BUSINESS STRATEGY

Business Strategy: There's a Hole in My (Revenue) Bucket! Revenue Leakage in Life Sciences — Who's Plugging the Holes, and How Can They Help?

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IDC HEALTH INSIGHTS OPINION

In 2009, IDC Health Insights conducted research that found that pharmaceutical companies lost approximately 4.4% of sales through revenue leakage in areas including chargeback discrepancies, duplicate chargebacks, omitted reverse chargebacks, rebate errors, return discrepancies, and concealed shortages. At the time, life science companies had high expectations for improvement in these trouble areas due to the upcoming track and trace regulations, which would have helped better illuminate product movement through the supply chain. Unfortunately, these regulations were delayed. Without the regulatory environment forcing systemic change, revenue leakage is nearly impossible to eliminate. However, while a complete fix is not yet available, many leading life science companies have taken important steps toward better identifying revenue leakage in their organizations and have made strides toward significantly reducing their exposure. Key takeaways from this report include:

- Manufacturers and distributors of pharmaceuticals, biologics, and medical devices have succeeded in reducing revenue leakage by teaming with industry experts who understand revenue management and sources of revenue leakage.
- In undertaking these initiatives, it is critical to first understand and document current business processes thoroughly, utilizing process operators.
- By identifying the largest sources of process errors and then determining root causes, the application of targeted automated technology solutions has a high rate of success.
- Further reduction of revenue leakage will require cooperative solutions between manufacturers, distributors, and customers.
- In coming years, manufacturers expect continued reduction in revenue leakage through the implementation of track and trace regulations and serialization of products.

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IN THIS STUDY

To help illustrate how life science companies are approaching the challenge of reducing revenue leakage, IDC Health Insights recently conducted several in-depth interviews on the topic with manufacturers and wholesalers, both generic and branded, including organizations ranging from smaller regional companies to top 5 global manufacturers. This case study-based report provides illustrative examples of how life science companies today are working to reduce their exposure and improve their approach to revenue leakage. This report also provides insight into how several key technology vendors and consulting firms are helping life science companies along this journey.

SITUATION OVERVIEW

Though regulations had been delayed, the 2013 passage of the Drug Quality and Security Act (DQSA) helped put serialization back on the plate of pharmaceutical manufacturers and distributors.

By January 1, 2015, the DQSA required manufacturers to incorporate product transaction data into a single document (either electronic or paper) each time ownership is transferred. This document must include lot-level transaction data information, complete transaction history, and a transaction statement. November 2017 will bring additional requirements, such that information must be available electronically and a product identifier must be affixed or imprinted on the label at the lot or case level. Unfortunately, the requirement for item-level serialization (which is the holy grail for fixing revenue leakage) has been postponed until 2023. However, once lot-level serialization is in effect, tracking of individual orders and products for returns, rebates, and special pricing such as 340B programs should be significantly improved. In addition, product diversion to other regions and unauthorized resellers or for unauthorized purposes will likewise be reduced.

Business Needs

Pharmaceutical manufacturers recognize that reconciliation process leakage exists and are eager to improve their bottom line by correcting these issues. Awareness around chargeback-related revenue leakage has continued to rise, with 63% of manufacturers considering this issue to be a large or medium-sized problem as long ago as 2009 and likely higher today.

Reducing revenue leakage remains a major opportunity for pharmaceutical manufacturers to improve their bottom line while under top-line pressure from regulation, patent expiration, and industry consolidation. Headlines scream about out-of-control drug prices, especially for specialty and rare disease formulations. By addressing chargeback reconciliation and other sources of revenue leakage more thoroughly, efficiently, and accurately, pharmas can ameliorate some of the effects of these converging forces.

Management Challenges

Management teams at pharmaceutical companies are under pressure to do more with less with regard to revenue leakage. There is a strong push to automate as much reconciliation of chargebacks and related transactions as possible. Industry consolidation, patent expiration and the rise of generics, new regulations related to the Affordable Care Act (ACA) of 2010, migration of enterprise software to the cloud, and other factors are converging to force companies to adopt more innovative and automated approaches to plugging the holes that allow revenue leakage.

Over the past few years, several revenue management software vendors and professional services firms with deep life science industry expertise have increased their focus on this issue and have evolved their offerings to better assist with the optimization of these processes. The following section presents several case studies that illustrate how this work is being done.

THE APPROACH

Case Study: Top 10 Pharma Saves $100 Million Using Revitas to Streamline Chargeback Requests

Background

A top 10 pharmaceutical manufacturer adopted the Revitas Revenue Manager system in 2011 to handle chargebacks and rebates after acquiring two other pharmas. Both of the acquired companies were running different classic versions of Revitas software prior to the mergers.

The parent company also used a legacy Revitas system but only began to use the Revenue Manager chargeback module after its first acquisition in 2009. Since going live with Revitas Revenue Manager companywide, over $100 million has been saved compared with the legacy system.

The combined Revitas Revenue Manager system runs on Revitas Flex, a scalable cloud platform designed to provide common interfaces, analytics, and master data across multiple Revitas applications.

What Happened

After consolidating chargeback and rebate activity under Revenue Manager, the company set out to streamline processes by assigning validations to the system. The pharmaceutical manufacturer reports that the Revitas system can create any number of custom validations in addition to the 80–100 standard validation fields. These can be utilized anywhere in the process, including at contract setup or new customer setup. The company utilizes about 40 custom validations. For example, a wholesaler might submit a chargeback request against an old contract, but the Revitas custom validation can recognize this. So instead of rejecting the chargeback request, the software will submit the request against the new contract. This saves time and money for both parties. In another example, the user can assign a tolerance such as the percentage of price. In this case, the request which would normally be rejected for "wrong price" can be accepted if the wrong price is within a small percentage of the correct contract price.

Chargeback request responses and processes can be tailored to specific customers. For instance, the company noticed that one large customer seemed to be automatically resubmitting chargeback requests that had been rejected. By monitoring and adjusting the format and timing of the response, this practice diminished. The manufacturer can now report that even with 18 million chargeback lines per year, 100% are resolved within 30 days.

Some 70% of chargeback activity at the company is related to membership status. Revitas has automated membership roster updates, which were previously a common cause of chargeback and rebate errors and delays. For example, when a group purchasing organization (GPO) sends a membership roster or update contained in a spreadsheet, it can be decoded (usually in Unix) and then sent to the Revitas system, which automatically processes the advanced membership roster. This propagates to membership eligibility and is put on the contract. The customer receives an updated

Price Authorization Acknowledgment/Status (845) within one day. Under the legacy system, this process might take a week or more. This capability is particularly valuable for products such as vaccines, where several companies may offer quite competitive pricing. A physician buying group may elect to buy the vaccine not on price but from the first valid quote received.

Previously, 25% of chargeback issues were related to Public Health Service (PHS) 340B pricing issues. Thanks to the faster, automated roster updates possible in the Revitas system, Health Resources and Services Administration (HRSA) databases are updated several times per month. Today, chargeback issues related to 340B pricing are extremely rare.

Looking Ahead

Although not commonly thought of as "revenue leakage," one indirect benefit made possible due to the Revitas system is a significant savings in required working capital by automatically timing chargeback and rebate payments to wholesalers and other customers. The pharma saves $12 million in working capital by intelligently timing rebates and reimbursements. Operationally, the rebate could be ready two weeks early, but the Revitas system allows the company to wait until two days before it is due to send the rebate. Revitas software automatically queries the payment terms to decide when to pay.

In ongoing work with Revitas, the pharmaceutical manufacturer plans to upgrade to the newest Revitas Government Pricing module to ensure automated price adherence for programs like the Medicaid Drug Rebate Program, Medicare Part D, PHS, and more. The company is also implementing Revitas Validata, which provides real-time and comprehensive script-level validation. In addition, the company's growing portfolio of generics mean high volumes and low margins, making accurate pricing, rebates, and chargebacks all the more important.

Case Study: iContracts Helps Pharma Subsidiary in the United States Plug Revenue Leakage After ACA Changes

Background

In 2009, a United States-based specialty pharmaceutical manufacturer was acquired by a larger European pharma. The resulting subsidiary was facing the challenge of merging its financial and operating systems. At this time, the subsidiary realized that it needed a much more automated approach for dealing with revenue leakage, particularly the management of chargeback requests by wholesalers in their generic and branded drug programs.

Prior to the merger, chargebacks and requests were being tracked on Microsoft Excel spreadsheets. Matching the requests with original orders was tedious and eventually impossible, given the volume of transactions. The company interviewed six providers of revenue management software to help it automate these processes. According to the director of Contracts and Compliance, iContracts was chosen for its suite of solutions, industry expertise, and emphasis on providing excellent customer service for manufacturers of all sizes.

What Happened

During the 2010 implementation of the iContracts system to handle chargeback requests and reconciliation, the Affordable Care Act was passed, complicating the company's task significantly. The company implemented the full suite of iContracts commercial and government solutions, including robust reporting and analytics solutions. Because of this implementation, the iContracts system helped the manufacturer not only with chargeback management but also with government programs such as Medicaid and changes resulting from the ACA. For example, "5i" drugs (inhalation, infusion, instilled,

implanted, and injectable) were required to pass a new test based on the percentage sold or destined (through wholesalers) to retail community pharmacies. iContracts was able to make the change immediately. The director of Contracts and Compliance commented, "iContracts helped us develop a solid class-of-trade schema where none had existed before."

Prior to the iContracts launch at the pharma, chargeback requests originating at the wholesalers were pushed through without verification due to the labor-intensive process of poring through spreadsheets. Now the company receives an immediate response (yes/no) upon entering the request. The company estimates that in the more manual, spreadsheet-based system, chargeback errors and unvalidated requests resulted in revenue leakage easily, costing the company more than 10% of total revenue. Now the rate is well under 5%, cutting the company's losses by more than half. These savings are verified automatically now in both internal and external audits.

Looking Ahead

An additional benefit realized after the iContracts launch was improvement of the pharma's EDI information and protocol. After considerable work tuning up its EDI situation, the company was better able to integrate with other systems, including its financial and accounting systems. In hindsight, the company would have benefited by having better EDI and business processes in place prior to launch.

The pharmaceutical manufacturer cited iContracts and its staff for excellent customer service and system knowledge. The director of Contracts and Compliance noted that "many of our questions and suggestions get addressed quickly through frequent new releases and enhancement of the software."

Case Study: Top 50 Pharmaceutical Manufacturer Reduces "Lost Sales" by Improving Wholesaler Inventory Visibility with ValueCentric

Background

In June 2009, one top 50 pharmaceutical manufacturer with a broad product range of injectable drugs went online with ValueTrak, the healthcare data intelligence platform by ValueCentric. At that time, this manufacturer suffered from a lack of visibility into inventory at its wholesalers, which contributed to uncertainty and delays in financial accrual reporting due to chargebacks and other factors. In addition, the pharma wanted more visibility through its channels for traceability for both security and shelf-life factors. Inventory audits were conducted but became quickly obsolete due to the lack of online tracking of levels at wholesalers. This pharmaceutical manufacturer now uses ValueTrak modules for Sales & Inventory Reporting (852), Detailed Sales Reporting (867), and Chargeback & Reversal Validation (844). ValueCentric was chosen for its strong base reporting and out-of-the-box software. The pharma found the ValueTrak software "intuitive and easy to use."

What Happened

One major benefit that this manufacturer has witnessed in using ValueTrak is a decrease in "lost sales" opportunities due to unforeseen inventory outages at wholesalers. In this scenario, without real-time inventory visibility, a wholesaler could find itself out of stock for the injectable product and therefore has to recommend a substitute product for the end customer or pharmacy. With the inventory reporting tool, shortages were reduced by more than 10%, resulting in increased sales. Status reports on wholesaler inventory went from taking several days to less than two hours in most cases.

Audits also became much easier once ValueTrak was implemented. By performing pre-analysis of inventory levels, the audit discussion could focus on only the pertinent issues. Internal audits were enhanced due to the consolidation of data in one system. Since ValueCentric hosts the Sales &

Inventory Reporting and Chargeback & Reversal Validation software and data, data queries and reports from both the manufacturer and wholesalers can go directly to ValueCentric to generate custom reports.

Looking Ahead

The pharmaceutical manufacturer reflected on some of the lessons learned through its implementation: "We should have appreciated the huge amount of data we were sending back and forth. More attention could have been paid to the timing of reports. That would have allowed us to set more accurate expectations for users such as sales representatives, marketing teams, and financial reporting teams." The pharma recommended the adoption of monitoring (where from, where to, when) of sales and inventory data prior to ordering reports. Another recommendation was to attend ValueCentric's annual user conference, where the company was able to exchange ideas and best practices with other users.

Case Study: Top 5 Drug Manufacturer Drives "Right First-Pass" with Help from PwC

Background

After two major acquisitions of smaller pharmas, this large manufacturer went live in 2012 with an out-of-the-box revenue management software system to consolidate chargeback management for the combined companies. Out of the box quickly became "out of control" as a critical "right first-pass" metric for chargeback reconciliation plunged from a premerger level of 98% to under 70%. After interviewing several candidate companies, PwC was engaged to write a business case to solve the chargeback management issues.

What Happened

PwC worked with the manufacturer to prioritize the relevant issues. After prioritization, the next step was to thoroughly document the individual processes by interviewing and consulting with managers and operators of the company's systems as well as with the revenue management software company. Together with the revenue management software team, PwC recommended a three-phase project.

Phase I included scrutinizing the company's master data management (MDM) system, including comparing the company's newly created rosters and customers with external databases such as HRSA . Also included in Phase I were automatic programs to check for and eliminate duplicate customer entries in membership rosters from the three merged companies and to test for and eliminate inactive customer entries in membership rosters. For example, this program turned up 60,000 members who had not ordered any products in the previous two years.

Phase II implemented changes to chargeback accept/reject logic and also provided customized methods for chargeback request approval. For example, tiered contracts could be incorporated by looking on the first line (tier 1) and, if no match is found, then looking on the second line (tier 2) and so on until an eligible contract tier was found. PwC helped implement an automatic roster import feature. Large GPO member rosters could be automatically updated on a weekly basis and smaller GPOs monthly.

Phase III continued to streamline membership roster management by creating automatic proposals for new customers if the membership was not found in the roster-based check. Source contracts could be serviced by just adding the new member.

Looking Ahead

The Business Process Optimization manager at the manufacturer pointed out that critical items in this successful project included thorough documentation of the processes up front, using the documentation to feed good functional design, and solid testing of the new processes. In addition, it was important to interview the operators actually using the system rather than only managers. She praised PwC for bringing in knowledgeable people and remaining committed for the 18-month duration of the project. In the end, the critical "right first-pass" metric was driven back up to over 98% for the combined larger company.

Case Study: Large Generics Manufacturer Relies on Model N to Consolidate Systems

Background

When this top 5 manufacturer of generics, biosimilars, and medical devices called on Model N in 2008, it was not anticipating a long-term project. However, in the discovery phase of the project, the company and Model N realized that nine separate systems built upon a 20-year-old proprietary MRP platform could no longer efficiently handle the job. The company sold hundreds of different SKUs, and the mainframe-based systems in use could not perform real-time pricing — customers needed to wait until the next day. After considering several potential software providers, the manufacturer came to the conclusion that only Model N could accommodate the consolidation of all nine systems and databases into a state-of-the-art revenue management system.

What Happened

Prior to going live with the Model N solution, Price Authorization Acknowledgement/Status (845) and Response to Product Transfer Account Adjustment (849) had been recently automated, with a "right first-pass" rate around 97%. Model N has helped the company cut the number of flagged requests almost in half, to the point that almost 99% of the chargeback reconciliation requests (Product Transfer Account Adjustment [844]) do not require any manual review or intervention. In addition, the proportion of orders with customer group or 340B membership roster errors has decreased from nearly 10% to less than 5%. Model N also automated the company's "anniversary pricing," where annual price increases built into a multiyear contract occur automatically. Contracts coming up for anniversary-increased pricing are automatically increased and sent to the trading partners. The implementation was accomplished with an IT department that was about 20% onsite and 80% outsourced.

Looking Ahead

The pharmaceutical manufacturer is exploring work with Model N to further automate government pricing compliance by implementing the Model N Government Reporting module. 340B and other government programs make up a substantial portion of the company's sales, with that proportion expected to increase.

Looking back on the Model N implementation, the manager of IT Commercial Relationships and Training commented that, "in designing a major IT project like this, it's important not only to document how stakeholders want a process to work in the future but also to document how the business process works now." Another important consideration is to determine if the software can support future processes with out-of-the-box functionality rather than customization. She also commented that project management using external consultants works better if the consultants are incentivized on a completion date for the project. If that is not possible, then internal company stakeholders would be a better choice for seeing the project through to completion.

She said, "Model N is very customer focused, and the people they put onsite were very good listeners. They remained committed to the implementation through delays and changes of scope."

Case Study: Large Wholesaler Expects 30% ROI by Teaming with Genpact on Chargeback Reconciliation

Background

Early in 2015, a large wholesaler of pharmaceutical and medical surgical products engaged with Genpact to consolidate and outsource its chargeback reconciliation program. The company had successfully partnered with Genpact since 2010 to outsource a large portion of other processes such as accounts payable, cash application and lockbox, and imaging and indexing of documents. Thin margins in the pharmaceutical wholesale distribution business, along with several billion dollars of chargeback and rebate requests every month, made this activity an attractive target for cost reduction.

What Happened

The wholesaler decided to take a very methodical, conservative approach to the project. After going live, the company and Genpact gradually increased the outsourced portion of the chargeback and related contract management processes to about 70% of the total, taking their usual approach of identifying core and noncore processes then keeping only the core processes in-house. Core processes, which were kept in-house, include contract loading and contract maintenance. Noncore processes, which are now performed by Genpact, include actual chargeback and rebate submissions, 90% of which are electronic processes not requiring manual intervention. Genpact also manned the resubmission process by EDI, along with research and email response on denials of chargeback requests (Product Transfer Account Adjustment [844]). Training was accomplished using a "shadow" method where Genpact personnel could observe and document the current process at the wholesaler, followed by a "reverse shadow" method where the wholesaler could observe and verify the process at Genpact's facilities.

After six months live with Genpact, the wholesaler reports that the project has achieved a state of "stabilization," with all outsourced processes working successfully. With over 16,000 contracts administered covering over $30 billion annually in chargebacks, customer pricing accuracy is nearly 99.7%.

The wholesaler identified three main sources of chargeback discrepancies: retroactive pricing negotiated between end customers and manufacturers, partly due to eligibility changes; membership roster errors due to outdated roster definitions; and customer identification problems such as DEA numbers or 340B identifiers. The next phase of the project will include process changes to reduce these discrepancies.

Looking Ahead

Now that the processes have been stabilized, process improvement activity can begin. Genpact and the company will take a similar, methodical approach by first learning, documenting, and understanding the business process and then planning modifications for improvement. The wholesaler has conservatively predicted at least a 30% return on investment for this project over the first five years.

Reflecting on lessons learned during the implementation, the senior vice president and general manager at the wholesaler commented, "If every contract was loaded before the effective date, every customer was rostered appropriately, and customer identifiers were synched between buying groups,

manufacturers, and wholesalers, most chargeback discrepancies would vanish overnight. We hope to help make that a reality."

FUTURE OUTLOOK

Revenue leakage will continue to be an important issue for pharmaceutical manufacturers and distributors in the areas of chargebacks, returns, and rebates. The continued advancement of revenue management software and process automation has helped improve revenue visibility and reduce revenue leakage in the life science industry, though much work remains to be done.

The Drug Quality and Security Act of 2013 has put serialization of pharmaceutical, biologic, and other therapeutic products back into view. As lot-level serialization requirements continue into electronic format in 2017 followed by item level in 2023, we expect continued innovation from software vendors, systems integrators, strategic consulting, and outsourcing firms. The resulting traceability from the adoption of these regulations will help life science manufacturers and those who serve them to develop new and more automated processes and solutions, driving higher visibility and profitability for all.

ESSENTIAL GUIDANCE

Pharmaceutical and life science product manufacturers and wholesalers must work closely with their strategic partners to document and understand their internal processes related to revenue management throughout their supply channels.

When evaluating processes to consider for automation or other software solutions, it is critical to understand the underlying business process. It is important to include not only managers but also operators in understanding and documenting the process.

It is also important to consider the underlying business issues driving any errors or inconsistency. For example, what are the most common sources of membership roster errors? What causes pricing errors? Addressing the sources of error at the business or partner level can have a great positive effect on the success of new applications as well as legacy systems.

Finally, when the business processes are understood and documented, find industry experts who can help improve those processes using software and automation solutions. In the field of revenue management in the life sciences, new and innovative ways of addressing sources of revenue leakage are constantly being developed and implemented. Cloud-based systems, data analytics, and access to industry clouds and databases are all helping drive this innovation.

Actions to Consider

- Select industry experts who understand revenue management and sources of revenue leakage.
- Understand and document current processes thoroughly, utilizing process operators.
- Identify the largest sources of process errors and determine root causes.
- Strive for cooperative solutions with business partners/customers/suppliers.
- Find proven solutions and process improvements.
- Set expectations and schedules realistically.
- Implement improvements methodically.

LEARN MORE

Related Research

- *IDC MarketScape: Worldwide Pharmaceutical ePedigree Software 2013 Vendor Assessment* (IDC Health Insights #HI241152, May 2013)
- *Business Strategy: Revenue Leakage - Pharma's $11 Billion Problem* (IDC Health Insights #HI220793, November 2009)

Synopsis

This IDC Health Insights report provides illustrative examples of how life science companies today are working to reduce their exposure and improve their approach to revenue leakage and provides insight into how several key technology vendors and consulting firms are helping life science companies along this journey. Pharmaceutical manufacturers recognize that reconciliation process leakage exists and are eager to improve their bottom line by correcting these issues. Awareness around chargeback-related revenue leakage has continued to rise, with 63% of manufacturers considering this issue to be a large or medium-sized problem as long ago as 2009 and likely higher today.

Reducing revenue leakage remains a major opportunity for pharmaceutical manufacturers to improve their bottom line while under top-line pressure from regulation, patent expiration, and industry consolidation. Headlines scream about out-of-control drug prices, especially for specialty and rare disease formulations. By addressing chargeback reconciliation and other sources of revenue leakage more thoroughly, efficiently, and accurately, pharmas can ameliorate some of the effects of these converging forces.

Michael Townsend, research manager for Life Science Business Systems Strategies at IDC, says, "Revenue leakage and revenue management automation remain an important issue for both manufacturers and distributors for pharmaceutical, biotech, and medical device products. We have seen that through the careful study, documentation, and improvement of processes, coupled with robust software and analytics solutions, companies can significantly reduce their exposure to revenue leakage and improve their bottom lines. As regulation concerning serialization and product tracking takes effect, we expect continued innovation and improved automated solutions from vendors and systems integrators, leading to greater savings."

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