



Importance of class of trade (COT) for government pricing calculations

Government Contract Services

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Class of trade (COT) assignment is one of the most critical activities that impacts government pricing calculations, such as the average manufacturer price (AMP) and the best price (BP) under the Medicaid Drug Rebate Program, the average sales price (ASP) under the Medicare Part B Program, and the non-federal average manufacturer price (NFAMP) under the Veterans Affairs Federal Supply Schedule.

COT is assigned to each customer of a manufacturer, both direct and indirect customers, as well as purchasing and non-purchasing customers. The purpose of a COT assignment is to describe the general business intent of the customer and help form the basis of a manufacturer's determination of whether that customer's transactions (e.g., sales, rebates) should be included or excluded in government pricing calculations.

Each government price is defined to represent a weighted average of sales, inclusive of any eligible discounts and rebates, to only certain types of customers' COTs (except for BP, which is the single lowest net price for certain types of customers). Therefore, accurate COT assignments are required to ensure a manufacturer calculates accurate government prices. Incorrect COT assignments, and a failure to monitor or consistently test customer COT assignments, can result in inaccurate government prices being reported and certified (as accurate) to the government agency.

Challenges in assigning and maintaining compliant COTs

Assignment of COT to a customer is not an easy task for manufacturers. It can be very time-consuming, is too often highly subjective and a costly task when a manufacturer has tens of thousands of existing customers with hundreds (or more) of new customers purchasing drug products monthly. In addition, in today's market, with many customers consolidating or increasing the scope of their existing services (and thereby the nature of their business), defining the one singular type of business (i.e., COT) the customer is engaged in has become even more complex.

So where does a manufacturer start? How can they minimize the time spent, substantially reduce the subjectivity of the COT assignment, maximize the credibility of their assignments and be compliant with government pricing requirements? Manufacturers should consider asking the following questions when establishing their customer COT assignment and maintenance policies and processes:

- ▶ What level of COT assignment granularity is required for government price reporting purposes? Can you consolidate COTs to reduce subjectivity (e.g., physician vs. clinic)?
- ▶ What types of documentation should be established to support reliable, repeatable, auditable, and compliant COT assignments?
- ▶ Are the customers with existing COTs still accurate, or has a customer's business model changed thereby requiring a change in COT?
- ▶ When was the last time your customers' COTs were tested for accuracy?



Manufacturers should leverage objective criteria and automation to assign and maintain COTs

Government pricing rules and regulations provide manufacturers with some guidance as to how they should compute their government prices. However, the regulations are open to interpretation and do not necessarily provide objective criteria to manufacturers to determine the types of customers that should be included or excluded in their calculations, nor how to assign COT to a customer. As a result, in addition to a manufacturer's policies, procedures and assumptions, they also need to establish their own objective criteria to rely upon as the basis for their COT assignments. Objective criteria should be impartial and based on factual information and can be very useful at eliminating subjectivity and enhancing the accuracy of COT assignments. Further, developing an automated approach using third-party databases commonly available to manufacturers for the COT assignment and maintenance will help mitigate the risk associated with COT assignments. Sophisticated automation can normalize the customer name and address information, increase efficiency of assigning and maintaining accurate COTs, and standardize the assignment process to consistently assign a COT to all customers.

The following are the commonly available third-party databases that can be used to build objective criteria and automation logic for COT assignments

- ▶ Drug Enforcement Administration (DEA)
- ▶ Health Industry Number (HIN)
- ▶ National Council for Prescription Drug Program (NCPDP)
- ▶ Indian Health System (IHS)
- ▶ Pharmaceutical Prime Vendor (PPV)
- ▶ Office of Pharmacy Affairs Information System (OPAIS)



Manufacturers should consider asking the following questions when establishing objective criteria and automated customer COT assignment and maintenance processes:

- What research methods or any 3rd party data will be used to determine COT assignments? Are they reliable, or is one more reliable than another?
- What automation logic can be built to eliminate manual and time-consuming COT assignment processes?
- How much diligence should be expended on COT assignments?
- Are there sufficient in-house resources to maintain COTs on an ongoing basis?
- What outsourcing options are available to assist in customer COT assignment and maintenance processes?

Key takeaways

The cornerstone of accurate COT assignments is participation in periodic internal or external training on emerging issues and regulatory requirements related to customer COT assignments to stay abreast of emerging and ever-changing government pricing rules, regulations and requirements. Overall, Manufacturers should consider the following questions:

- ▶ Is it time for you to take an indepth look at COT assignment and maintenance processes?
- ▶ Are you comfortable and confident that your COT assignment and maintenance processes are producing compliant government prices?

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