A Framework to Evaluate Interoperable Data Exchange Models for Drug Supply Chain Security Act Compliance

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Summary: This research develops a framework to formulate a data management strategy for the U.S. pharmaceutical industry, which is challenged by the compliance requirements from the Drug Supply Chain Security Act (DSCSA) by 2023. Numerous strategies have been developed by domain experts. We will focus on choosing the most viable one through a robust comparison. We simplified the process by categorizing the known strategies and strengthened the criteria by including various factors across the entire supply chain. We concluded the research with our recommended strategy after examining the categorized models using an extensive set of criteria.

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KEY INSIGHTS

1. Companies should first work collaboratively to decide the best solution for the industry as a whole before negotiating about how their efforts are best compensated.

2. The semi-centralized model is the most viable for compliance with the DSCSA, because it provides a balanced mix of compliance-variation flexibility and cost-sharing synergy.

Introduction

The United States has one of the safest drug supply chains in the world. However, its security is threatened by new challenges such as counterfeit, diverted, and illegally imported drugs. To counter the new challenges, the Drug Supply Chain Security Act (DSCSA) was signed into law by President Obama on November 27, 2013, with a 10-year implementation timeframe. As a result, companies in the U.S. pharmaceutical industry, including drug manufacturers, distributors, and dispensers, are challenged to fully comply with the DSCSA by 2023. Information flows in the drug supply chain are depicted in Figure 1.

Figure 1 Information Flows in the Drug Supply Chain

The compliance with the DSCSA will enable companies to operate and manage the risks of their supply chains more efficiently. Industry consortiums, such as the Healthcare Distribution Management Association (HDMA), and the industry leaders have

recommended various interoperable data exchange models for the implementation of the compliance. However, domestic and international complexities make it difficult to pick the optimal model for the industry.

In this research, we start with categorizing the known data exchange models that can be potentially used by the U.S. pharmaceutical industry. Second, we develop a scorecard methodology based on a framework that considers various factors across the entire supply chain. Next, we examine the categorized models using this scorecard methodology. Lastly, we conclude with recommendations on the data strategy decision for the U.S. pharmaceutical industry.

Methodology

Compliance with the DSCSA is not just a requirement but also an opportunity for pharmaceutical companies to better manage their supply chain risks. Different data sharing models imply different costs and efficiencies. In our research, we will show these differences by developing a balanced scorecard, against which all three data models will be rated and compared.

1. Three Types of Data Exchange Models

Although the transaction data management strategies used in various countries are different from one to another, they all fall into three categories: centralized, semi-centralized, and distributed. The centralized model employs a central repository in which all stakeholders store their transaction data. The semi-centralized model stores transaction data in different repositories that are selected according to certain criteria. Depending on implementation details, a hub system might be created to connect all the repositories. The distributed model allows each data creator stores its transaction data in its own repository which can be queried to obtain data required for reporting.

The most distinct difference between the three models comes from the number of places to store transaction data. The centralized model employs only one place of storage, whereas the semi-centralized and distributed ones use multiple repositories; the distributed model allows every stakeholder to keep the transaction data they create, whereas the centralized and semi-centralized ones require transaction data to be stored in the specified repository.

2. Five Dimensions Affecting the Model Selection

According to the HDMA Phase I white paper, motivations for sharing item-level transactional product data across the supply chain are strong, while concerns about the sharing of confidential data and protecting the privacy of patient and business information are equally evident (privacy). Most participants in Phase I believed that the product track-and-trace capability is an important component that can further enhance patient safety and the continued security of the supply chain. They believed that a complete solution would encompass proper storage and handling of all products, coordinated legislative and regulatory requirements and additional safeguards to further ensure that the right products are given to the right patients at the right times (patient safety). To all participants, compliance with government requirements is the most immediate benefit (compliance). Participants also identified other benefits (operational efficiency), such as potential cost reduction in product returns, recalls, inventory management efficiencies, improved forecasting capabilities, increased service levels, reduced out-of-stock items and overall reduced operating costs.

The limitation of this report is that it only considers the domestic market environment. However, we believe that companies should also consider compliance with international regulations (international compliance) when implementing compliance. In addition, solutions from other markets can be leveraged if appropriate.

In summary, the U.S. pharmaceutical industry is generally concerned about five dimensions when implementing compliance with the DSCSA: **C**ompliance, **O**perational efficiency, **S**ecurity, **P**rivacy, and **I**nternational compliance. We name our scorecard methodology as the COSPI Scorecard, where COSPI is the acronym of the five dimensions.

3. 1-to-5 Scale of Scores based on Two Costs

To rate the three models, we carried out an intensive research on tangible capabilities required by each of the five dimensions and assigned a score to each of the capabilities under each model. Scores are decided based on a qualitative analysis of two types of costs that are related to the interoperable data sharing model: upfront and on-going cost.

The upfront cost may or may not have cost-sharing synergy. Complying with the DSCSA requires acquiring new capabilities for processing transaction data. Given the large size of transaction data, these capabilities can only be acquired with the aid of new software systems. Companies can choose to build their own systems separately or to collaborate to build shared systems. If companies choose to build shared systems together, a cost sharing synergy appears. Depending on who builds these shared systems, the synergy can be achieved in different manners. If the shared systems are built by one of the companies working towards compliance, the other companies can share the system development cost so that each party has access to the new systems at a lower cost. If these shared systems are built by a third-party software service provider, all the companies working towards compliance can negotiate jointly to obtain a lower price, and share the cost of the third-party software. Not all three data sharing models allow companies to build shared systems collaboratively. Therefore, the potential cost sharing synergy varies with the choice of the data sharing model.

Another cost associated with compliance is the day-to-day effort interacting with the software systems and the transaction data stored in these systems. The day-to-day interactions involve reference activities and maintenance efforts. Reference activities do not require significant efforts; one example of a reference activity is the retrieval of transaction data from the system for reporting purposes. On the other hand, some of the maintenance activities only require efforts from individual companies, such as inputting newly generated transaction data into the system. Other maintenance efforts require collaboration between different companies, which means higher costs due to the need to coordinate multiple parties. In some of the collaboration-based maintenance scenarios, the coordinator is obvious. One example of such a scenario is the decision of when to update the system. In other scenarios, any company involved can potentially play the coordinator's role. One example of such a scenario is the decision of who has access to what transaction data. In general, collaboration efforts without an obvious coordinator are more costly than those with an obvious coordinator. Depending on the choice of data sharing models, the day-to-day interaction cost or on-going cost may vary in four different ways.

The more a data sharing model costs, the less favorable the model is, and therefore, the lower the score the model will get. In the worst scenario, capabilities have qualitatively the highest upfront and on-going costs and consequently are assigned the lowest possible score, which is 1. Of the two neighboring scenarios, one has lower upfront cost, while the other has lower on-going cost. Since there is no evidence showing the qualitative difference between a lower upfront cost and a lower on-going cost, we arbitrarily assign capabilities in two scenarios the second lowest score, which is 2. Similarly, the scores for the remaining capabilities are decided following the same process and rationale.

Results

The COSPI score of the semi-centralized model is 113, outweighing those of the centralized and distributed models - 110 and 85 respectively. Since the analysis is qualitative, the values do not have any meaning by themselves, neither are they representative of or proportional to the actual costs. However, they do indicate the relative performance of these models.

The resulting scores represent pros and cons of these three data sharing models as described in Figure 2. The score of the distributed model is much lower than that of the other two models, mainly due to the lack of its cost-sharing synergy. However, the distributed model has its own advantages. It is the most flexible model to deal with compliance variations. The centralized model is the opposite of the distributed model. It has the best cost-sharing synergy, but the least compliance-variation flexibility. The semi-centralized model is a combination of the centralized and distributed models. Therefore, the semi-centralized model has the benefits of the other two models, which leads to the highest total score for the semi-centralized model.

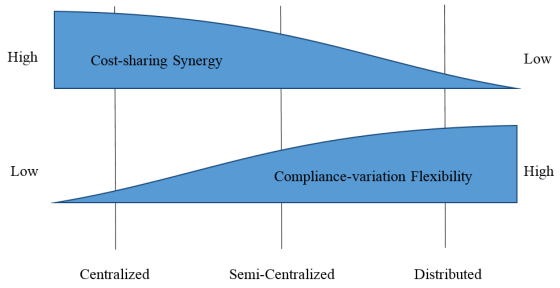

Figure 2 Pros and Cons of the Three Data Sharing Models

To further demonstrate the disadvantages of the centralized and distributed models, let's suppose company A is a multinational drug manufacturer with subsidiaries in the US, Europe and South America, and South America undergoes policy changes. In the centralized model, the U.S. and European subsidiaries will be affected by the system updates reflecting the policy changes. In the distributed model, the company has to build the system from scratch for all of its subsidiaries without any cost sharing benefits.

Conclusions

Based on these scores, we recommend the semi-centralized model for compliance with the DSCSA, because it provides a balanced mix of compliance-variation flexibility and cost-sharing synergy.

The centralized model is slightly less desirable than the semi-centralized model, because of more difficult coordination in scenarios that require collaboration. A semi-centralized data exchange model is usually built around drugs that are distributed in similar supply chain models, which are either from the same manufacturer or sold by the same distributor or dispenser. The similarity of the drugs makes it easier to negotiate between the different stakeholders that are involved in the model.

The distributed model is less favorable compared to the other two models, since it has the least cost-sharing synergy. The upfront cost to set up the software system required by compliance with the DSCSA cannot be shared among related entities. Each company has to build and maintain its own system separately.

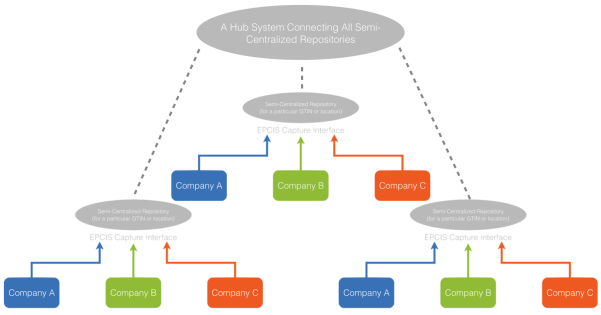

Figure 3 Semi-centralized Data Exchange Model

Figure 3 Semi-centralized Data Exchange Model offers a visualized demonstration of the semi-centralized model. The EU has implemented the semi-centralized model with a hub system, known as the European Hub, and different repositories. These different repositories store transaction data generated in different countries, while the European Hub provides interconnection between the different national repositories. The European Hub and the national repository systems are funded by the manufacturers, while those systems interacting with serial numbers for verification are funded by distributors and pharmacies. All data posted to a data repository is owned by the creator and not by the government. Access to another party's data is allowed only for verification purposes.

The U.S. pharmaceutical industry does not have to implement the semi-centralized model in exactly the same way as The EU. The location of the repository to store transaction data can be decided in many different ways. One such way is based on relative positions along the supply chain; for instance, the data can be stored in the repository belonging to the last stakeholder handling the specific product. Another possibility is to store the data in the repository of one of the most influential stakeholders in the supply chain, which is usually the manufacturer or distributor. Once the repository is decided, transaction data will be sent to that specific repository.

Once the location of the repository is decided, the next step is to decide what transaction data should be stored in a given repository. Similar to the decision of locations, deciding transaction data also involves flexible criteria. For example, one system can capture one drug supply chain, or the supply chains of multiple drugs that are similar in some respect. Another way to do this is to segment by geographical location/country.

In conclusion, we recommend the semi-centralized model as the foundation for compliance of the DSCSA. This foundation allows for customization and innovation, which are needed to meet the reality of the U.S. market.