

**CHANGE MANAGEMENT:
BEST PRACTICES IN CONTRACT AND CHARGEBACK ADMINISTRATION**



in collaboration with



| | |
|---|----|
| Project Participants..... | 3 |
| Introduction | 4 |
| Project Scope and Background | 4 |
| Methodology | 5 |
| Survey Background | 5 |
| Interview Profile | 5 |
| Current Situation | 6 |
| Issues | 9 |
| Focus Areas | 9 |
| Communication | 9 |
| Lead Time | 9 |
| IT & Systems | 10 |
| Project Management, Terminology, Definitions & Other | 10 |
| Involvement from Contract and Chargebacks Teams | 11 |
| Rejected Chargebacks | 11 |
| Trade Letter | 13 |
| Chargeback Information | 13 |
| Return Information | 16 |
| Start Date Information | 17 |
| Recommendations | 18 |
| 1. Initiation Stage | 18 |
| 2. Planning/Due Diligence | 18 |
| 3. Execution Stage | 20 |
| 4. Monitor/Control (for the entire duration of the project) | 20 |
| 5. Close/Post-Close Stage | 20 |
| Works Cited | 21 |

Project Participants

Project Committee

The HDA Research Foundation would like to recognize the following individuals and companies who invested their time and expertise as project committee members to assist with the development of this paper through their participation in group discussions and individual interviews.

Fredrick Fieder, Director, Manufacturer Services, McKesson Corporation

Douglas Kucera, Senior Director, Contract Services, Vizient

Deanna Max, US G2N CoE Manager, Pfizer Inc.

Tim Sterns, Senior B2B E-Commerce Analyst, Baxter Healthcare

Chad Snyder, Manager, Financial Operations, PD & SPD Chargebacks, Cardinal Health, Inc

David Young, US Gross to Net CoE, Manager, Pfizer Inc

Vanessa Zanni, Specialty Pharmacy Acute Care Contract Management Associate Director, Novartis Pharmaceuticals Corporation

Rutgers University Team

Professor Irene Gerlovin

Linus Rackus

David Solomon

Olena Stratiyenko

Ying Hong

Kyle Nosker

HDA and HDA Research Foundation

Perry Fri, EVP Industry Relations, Membership and Education, HDA; COO, HDA Research Foundation

Anne Nevel, Senior Director Education, HDA

Rachel Sullivan, Project Manager, HDA Research Foundation

Introduction

Project Scope and Background

Mergers and acquisitions in the pharmaceutical industry today are driven by blockbuster drugs coming off patent, increased competition from generic drugs and recent US tax reforms which have prompted companies to repatriate profits from overseas (Jewell). A merger or acquisition, whether it involves an entire company, or a single product line presents a company with a unique set of challenges. A company in this situation may have to work through an integration for which it has no precedent and attempt to implement the changes without an experienced integration team. Each integration will be different, and its effect can vary significantly based on the size of the companies involved and number of product lines acquired or divested.

The Rutgers team in collaboration with the Healthcare Distribution Alliance (HDA) Research Foundation worked to identify and describe best practices for managing change in contract and chargeback administration due to system conversions and company mergers and acquisitions. Subject-matter experts (SME) from HDA member and affiliate companies volunteered their time to participate in interviews, enabling the team to gain a deep understanding of how the SME's organizations manage contract and chargebacks. Furthermore, the team analyzed data collected generated by surveying HDA member and affiliate companies.

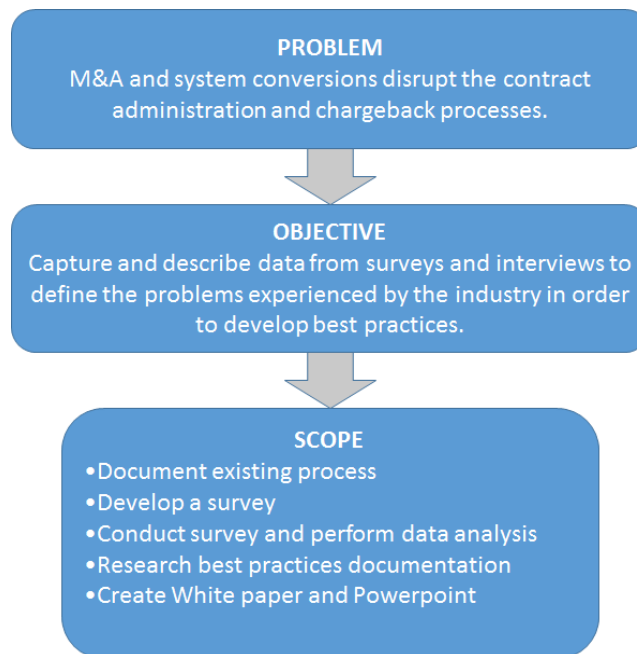


Figure 1

Methodology

To document the existing process and research best practices, the team gathered information via two methods, a survey of the industry and through interviews conducted with SMEs in the field of contract and chargeback administration. For the survey, the team spent three weeks gathering information which included; research into contract and chargeback administration, speaking with sponsors at HDA and through conversations with SMEs during weekly status calls and the initial round of interviews. The survey was initially sent by HDA to organizations such as, distributors, manufacturers and group purchasing organizations (GPOs). After the survey was sent to all participants, the team continued weekly calls and conducted in-depth interviews with SMEs. When the survey was closed, the team analyzed responses to identify patterns that could negatively or positively affect contract and chargeback administration processes during mergers and acquisitions and system conversions. Based on the survey data and information gathered from interviews, the team developed recommendations which can be found at the conclusion of this paper.

Survey Background

The scope of the survey sought to discover how mergers and acquisitions and system conversions may lead to disruption in the chargeback and contract administration process.

The survey was sent to 147 HDA member and affiliate companies, of which 32 Distributors, Manufacturers and GPOs responded to the survey via an online survey platform, Qualtrics. The survey had 42 questions ranging from closed-ended, rating scale, heat map and open-ended questions. The results from the survey can be found in later sections of this paper.

Interview Profile

Within a three-month period, the team conducted 10 interviews with SMEs in a variety of different organization types across the healthcare industry, including three manufacturers, two distributors and two GPOs. In conducting these interviews, the team sought to capture the voice of trade partners in their own words pertaining to managing change in contract and chargeback administration as well as contract and chargeback administration in general. This information extended beyond what the survey was able to capture and allowed the team to clarify certain areas that remained unclear in researching best practices.

Current Situation

Within the context of contract and chargeback administration, organizational and product line changes can have a negative financial impact if they are not managed properly. In the typical process, a manufacturer first negotiates a contract price for pharmaceuticals with a contracting entity such as a GPO or hospital. Once the contract is negotiated, the manufacturer will then notify the distributors of the contract pricing, typically using an EDI 845 message. At any point, the distributor will purchase pharmaceutical drugs from the manufacturer at the wholesale acquisition cost (WAC) and hold them in inventory. A pharmacy covered under the contract will order pharmaceutical drugs from their distributor, specifying the contract and contract pricing associated with the order and the distributor will honor the contract price.

The distributor will notify the manufacturer of all the pharmaceutical drugs that were sold under contract pricing, typically using EDI 844 messages. The EDI 844 messages are sent from the distributor to the manufacturer to request payment for the difference between the WAC price paid by the distributor and the contract price for which the pharmaceuticals were sold, or the “chargeback.” The manufacturer will notify the distributor that they either agree with the chargeback or have decided to reject the chargeback, typically using an EDI 849 message.

The constant changes in the supply chain due to company mergers, acquisitions, product line acquisitions and product line divestitures add complexity to the contract and chargeback process. For example, consider the scenario when one manufacturer purchases a product line from another manufacturer. The distributor must be informed of this change with sufficient lead time so that the distributor can send their EDI 844 messages regarding contract sales to the correct manufacturer. The distributor will also need enough time to load all the pricing information from the new manufacturer. If the distributor sends the EDI 844 message to the wrong manufacturer they will likely receive an EDI 849 message with a rejection. This will delay the remittance to the distributor while the issue is worked out, tying up cash owed to the distributor. In some cases, the distributor may not have an existing EDI 844/849 feed with the acquiring manufacturer, so time and resources will need to be dedicated at both the distributor and the acquiring manufacturer to implement the new interfaces.

The above example makes it clear that communications related to these changes are extremely important throughout many levels within both the manufacturer and the distributor and must be shared with enough lead time. Undoubtedly, many people at the acquiring manufacturer and at the distributor will be aware of the product line acquisition due to the steps necessary to ensure continuity of supply. However, it may not be as apparent that many stakeholders in the contracts and chargeback administration areas as well as stakeholders in information technology will need to be aware of the changes with sufficient lead time to adjust the systems accordingly.

Contract administration and chargebacks are activities that take place daily in the supply chain. However, organizational changes, product changes and system conversions can impact these processes, both inside the organizations involved and across the supply chain. In the survey, 28 respondents reported being involved in 94 different types of transactions in the last 24 months. For the purpose of the survey, transactions were defined as: company mergers, company acquisitions, business segment acquisitions, business segment divestitures, product line acquisitions and product line divestitures. See Figure 2.

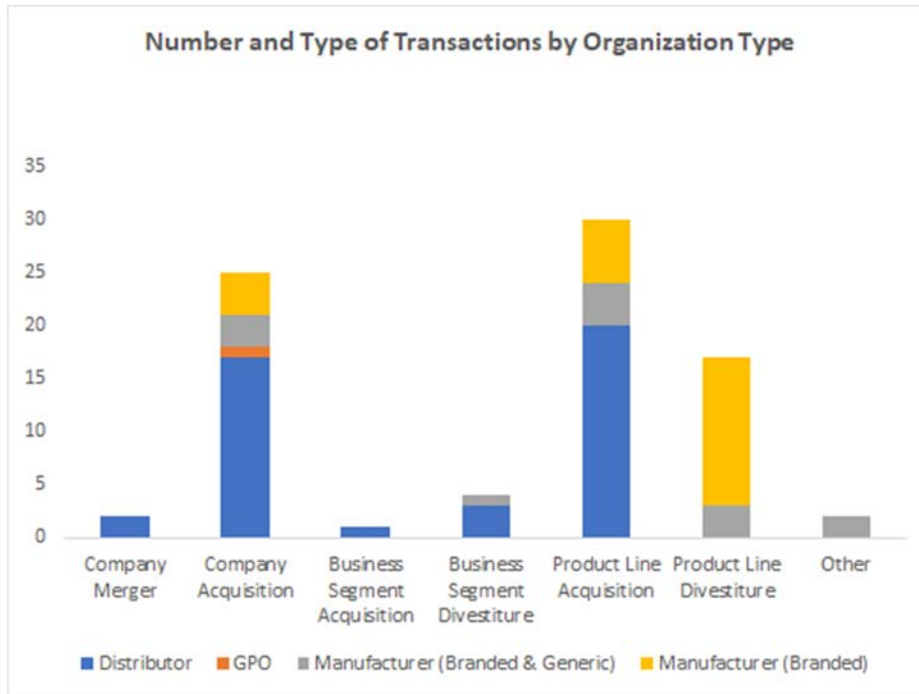


Figure 2

With frequent organizational and product change activity taking place across the supply chain and organizations updating their technology, the impact on the chargeback process is an increase in the number of chargeback rejections. According to the 2017 HDA Factbook, the industry chargeback rejection rate was a weighted average of 0.7% which makes it an approximately 4 Sigma processes. Almost 45% of survey respondents reported chargeback rejection rates post-transaction in the range of 1-5% yielding a process sigma of 3.8 to 3.1.

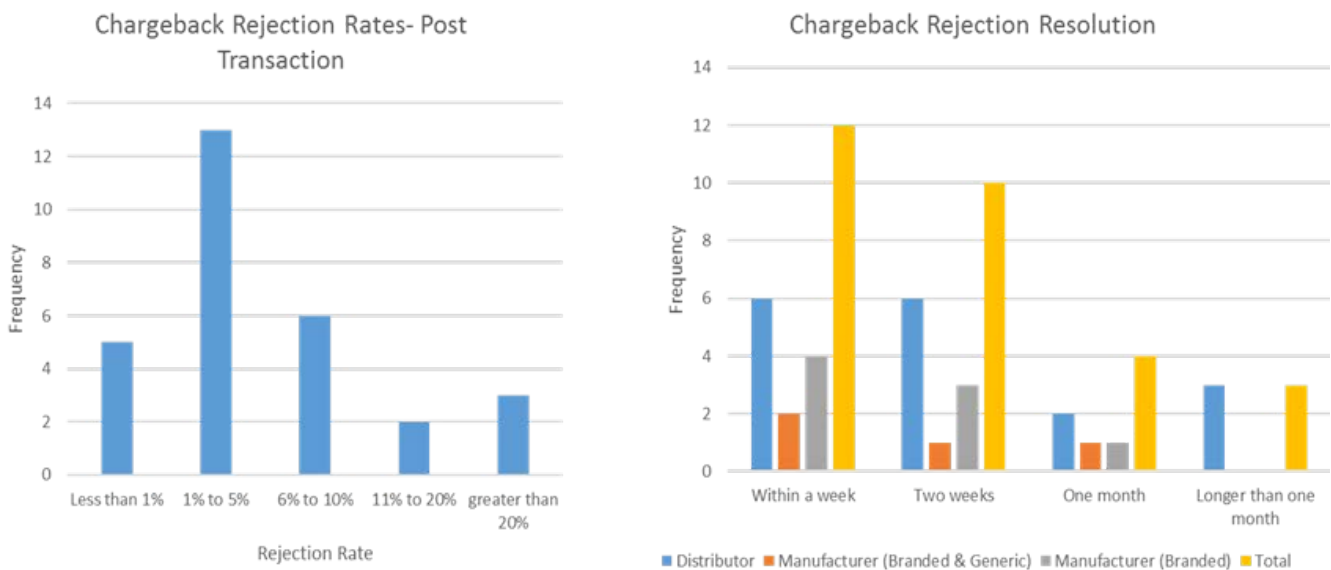


Figure 3

While unable to derive an industry cost of rejected chargebacks, the team found through industry interviews that costs related to rejections included: opportunity costs of analysts working on additional rejections, write-offs on rejections when resolutions cannot be reached and price differences that cannot be passed back to the ordering entity.

Other complications identified were a lack of standardization across the industry including terminology and communication. For example, the survey captured participants using anywhere between 1 and 30 classes of trade. Additionally, information included on trade letter announcements varied notably and contained terminology which can have various interpretations in the industry.

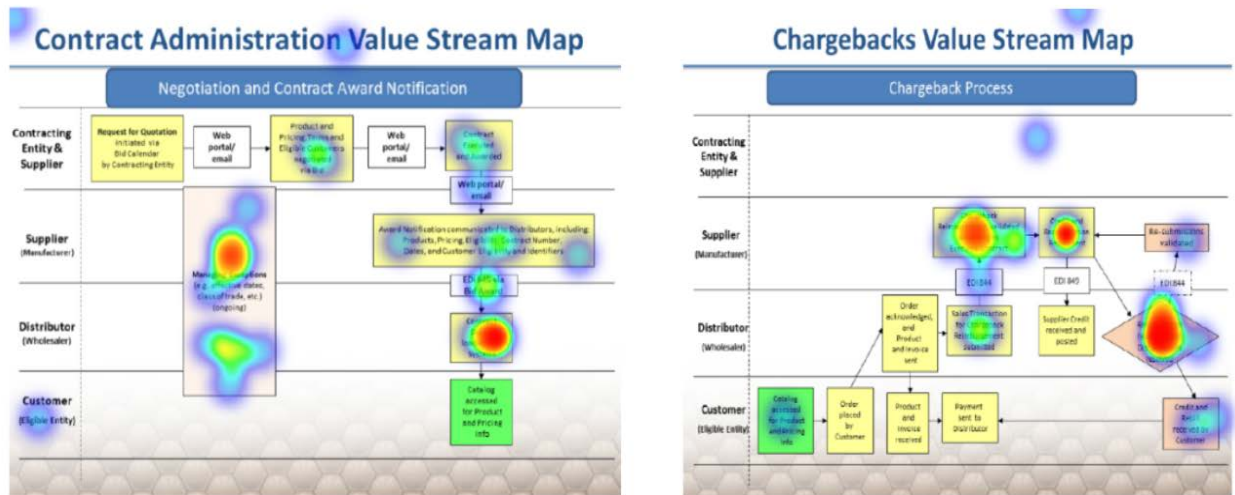


Figure 4

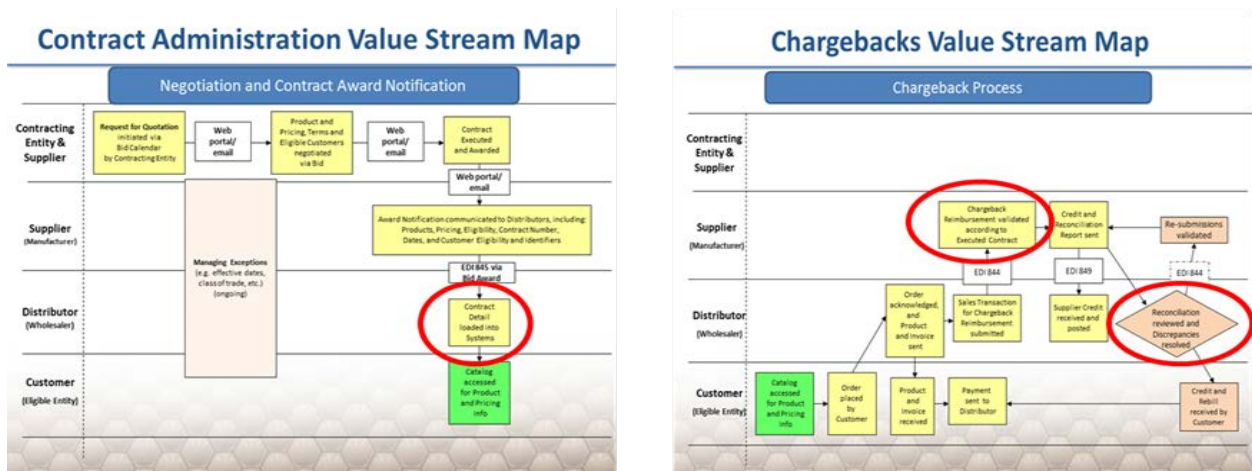


Figure 5

The above process maps highlight the areas in which respondents thought issues were most likely to occur. The survey identified six key focus areas that led to issues during organizational changes with the top two issues identified as communication and amount of lead time available for planning and integration purposes.

Issues

Focus Areas

The top six focus areas identified through the survey included: communication, amount of lead time, IT/systems, project management, terminology/definitions and other. When the survey participants were asked to select obstacles that contributed to smooth transitions, communication and amount of lead time were the top two areas identified by all participants as key factors that contributed the most to the success of the transactions.

Communication

Communication related responses identified the need for consistent and timely coordination of transparent communication among all internal and all external stakeholders to keep everyone apprised of evolving changes and evolving timelines. Additionally, a need for relentless follow-up, to assure that all stakeholders are aware of all changes at all times, played a crucial role primarily due to aggressive timing constraints.

Lead Time

The survey identified a clear correlation between amount of lead time and the number of issues experienced. According to survey comments, 91% of all respondents pointed out that an adequate amount of lead time available for planning, testing and integration efforts significantly contributed to successful outcomes. On average, companies required 3-5 days to successfully complete each step.

However, when steps were added to the initial plan or when stakeholders were required to either submit additional paperwork, for example, to confirm member eligibility under certain programs, participants pointed out the importance of adjusting initial timelines to further extend the lead time required to complete each affected step.

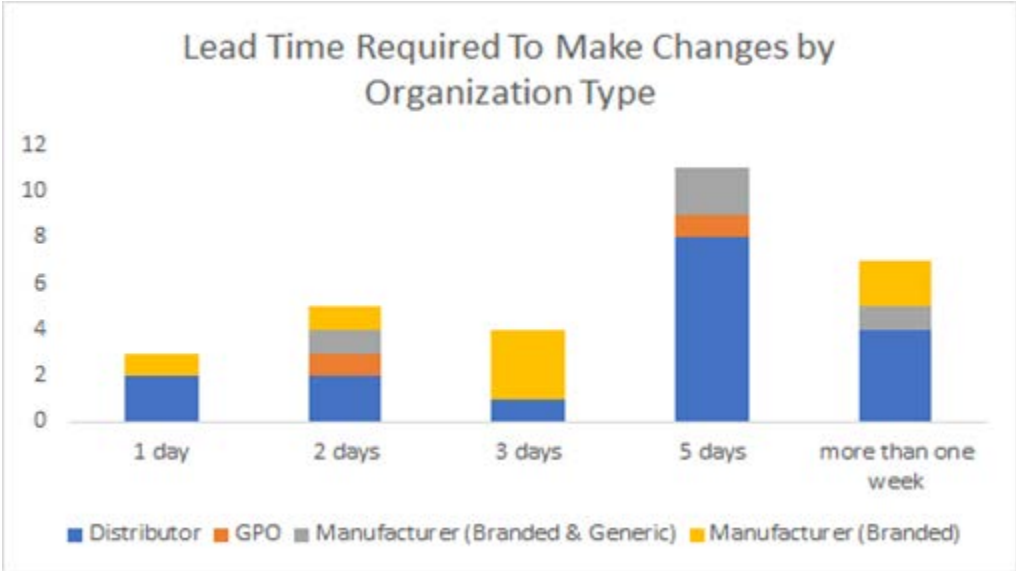


Figure 6

When asked to provide further details on lead time related issues, the survey responses can be categorized as follows:

Planning & Preparation

“Adequate lead time allows for proper planning and preparation prior to a transaction. During this time, a proactive approach can be taken towards potential issues and allows for ample testing and validation. With enough time, proper and complete communication can be prepared and disseminated to all involved parties both internal and external. Additionally, training and user guides can be developed prior to going live in order to minimize issues once live.”

Reduced Errors

“With a rushed timeline, the need for faster entries creates an opportunity for increased errors. Adequate lead time allows for proper data validation to ensure accuracy.”

Systems & Pricing

“Delays in loading contract pricing has the potential to create issues downstream in the form of rejected chargebacks. This increase in rejections requires time for both the manufacturer and distributor to resolve. In addition to pricing, lead time is necessary to ensure agreement on contract eligibility.”

Ability to Resolve Issues

“Having time to perform an assessment to determine what potential issues may occur and create mitigation plans can improve the ability to resolve issues once they occur. With limited timelines, issues not resolved or detected can lead to an overwhelming number of rejected chargebacks. For larger organizations and a high volume of chargebacks, issues causing an overwhelming amount of rejections require significant time and resources to resolve.”

IT & Systems

At least 10 various IT/systems were identified through the survey as currently being used for contract and chargeback administration. According to survey participants, an adequate amount of lead time for testing IT/systems prior to going live, was one of the most important components to a successful integration. Additional time was required to implement changes when integrating homegrown and legacy systems. One comment pointed out that system conversion can result in “different or new data fields sent via EDI” and if integration efforts are not tested prior to going live it can cause “all EDI to fail on either side with complete loss of data.”

Project Management, Terminology, Definitions & Other

Additionally, participants pointed out a need to take companies’ cultures and business models into consideration when planning to integrate. Other challenges included large companies with business units operating as silos, causing delays in the decision-making as well as delays due to layered, trickle up and down flow of information. Inconsistent definitions, numerous classes of trade, complex contracts/rebates and pricing structures were identified as additional components that added further complexity to integration process. The ability to manage the smallest details in large scale transactions with numerous stakeholders, numerous changes and evolving timelines highlighted the need for a formalized project management process.

Involvement from Contract and Chargebacks Teams

When survey respondents were asked how the contracts and chargeback teams are involved in integration processes related to transactions and system conversions, there was a wide range of responses provided. In general, responses can be grouped into those that identified either strategic involvement or tactical involvement. Responses that indicated a strategic involvement referred to instances where the contract and chargeback teams were involved in all phases of the project including initiation and planning phases. Tactical involvement indicated that the contract and chargeback teams were only involved in the testing of the changes. Involvement of contract and chargeback teams in the initial and planning phases can help identify all affected resources including employees and IT/systems and help uncover issues and concerns prior to implementation and minimize rework.

Rejected Chargebacks

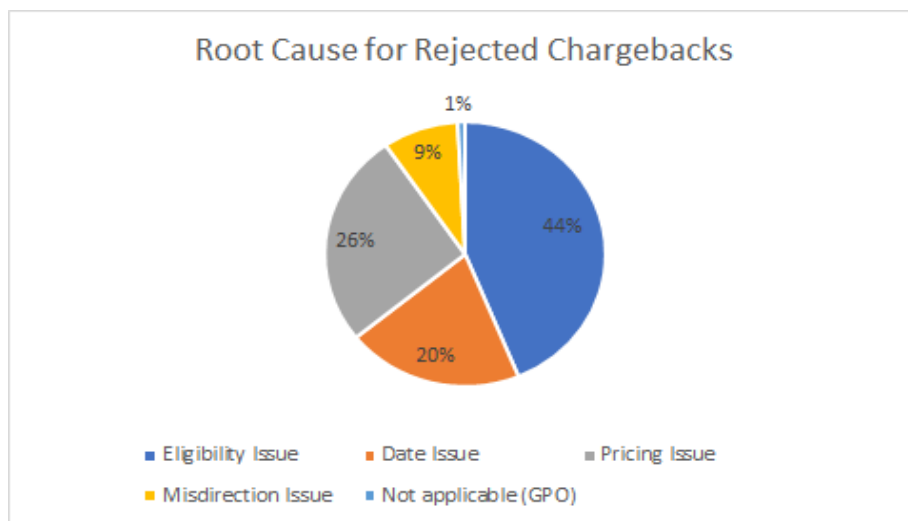


Figure 7

There was a total of 31 responses for the root cause of rejected chargebacks; 8 manufacturers (branded), 4 manufacturers (branded and generic), and 17 distributors. Two responses were not applicable (GPOs). Recipients were asked to rank the prevalence of root causes for rejected chargebacks. The most prevalent categories indicated by recipients were eligibility, pricing and date issues. In addition, a major element within eligibility issues indicated by SMEs and within the open-ended survey questions was class of trade.

Class of Trade

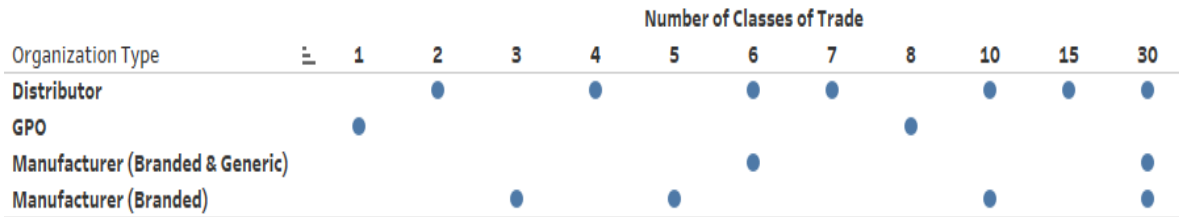


Figure 8

In contract administration, pharmaceutical companies have a varying number of classes of trade. When contracts are written, and systems are set up, class of trade becomes an extremely important factor that may lead to eligibility issues when dealing with chargebacks. Unfortunately, in defining class of trade, being able to identify a specific customer or organizational unit within a customer for the purposes of class of trade can be challenging. Customers can operate under varying classes of trades, for example different units of the same hospital might be defined as having different classes of trade according to a manufacturer. The team learned that while there may be benefits to standardizing on class of trade definitions across the supply chain, many companies view their class of trade definitions as proprietary information that provides a strategic advantage that would be lost if standardization was required. Figure 8 shows the range of responses to the question asking HDA member and affiliate companies about number of classes managed at each company.

Trade Letter

During the acquisition or divestiture of a product, a notification is sent to the affected parties through a trade letter announcement. The announcement provides key information that can be used to reduce issues during the chargeback administration process. The survey recipients were asked as to how often chargeback information, return information and start date information are included in the announcement and if having this information has any effect on the chargeback administration process.

Chargeback Information

According to the survey, over 75% of the distributors responded that chargeback information is included 60% or less of the time and slightly over 50% for the overall response. See Figure 9 for total number of responses and Figure 10 on percentage of total responses.

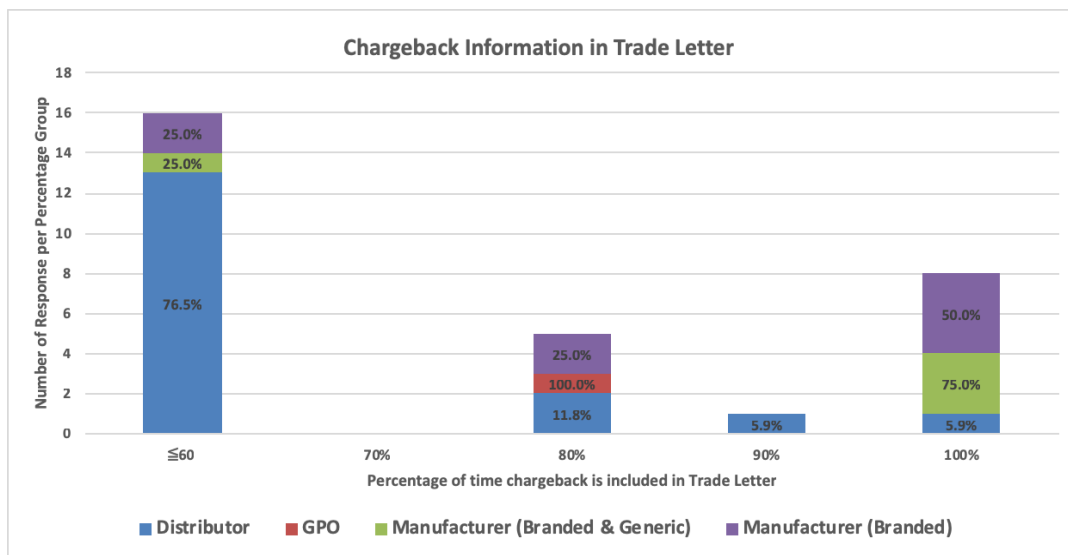


Figure 9

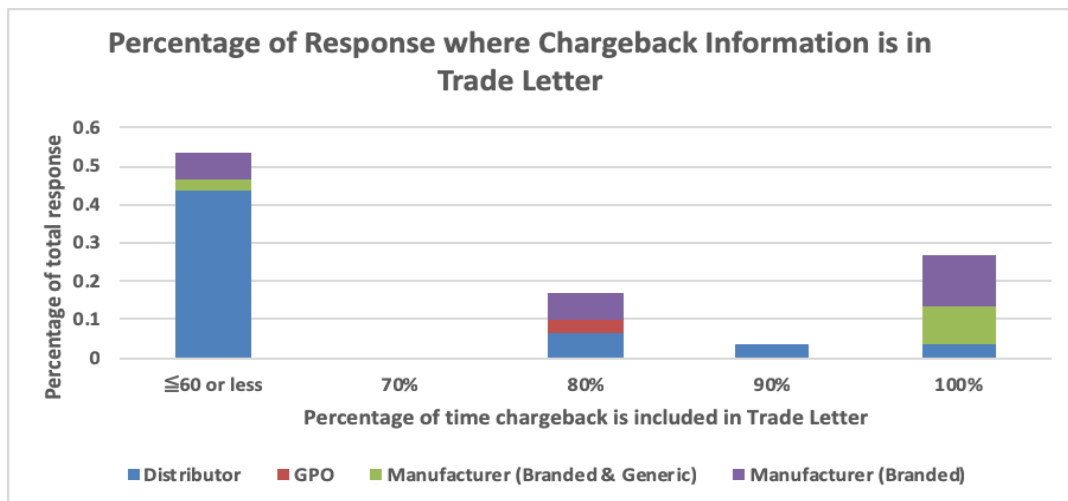


Figure 10

When looking into how often chargeback claims are rejected following the completion of an integration, the Rutgers team found that when 60% or less of the chargeback information is included in the trade letter announcement, the rejection claim is 27%. Whereas when chargeback information is included in the announcement more than 60% of the time, the rejection claim is only 8%. See Figure 11.

In addition, when 60% or less of chargeback information is included in the trade letter announcement, the response shows that 33% of the time it will take over two weeks to resolve the issue. This is much higher than when chargeback information is included over 60% of the time, which is only 8%. See Figure 12. Overall, when chargeback information is included 60% or less of the time, the rate of chargeback claims being rejected is higher and it also takes longer to resolve the issue.

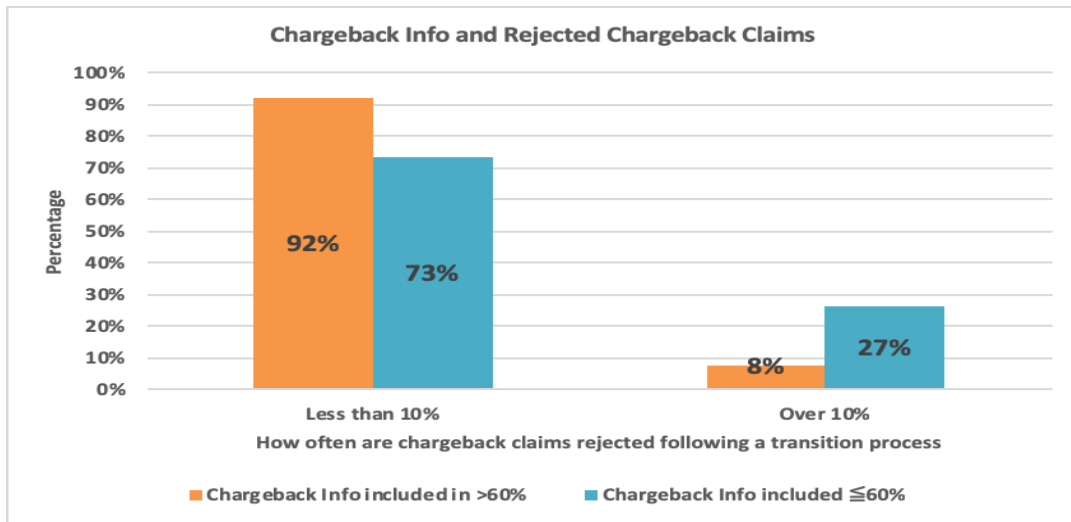


Figure 11

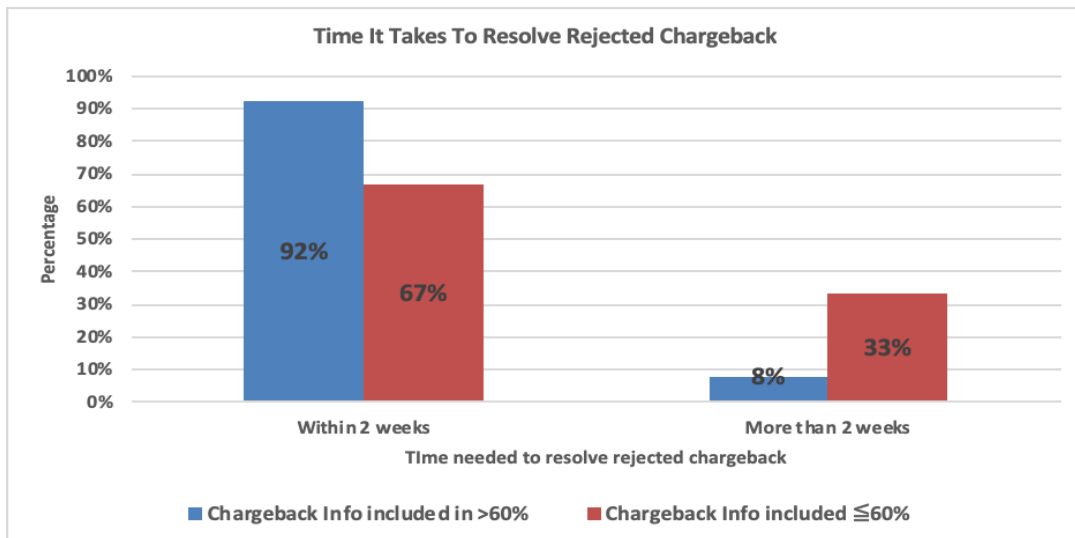


Figure 12

When comparing the response between trade letter and root cause from chargebacks there were no significant differences between scenarios where chargeback information is included 60% or less of the time vs. when the information was included more than 60% of the time.

Per Figure 13, when chargeback information is included 60% or less of the time; 43% indicated eligibility, 30% indicated pricing and 21% indicated start date as the root cause. When the information is included over 60% of the time; 46% indicated eligibility, 21% indicated pricing and 19% indicated start date as the root cause. Based on the survey responses, the team found that having chargeback information can reduce the rejection rate. For a rejected chargeback, the team cannot determine the root cause based on not having the information in the trade letter announcement.

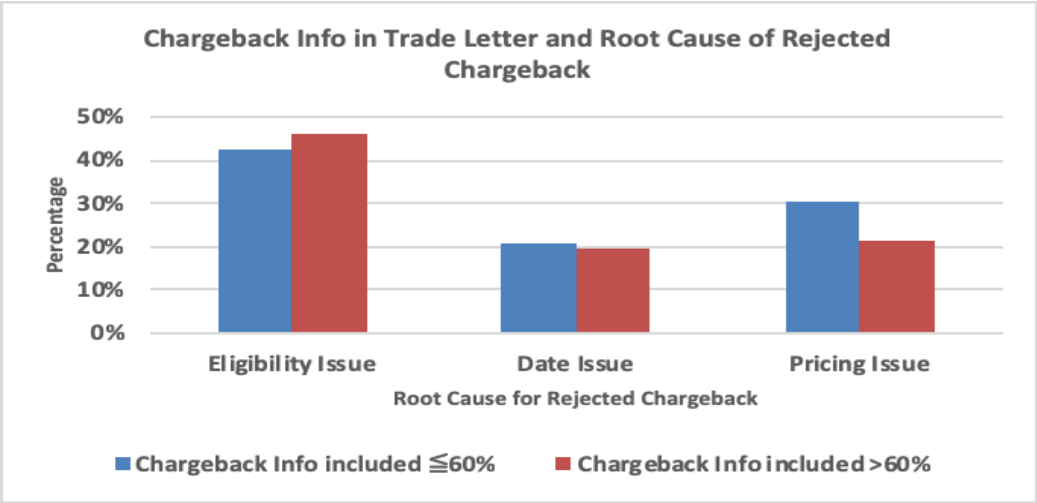


Figure 13

Return Information

Figure 14 shows the total number of responses per percentage group and Figure 15 shows the percentage of total response regarding return information included in the trade letter announcement. From the two graphs, the team found that unlike chargeback information, return information is more likely to be included in the trade letter.

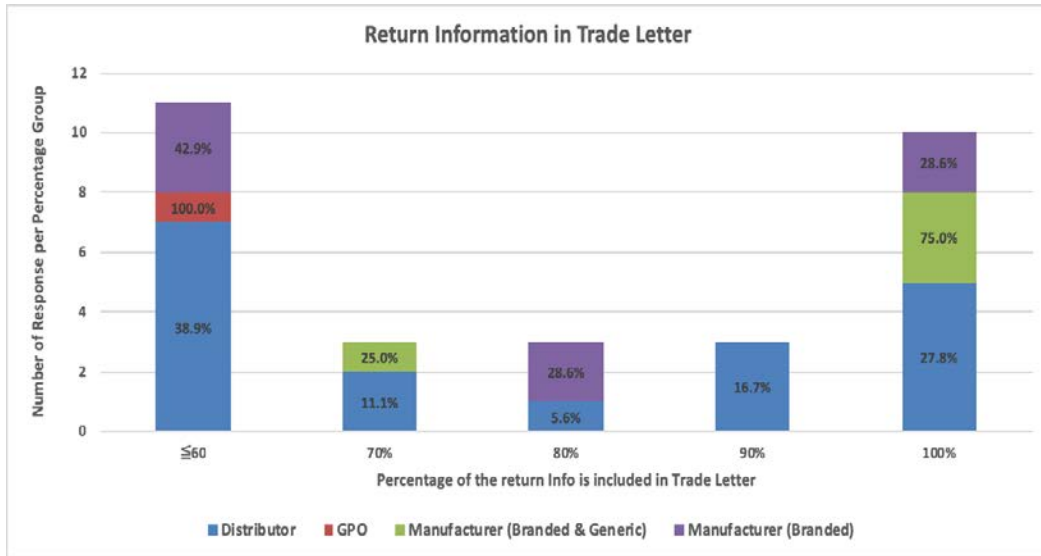


Figure 14

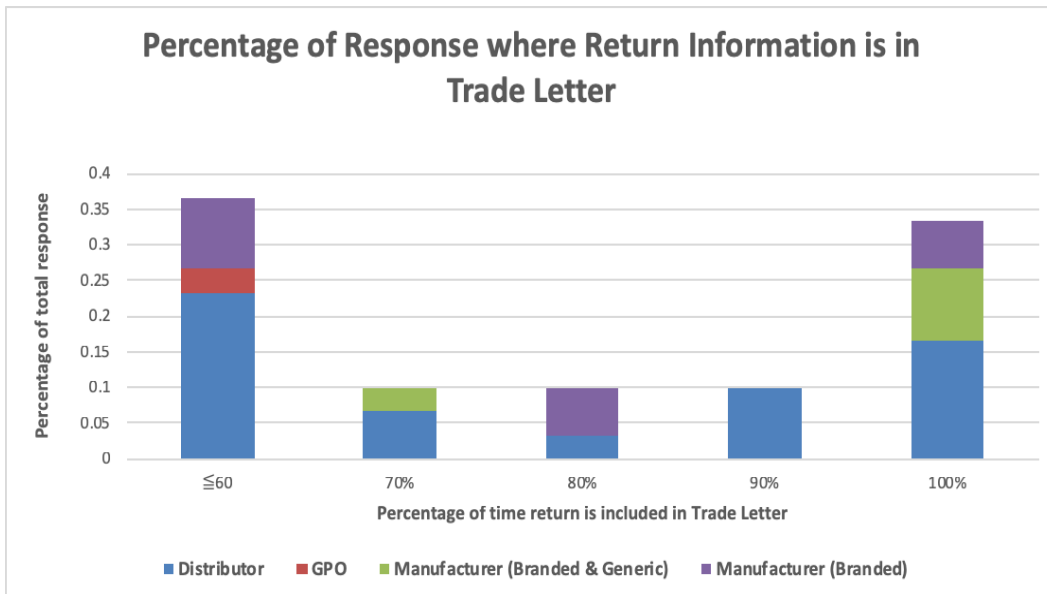


Figure 15

Start Date Information

65% of total respondents indicated that start date information is included in the trade letter announcement 100% of the time. See Figure 16 for total number of response and Figure 17 on percentage of total response.

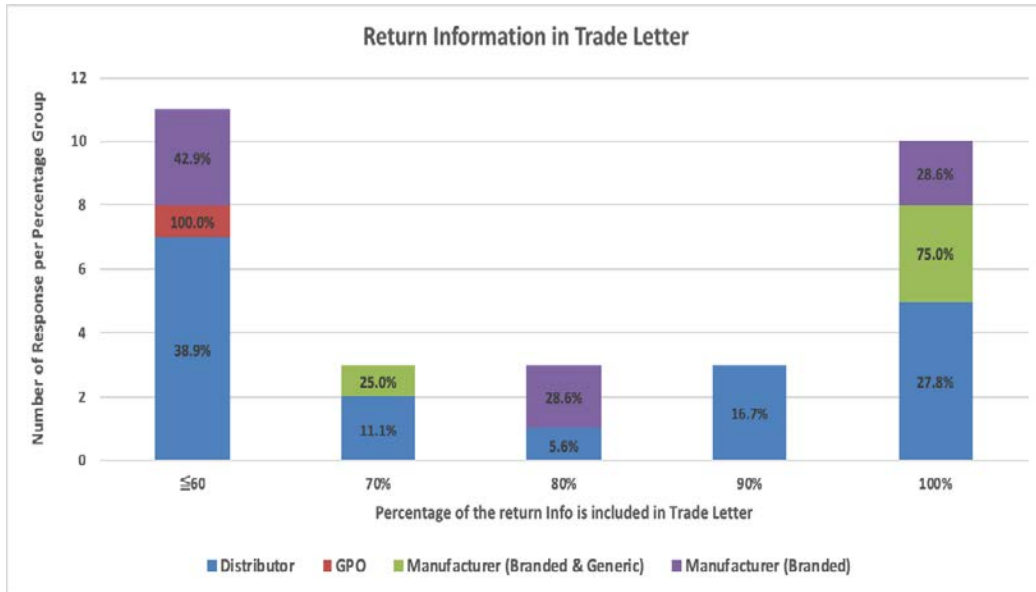


Figure 16

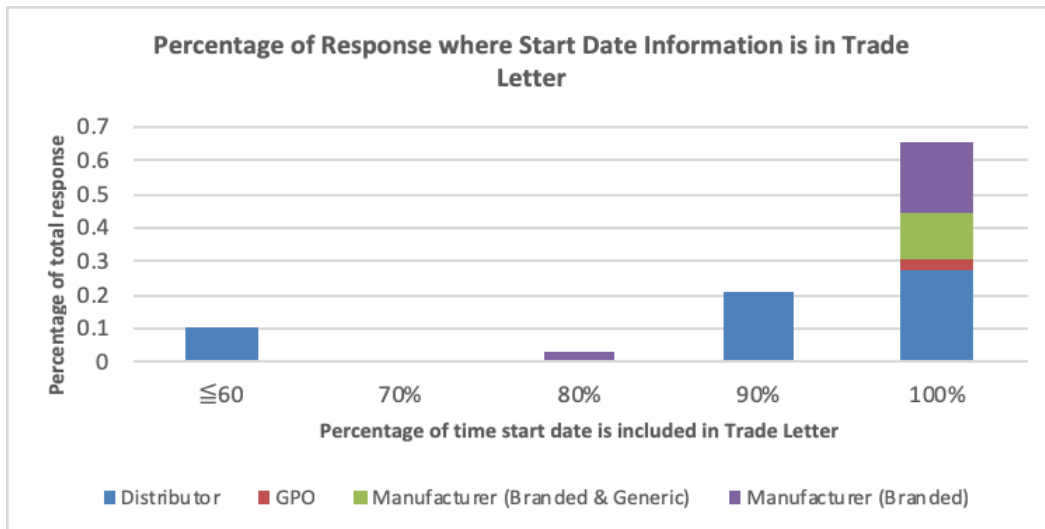


Figure 17

Unlike chargeback information, the team is unable to determine any correlation between having return information and start date information on the trade letter announcement and the percentage of rejected chargeback claims and time it takes to resolve the chargeback issues.

Recommendations

In putting recommendations together, the team focused not only on the top identified focus areas, but also took into consideration that for many companies going through transactions it is still a one-time process and each one of those transactions is unique. It is important to also develop an understanding of the final state of entities involved following a completion of the transaction.

Therefore, the team believes that a good approach would be to treat each transaction as a project. The below points include relevant project stages and contract and chargeback administration integration related recommendations.

1. Initiation Stage

- A. Create a contract and chargeback administration integration team as soon as a transaction is announced consisting of:
 - a) Project manager who will serve as a representative for the contract and chargeback administration team at the main integration team meetings. The project manager should have a solid understanding of: all players in the supply chain, contract and chargeback administration processes, and business models and cultures of the entities involved in the transaction.
 - b) Subject-matter experts
 - c) Membership/eligibility expert(s) in organizations that will need support integrating contracts, membership/eligibility expert(s) will work on aligning eligibility and membership information prior, during and following a transaction.

2. Planning/Due Diligence

- A. Identify all stakeholders involved and all products/contracts affected following a transaction – identify how members under all contracts will be defined during and following a transaction.
 - a) Manufacturer
 - b) Distributor
 - c) GPO
 - d) Health Entity
- B. Identify all resources affected prior, during and following a transaction including:
 - a) Employees
 - b) IT/systems
- C. Create a terminology reference document – where each definition is clearly defined. Automatically attach to all internal and external communication.
- D. Create communication plan – all communication should be managed by the Project Manager including:
 - a) Internal communications SOP:
 - General mailbox (with terminology document automatically attached to all emails) should be set up with all identified (need to know) internal stakeholders included on the distribution list – emails sent or received would be sent to general mailbox and automatically forwarded to all recipients on the distribution list; if participants are added to the distribution list – they will also have access to full content of the mailbox;

- Weekly calls should be set-up among all internal stakeholders — to discuss completed steps and next steps; and,
 - Status Report should be sent each week — with completed and next steps.
- b) External communications SOP:
- General mailbox (with terminology document automatically attached to all emails) should be set up with all identified (need to know) external stakeholders included on the distribution list emails sent or received would be sent to general mailbox and automatically forwarded to all recipients on the distribution list; if participants are added to distribution list — they will also have access to full content of the mailbox;
 - Weekly calls should be set-up among all external stakeholders — to discuss completed steps and next steps; and,
 - Status report should be sent each week — with completed and next steps.
- c) Communication with respect to details of the transaction:
- Information in the trade letter announcement; and,
 - Follow up communication after trade letter announcement.
- E. Create and maintain a change log — for all internal and all external steps (completed and planned).
- F. Create a timeline indicating a critical path:
- a) Specify minimum amount of time needed to complete each step (3-5 days as per Survey);
 - b) Identify interdependent steps and allocate more time if changes are needed; and,
 - c) Take into consideration additional steps required to complete paperwork to verify that entities are eligible under certain programs, as well as allocate time to verify that the Drug Enforcement Agency (DEA) numbers are up to date.
- G. Create IT/systems integration and testing timeline:
- a) Identify which systems will need to change;
 - b) Identify which technical people will be needed to make the changes and get buy-in on the changes and the schedule;
 - c) Seek out opportunities to minimize change required by other parties;
 - d) Whenever possible validate changes in a non-production environment; and,
 - e) Pursue multiple incremental changes instead of one very large change.
- H. Create risk identification/management such as an FMEA (failure modes and effects analysis) to understand potential risks that may be faced, their priority, and mitigation plans.

3. Execution Stage

- A. All planning/due diligence steps should be completed prior to start of the execution stage.

4. Monitor/Control (for the entire duration of the project)

- A. Relentless follow-up (timing is crucial);
- B. Monitor deliverables against the plan and timelines;
- C. Monitor changes to original requests - make sure that all changes to timelines are immediately communicated to all applicable stakeholders (internal and external);
- D. Develop reporting for chargeback rejections in order to capture trends and understand root causes; and,
- E. Monitor testing of all system changes.

5. Close/Post-Close Stage

- A. Make project documentation accessible that documents what decisions and changes (and justifications) were made as part of the project.
- B. Capture Lessons Learned after each transaction/system conversion.
 - a) What went well and why?
 - b) Did it not go well? How do we mitigate these in the future?
- C. Create centralized repository of lessons learned for knowledge sharing in the event of employee turnover.
- D. Review previous lessons learned prior to new transactions/system conversions and share key points with all parties involved.

Works Cited

Lagano, Stephen. "Understanding Class of Trade Concepts." Pharmaceutical Commerce, 8 Jan. 2012, pharmaceuticalcommerce.com/information-technology/understanding-class-of-trade-concepts/.

"HDMA Guidelines for Optimizing the Contract Administration and Chargeback Processes." Healthcare Distribution Management Association. 2014.

"88th Edition HDA Factbook." HDA Research Foundation, 2017.