The Systems House, Inc.

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As many of you may be getting questions or concerns about your compliance, I wanted to reach and outline how the MDS system will help you address these challenges. As well as point out our suggested business practices. While we do not enforce or force you to follow these rules, this document is intended more as a guide to allow you to decide internally how you might want to update your practices and systems.

Please note this is a combination of Information collected from various conferences and Industry Groups HDMA, NCPA, HIDA, FDA, etc. however since the FDA is the current enforcement agency in charge I have used their site as the model for compliance. For those with more specific needs this document may not suffice.

If you have any comments or questions please email support@tshinc.com

And we will reach out directly.

Please note: The FDA Website has said they will not be enforcing until May 1 2015. (link below)

http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm427033.htm

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Step 1.

Report licensure (third-party logistics providers and wholesale distributors)

Start Date	Trading Partner(s)	Requirement
11/27/2014	Third-party logistics providers	Report licensure and other information to FDA
1/1/2015	Wholesale distributors	Report licensure and other information to FDA

To assist third-party logistics providers and wholesale distributors to comply with the new reporting requirements, FDA published a draft guidance, Drug Supply Chain Security Act Implementation: Annual Reporting by Prescription Drug Wholesale Distributors and Third-Party Logistics Providers (December 2014). The draft guidance outlines the information that should be submitted to FDA, the timing of the submissions, a preferred format for the submissions, and a preferred method for reporting using FDA's CDER Direct Electronic Submissions Portal. FDA posted a webinar that provides an overview of annual reporting requirements.

Please note that MDS Does not do this for you. Your company will have to actually go to the CDER Website and register assuming you will be selling Pharmaceuticals or any Tracked item. Please review the links above on what is involved. Based upon feedback from MDS Clients this was not a big project and should allow you to get registered relatively quickly.

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Step 2.

Provide product tracing information (manufacturers, repackagers, wholesale distributors, and dispensers)

Start Date	Trading Partner(s)	Requirement
1/1/2015	• Manufacturers • Repackagers • Wholesale distributors	Lot-level product tracing: provide transaction information, history, and statement
7/1/2015	Dispensers (primarily pharmacies)	Lot-level product tracing: provide transaction information, history, and statement

To assist manufacturers, repackagers, wholesale distributors, and dispensers to comply with the new product tracing requirements, FDA has published a draft guidance for industry, DSCSA Standards for the Interoperable Exchange of Information for Tracing of Human, Finished Prescription Drugs: How to exchange product tracing information (November 2014).

- Accept ownership of product with applicable transaction information, transaction history, and transaction statements.
  - If your trading partner does not provide the proper transaction documentation, work with your trading partner to promptly get the proper documentation and to minimize disruption in the supply chain.

The MDS Pharma Module must be activated and configured to be able to track and pass this information (formerly known as a pedigree) we now refer to them as DSCSA Documents. And they include TI (Transaction Information), TS (Transaction Statements), and TH (Transaction History). You will enter the transaction history manually or can import it using the EDI 856 documents based upon the HDMA standards released, please note you will still need to inspect all goods and verify them, We will have the MDS QC and Audit Compliance Modules available to you to allow you to statistically sample your products rather than checking every item. Also the requirement to have someone sign and authenticate each transaction has been replaced by the TS (transaction statement) on the form.

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Step 3.

Know how to handle suspect and illegitimate product(manufacturers, repackagers, wholesale distributors, and dispensers)

Start Date	Trading Partner(s)	Requirement
1/1/2015	• Manufacturers • Repackagers • Wholesale distributors • Dispensers (primarily pharmacies)	Establish systems for verification and handling of suspect or illegitimate product.

o assist manufacturers, repackagers, wholesale distributors, and dispensers to comply with the new verification requirements, FDA published the draft guidance for industry, Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification (June 2014). FDA posted a webinar that reviews how to identify suspect product and the process for notification.

- Establish systems to:
  - Quarantine and investigate *suspect product* to determine if it is illegitimate.
  - Notify FDA and immediate trading partners, if *illegitimate product* is found.

The MDS Pharma module includes our Excessive Product Usage System to assist you in setting up business rules to identify and stop any suspicious product. Additionally you can use the MDS QC and Audit Compliance module to check on a statistical sampling of products receipts and invoices to verify that the items coming in and out are legitimate.

In the event of a suspicious item being identified the FDA requires you to fill out and submit a form (manually) *" Trading partners should follow the instructions on the Web page for accessing Form FDA 3911"* Using this form, trading partners should provide information about the person or entity initiating the notification, the product determined to be illegitimate or to pose a high risk of illegitimacy that is the subject of the notification to FDA, and a description of the circumstances surrounding the event that prompted the notification. Form FDA 3911 should be submitted by using the method provided in the form or on the Web page.

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Step 4.

Confirm authorized trading partners (manufacturers, repackagers, wholesale distributors, dispensers, and third-party logistics providers)

Start Date	Trading Partner(s)	Requirement
1/1/2015	• Manufacturers • Repackagers • Wholesale distributors • Dispensers • Third-party logistic providers	Must be authorized, as defined by the FD&C Act

- Check with your trading partner directly to confirm they are authorized, or
  - For manufacturers and repackagers, check FDA's drug establishment registration database for registration;
  - For wholesale distributors, third-party logistic providers and dispensers, you can check with your respective state authority to confirm licensure.

Note, third-party logistic providers are considered to be licensed under the DSCSA until the effective date of the third-party logistic provider licensing regulations issued by FDA, unless the third-party logistic provider is licensed by a state having a specific third-party logistic provider licensing program.

For more information about DSCSA implementation and new requirements to enhance drug distribution security, please visit FDA's Drug Supply Chain Security Act web page.

You will need to do this manually but the MDS system has been enhanced to allow you to store and report on any expiring licenses and codes.

There are a combination of state and federal licenses but the goal is to consolidate them and the FDA has fallen back on the DUNS number at this time. We shall see what the future holds but for now we have added fields for store and report on these licenses both for customer and vendors (all trading partners.) Additionally the MDS Pharma System will warn and put orders on hold for license check failures allowing you to ensure compliance.

As a reminder if you do not have the latest updates you will likely not have all of these feature so please make sure to update your MDS system as soon as possible to remain in compliance.