CHAPTER 10 Chargebacks under 340B Constraints

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The Health Resources and Services Administration (HRSA), 340B covered entities, distributors, and manufacturers all share a common interest—transparency that the 340B price is provided to the participating covered entities. Considering 340B purchases involve over 30 distributors, hundreds of manufacturers, and approximately 40,000 covered entity sites, the accurate exchange of 340B-related information is critical to sustain 340B program integrity. For the vast majority of 340B transactions, the chargeback is the cornerstone for communicating key information in order to support accurate provision of the 340B price to enrolled covered entities. To describe the pivotal role chargebacks play in supporting the 340B program, this chapter presents an overview of the chargeback process, the stakeholder roles, and special situations associated with chargebacks in the 340B program, as well as challenges and tips for prevention and resolution of chargeback-related problems.

OVERVIEW OF THE CHARGEBACK PROCESS

When a manufacturer sells a drug directly to a purchaser, it is straightforward for the manufacturer to verify eligibility of the sale and ensure the right price is extended to the right customer. However, for the majority of manufacturers, drug sales take place indirectly through national, regional, and specialty pharmacy distributors, where the product is first sold to the distributor at wholesale acquisition cost (WAC) to fill its distribution centers, and later sold to the end customer at a group contract price. To ensure accurate pricing is applied to customers, distributors take membership lists supplied by group purchasing organizations (GPOs), the Federal Government and others, and use that in combination with the manufacturer-supplied *chargeback ID*, a data element that identifies the products, pricing, and eligible customer or group. Manufacturers' use of distributors creates two immediate issues that require a chargeback for resolution:

1. The drug manufacturer must be able to identify the purchasing customer of its product to ensure eligibility and the correct contract price is extended for sales in accordance with federal requirements. Because the distributor sold the drug to the final purchaser, the drug manufacturer requires a mechanism to identify basic information about the purchaser and contract accessed to determine the price that the purchaser should have received.
2. Because the distributor purchased the drug from the manufacturer at WAC, but may have sold the drug to the end customer at discounted contract price (340B, prime vendor program [PVP], GPO, or other), the distributor needs to be made whole for the difference in price between the WAC price and the end customer's contract price.

A *chargeback* is an electronic communication, comprised of many data points, and occurs when the manufacturer sells a product at a higher price to the distributor than the price the distributor has set with the end user. The distributor submits a chargeback to the manufacturer to confirm the end user should receive that price and while enabling the distributor to recover the difference between what the distributor initially paid for the drug and the price that the end user paid.

To ensure that chargebacks occur in a standard manner, the Healthcare Distribution Alliance's (HDA) eCommerce Task Force (eCTF) developed a voluntary implementation guideline to outline electronic standards for price communication between industry stakeholders, "Contract and Chargeback Administration Guidelines for Electronic Data Interchange (EDI), to Support Distributor Service Agreements."[1] Although this document is important for providing guidelines for stakeholders across the pharmaceutical marketplace, manufacturers and distributors in the realm of 340B have also created specific requirements in addition to, or in a departure from the core standards.

GPOs and federal contracts, such as the 340B program, rely on the chargeback process to facilitate accurate pricing. The 340B program presents especially unique challenges that occur with the indirect sales model, including quarterly updates to price files, changing lists of eligible entities, federal reporting requirements for pricing, the impact of contract pharmacies, different standards/expectations set by the different distributors and manufacturers—and all of this occurs in an environment focused on compliance. Seamless communication among 340B stakeholders is pivotal to ensuring these challenges are handled, and the chargeback process is critical to the entire program's integrity and operational success. A recurring theme in the world of 340B chargebacks is the challenge for manufacturers to validate 340B eligibility—the manufacturer must link standard industry identifiers with the 340B unique ID issued by HRSA, and often incorporates other identifiers such as the Health Industry Number (HIN) or Drug Enforcement Agency (DEA) number as well.

Figure 10-1 illustrates how the chargeback process provides transparency to the manufacturer and distributor, enabling the extension of the correct contract price to the customer, and ensuring the distributor is made whole on the sale.

A summary of some of the identifiers that make the chargeback process work is provided in **Table 10-1**.

Example of How Identifiers Are Used

A single 340B covered entity may have several different distributor accounts, but they may all have the same ship-to address. If the distributor submits chargebacks that only have the ship-to address on it, the manufacturer would have challenges validating the pricing for the appropriate account. The assignment of an additional identifier, such as the HIN to each account, allows for each identification of accurate pricing for each account and simplifies the 340B chargeback processing for all parties.

Additional information about EDI transactions is helpful in understanding terminology used in association with the chargeback process and is summarized in **Table 10-2**.

Each manufacturer establishes criteria for processing its chargebacks, which include a list of data elements required (see examples summarized in **Table 10-3**) as well as rules for the timeframe in which chargebacks may occur (see examples summarized in **Table 10-4**).

HRSA initiated auditing in late 2010 to improve program oversight and integrity. Over time, the number of audits has increased as well as the details examined in the audit. The ordering account and contract load structure must be kept organized for 340B entities, distributors, and manufacturers to support program integrity. HRSA's contracted 340B prime vendor, managed by Apexus, has worked with stakeholders to establish an account structure that supports compliance. Without this fundamental structure for establishing accounts and contract loads, oversight of 340B