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The Importance of Class of Trade in Master Data Governance

Every company in the healthcare and life sciences sectors depends on customer data. Customer-related statistics are used by pharmaceutical, medical device, and healthcare organizations to drive commercial strategy and monitor performance, and are intrinsically involved in commercial and regulatory processes. Class of Trade (COT) is a key element in maintaining an accurate, reliable customer record, and it is essential for healthcare professionals to understand the impact it has on manufacturers.

COT is crucial for gaining insight into the product market and distribution channels, has a significant impact on commercial contracting and pricing strategies, and aids in the identification of government contracts and pricing tactics. The process of assigning COT can be time consuming, but if done incorrectly, it can have serious impacts on payments and lead to compliance issues. This article will address the definition of "Class of Trade", as well as some typical designation issues and solutions.

Defining COT

Class of Trade has a simple general description, but its application in contracts, marketing strategies, and how price data is reported to the federal government are complex. The simple definition relates to the various channels through which pharmaceuticals and other healthcare products reach consumers, including retail pharmacies, outpatient centers, hospitals, and mail-order pharmacies. The COT classification of a pharmacy affects both the product's availability and the price at which it is purchased. By shaping COT decisions and eventually deciding on designations, manufacturers have the most influence on the COT system. Some have dozens or more definitions in their schemas, whereas others only have a handful. The graphic below highlights a few common classes of trade with descriptions as defined by IQVIA's OneKey.

ACUTE CARE HOSPITAL — GENERAL ACUTE	In-patient facility that provides patients with such services as emergency, intensive care, and medical-surgical services
OUTPATIENT CENTER — CLINIC	Healthcare facility that provides ambulatory services to the general public
CLINIC - RETAIL WALK-IN	Outpatient facility that provides treatment for routine family illnesses and preventative healthcare services to the general public
CLOSED-DOOR — MAIL SERVICE	Retail pharmacy that provides by-mail-service-only prescription and conventional over-the-counter drugs and support services to the general public
HOME HEALTH — NURSING HOMES	Extended-care facility that provides medical nursing or custodial care to people who cannot care for themselves but who do not require hospitalization
CLOSED-DOOR — LONG-TERM CARE	Not open to the public and work within the closed communities of LTC-site residents (e.g., assisted living, residential care, and nursing homes)

Importance of COT

COT becomes essential when contracts are created and data collection techniques are implemented. This is especially true for government pricing (GP) systems — COT is used to confirm customer contract eligibility, identify which transactions will be included or omitted in the government price calculation, and adjudicate chargebacks accurately. The essential topic of using COT for GP calculations to satisfy government reporting requirements is regularly brought up.

Other internal and external stakeholders to consider include contract management, legal, group purchasing organizations (GPOs), wholesalers, and managed markets. The demands and practical understanding of COT for stakeholders has a direct impact on their interests. When manufacturers employ COT, external stakeholders such as pharmacies, GPOs, and wholesalers must adhere to the COT guidelines defined by the manufacturer to guarantee that pharmacy providers are using the correct COT when gaining access to products and pricing.

Common challenges in COT designation

When attempting to establish and maintain a consistent approach for assigning COT, manufacturers must overcome a few key obstacles. This is done by using efficient master data management (MDM) methods that are formally defined with COT schema reference in SOPs, user guides, and/or other working documents that can be utilized by all teams and/or individuals who may be referring to the same data sets. Refer to Figure 1 for the most common challenges encountered when assigning COT.

Figure 1

Common challenges encountered in the COT designation process:

- No standard schema exists within the industry, resulting in various definitions and a range of simple-to-complex granularity. For example, a GPO may have five COTs, while a manufacturer may have 20, and a wholesaler might use a subsidiary with 100+.

- A pharmacy may seem to fit into multiple categories. For example, a purchaser with "Hospital" in its name could be classified as a "Hospital" if it has a bed count, but it could also be an "Outpatient Facility" if it is located within a hospital servicing outpatient clients.

- Pharmacies may participate in 340B and have a separate inventory, making them eligible for both commercial and 340B. The ability to distinguish 340B purchases from commercial purchases is a significant challenge, not just with regard to COT assignment, but also within the industry.

- The COT designations for a specific entity are susceptible to change due to merger and acquisition activity and changing business models. This is particularly common in channels that are adapting to rapid development, such as the specialty market. Changes in names and identification numbers at the same address could signify a change.

- It can be difficult for numerous people or teams to use a consistent process to determine COT because COT must be determined subjectively.

Approaches to defining COT

Master data governance (MDG), specifically data stewardship, is a key MDM component. Proper master data governance provides a single source of truth, standard definitions and business rules, workflows to change and approve data, and an audit trail for changes in master data. To ensure accurate, reliable data and consistent COT assignment of external stakeholders, adopt the suggested data stewardship methods depicted in Figure 2.

Figure 2

CUSTOMER DATA STEWARDSHIP BEST PRACTICES

1. Require and maintain active identifiers from a minimum of one of the following to validate purchase members

Leverage these as the source of truth for name and address in MDM systems.

- Drug Enforcement Agency (DEA) — unique identifier required for anyone who intends to prescribe legal controlled substances in the U.S.
- Health Industry Business Communications Council (HIBCC/HIN) — unique identifier assigned to hospitals, providers, suppliers, and other partners doing business in the supply chain that identifies locations of services and activities at facilities
- Health Resource and Services Administration (HRSA/340B) — unique identifier for covered entities participating in the 340B Program

These sources provide effective dates and status of Healthcare Providers (HCPs)/Healthcare Institutions (HCIs), along with the legal name and address registered with the agency. A variety of downstream business processes, from informing commercial activity to satisfying regulatory obligations, depend on accurate client address information. This also helps maintain current, valid customers which results in less revenue leakage due to invalid sales/rebates, particularly in chargeback discrepancies.

2. Align all identifiers to one record in MDM systems wherever possible to avoid duplication

Often, GPOs will have these aligned on their rosters and wholesalers will leverage one, or many, in chargeback submissions. A DEA is commonly assigned to a doctor, while a HIN is assigned to a facility. If these are broken out into two records and pricing is COT-driven, the customer now has two accounts from which they can choose to purchase, potentially resulting in revenue leakage due to invalid COT.

Allow only one active identifier for each customer record - i.e., do not allow multiple active DEAs on one record for an overlapping time period. This can cause confusion for wholesalers/GPOs when bid awards go out as they may have these aligned to different facilities.

Ingestion rules should apply to sales reps and/or other business development personnel adding new customers to the ecosystem.

3. Require multiple sources for COT designation

In addition to the primary sources (DEA/HIN/340B), leverage secondary sources from third-party databases, such as:

- IQVIA OneKey — comprehensive data integrated from IMS, SK&A, and Healthcare Data Solutions that provide information on more than 10.7 million HCPs and 700k organizations
- NPI/NCPDP — used by HCPs/HCIs to identify themselves in HIPAA and transactions/correspondence and prescribe medications
- American Hospital Directory (AHD) — provides data, statistics, and analytics about hospitals nationwide
- WebMD — directory of physicians, including education, practice type, insurance, and contact information
- VA PPV Eligibility Listing — validate VA and other government agencies

GPO rosters and customer self-designation should not be used as the source of the COT or name/address. The criteria that GPO customers use to choose which COT to provide on their GPO roster may not match the manufacturer's schema. Additionally, rosters are often not routinely updated, and the data may be out-of-date unless the customer has given the GPO updated information.

4. Contact the facility or use keywords from the name when identifiers are not available

It is common to come across facilities that lack the information necessary to designate a COT with accuracy. Keywords such as "Rx" or "Pharmacy" may point to outpatient, while "Inpatient" or "IP" may indicate "Hospital". If a designation cannot be made, a default should be assigned, and this customer should be excluded from government price calculations until the COT can be confirmed.

5. Implement an audit process to proactively assess purchase members COT

An effective audit process helps identify invalid COT assignments and identify where improvements could be made in work processes.

6. Assign ownership and accountability for MDM systems and processes

Without ownership and accountability, information begins to fall out of sync between departments. Lack of this can also result in unreliable data and compliance issues.

COT assignment you can trust

Being consistent is essential as COT is a complex matter with numerous moving parts. COT assignments that you can trust will be produced by developing a technique that enables assignments to follow a pre-determined process and diligently applying that process each time. The ideal approach to creating a COT schema is to implement a comprehensive COT solution that takes into account the needs of all stakeholders, product requirements, regulatory and legal compliance, and GP provisions. What could seem like a laborious process to some manufacturers may actually offer extensive advantages that can be recognized throughout the organization in terms of compliance, visibility, and operational efficiencies.

The IQVIA GPC team has helped clients successfully execute on the topics discussed in this article. If you'd like to learn more, please read our case study, Customer Clean-up and Data Governance Policy Implementation, illustrating a recent example of real world success.

Our team would be happy to assist your organization with your customer data needs. For information, please contact Heenal Patel, Sr. Principal, Global Pricing, Contracting & Market Access, at heenal.patel@iqvia.com.

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