Serialization of Prescription Drugs in the US: A Centralized View

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Summary: The 2013 Drug Supply Chain Security Act (DSCSA) of 2013 requires serialization of prescription drugs across the whole pharmaceutical supply chain. This thesis assesses the costs associated with serialization implementation on manufacturers and distributors/retailers. Taking the perspective of a centralized data model, we tested the feasibility of implementing a centralized database under both data nesting and unit level relational models. The findings suggest that serialization using a centralized data model would in all cases incur a higher proportional cost than using a decentralized model.

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KEY INSIGHTS FOR PHARMA INDUSTRY SERIALIZATION

1. More specific regulations around data standards, serialization responsibilities, and data management accountability is needed to align players across the supply chain.
2. The industry anticipates an increase in working capital across all scenarios, but most obviously in options involving a Unit-Level relational model.
3. A centralized model with data nesting, although costly, offers the best chance to achieve the information system reliability needed for long term success.

Introduction

The pharmaceutical industry currently faces the challenge of readying themselves for serialization of all prescription drugs. With the first phase slated for completion in Fall of 2017, this topic is top-of-mind for many industry players. This thesis explores the impact of the Drug Supply Chain Security Act (DSCSA) on various stakeholders in the pharmaceutical supply chain. Specific attention has been dedicated to the impact on manufacturers and distributors/retailers. This thesis tests the feasibility of implementing a centralized database under both data nesting and unit level relational models. This is in contrast to the decentralized system, which is further explored in the partner thesis by Chang and Mohan, *Impact of Drug Supply Chain Security Act on US Pharmaceutical Industry Under Decentralized Information Flow*.

Both quantitative and qualitative analysis are employed in this thesis. Quantitative modeling of supply chain costs was conducted using publically available industry data. Qualitative analysis consisted of stakeholder interviews, process mapping, and time studies to determine the extent of process changes and what they should look like to conform to DSCSA. After accounting for the current state of implementation, as well as real-world constraints, the findings indicate that the best-practice scenario to conform to DSCSA is to use a Centralized data management and data nesting model. Although this option is estimated to be 67% costlier than the least expensive scenario, it offers a more robust and secure system that allows for better long-term scalability.

Methodology

The analysis of the impact of DSCSA and serialization on the pharmaceuticals supply chain was carried out by modelling the financial and inventory impacts in a hypothetical network. Information gathered during the interview process indicated that, in order to measure the costs and advantages of each possible serialization model, estimates for each cost factor needed to be drawn up. These cost factors were determined to be: Ongoing Operational Costs, IT Investment Costs, and Capital Expenditures. Each of these cost factors were individually estimated using a top-down methodology, using industry data available through public sources, and validated for directional accuracy using a bottom-up analyses with the thesis sponsors.

Eight distinct scenarios were determined based on a combination of the data model and the relational model. Within the data model, four possible options were available: Centralized – Manufacturer lead, Centralized – 3rd Party lead, Centralized – Government lead, and Decentralized. Within the relational model, two options existed: either Unit Level tracing, or Nested Data tracing. The Nested Data model is also referred to as the "inference" model where individual product units are serialized and grouped together in a serialized outer box. This allows the outer box serial number to link to all the inner individual serialized products, reducing the steps needed by eliminating the need to scan each individual product. A combination of the data and relational model options result in the eight distinct scenarios mentioned. The full tables for each scenario is provided in Figure 1 below.

Cost Categories

To assess total cost impact from Serialization the following costs are considered:

- Ongoing Operational Costs
- One Time Capex Costs
- IT Investment Costs Recurring and One Time

Ongoing Operational Cost

Ongoing Operational Costs was estimated based on the assumption that Serialization using the Nested Data relational model would require additional labor and equipment maintenance to implement effectively. This approach modeled the time necessary to complete each step of the packing, shipping and receiving process, and then estimates the total costs. Information was collected on the number of individual cases required, and the number of cases per pallet, as well as the steps required at each stage in the process. Average time per task was obtained through interviews with industry stakeholders. An industry average labor cost rate was then used to convert the total time required to a cost figure. The formula below illustrates the Operational Cost calculation method:

*Operational Costs = Minutes per task * Annual Volume * Hourly labor rate*

One Time Capex Costs

Capital Expenditures differed significantly depending on the serialization scenario. In this case, the cost difference is driven by the distinction between a Nested Data relational model vs a Unit Level relational model. In a Nested Data model, the capital expenditures are expected to be higher due to the added complexity of data aggregation. In a Unit Level model, some of the capital equipment would not be necessary. In each case, production volume was used to determine the quantity of equipment needed to obtain sufficient serialization capacity. Published equipment prices were then used to determine the total investment cost.
To estimate the industry wide initial capital requirements we have constructed the tree of all applicable costs. These costs relate to

- Line upgrade for serialization,
- Additional inbound equipment,
- Additional outbound equipment.

The Nested Data approach only applies to Manufacturer and Wholesaler levels, since the upstream supply chain is assumed to all be comprised of unit-level transactions.

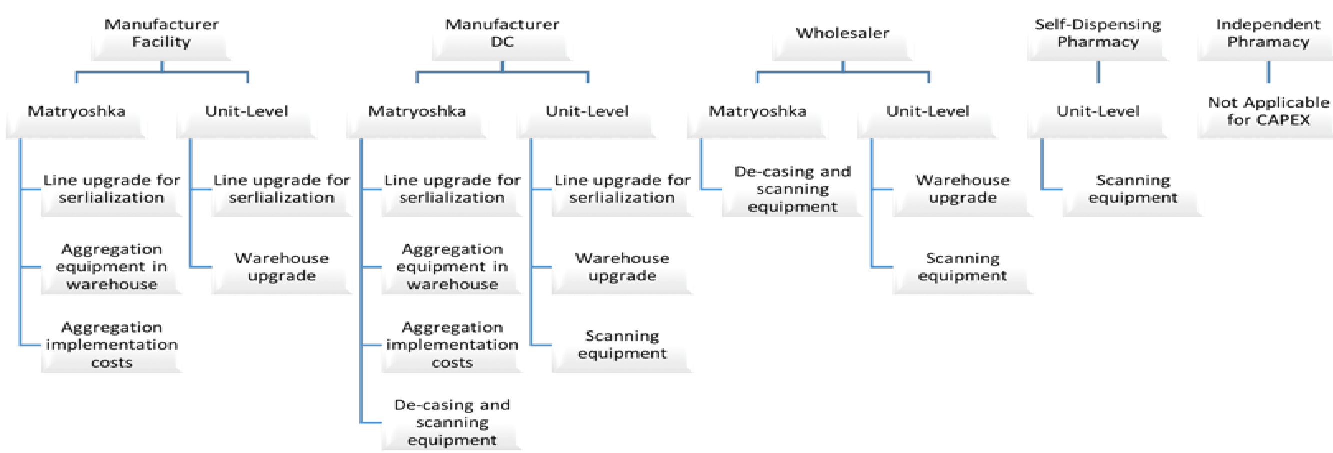

Figure 1 - One-Time Capex Costs Structure

IT Investment Costs

IT Investment Cost is calculated using a combination of the investment necessary in storage space, as well as the cost of setting up the data interfaces between partners in the supply chain. Storage space investments include the capital expenditures on physical assets (servers and racks), as well as the cost of cloud storage if managed by a 3rd party. The cost of setting up data interfaces includes all the IT implementation costs associated with integrating the serialization database with the existing IT architecture. This portion includes both a one-time cost, as well as an ongoing annual cost.
The IT costs have been calculated based on the number of storage requirements and transactions required per each echelon. It also considers that at each point of transaction all the information will be provided by the receiver of the product.

*IT Investment One-time Cost = [(Annual Production Volume * Data Storage needed) / (Storage Capacity per server)] + [Number of downstream supply chain partners * Cost per database linkage]*

*IT Investment Recurring Cost = (Annual maintenance hours needed * Labor cost per hour)*

Manufacturer	
anuual production QTY	1,524,440,649
required storage year	8
unit data volume for TS/TH/TI (Byte)	1000
Annual Data Volume (GB)	12195.52519
Cloud Data Storage Cost/GB/Year	$0.27
Data Storage Cost	**$3,292.79**

Figure 2 - Investment Costs Calculation

Comparison of Centralized and Decentralized, Nested Data vs Unit Level Scenarios

All the costs above are calculated based on a number of assumptions. The assumptions and the dynamics of the industry complicate the precise calculation of the financial impact of serialization on the whole supply chain. For this reason, relative comparison of the scenarios is introduced (Figure 3).

Further limitations and areas for future research are explored in the conclusion sections of the thesis.

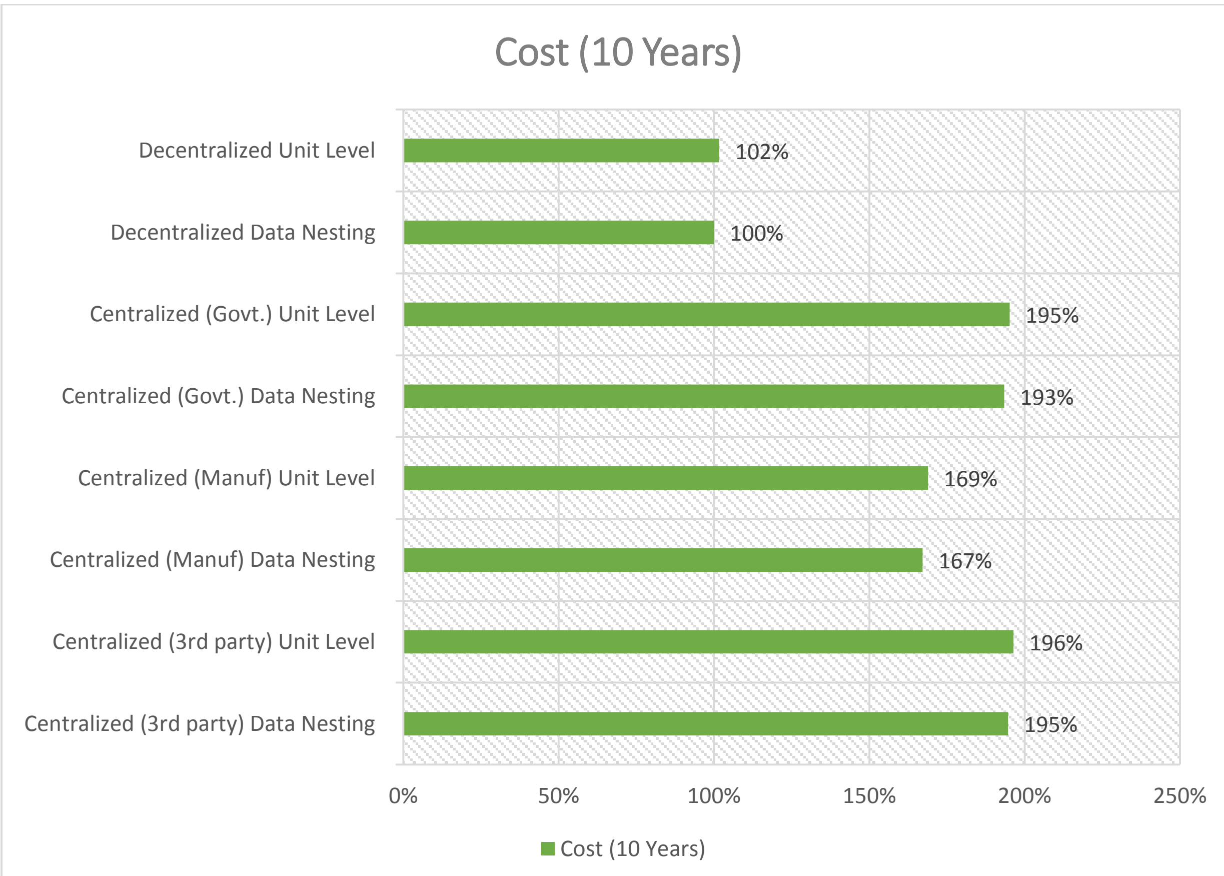

Figure 3 - 10 Year Cost Comparison