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Partnership for DSCSA Governance

PDG Point of View on the DSCSA and Business Continuity Planning

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1. Introduction

1.1 Background

The Drug Supply Chain Security Act (DSCSA) was signed into law in 2013 with the aim of enhancing the security and integrity of the pharmaceutical supply chain in the United States. The DSCSA imposes various requirements on trading partners involved in the distribution of prescription drugs, including the provision of Transaction Information (TI) and Transaction Statements (TS) for each product.[1]

1.2 Purpose of the Report

This Point of View statement helps trading partners understand the impact of the DSCSA on their business continuity planning. It explores the requirements for incident management and communication with immediate trading partners in the event of system outages, disasters, data breaches, or other unplanned incidents. Additionally, it discusses the concept of the FDA granting a temporary waiver of the DSCSA Transaction Information (TI) exchange requirements and its potential implications on patient well-being and the drug supply chain.

2. Overview of the Drug Supply Chain Security Act (DSCSA)

2.1 Legislative Background

The DSCSA was enacted to address concerns about the presence of counterfeit and adulterated drugs in the pharmaceutical supply chain. It establishes a framework for tracing and tracking prescription drugs as they move through the supply chain, from manufacturers to wholesalers, repackagers, and dispensers.

2.2 Key Objectives and Requirements

The primary objectives of the DSCSA are to enhance supply chain security, improve product tracing capabilities, and protect patient safety. To achieve these objectives, the DSCSA sets forth several requirements for trading partners, including manufacturers, repackagers, wholesalers, and dispensers.

2.3 Transaction Information (TI) and Transaction Statements (TS)

Under the DSCSA starting November 27, 2023, trading partners are required to exchange Transaction Information (TI) and Transaction Statements (TS) for each product change of ownership. TI includes the product's proprietary or established name, strength, dosage form, National Drug Code (NDC), container size, lot number, and date of the transaction. TS includes statements regarding the product's legitimacy and compliance with the DSCSA requirements.

2.4 Serialized Identifiers for Medication Packages

The DSCSA also mandates the use of unique, serialized identifiers for each package of medication. These identifiers enable the tracking and tracing of products throughout the supply chain. The serialized identifiers must be encoded in a machine-readable format (barcode).

[1] https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/title-ii-drug-quality-and-security-act

2.5 Consequences of Non-Compliance

Failure to comply with the DSCSA requirements can have serious consequences. The FDA has the authority to quarantine suspect or illegitimate drugs, potentially leading to disruptions in the supply chain. Non-compliance may also result in civil and criminal penalties for trading partners involved in distributing non-compliant products.

3. Importance of Business Continuity Planning

3.1 Business Continuity Planning in the Pharmaceutical Industry

In the pharmaceutical industry, business continuity planning involves identifying critical processes, establishing backup systems, implementing disaster recovery strategies, and ensuring the availability of essential resources. Effective planning helps organizations maintain operations, uphold regulatory compliance, and mitigate risks to patient safety and the drug supply chain.

3.2 Understanding System Outages and Disasters

System outages, disasters, data breaches, and other incidents can disrupt the normal operation of trading partners, impacting their ability to comply with the DSCSA requirements. It is crucial for organizations to have robust business continuity plans in place to prevent or minimize the impact of such incidents.

3.3 Preventing and Mitigating the Impact of System Outages

To prevent or minimize the impact of system outages, trading partners should invest in resilient IT infrastructure, implement redundancy measures, regularly test backup systems, and establish alternative communication channels with immediate trading partners. Disaster recovery plans should include protocols for incident response, incident escalation, and recovery strategies.

3.4 Incident Management Best Practices

Incident management in the pharmaceutical industry includes establishing an incident response team, defining roles and responsibilities, documenting incident response procedures, conducting regular training and drills, and fostering collaboration with immediate trading partners and regulatory authorities.

3.5 Communication with Immediate Trading Partners

Effective communication with immediate trading partners during incidents is crucial for maintaining the integrity of the drug supply chain. Trading partners should establish multiple clear lines of communication, share incident-related information promptly, and collaborate on remediation efforts.

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3.6 Post-Incident Communication with Immediate Trading Partners

Effective communication with trading partners once an incident is resolved is important for maintaining records and mitigating downstream issues. If able to determine which product was exchanged during the business interruption, and if downstream trading partners are able to receive TI/TS on product exchanged during the incident, ensure the accurate exchange of transaction information once systems are restored.

4. Consideration: FDA grants Temporary Exemption of DSCSA Transaction Information (TI) Exchange Requirements[2]

4.1 Rationale for Temporary Exemption

In the event of system outages, disasters, or other unplanned incidents that impact the ability of trading partners to exchange Transaction Information (TI) a trading partner may seek a temporary exemption from the FDA to mitigate drug shortages. The FDA may grant temporary exemptions to affected trading partners, acknowledging the challenges faced by trading partners during these circumstances and aim to prevent disruptions in the drug supply chain.

4.2 Implications on the Drug Supply Chain

The temporary exemptions granted by the FDA may have implications on the drug supply chain. Exemptions could pose challenges to trading partners' ability to manage products and data during and after an incident. If temporary exemption is acquired, communicating waivers, exceptions, or exemptions through the supply chain may not follow the existing channels in place for exchanging TI and TS documentation once a system outage is restored. Processes to appropriately handle temporary exemptions need to be established and activated by the party acquiring temporary exemption and its downstream trading partners. It is essential to balance the need for temporary relief during system outages with the long-term objectives of the DSCSA in ensuring supply chain security and patient safety.

4.3 Feasibility

The Waiver, Exception, and Exemption application process includes measured analysis by the FDA in coordination with the requestor. The processing timeframe should be considered when addressing an unexpected short-lived business continuity issue.

5. Conclusion

5.1 Recommendations

It is recommended that trading partners in the pharmaceutical industry prioritize business continuity planning to prevent or mitigate the impact of system outages. Implementing best practices for incident management and communication with immediate trading partners is crucial for ensuring supply chain integrity and patient safety.

[2] see PDG Point of View on Waivers, Exceptions, and Exemptions

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5.2 Resources for Business Continuity Planning

There are many resources such as templates, training, and guidance available online (ex: Business Continuity Plan. Ready.Gov website. URL: https://www.ready.gov/business-continuity-plan). Trading partners should consider the specific challenges a business continuity incident may have on being able to stay conformant to DSCSA requirements.

5.3 Conclusion

The DSCSA plays a vital role in enhancing the security and integrity of the pharmaceutical supply chain. Trading partners must adhere to the requirements of the DSCSA and prioritize business continuity planning to minimize disruptions. The FDA's consideration of temporary waivers should carefully balance trading partners' needs during system outages while ensuring the long-term objectives of supply chain security and patient well-being are upheld.

6. Additional Information:

6.1 Best Practices for Incident Management and Communication

To ensure effective incident management and communication with immediate trading partners during outages, trading partners should follow best practices such as:

- Develop a business continuity plan that includes procedures for incident management and communication with immediate trading partners.
- Conduct regular testing and training to ensure that the plan is effective and that all employees are aware of their roles and responsibilities.
- Establishing multiple clear lines of communication with immediate trading partners and ensuring that they are aware of the plan and their roles and responsibilities.
- Maintaining up-to-date contact information for immediate trading partners and establishing alternative communication channels in the event of system outages.
- Establishing procedures for reporting incidents to regulatory authorities and other stakeholders as required.

6.2 What is important to Document

To support Corrective and Preventive Action (CAPA) processes, trading partners should capture business continuity incident data such as:

- Incident logging
- Incident categorization
- Incident prioritization
- Incident management and escalation
- Incident resolution
- Incident follow-through (with affected Trading Partners)

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6.3 Potential consequences of not having a business continuity plan in place for trading partners in the pharmaceutical industry

Not having a business continuity plan in place for trading partners in the pharmaceutical industry can have several potential consequences, including:

- **Medication shortages:** Without a business continuity plan, trading partners may not be able to maintain an uninterrupted supply of critical medicines for patients in challenging manufacturing circumstances, leading to medication shortages.

- **Increased risk:** The lack of a business continuity plan can increase the risk of business interruptions, which can cause significant financial losses and reputational damage.

- **Liability:** Depending on the severity of the situation, a company may be liable for any damages or losses incurred due to a lack of a business continuity plan.

- **Inability to restore operations:** Without a business continuity plan, it may take longer to restore operations to a state of business as usual, leading to increased downtime and financial losses.

Overall, having a business continuity plan is essential for trading partners in the pharmaceutical industry to prevent or mitigate the impact of system outages and communicate effectively with immediate trading partners during incidents. A business continuity plan can help ensure the safety and security of the drug supply chain, maintain an uninterrupted supply of critical medicines for patients, and reduce financial losses and reputational damage.