaid program that is itself claiming rebates from participating manufacturers. This exclusion, commonly known as the prohibition against 'duplicate discounts', is designed to protect manufacturers from providing both a Section 340B discount and a rebate under the Medicaid Drug Rebate Program on the same drugs. In most states, Covered Entities are allowed to "carve out" their Medicaid fee-for-service drugs from the 340B program to address the duplicate discount issue.

2.2.1 MEDICAID 'CARVE-IN'

Section 340B does offer Covered Entities and fee-for-service Medicaid programs to implement processes whereby claims can be submitted to the fee-for-service Medicaid program for Section 340B drugs and are excluded from rebate submissions by the fee-for-service Medicaid program. This practice, although not officially named, is often referred to as a 'Carve-In' by the fee-for-service Medicaid program.

How 340B drugs should be billed and reimbursed by state Medicaid agencies is a matter of state law, not federal policy. Many states choose to pay 'carve-In' claims at the Covered Entity's Section 340B acquisition cost plus a dispensing fee and any other applicable amounts (e.g. delivery charges, sales tax). The dispensing fee is established by the fee-for-service Medicaid program and is often enhanced relative to the non-Section 340B drug dispensing fee due to an inability for the Covered Entity to achieve any margin on the ingredient cost. Other states reimburse at levels above 340B acquisition cost.

A technical consequence of a 'Carve-In' program is the need for pharmacies to identify their 'carve-in' claims to the fee-for-service Medicaid agency for proper adjudication of the claim.

2.2.2 MEDICAID MANAGED CARE

Covered Entities are not subject to the same statutory prohibition against duplicate discounts that fee-for-service Medicaid programs receive when claiming payment for Section 340B drugs from Medicaid Managed Care Organizations (MMCOS). However, as a result of the Patient Protection and Affordable Care Act of 2010, Public Law 111-148, MMCOS are required to submit to the applicable Medicaid agency drug claim utilization files each quarter that are used by the Medicaid agency to claim rebates from participating manufacturers under the Medicaid Drug Rebate Program. The MMCO is prohibited from including claims for Section 340B drugs in these files when submitting to the Medicaid agency. A technical consequence of this requirement is a need for MMCOS to know which claims are for Section 340B drugs so they may be excluded from the utilization files submitted to the Medicaid agency.

2.3 SECTION 340B IN COMMERCIAL INSURANCE

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. There are no direct restrictions or mandates in law related to how Section 340B drugs are to interact with these plans, including no prohibition on duplicate discounts. 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 that a Payer/Processor must identify claims for Section 340B drugs to properly complete their rebate submission to the manufacturer.

To date, there have been no standard or reliable methods by which a Payer/Processor could identify claims for Section 340B drugs. This has led to widespread variation in methods of identification that are often charged as being too exclusionary or too inclusive in their application by trading partners leading to disputes and perceived over or under payments.

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 funded by the drug's manufacturer. Occasionally, based on trading partner agreements or prevailing law, there is a need for a payer/processor to require knowledge of claims for drugs purchased pursuant to Section 340B for their internal use or downstream reporting to manufacturers, government entities or others.

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 rights available to a Covered Entity and how they impact claim scenarios.

3.2 PARTICIPANTS

Business environments related to Section 340B can come in a number of different forms from simple to complex and can vary widely from relationship to relationship.

- 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 (hereinafter 'OPA') within the Health Resources and Services Administration. 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
- 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:** An entity under contract with the United States Department of Health and Human Services to provide purchase discounts on drugs to which they manufacture, license and/or market to Covered Entities pursuant to Section 340B.
- **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.

3.3 COMMON BUSINESS MODELS

The 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 who 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 Eligible Patients of the Covered Entity, and subject to the Covered Entity's rules, the Contract Pharmacy may dispense drugs purchased under Section 340B. In this model the Contract Pharmacy holds contracts with various Payer/Processors who cover the lives of its patient-customers, including those of Covered Entity.

3.3.3 CONTRACT PHARMACY WITH AN 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 that 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 who 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 Business Models](#)” above may elect to utilize a physically segregated inventory of Section 340B drugs and non-Section 340B drugs. Strategies to ensure integrity of this 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 that the person or machine dispensing a prescription must be aware of the eligibility rules of the Covered Entity 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 Business Models](#)” above may elect to utilize a virtually segregated inventory of Section 340B drugs and non-Section 340B drugs. 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. At some point after a dispensing event has completed, a determination is made that a specific dispensing meets the eligibility rules of the Covered Entity and is eligible for Section 340B drugs. Once the number of units of a particular drug dispensed from eligible dispensing events exceeds one purchase unit (e.g. 100 tablets in a bottle) the Covered Entity may purchase one unit at the Section 340B price and use it to replenish the non-Section 340B inventory. At this time the unit purchased is not Section 340B inventory despite its acquisition at a Section 340B price. Rather, the previously dispensed eligible units become Section 340B drugs and the newly purchased item is now non-Section 340B inventory.

Using this inventory method almost always means that the person or machine dispensing a prescription has no knowledge of whether Section 340B drugs or non-Section 340B drugs are being dispensed. In fact, in nearly all cases it would be impossible to know whether the specific dispensing will later involve a Section 340B drug even if a dispensing meets all eligibility rules as one can never be certain that replenishment will occur. Replenishment efforts can be thwarted due to out-of-stock items, discontinued items, recalls, NDC changes, cessation of the contract pharmacy arrangement with HRSA, price fluctuations making it economically fruitless, market conditions affecting future demand, and so on.

The order in which eligible Section 340B dispensing events become Section 340B dispensing events is an accounting choice based on the rules in place between/among/within the Covered Entity, Contract Pharmacy and Administrator depending on the model selected. Inventory valuation methods may not always be first-in-first-out, last-in-first-out, or something straightforward. Eligible dispensing events may be selected for replenishment in a non-linear order based on business needs and trading partners must be prepared for such.

3.4.3 COMBINATION

Although not common, and often not intended, 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 REMS channels, return-to-stock of already replenished items or wholesaler/manufacturer shipping errors.

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 IDENTIFICATION DATA ELEMENT

A claim is identified as being for Section 340B drugs 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 that a claim is billing for Section 340B drugs, the value of 20 is used.

Field	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)).

4.2 340B DETERMINATION MADE PRIOR TO SERVICE

When a pharmacy makes the determination that a claim is being billed for Section 340B drugs prior to providing service, usually when using a physical inventory, it may convey this information to a Payer/Processor at the point of service using the value of 20 in field Submission Clarification Code (420-DK) in the Claim Segment of a Claim Billing (B1) transaction.

4.3 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 include the Submission Clarification Code (420-DK) value of 20 on a Claim Billing (B1) transaction. However, should trading partners need to exchange this information a process was developed to submit an Information Reporting (N1) transaction to the Payer/Processor subsequent to service to essentially attach the 340B Submission Clarification Code to the paid claim after the fact. More information on the structure of this transaction can be found in Appendix I of the *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 B1 transaction is submitted with no Section 340B information. At a subsequent time a 340B-N1 is submitted with the Section 340B Submission Clarification Code 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.

4.3.1 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 34ØB-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 B1 transaction.

4.3.2 WHEN A CLAIM “BECOMES” 34ØB

In the virtual inventory replenishment model, the initial B1 claim is for a prescription filled with non-Section 34ØB drugs. At a later time, the prescription is determined to be eligible for Section 34ØB drugs and a replenishment order is placed with a wholesaler or the manufacturer for the drug. At the time the pharmacy (either Contract Pharmacy or Covered Entity) accepts delivery of the replenished drugs purchased at Section 34ØB prices, the eligible claims become Section 34ØB claims and the drugs become non-Section 34ØB drugs.

4.3.3 WHEN TO SUBMIT A 34ØB-N1

When required by trading partner agreement, the 34ØB-N1 transaction should be submitted to a Payer/Processor after the claim becomes filled with Section 34ØB drugs as described in Section 4.3.2. After such occurs, it is expected the 34ØB-N1 be submitted within 3Ø days.

4.3.4 OBSOLETE CLAIMS

NCPDP recommends that any *de minimis* 34ØB-N1 transactions related to B1 transactions over two years old not be exchanged between trading partners as their actual use will likely be inconsequential.

4.3.5 HISTORICAL 34ØB CLAIMS

Trading partners are encouraged to place in their contracts how to address reporting of claims that become filled with Section 34ØB drugs after the reporting process has started (sometime in 2Ø12 or beyond) but have dates of service prior to such start date. In theory a Covered Entity could have dispensing events that are eligible for Section 34ØB drugs but have yet to be replenished going back as far as 1993.

4.3.6 RXBIN/RXPCN ROUTING

A 34ØB-N1 should always be submitted to the RXBIN/RXPCN combination of the original B1 transaction.

5. 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 Work Group 9 Government Programs 340B task group for potential future inclusion in this document.

5.1 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.

5.1.1 WILL ALL OF A PHARMACY'S CLAIMS BE FOR SECTION 340B DRUGS?

It is possible, but highly unlikely, that all of a pharmacy's claims will be for Section 340B drugs. Section 340B covers drugs for which a participating manufacturer has executed an agreement with the Secretary of the Department of Health and Human Services. Therefore, 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, syringes, valved holding chambers, etc. While there is nothing prohibiting a pharmacy from servicing only Eligible Patients and dispensing only Section 340B drugs, such would be rare in practice.

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

Being an Eligible Patient who receives drugs from a pharmacy with access to Section 340B drugs does not necessarily mean that the Eligible Patient will receive Section 340B drugs. Eligibility alone does not mean that the Covered Entity or Contract Pharmacy purchased Section 340B drugs and dispensed them to the Eligible Patient.

5.1.3 CAN A PAYER/PROCESSOR SUPPORT ONLY ONE METHOD OF SECTION 340B CLAIM IDENTIFICATION?

A Payer/Processor will likely need to support both the inclusion of the Submission Clarification Code value of 20 on a B1 and a 340B-N1 if the Payer/Processor is required by trading partner agreement to identify claims for Section 340B drugs. Each pharmacy in a Payer/Processor's network required to report on claims for Section 340B drugs would likely be able to utilize only one of the two methods, and not both. In a very small network of affected pharmacies it is theoretically possible for a Payer/Processor to support only one method of Section 340B claim identification (See Sections 4.2 and 4.3) if the pharmacies all use the same model. It is expected that Payer/Processors support the methods of Section 340B claim identification used by their network pharmacies, which will almost always mean supporting both methods.

5.1.4 CAN A PHARMACY SUPPORT ONLY ONE METHOD OF SECTION 340B CLAIM IDENTIFICATION?

Yes. The two 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.

5.2 PARTIAL SECTION 340B CLAIMS

While most claims involving Section 340B drugs will be entirely for Section 340B drugs, it is possible that an 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.

5.2.1 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 no reason at all. 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.

5.2.1.1 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 that 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 way in a B1 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.

5.2.1.2 REPORTING A PARTIAL SECTION 340B CLAIM WHEN THE DETERMINATION IS MADE POST-SERVICE

When a pharmacy has determined that only a portion of a paid claim has become filled with Section 340B drugs, a 340-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 B1 claim.

5.2.2 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 B1 claim.

Example:

A new drug is purchased in bottles of 100 tablets. A pharmacy dispenses from its non-Section 340B inventory a total of 6 prescriptions for 30 tablets each in the month of January. At the end of the month it is concluded that 5 of the 6 prescriptions were for Eligible Patients. A bottle of 100 tablets is then purchased

Version 1.0

July 2011

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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 that the first 3 prescriptions for Eligible Patients are now 30 tablets of Section 340B drugs and the 4th is 20 tablets of non-Section 340B drugs and 10 tablets of Section 340B drugs. The 5th prescription is still 30 tablets of non-Section 340B drugs.

In February, the pharmacy again dispenses 6 prescriptions for the same drug of 30 tablets each. At the end of the month again 5 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 4th eligible prescription, the 30 tablets from January's 5th eligible prescription and all 30 of each of February's 5 eligible prescriptions are determined to be for Section 340B drugs.

Assuming that the Payer/Processor of January's 4th 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.

5.2.2.1 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.

5.2.3 IS IT POSSIBLE TO RECEIVE A 340B-N1 TRANSACTION WHERE THE QUANTITY DISPENSED IS LESS THAN THAT OF THE ORIGINAL B1 AND NOT RECEIVE ANY FURTHER 340B-N1s?

Yes. Once a Payer/Processor has received a 340B-N1 associated to a paid B1 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).

5.2.4 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 B1 transaction.

5.2.5 IS IT POSSIBLE TO RECEIVE A VALID 340B-N1 TRANSACTION WHERE THE QUANTITY DISPENSED IS GREATER THAN THAT OF THE ORIGINAL B1?

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.

5.2.6 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 way in a B1 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 B1 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 B1, 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.

5.3 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.

5.3.1 DOES BASIS OF COST DETERMINATION (423-DN) VALUE OF Ø8 MEAN A CLAIM IS FOR A SECTION 340B DRUG?

No. Basis of Cost Determination (423-DN) value Ø8 (340B Disproportionate Share Pricing) has an explicit link to the Ingredient Cost Submitted (4Ø9-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 Ø8 in the request Pricing Segment would be related to Section 340B drugs, there is no direct link in the standard between the dollar amounts in the Pricing Segment and the type of product being billed.

5.3.2 CAN A PAYER/PROCESSOR REQUIRE BASIS OF COST DETERMINATION (423-DN) VALUE OF Ø8 ON ALL CLAIMS FOR SECTION 340B DRUGS?

Yes. A Payer/Processor can require the Basis of Cost Determination (423-DN) value to be Ø8 when a pharmacy is submitting a Section 340B cost in the Ingredient Cost Submitted (4Ø9-D9). In fact, a pharmacy must use a Basis of Cost Determination (423-DN) value of Ø8 when submitting a Section 340B cost. If a pharmacy is not submitting a Section 340B cost in Ingredient Cost Submitted (4Ø9-D9) a Payer/Processor cannot require submission of a Basis of Cost Determination value of Ø8.

5.3.3 CAN A PAYER/PROCESSOR REQUIRE SUBMISSION OF THE SECTION 340B ACQUISITION COST ON A B1 TRANSACTION?

The pricing arrangements in place between trading partners are outside the scope of NCPDP's involvement. However, as discussed throughout this document, in many cases it is impossible at the point of a B1

submission to know that Section 340B drugs will be used. Trading partners are encouraged to keep this in mind when developing their agreements.

5.3.4 MUST A SECTION 340B COST BE SUBMITTED IN THE PRICING SEGMENT WHEN USING SUBMISSION CLARIFICATION CODE VALUE 20?

No. The Submission Clarification Code value of 20, whether used in a B1 or a 340B-N1 indicates that the drugs were purchased using Section 340B rights. Pricing is independent of the source of drug procurement. In other words, it is possible and expected that trading partners will submit/accept non-340B prices in the Pricing Segment. All matters of claim pricing are based on trading partner agreement.

5.3.5 CAN A PAYER/PROCESSOR PRICE A CLAIM FOR A SECTION 340B DRUG DIFFERENTLY THAN A NON-SECTION 340B DRUG?

Yes. All claim pricing is subject to trading partner agreements and is outside the scope of NCPDP's involvement.

5.3.6 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.

5.3.7 IS THERE A WAY FOR A PAYER/PROCESSOR TO REPRICE A PREVIOUSLY PAID B1 IN THE RESPONSE TO A 340B-N1 TRANSACTION?

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

5.4 340B-N1 MATCHING ISSUES

When a Payer/Processor receives a 340B-N1 it must match it to an underlying paid B1. Questions in this section are related to the differences, expectations and conclusions surrounding such matching.

5.4.1 HOW DOES A PAYER/PROCESSOR RESPOND IF IT RECEIVES A 340B-N1 THAT CANNOT BE MAPPED TO A PAID B1?

The Payer/Processor will reject the 340B-N1 using NCPDP Reject Code 607.

5.4.2 IF THE ASSOCIATED PAID B1 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 B1 transaction, it must also submit a partial and completion 340B-N1 transaction. If the pharmacy initially submitted a B1 for a partial fill but never completed the partial fill, the pharmacy will submit a 340B-N1 just indicating the partial fill dispensing status.

6. APPENDIX A. HISTORY OF 340B INFORMATION EXCHANGE REFERENCE GUIDE CHANGES

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July 2011

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