EDGE DYNAMICS

Extending Channel Vision Today

Unlocking the Value in the 867 Product Transfer and Resale Report

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Abstract

For many manufacturers, the EDI 867 Product Transfer and Resale Report remains a locked vault of economic value. Unlocking the 867 enables validation of submitted chargebacks, returns, and other channel data. The 867 provides the first indication of new downstream customers and uptake of new products. And it extends visibility towards the patient and brings clarity to near-term forecasts of channel activity. This white paper reveals the keys and the challenges to unlocking this value, which allows manufacturers to reclaim control of the channel and to position themselves to embrace future challenges.

Introduction

For pharmaceutical manufacturers, the EDI 867 Product Transfer and Resale Report provides invoice-level details on all product movements between wholesalers and their downstream customers. While manufacturers have gained significant insight into channel activities through the EDI 852 report, the EDI 867 largely remains underutilized due to the prodigious volumes of data and the challenges of reconciling it with other data sources. Yet, buried in the details of the 867 transaction stream are precise images of the activities of downstream channel customers, which can reveal discrepancies that can compromise manufacturer revenue, product availability and integrity, and even patient safety. For these reasons, mastering the 867 can yield significant rewards.

This paper demystifies the often incomplete and always massive EDI 867 document to assess its true economic value to the pharmaceutical manufacturer and, by extension, to wholesaler partners. As the distribution channel becomes more collaborative, capturing the essentials of the 867 provides another step towards a transparent and safe route to the patient.

- For a brief overview of the terminology used in this paper, see Appendix: Glossary.

Structuring the 867 for Value

"There is nothing exempt from the peril of mutation; the earth, heavens, and whole world is thereunto subject." -- Sir Walter Raleigh

Despite the recent attention paid to IMA and FFS agreements, pharmaceutical manufacturers and wholesalers have just begun to scratch the surface of the economic value hidden in the channel. Primarily, these agreements have focused on enhancing visibility into the relationship between wholesaler and manufacturer, and the main reporting instrument of this relationship has been the EDI 852 Product Activity Report. But the scope of the 852 is essentially limited to the wholesaler's activities at the wholesaler's front door and inside the warehouse, which is a long way from the customer. While the current level of reporting provides some visibility into channel activity, for most manufacturers, downstream activities remain a mystery.

The EDI 867 Product Transfer and Resale Report is intended to provide detailed information on each product moved from any wholesaler Ship-From location to any receiving Ship-To location, which can include other wholesaler distribution centers and downstream customers. As the industry has begun to internalize the value of 852 channel data, the horizon for pharmaceutical manufacturers has extended further into the channel, where lurk much of the channel's uncertainty and opportunity. The map to this area is buried in the details of the 867.

Minimum Data Requirements for the 867

Extracting value from the 867 begins with the careful specification of required fields and transaction types in IMA/FFS agreements. During specification, manufacturers should scope their plans for the data and the information wholesalers are able to provide, which determine the appropriate data elements and expected data quality. For example, if lot numbers are widely available in 867 data, the verification of returns is greatly improved.

Additionally, the frequency of data arrival factors into its overall quality; where available, daily data feeds greatly enhances the value of the 867.

- For a brief summary of the contents of the EDI 867 transaction set, see Appendix: Notes on the EDI 867 Standard.

Below is a list of the data required to unlock the details of all product movement out of a wholesaler or other direct trading partner. The following data requirements offer a big

step towards gaining visibility into and tangible benefit out of the channel. As experienced with the expanding usage of the 852 in the channel, the capabilities of the wholesaler community to universally deliver these fields should continue to improve over time.

- **Customer identifiers.** Customer name, city, state, zip code, and other contact information facilitate the development of detailed customer profiles and rapid resolution of issues. Additionally, each transaction should have a valid customer ID (a DEA or HIN number) and the shipping distribution center (DC) for the wholesaler. For more information on the 867's role in customer profiling, see Extracting Downstream Value: The Gateway to the End-Customer.
- **Invoice numbers and invoice dates.** Use of the 867 to determine missing negative chargebacks requires a valid invoice number and date and 867's for both contracted and non-contracted sales. These data fields can also be used to reconcile the 867 with the 852, validate sales occurred for each chargeback, and more.
- **Intra-company transfers.** Knowledge of intra-company transfers (between wholesaler locations) assists in resolving regional distribution mappings and improves validation of the 852 document. Since some wholesalers use a centralized distribution model or deploy regional distribution centers, explicitly requiring intra-company transfers in the 867 sheds more light on down-channel operations. These transfers are identified with the IB (inter-branch) product transfer code (see below).
- **Returns.** Tracking returns to the wholesaler and shipments from the wholesaler are keys to improved visibility and cross-transaction validation. Spikes in returns or changes in the pattern of returns can be key signals to issues in the channel to which a manufacturer must respond. In the 867, returns should be identified with the RV (Return to Vendor) product transfer code.
- **Quantity.** Regardless of product transfer code, a value for quantity should be included in each transaction, even if the quantity is zero. Some trading partners have reported returns without a quantity, but this practice should be discouraged. Adding the quantity as a requirement enables cross-transaction verification, among other things.

At a minimum, the transactions in an 867 document should contain all downstream customer transactions, including both shipments and returns, as well as any transactions that are not linked to a shipment or a return (e.g. "bill only" or "credit only" transactions) for the specified period. While the current guidelines under consideration by the Healthcare Distribution Management Association's electronic Commerce Task Force do not include codes for non-shipment transactions, these transaction types should be identified by specific qualifiers for clear resolution. Unless the 844 is modified to allow coding for chargebacks unrelated to shipments, validation of those chargebacks becomes problematic. For more information, see Chargebacks.

- For downstream customers that require masking of purchase data, the wholesaler can provide the information generically, using the wholesaler's shipping distribution center (DC) as the customer. A separate list of customers that mask data should be provided, as well. For transparency, it is best to receive the unmasked data. For more information, see Blinded Customer Data.

In the 867, individual transactions are associated with a product transfer code. Below is the recommended set of product transfer codes under which details on sales should be received by the manufacturer:

Identifier	Name
DS	Drop Ship Sale
IB	Inter-Branch
RV	Return to Vendor
SS	Stock Sale

Additionally, 867 data provided under the following product transfer codes can provide useful information about downstream activities especially for non-shipment transactions, such as bill-only or credit-only transactions. These transactions are often used to correct errors in shipping and delivery and to describe the effects on sales of transactions that are only financial in nature:

Identifier	Name
BQ	Other
SD	Ship and Debit Sale
SH	Ship and Debit
SU	Summary

In 2006, the HDMA eCTF standards group issued a revised guideline for the 867 that incorporates many of the above suggestions. These data requirements are still evolving and have not yet been universally adopted, which raises the importance of collaboration in the channel. The wholesaler community has various systems and processes and consequently continues to offer different versions of these standards. By understanding the operations of channel trading partners, manufacturers can work within their constraints to determine the most accurate way to interpret their data. Close collaboration also ensures the sharing of any changes to the data specification and any operational issues with the data, such as system failures causing missing feeds. A strong working relationship with channel partners presents opportunities to discuss anomalies and determine causes. Nine times out of ten, data inconsistencies are due to misinterpretation or an error in the way the data was constructed. By maintaining an open dialog, manufacturers and wholesalers can work together to smooth channel operations. The challenge is to manage large data volumes in a timely manner across widely varying standards.

The pharmaceutical industry still has a ways to go before generally accepted standards can be mapped into channel agreements. Until then, manufacturers and wholesalers must collaborate to build equitable channel agreements that provide sufficient data to validate all channel documents submitted to the manufacturer.

Key Insight

The key is to ensure that all types of customer transactions needed to ensure visibility in the channel are captured in an EDI document and can be validated. In the following table, the key benefits extracted from identified fields of the 867 are listed. These benefits are described in greater detail later in this paper:

TABLE 1 Key Benefits by Field in EDI 867 Data

	Customer ID	Cust. Name	Cust. Address	CSZ	Sales Type Code	Qty	Invoice #	Inv Date	Lot #
Unreported Chargebacks	✓				✓	✓	✓	✓	✓
852 Reconciliation					✓	✓		✓	
Chargeback Validation	✓				✓	✓	✓	✓	
New Product Launch	✓	✓	✓	✓	✓	✓		✓	
Forecasts			✓	✓	✓	✓		✓	
Negative Chargebacks	✓	✓	✓	✓	✓	✓	✓	✓	✓
Downstream Speculation	✓	✓	✓	✓	✓	✓	✓	✓	✓
Seasonal Tracking	✓	✓	✓	✓	✓	✓		✓	
Returns	✓	✓	✓	✓	✓	✓	✓	✓	✓
New Customers and Markets	✓	✓	✓	✓	✓	✓		✓	
Diversion and Illegal Activity	✓	✓	✓	✓	✓	✓	✓	✓	✓

The listed benefits are discussed in this paper. To acquire these benefits, the marked fields are required in the 867.

Careful analysis of the 867 reveals specific economic value that is hidden in the channel, and superior inline analysis of the 867 and all channel documents provides the means to capture that economic value and, as a result, to gain control of the channel.

Enhancing the Value of the Manufacturer-Wholesaler Relationship

Product leaving a wholesaler's warehouse may pass through multiple distribution points before finally reaching the retail pharmacy for the patient's use. In the US pharmaceutical market, the enormous volumes and overall value in the channel have introduced all kinds of bit players and specialists, and the relatively low cost to become a distributor means that these players can come and go. While recent pedigree regulations have forced many of them to alter their approaches, they are nevertheless still in operation.

Given the dynamics of the downstream channel, 867 documents should be submitted on a daily basis and processed as soon as they are received. Processing at less frequent intervals degrades data quality and the resulting analyses and slows responsiveness.

Key Insight

Daily receipt and processing of 867 data has immediate benefits across the broader enterprise. For example, rapid responses to changes in the channel are critical to effective Sales & Operations Planning (S&OP) processes. AMR Research, a supply chain analyst firm, estimates that effective S&OP processes are three times more likely to have successful new product introductions. For manufacturers and wholesalers, collaborating on ways to optimize channel operations can create synergistic results and remove administrative tasks that do not add value.

Looking Upstream: Validation of the 852

A primary value of the 867 is its inherent ability to validate data previously submitted to the manufacturer via the EDI 852. By aggregating the outbound shipments found in an 867 document, a corresponding "total shipment" by the wholesaler should be present in a previously received 852 document. At the invoice level and by line item date, records in the 867 should be reconcilable with received 852 records.

A deeper examination of 867 data can reveal changes in product flows in the distribution channel that are not readily apparent in the 852, where shipment data is aggregated. At the customer level, the 852 can be used to validate the 867 shipment flows. For example, comparing changes in quantities sold in the 852 may show few changes, while comparing changes in the 867 in quantities shipped over time to individual downstream customers can indicate shifts in customer or regional demand. By sensing these shifts in demand as early as possible, manufacturers can adjust internal manufacturing and planning processes to avoid product shortages or overstocks.

- Quantity and product information can be sliced across geographic, brand, customer, or other dimensional axes to identify changes in existing markets. For example, in the customer dimension, new downstream customers may represent new opportunities, while fall-off from existing customers may signal major market shifts.

The locus of channel movements described in the 852 and 867 documents provides clear mappings of product movements from the manufacturer to the second level of the distribution channel. By validating these two documents against each other, the images of manufacturer-wholesaler and wholesaler-downstream customer interactions can be connected to build a broader picture of the pipeline.

Key Insight

Chargebacks

Before the deployment of the 867 in the distribution channel, there was no mechanism for confirming the sale and shipment of submitted chargebacks prior to payment; chargebacks were paid by the manufacturer and were assumed to be valid for the submitted customer and quantity.

The 867 can be used to ensure that chargebacks submitted on an EDI 844 correspond to a specific shipment, as recorded in the 867. Some auditors have requested that manufacturers provide this validation of sale before paying a chargeback. In most cases, manufacturers who have initiated this validation process uncover missing invoices. Wholesalers usually are able to produce the missing invoices when requested, which

provides a level of assurance for all parties. In many cases, the invoice covers a "bill-only" transaction to correct a previous shipping or billing error. Receiving this data in the 867 speeds the validation process and closes the loop on these missing invoices.

Missing chargebacks can also be uncovered through this reconciliation process. One manufacturer was offering volume-based rebates to downstream contract customers yet relied on chargebacks to calculate the purchase volume. Missing chargebacks resulted in incorrect volume rebate calculations and, consequently, some unhappy downstream customers. By reconciling chargebacks with 867's, this problem can be curtailed.

Like orders, chargebacks can be validated inline before acceptance and can use many of the same validation checks that are applied to "direct" purchase orders. For example, trend-based expectations for chargebacks can be applied to the incoming stream, and exceptions can be flagged for review at the customer/entity level.

- In some cases, chargebacks may be submitted daily while 867 data may be submitted weekly, which makes in-line validation difficult. However, even post-processing validation offers up-side benefits to the manufacturer and steps in the direction of complete validation prior to payment.

In addition to rapid analysis of exceptions and other downstream issues, inline analysis of chargebacks can provide immediate feedback to sales and marketing about product usage in the channel. For example, linking chargebacks to non-chargeback shipments can be combined with inventory data for a wholesaler location to create a detailed picture of the near-term future demand for a geographic area. This type of forecasting can be very important for seasonal demand analysis or for planning epidemic or disaster recovery scenarios. Additionally, when contracts are about to expire, this data linking can predict a run on a wholesaler's inventory by contract accounts.

By validating the 844 against the 867 prior to acceptance, manufacturers can curtail the unnecessary outflow of credit without supporting evidence of sales. Validating the 852, 867, and 844 together improves the data quality of each EDI document type and raises confidence in the data and its overall economic value to the manufacturer.

- Note that these cross-document validation tests are predicated on receiving internally consistent and complete documents in a timely manner. Relevant tests are discussed later in this paper.

The same methods of analysis can be applied to missing chargebacks. While identifying chargebacks that have not been submitted results in capital outflow from the manufacturer, it also fulfills the contractual obligation, improves contract customer satisfaction, limits reconciliation effort and repayment issues, and engenders cooperation in the channel.

In the following diagram, a chargeback reconciliation process for a typical manufacturer indicates the systems through which 844 and 867 chargebacks may be submitted.

FIGURE 1 Chargeback Reconciliation Process

Chargebacks and negative chargebacks can be validated against multiple channel documents for more accurate results.

Negative Chargebacks

When some or all of a contracted sale is returned, any associated chargeback should be reduced by the chargeback amount that applies to the returned volume. This negative chargeback should be submitted in an 844. The submission of negative chargebacks is not nearly as consistent as regular chargebacks, yet they can represent large dollar values to the manufacturer.

Reconciliation of 844's and 867's can reveal situations in which a negative chargeback should be submitted to the manufacturer. Due diligence in matching invoice numbers, prices, chargebacks, and shipments must be pursued to identify possible negative chargeback situations, which can then simplify conversations with channel partners. While negative chargebacks are hard to measure, reduction of missing negative chargebacks may return 0.1% to 1% of chargeback revenue to the manufacturer. Several recent audits of channel performance have uncovered millions of dollars in missing negative chargebacks.

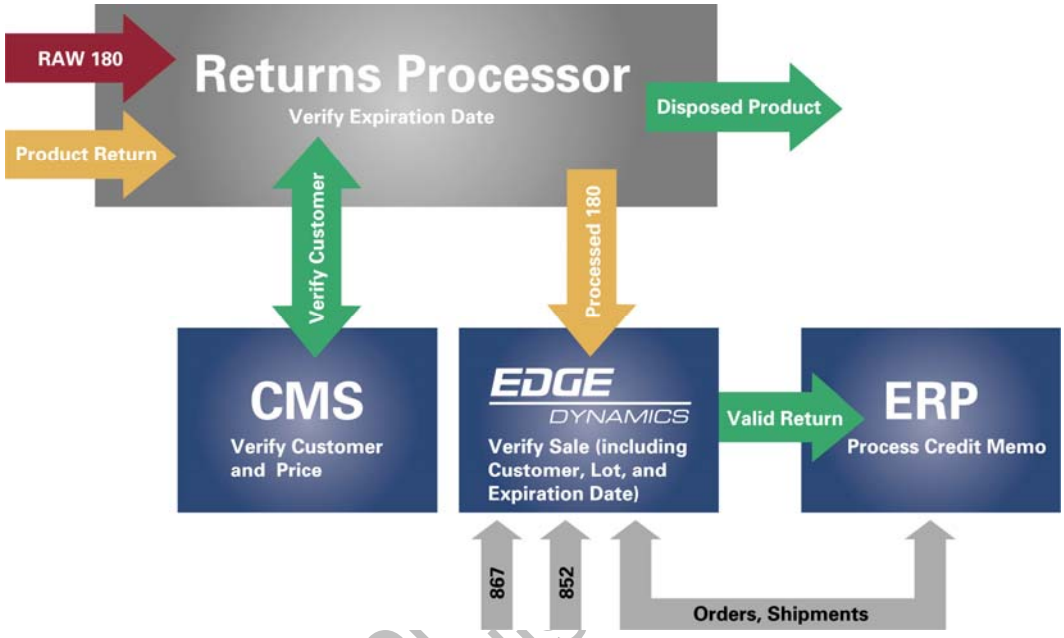
By integrating 867 shipments with 844 chargebacks and negative chargebacks, a clear picture of the net transfer of chargeback payments can be created. Consistent and verifiable reporting of these transactions ensures accurate accounting on both sides.

Returns

Most pharmaceutical manufacturers rely on third-party processors to handle returns of product. However, these third parties do not have access to enterprise channel data and therefore cannot validate returns against shipments and transfers reported in the 867. Returns are often processed based on lot expiration and the Customer Master and little else, with manufacturer reconciliation occurring well after compensation to a channel partner for returns, if at all. Return of product made from a non-Authorized Distributor of Record or an unknown entity may not be eligible for credit and should be reviewed by the manufacturer. Returns from unknown entities should also be flagged for product integrity investigation. At least one manufacturer has detected diversion of a signature product when an unauthorized distributor attempted to return the product.

By tying an individual return (EDI 180) to a specific shipment or transfer (EDI 867) in advance of acceptance of the return, manufacturers can perform accurate validation and, in aggregate, build a clearer profile of returns in the channel. Returns that are not linked to known sales could warrant further examination by the manufacturer. For known downstream customers, return levels that exceed predefined threshold percentages can be rejected or flagged for review. Over multiple time periods, the returns profile can be used to build accurate forecasts of and accruals for returns and to spot potential diversionary activities. Returns forecasts that are not supported by 867 validation lack contextual clarity.

FIGURE 2 Unsaleable Returns Reconciliation Process



Returns of product to third-party processors can be verified before issuance of the credit memo.

Forecasting

Historically, a manufacturer's forecast and projected sales have been tied together using third-party script data that, due to the time lag in generating the data, may not accurately reflect the current picture of the channel. While the 867 cannot completely replace that data, it can provide snapshots of product distribution in the channel 2-3 weeks before that information appears in script data.

In an efficient channel, a manufacturer's shipments should mirror end-customer demand for its products. For example, if shipments to chain warehouses are trending upward while regular retail pharmacy and clinic shipments remain steady, a manufacturer should examine the discrepancies for potential speculation or hording. Visibility into the purchasing patterns of a wholesaler's customers can illuminate such downstream inefficiencies.

Analysis of real end-customer ordering can signal changes in the market, with consequent impacts on the forecast. With across-the-board processing of inline channel

transactions, a manufacturer can generate period forecasts at any time and can compare enterprise forecasts to channel reality. Based on analysis, channel ordering thresholds can be adjusted to align incoming orders with enterprise forecasts and actual demand in the market.

- Such forecasting capabilities can also be applied to returns, chargebacks, and other channel transactions tied to revenue.

Analysis of the 867 can reveal multiple points of interest for manufacturers and wholesalers, yet its value is strongly correlated to the accuracy and freshness of the data. To minimize the cost of extracting this value, 867 data must be analyzed in real-time and inline with enterprise management systems.

The economic value of the 867 document resides in two areas: 1) its ability to validate and reconcile data in other channel documents and, as a result, 2) its use as a map to downstream channel activities. In both cases, its greatest value is extracted through deep, inline analysis.

Key Insight

Extracting Downstream Value: The Gateway to the End-Customer

At the heart of the 867 is the downstream customer, the recipient of wholesaler shipments. Of particular value in the 867 are the geographical characteristics associated with the downstream customer, which can be aggregated to build an accurate view of product distribution across regions and customer types.

Unfortunately, the volume of 867 data clouds awareness of downstream customers, their relationships, and their parenting hierarchies. While contract and direct customers are known to the manufacturer, many downstream customers are not present in the manufacturer's Customer Master and therefore have not been assigned to any hierarchy, parent organization, or class of trade. Naturally, these unknowns complicate analysis.

Earlier, the recommended 867 specification listed Ship-From, Ship-To, Quantity, Invoice Date, Invoice Number, Product ID and Sales Type as required fields. When unknown Ship-To identifiers appear in the 867, the required fields are building blocks for a new downstream customer profile, which can be integrated into the known channel.

By discovering new customers, a manufacturer may find that its products are being delivered through the wholesaler as non-contract sales to customers to which the manufacturer had not been explicitly marketing. This can be both positive and negative.

Key Insight

Meet the New Customer

In positive instances, the manufacturer may discover that previously unknown downstream customers are acquiring product for legitimate uses. If a downstream customer does not have a relationship with the manufacturer, detecting this form of secondary distribution represents an opportunity for the manufacturer to rapidly respond to changes in demand.

These non-contract sales have been historically invisible to the manufacturer. With improved visibility, the manufacturer can move a newfound customer to a contracted relationship with incentives to stimulate demand. As shipment reports arrive for these

new customers, individualized forecasts can be developed to properly address their needs in the future, especially when projections are integrated with third-party channel data, such as IMS.

If a series of similar new customers is appearing in 867's, then further analysis may reveal an entirely new market and provide answers as to why these groups of customers are buying similar products. At least one manufacturer has significantly expanded its marketing universe with this type of customer mining from the 867.

Looking Downstream: Monitoring the Channel

The discovery of new customers can also be less than positive. While IMA/FFS agreements have curtailed forward buying at the wholesaler level, the practice is still pursued downstream of the principal parties to the agreement. Large chains and secondary arbitrage agents are still attempting to speculate on price changes, as small changes in price can translate to significant cost differentials for high-volume and expensive products.

Shortfalls and Ad-Hoc Allocation

Analysis of the Ship-To locations in 867 transactions can reveal customer locations that are part of another wholesaler entity, indicating secondary distribution within the channel. While most agreements prohibit purchases from any source other than the manufacturer, they do not typically prohibit sales to non-dispensing parties such as non-ADR wholesalers. Visibility into this branch of the channel can be very beneficial to the manufacturer, aiding in returns evaluations and allocation of limited supply products.

- 867 data does not indicate parentage information for Ship-To destinations, so identifying a parent entity for a downstream customer must be handled through lookups in the enterprise Customer Master or in external data sources. This process can become complicated when the receiving entity has a multi-level customer hierarchy. However, it is possible for these discovered customers to be knitted into the distribution web.

Similarly, when downstream customers purchase from multiple wholesalers, those purchases may be creating supply issues elsewhere in the channel. Product re-directed out of a geographic region by a purchaser may lead to shortfalls within the region. The redirected product becomes more difficult to track. Seeing these kinds of product movements enables better accountability, even when the individual wholesaler has no knowledge of these kinds of buying patterns.

Diversion and Illegal Activity

While some secondary distribution serves legitimate business purposes, illegal diversionary practices must be controlled and stopped by manufacturer, wholesaler, and other legitimate channel players. Illegal drug diversion activities fall into several categories:

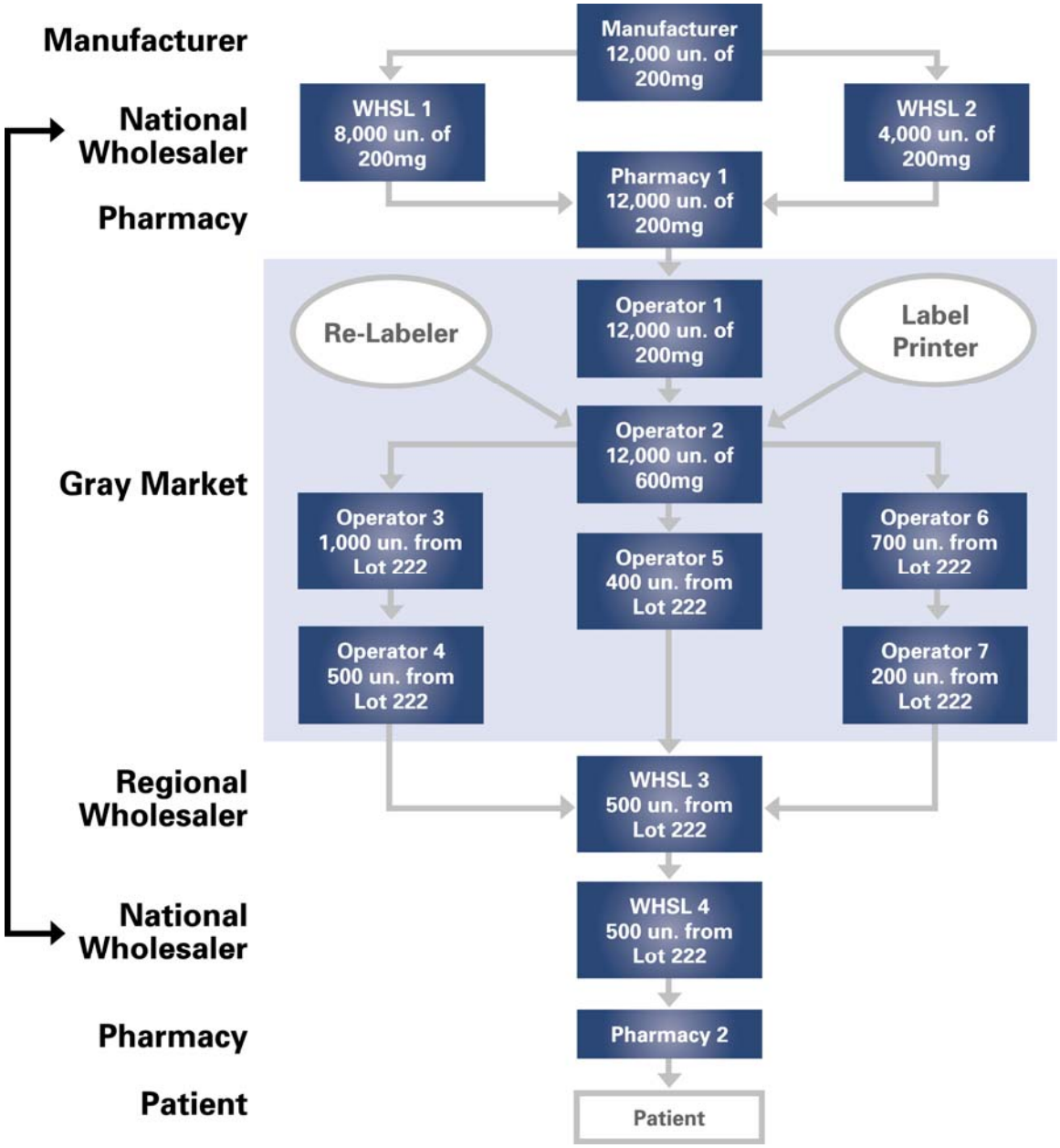
- diversion of contracted product to non-contract customers
- diversion of product to unscrupulous operators who re-label lower dosages to higher dosages for sale at higher prices
- outright counterfeiting

Similar to secondary distribution, downstream channel diversion involves the sale of contracted product at contract prices to entities that do not intend to dispense them. These products are resold at profit by the purchasing entity. When pharmacies have been removed from government-approved lists such as PHS or IHS, their Ship-To identifiers in 867's can be matched against available lists. By analyzing individual 867 channel transactions, manufacturers can identify purchases that are made by suspicious buyers. Using the 867 and 844 data, analysis can map changes in purchases and compare purchases to other entities of similar class of trade. Such insights help detect purchases made for ulterior reasons.

Diversion can be very dangerous to the patient and to a manufacturer's reputation and brand value. The following diagram summarizes the findings of *Dangerous Doses*[1] by Katherine Eban, which details her three-year investigation into diversionary practices in the pharmaceutical distribution channel. The diagram suggests how the pharmaceutical gray market diluted critical medication, which nearly killed a patient.

[1] Eban, Katherine; *Dangerous Doses*; Harcourt Trade Publishers; San Diego, California; May 2005.

FIGURE 3 Cross-Section of the Gray Market



The many players in the gray market complicate tracking product movements and curtailing undesirable practices.

Eban identified several small operators who were buying excessive quantities of product to divert into the gray market. Often, these products ended up in the hands of re-labelers, who placed fraudulent labels on the product and sold it as stronger dosages. The diagram above illustrates how counterfeit drugs can reach patients through traditional sources. Although the penetration of counterfeit drugs into the US legitimate supply chain is very low, manufacturers should remain alert to the possibility.

Manufacturers that can identify suspect Ship-To locations through individual transaction review may be able to prevent this leakage into the gray market, but to control it requires codification and proper metrics in the binding IMA/FFS agreement and real-time analysis of channel information.

Through the 867, manufacturers can monitor the following suspicious channel activities:

- Unusual buying patterns from downstream entities
- Volumes sold to a pharmacy that are out of line with purchases of similar entities and market forecasts for the region
- Sales of low dosage product vs. high dosage product within the same zip code in comparison to other geographic areas or customers

At some point in the future, pedigree regulations will go into effect, and manufacturers and legitimate wholesalers will be held accountable in some measure for the entire length of the distribution chain. Pedigree will necessitate a clear chain of custody of product and, consequently, the data that describes that chain. In that stronger regulatory environment, manufacturers and wholesalers will have to take control of channel data earlier in the process.

Blinded Customer Data

As part of contractual agreements, some downstream customers refuse to allow wholesalers to provide to the manufacturer detailed shipment information in the 867, as it may represent a competitive advantage to the manufacturer in negotiations or may be leaked to competitors. Blinded data is submitted without identifying the Ship-To location. For manufacturers with a significant portion of their business going to blinded customers, blinded customer data represents a large, uncharted area and adds uncertainty to the overall value of the rest of the channel data.

Some manufacturers have been able to acquire this blinded and blocked data through direct negotiation with the end customer. Manufacturers have used the following methods to acquire blinded data from downstream customers:

1. Financial incentives
2. Direct sales
3. Extracting it from other channel documents
4. Getting data directly from the end customer
5. Providing a list of customers with whom the data can be shared

Acquiring this data requires diligence and a willingness to meet end-customer requirements.

New Product Introductions

The great expense associated with development and approval of new pharmaceutical products places considerable value on responsiveness to downstream demand soon after the product is launched. For many manufacturers, the first definitive indication of downstream uptake of product arrives in the form of script data, weeks after the fact. In order to ensure availability throughout the channel, manufacturers utilize multiple methods to promote the stocking of product by wholesalers and pharmacies unsure of the coming scripts. However, these incentives typically promote the initial stocking without adequately addressing follow-on demand and unexpectedly rapid uptake in the channel. As a result, manufacturers are chasing shortages in some regions while faced with excessive inventory in other areas, which creates imbalances and can lead to unfulfilled scripts.

Through the 867, manufacturers can begin receiving downstream activity reports the day after a new product launch. At the order and line item level, this kind of detailed information can be immediately provided to Marketing and Sales for shaping subsequent promotions and specific discussions with downstream customers. Early in the launch cycle, the manufacturer can track inventory stockpiling, uneven distribution, or sporadic downstream availability to ensure proper supplies throughout the channel.

Additionally, the 867 can provide cross-reference information on incentives provided to the distribution channel to stimulate product stocking and availability. Historically, proof of stocking allowance volumes was virtually impossible to validate, yet through

867 reports, the manufacturer can verify these allowances on submitted data and quickly compensate for the sales, which encourages cooperation in the relationship and provides sounder financial accountability for these payments.

- The 867 can also be used to validate downstream shipments to valid customers within specified parameters such as date and quantity limits. Since stocking allowances are typically not paid to contract customers, they can be checked against submitted 844's to ensure that wholesalers are not receiving duplicate discounting.

A product can only be launched once; getting it right from the start is critical. The immediate feedback on channel uptake provided by the 867 allows multiple areas of the enterprise to make rapid adjustments to emerging channel activities.

Key Insight

This form of monitoring provides value for seasonal products, as well. Vaccines and flu medicines must be monitored like new product introductions to ensure adequate supplies are reaching the appropriate locations in a timely manner. Later in product life cycles, rapid evaluation of channel data can also help manufacturers to optimize activities around products reaching the end of their commercial life, including managing inventory to minimize returns of a product that is soon to be replaced or to be facing new competition.

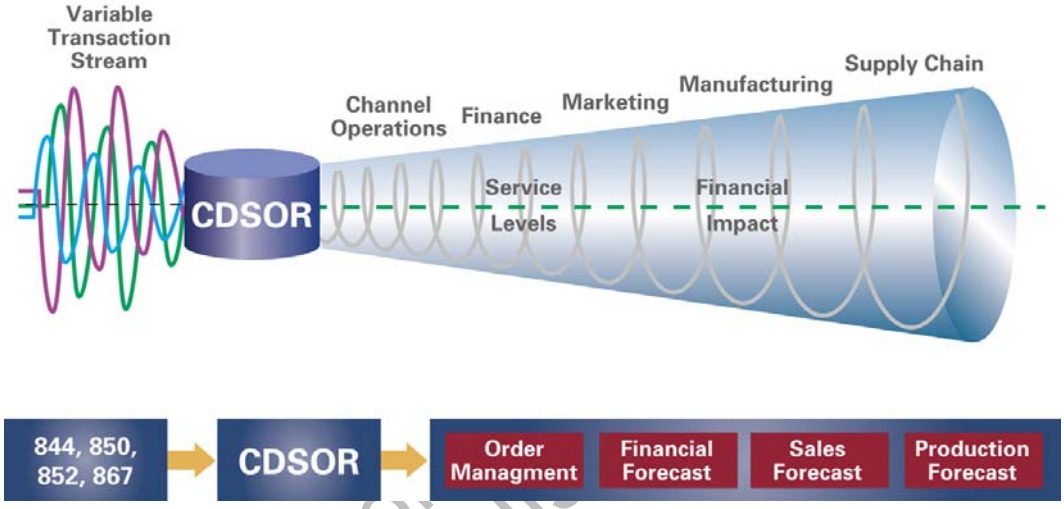
Towards the Demand-Driven Enterprise

According to AMR Research, the truly demand-driven enterprise can manage demand in the channel to optimize business performance. Accurate demand sensing enables a manufacturer to tune production plans, marketing programs, and sales efforts to meet company objectives.

More and more manufacturers are realizing that access to detailed channel data is critical to reclaiming control of the distribution channel and managing the entire corporate value chain. Through real-time analysis of channel data, response times in the trade group are greatly reduced, and discrepancies between forecast and performance diminish. Finance can use the timely and accurate information to improve revenue forecasts and accruals for returns and chargebacks. Marketing and Sales can quickly

respond to downstream trends and conditions, revising programs to better meet objectives. Overall, operating costs decrease, as production schedules become more aligned with true demand, enabling the demand-driven enterprise.

FIGURE 4 Channel Control and the Demand-Driven Enterprise



A Channel Data System of Record provides channel control and broad benefits across the enterprise.

Acquiring these benefits is, of course, non-trivial. The next chapter outlines the challenges of capture, validation, and analysis standing between most manufacturers and the economic value hidden in the 867.

Challenges with 867 Data

"The mill cannot grind with water that is past." -- English 17th Century Proverb

Unlike the 852, which reports on aggregate activities involving known entities, the 867 describes invoice line item activities between wholesalers and downstream entities that may be unknown to the manufacturer. For example, a manufacturer's first awareness of a new downstream customer may be extracted from an 867 report received from the wholesaler that shipped product to this new customer. The 867's many-to-many mappings between wholesalers, products, and downstream customers provide disconnected snapshots of the network. Assembling these disconnected pieces into a clear image requires reconciling them upward with other channel documents and the manufacturer's enterprise systems and downward with activities reported from deeper in the distribution channel, such as script data. Fitting these pieces together is complicated by the following factors:

1. **Huge Data Volume.** Since the 867 report represents each transaction involving wholesaler locations and downstream partners, the data volume can be problematic to capture and analyze in a timely manner. When it is not, the image of the channel quickly blurs.
2. **Dirty Data.** Channel data is dirty. Required fields may be omitted. There may be discrepancies between how fields are used among reporting locations. Missing data muddies reporting and dilutes the consistency and validity of other data.
3. **Lack of Industry Standards.** Even if the data arrives in a clean and consistent structure, each channel entity may implement the EDI 867 standard in a different way.
4. **Contractually Blinded Data.** Some downstream customers negotiate agreements with wholesalers in which their ordering patterns are deliberately omitted from channel reports forwarded to the manufacturer. Sifting the data to reveal these situations requires deep analysis and detailed comparisons.
5. **Inconsistent Support in IMA/FFS Agreements.** With their emphasis on the relationship between manufacturer and wholesaler, many current channel agreements fail to integrate proper 867 requirements into the channel program, resulting in an incomplete picture.

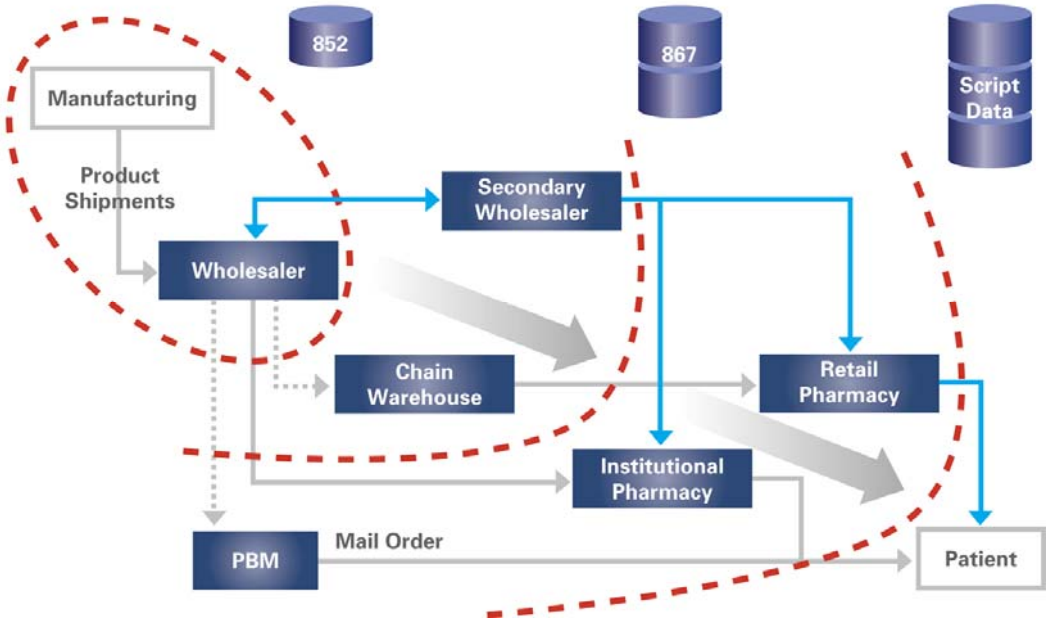
Methods for addressing these issues are described in the following sections.

Huge Data Volume

A wholesaler's 867 should contain references to all downstream transactions for daily or weekly periods. This volume is multiplied across all wholesaler locations within the parent entity and all wholesalers that purchase product from the manufacturer. For one major US pharmaceutical manufacturer, the total volume amounts to over 480,000 line items per week to capture, clean, internalize, and analyze. These line items encompass multiple transaction types, each of which must be normalized to a standard format. The sheer volume of 867 transactions and the variety of healthcare entities to which a wholesaler ships require enormous efforts to sift to extract nuggets of value.

Deeper in the channel, beyond a wholesaler's direct customers, the volume grows even larger. The figure below displays a representation of the expanding wave of data required to track channel activities. As product lots get splintered into smaller and smaller transfers, the volume of transactions balloons.

FIGURE 5 Extending Visibility to the Patient



To build a map to the patient, data capture must be able to scale to handle exponentially larger volumes deep in the channel.

Dirty Data

Each wholesaler partner may provide the same information in different fields and segments of the 867. Even if data translators can account for these differences, variations in coding schemas and data definitions make analysis and reporting a challenge, at best. Manufacturers receive a set of text and numeric data and may not be able to easily review the numbers behind the numbers.

And sometimes numbers are missing. And sometimes the report arrives days late.

The following tests should be performed at a minimum on each 867 document that is received:

1. **Data Timeliness.** Did the 867 arrive according to the scheduled delivery date? If not, is the lag within an acceptable range? Is the reporting interval short enough to be meaningful?
2. **Data Completeness.** Have all required fields been included? Do they include proper data types?
3. **Data Consistency.** Can the data in the 867 be reconciled with corresponding data in other channel documents, such as the 852? Can it be reconciled with customer, DEA, or HIN databases? If not, what is the source of the inconsistency?

For the 867 document in particular, data consistency tests can be quite challenging, as line items in the document may correspond to line items that arrived in earlier documents or, in some cases, items that have not yet arrived. These issues are amplified when channel documents are evaluated after they have been accepted. In such situations, the manufacturer is always struggling to catch up to and correct channel realities. Such a reactive position ensures that at best a manufacturer can monitor the channel – yet never maximize its value.

To build a current image of the distribution channel at any time, 867 data must be captured, cleansed, internalized, and analyzed in real-time. Any lag in these processes degrades the quality of the data, introduces error in decisions, and dissipates control into the channel.

Key Insight

No Accepted 867 Standards

The current lack of accepted standards is problematic for both manufacturer and wholesaler. To address the nuances of each IMA/FFS agreement, a wholesaler may be required to deliver custom 867's to each manufacturer. Each manufacturer-wholesaler relationship may feature different performance metrics. For identical metrics, the computations may vary. The diversity of metrics and resulting uncertainty about definitions add confusion and cost to both parties. With potentially hundreds of manufacturers to support, wholesalers are challenged to provide clear and accurate data in a consistent manner.

For example, in the table below are the different transfer type codes that can be passed in the 867 document to handle returns.

Identifier	Name
BN	Return
RB	Return of Broken Price
RP	Return of List Price
RU	Return to Usable Inventory
RV	Return to Vendor
SS	Stock Sale

Wholesalers may submit returns under some of these codes using positive quantity values, while some channel partners submit returns as a negative quantity Stock Sale (SS). These various methods of reporting returns in the 867 must be normalized to an internally consistent standard. As part of any validation check, returns must be determined to come from a valid downstream customer and reconciled with a recognized sale, as well.

Non-Integrated Channel Agreements

In many instances in the pharmaceutical industry, IMA/FFS agreements have been defined without careful attention to inter-dependencies in channel data documents. For example, if a manufacturer's FFS agreement with a wholesaler does not include reporting of returns on the 852 document, then the 867 document can only be used to reconcile the shipments reported in the 852. As a result, returns cannot be verified, and the picture is unfinished. It is estimated that unverified returns constitute 0.05% to 0.3% of channel revenue.

EDGE INSIGHTS

To maximize the value out of the 867, manufacturers need to integrate 867 requirements and 852 requirements within their channel agreements.

Based on numerous interviews, the wholesaler community has expressed strong interest in embracing common standards. Instead of investing time and resources in monitoring the details of the agreements, standardized definitions, metrics, and data would make agreements more manageable through consistent mechanisms and allow both parties to focus on the core business of delivering medication across a safe map to the patient.

Conclusions: The 867 and Beyond

This paper has identified the buried treasures in the EDI 867 document. As both a validation tool and a map to locations deeper in the channel, the 867 is a largely untapped resource for both pharmaceutical manufacturer and wholesaler.

In many respects, an EDI 867 transaction is another order for product; although it is an indirect request for the manufacturer's product, it is still a claim against the available supply. As such, EDI 867 transactions should be treated with the same care as orders for product. Controlling product movements and preventing illegal, unethical, or otherwise inappropriate orders are critical for any viable manufacturer, and visibility on these issues beyond the wholesaler is available only through deep analysis of the 867.

A True Channel Data System of Record

Given the volume and value of data arriving at the wholesaler and manufacturer from the distribution channel, it is becoming more and more apparent that a dedicated solution is required to manage this data in a timely and consistent manner. As the struggles with managing 867 data volumes exemplify, this solution must meet the ever-growing requirements for pharmaceutical manufacturers:

- **Real-time analysis.** All channel data must be captured, validated, and analyzed in real-time, including EDI 852 and EDI 867.
- **End-to-end auditability.** To comply with current regulatory requirements such as SEC and Sarbanes-Oxley and with good business practices in general, all captured data and the resulting actions must be auditable from the point of receipt through all stages of validation and analysis.
- **Flexible and scalable.** As regulatory requirements expand the manufacturer and wholesaler's liability for activities deeper in the channel, the solution must be flexible and scalable to handle the even greater volumes of data required to meet future Pedigree standards.

Simply capturing these volumes of data inline with transaction acceptance requires a dedicated, enterprise-class solution, from which emerges a true system of record for data in the pharmaceutical distribution channel.

Taking Control of the Channel

After channel data has been captured into a system of record, it must be deeply analyzed to extract its full value. Detailed analysis of channel data requires deep domain expertise to build the sophisticated business policies that properly govern channel inventory levels, secondary market activity, diversionary practices, inaccurate or missing chargeback submissions, and the growing variety of distribution metrics to fulfill IMA/FFS agreements.

It is insufficient to perform this analysis offline or after the fact. Analysis must be applied at the point of the receiving enterprise accepting the transaction. All enterprise contextual information – all order history, 852 and 867 transactions, and known inventory and demand conditions – must be brought to bear in the decision to accept, reject, or modify each transaction. The gap between this point and some future point when offline review is completed is the difference between controlling the channel and simply monitoring it. As that gap widens, more and more revenue and risk falls into it.

A critical component of such a system is to turn control of the business policies over to the experts in those policies. Trade, finance, and compliance personnel must have the means of adjusting these business policies on the fly to respond to changing corporate priorities and to extend channel performance analysis to the limits of their capabilities. Such control moves the pharmaceutical manufacturer closer to the truly demand-driven enterprise.

The Future Is Still Pedigree

The FFS revolution has brought an unprecedented challenge to the pharmaceutical industry, and where there is challenge, there is opportunity. While emerging legal requirements for Pedigree tracing have raised general interest in downstream activities, it will be a matter of years before these standards are commonplace. Until then, building a viable map to these more distant locations begins with the 867.

Already, leading manufacturers have embraced the opportunity and, in the process, have discovered much deeper and richer veins for exploring channel data. These manufacturers are well-positioned for the future. While the RFID revolution won't arrive for years, the industry-wide push towards serialization has gained momentum. In the near-term, the 867 is the vehicle to begin realizing positive benefits from serialization by reporting down to the lot level. As the next round of FFS agreements begin to embrace reporting by lot numbers, additional treasure will emerge from the 867, and those manufacturers who explore this territory are in line for rich rewards.

Appendix: Notes on the EDI 867 Standard

While sharing 867 data is new to the pharmaceutical industry, the standard and guidelines for its use have been around for some time. The HDMA has published voluntary guidelines and intends to update them in 2007.

In the EDI 867 standard, transactional data is contained in the Transactions segment. Within Transactions, specific segments can be used to identify contact, currency, measurement, and reference information that pertain to the transactions. According to the EDI X12.V4010 standard, each bundle of Transactions contains the following segments:

- **Name.** Name of organization, identification codes, and relationship information.
- **Code Source Information.** Enterprise and industry code information can be included in this optional segment.
- **Product Transfer and Resale Detail.** The only mandatory segment, this one contains the essential information for the transaction, including quantity, purchase order, type codes, and contract identifiers. Most of the information critical to the manufacturer is contained in this segment.
- **Transaction Totals.** Total line items, weights, and units of measure can be submitted in this segment.

For more information on the structure of the EDI 867 document as it applies to the pharmaceutical industry, please visit the Healthcare Distribution Management Association (HDMA) at healthcaredistribution.org.

Appendix: Glossary

The following types of EDI documents may be submitted from wholesalers or from other sources to pharmaceutical manufacturers. These documents are referenced in this white paper:

- **EDI 180 Return Merchandise Authorization and Notification.** Submitted by the wholesaler for authorization and crediting of returns and by third-party processors with returns details.
- **EDI 844 Product Transfer Account Adjustment.** Submitted for the processing of chargebacks, which result in payments from the manufacturer to the wholesaler for differences between contract sales to downstream customers and prices charged to the wholesaler.
- **EDI 850 Purchase Order.** Submitted for the purchase of product by the wholesaler.
- **EDI 852 Product Activity Report.** Submitted to the manufacturer to provide details on product inventory, gross shipments, transfers, and other activities.
- **EDI 867 Product Transfer and Resale Report.** Submitted to the manufacturer to detail movements from wholesaler locations to downstream channel partners or to other wholesaler locations within the same parent organization and to detail returns from these locations to the wholesaler.

The following terms are referenced in this document or apply to the 867:

- **HDMA.** The Healthcare Distribution Management Association develops standards, policies, and business processes to ensure safe distribution of healthcare products. For more information, see www.hdma.net.
- **eCTF.** A committee of the HDMA, the electronic Commerce Task Force provides recommendations for pharmaceutical industry use of EDI transactions.
- **FFS.** In a Fee For Service agreement, the manufacturer pays for services performed by a wholesaler.
- **IMA.** An Inventory Management Agreement is a form of Fee For Service agreement.

- **EPC.** Electronic Product Code is a standard for serialization at the bottle/vial/syringe level to facilitate pedigree. For more information, see www.epcglobalinc.org.
- **HIN.** The Health Industry Number scheme identifies healthcare entities and facilitates contract programs. For more information, see www.HIBCC.org.
- **IMS.** A source for pharmaceutical market information, usually at the script level. For more information, see www.IMSHealth.com.
- **ADR.** The Authorized Distributor of Record denotes a wholesaler that has been given formal status as an authorized distributor of a manufacturer's products.
- **PHS.** Public Health Service.
- **IHS.** Indian Health Service.
- **CDSOR.** The Channel Data System of Record is a repository of channel data stored in a secure, auditable, and accessible system. This repository contains raw as-received data, an auditable record of all transformations and evaluations of the data, and the normalized data that is evaluated by accessing applications.
- **DEA.** The Drug Enforcement Agency issues a unique identifier to entities that are authorized to handle controlled substances. This number is often used in EDI transactions to identify the source and destination of shipments.