Healthcare Transformation Group

HTG DSCSA Summit 2019 Agenda

Friday, October 25, 2019

Time	Topic	Presenter/Facilitator
8:00 am - 8:30 am	**Registration & Breakfast**	
8:30 am – 8:45 am	Welcome and Introduction to the FMOLHS DSCSA Journey	Bill Mosser
8:45 am - 9:15 am	PDSA Update – DSCSA Governance	Lloyd Mager
9:15 am – 9:45 am	FDA Pilot Report - DSCSA Verification to Improve Product Traceability at FMOL Health System	Chris Chandler
9:45 am – 10:00 am	Break	
10:00 am – 11:00 am	HTG DSCSA Updates	HTG Members
11:00 am – 11:30 am	Open Discussion	All
11:30 am - 12:00 pm	Boxed Lunch	

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HTG DSCSA Summit

DSCSA Readiness Update

Kathy Anderson
Senior Category Manager
October 25, 2019

Mayo DSCSA Solution

- Initial vendor procurement in 2016, to meet impending regulatory guideline
  - 3 year initial contract term
- Wanted to be ahead of the curve
- Rolled out in late 2016 and early 2017
  - Overall pharmacy adoption was weak
- Did not anticipate level of pharmacy commitment or resources needed to implement
- Realized Master data management is a ….

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Mayo GPO with Vizient Procurement Path

- GPO provides sourcing and contracting services for Captis members*
- Contracting initiatives engage Captis members and follow Mayo Clinic's go-to-market strategy
- Contracts are typically addendums to Vizient base agreements which reflect Captis member aggregated spend or other member commitments such as market share or volume
- **Vizient and Captis graciously provided permission to Mayo to share our GPO's DSCSA readiness journey*

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Captis Pharmacy Council and Members

- Initial RFP for DSCSA software solution issued in December 2017
  - Standard bid process followed
  - Pharmacy members surveyed for readiness
    - @35% responded to survey
    - Current Membership = 64 members, representing 260+ hospitals/clinics
- Four vendors chosen and all submitted proposals
- RFP fully vetted and shared with members and Pharmacy Council

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Recommendation Post RFP Submission

- Table RFP and Remove From Bid Calendar
  - Members are not aligned on current need for DSCSA vended solution
  - Many would prefer to hold on purchasing a solution until 2019/2020 when serialization is closer on the horizon
  - Current DSCSA vendors are fairly new to the entire track and trace software solution ***for DSCSA***
  - No one vendor really delivering a solid end to end solution

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Additional DSCSA Issues Identified

- Drop ships
- Recalls
- Software UX
- Faulty or incomplete GTIN

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Initial Guidance and Risk Management

- Consider your risks if waiting until closer to serialization deadline
- Assess level of confidence in knowing and understanding DSCSA requirements
- Assess level of confidence in retrieving required data on a particular drug within 48 hours of federal audit
- Any chance your organization is defined as more than one group under DSCSA?

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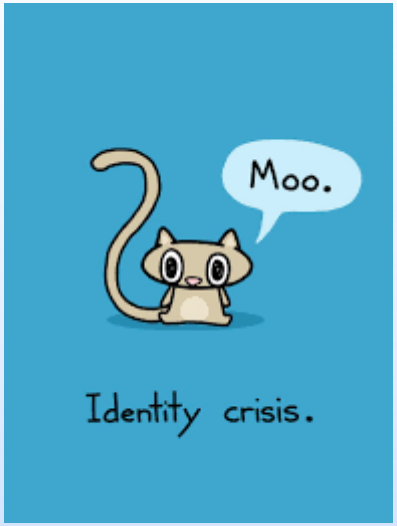
Who Am I?



Wholesaler? Dispenser? Distributor?

2018 Interim Strategy Recommendations

- If renewing an existing vendor agreement or looking to purchase before Captis RFP is resurrected, consider the following procurement strategy
  - Demand flat rate license, enterprise-wide, covering all dispensing areas
  - Limit contract term to two years or less
  - Understand professional service offerings and negotiate a rate sheet
  - **Protect your data – it's valuable**
  - Include a service level agreement that covers expected response times and uptime guarantees
  - Upgrades, updates, bug-fixes included

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Fast Forward - 2019

- Captis renewed interest in issuing an updated RFP or RFQ
- New Captis Pharmacy Member Advisory Council (MAC) Engaged
- Initial RFQ issuance proposed date Sept/Oct 2019
- New survey to existing pharmacy members
  - Member response down from 35% rate of 2019
  - Overall member readiness is about the same as prior year

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MAC Recommended Approach

- Push RFP/RFQ date to early Q1 2020
- Captis works with MAC to review and address
  - Member DSCSA education needs
  - Member DSCSA readiness needs
  - Overall DSCSA policy and procedure needs
- Captis and MAC work to create DSCSA Implementation Manual

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Captis DSCSA Implementation Manual and Guidance

- Readiness Resources
  - Includes DSCSA Act
  - FDA guidance and proposed guidance
- Readiness Gap Analysis Assessment Tool
- Volunteer for mock audit
- Iterate to great mentality

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MEMBER GUIDANCE. This is intended to serve as a general reference for members. Even though Captis has attempted to make sure this guidance is accurate and useful, this is not guaranteed to be correct, complete, or up-to-date and should not be relied upon as authoritative. This guidance is not a substitute for the advice of your own attorney. Please consult your own attorney for advice regarding your particular situation.

DSCSA Requirement * If Y (yes), you will need to follow through and complete the recommended actions.	**Do you have a gap? (Y/N)***	**Actions to complete to better ready for DSCSA**	**Rationale for completing this action**	**Available Resources**
Do you have an understanding of what is required for you with the upcoming FDA mandated time lines?		Review these documents	Need to have knowledge	See Appendix A
Have you read that FDA DSCSA Guidance documents?		Review these documents	Need to have knowledge	See Appendix B
Know how DSCSA will affect your operational work flow?		Develop current ("As-Is") and future ("To-Be") process flows	You will need to create new process flows and actually make these process changes in order to be DSCSA compliant.	See Appendix C
Do you have DSCSA policies and procedures?		Have active DSCSA policies and procedures developed.	Referenced in DSCSA Guidances	See Appendix D (and B)
Which policies should I develop?		There are six key areas identified in Appendix D	Referenced in DSCSA Guidances	See Appendix D (and B)
Which procedures should I develop?		Procedures are based in key actions that staff will need to perform. Each member will have different procedures.	Referenced in DSCSA Guidances	See Appendix D (and B)
Is there one person identified who is accountable for DSCSA compliance?		Develop into DSCSA Policies. Six key areas are noted in the Appendices.	Best practice	See Appendix D (and B)
Do you have past records – stored in reverse chronological order – since 2015?		As most members do not have software systems for track and trace, begin to organize how your facility stores this data.	Referenced in DSCSA Guidance's	See Appendix D (and B)
Do you have a room for suspect product sequestration?		Develop into DSCSA Policies and into your facility procedures.	Referenced in DSCSA Guidances	See Appendix D (and B)
Do you have mock DSCSA compliance audits in place to assure/test compliance?		• Review the examples of one DSCSA Compliance Audit in this manual and alter to best meet your needs. • Does your staff know how to respond, if asked by FDA audit, what your policies/procedures state?	Although there is no requirement to conduct these audits, it is viewed as best practice. We believe that the FDA audits may contain both policy review, process review (Including staff discussions) and data review.	See Appendix E
Are you aware of the resources available for DSCSA for your own knowledge and staff education?				See Appendix F

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This Is Not A Good Solution

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Special Thanks

Jan McNelly, MS, RN

- Programs Manager
- Captis | Member Business Ventures

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DISCUSSION

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DSCSA from a Healthcare (Provider) Supply Chain Perspective

Published on LinkedIn July 2019

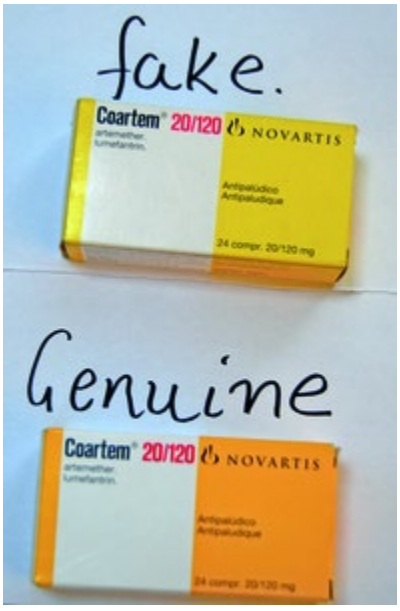
Written by Joe Dudas and Kathy Anderson

Opening

The intent of this document is to provide a slightly different perspective on the Drug Supply Chain Security Act (DSCSA). We fully acknowledge that DSCSA is much broader than our vantage point and that we are not Regulatory, Compliance, Practice or Pharmacy Operations experts; however we wanted to provide a starting point and perspective from the Provider Supply Chain point of view that we hope encourages productive and prudent discussion and action. It is our hope that this document will help Healthcare Providers (as well as other stakeholders) to move forward in the spirit of the law and in the best interest of our patients.

Regulation Summary

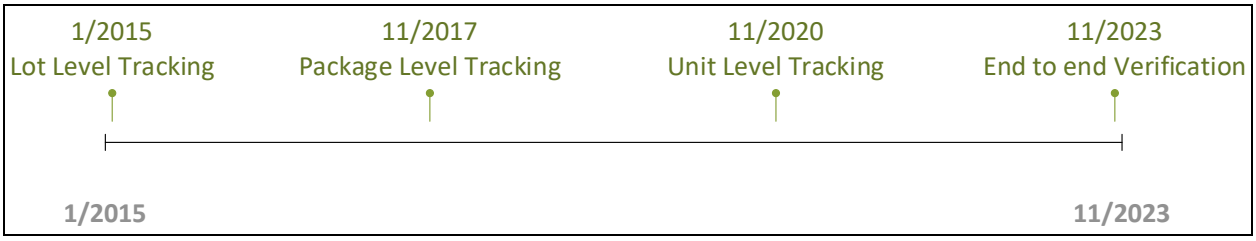
The purpose of the DSCSA is to create an electronic surveillance system for prescription drugs in the United States. So why is this important? The most pressing issue at hand is that of patient safety. Today drug counterfeiting presents a significant issue to patient safety.



- Counterfeiting medication is very profitable for criminals. They take advantage of the good reputation of products and brands that the original manufacturer established through its consistently high-quality products. Fraudsters are only interested in producing what looks like an exact copy, and do not care about the quality and effectiveness of the contents.
- A Pfizer-sponsored study, one of the largest investigations conducted in 14 European countries, estimated that western Europeans spend more than US$ 14 billion a year on illicitly-sourced drugs, many of them counterfeit.
- The overall death toll attributable to counterfeit medicines, like the scale of the business, is unknown but the costs to public health are huge. Quite apart from the direct impact on individuals, counterfeits can cause resistance to medicines for tackling diseases that are leading causes of mortality.

DSCSA created national licensing standards, by building in a phased in approach via the use of transactional and verifiable data sets and with the final phase requiring serialization of drug products. The requirements build over a period of eight years from 2015 through 2023. The law regulates transactions between dispensers, manufacturers, repackagers, wholesale distributors (wholesalers), third party logistics providers and trading partners. Currently tracing, verification, detection and response are required at the lot level. Additional changes continue through 2023, when all pharmaceuticals are required to be traced at the unit level.

Below is a high-level timeline:



The following provides clarity pertaining to a few of the key terms associated with the new regulations.

Transactions: In the law this is spelled out as transaction information (TI), transaction history (TH) and transaction summary (TS) sometimes referred to as T3. The TI is generally a completed purchase. The TH is a listing of all the completed purchases through the chain of custody (not required as it can be derived). TS are generally an attestation that verification was conducted prior to taking possession.

Tracking (Trace): A step-by-step account of where a drug product has been located and who has handled it.

Verification: To ensure that a drug product is legitimate and unaltered.

Detection and Response: A mandate that requires any entity covered under the act (basically everyone) to quarantine and investigate any suspect drug (including notification to the FDA).

As an industry there is continuing debate as to the letter of the law as well as potential punitive actions particularly as it applies to the Provider and two very well published but often confused dates, 2020 and 2023. That said, the intent is quite clear. Patient safety is everyone's responsibility and as the last link in the supply chain to the patient, the dispenser (who ever fills and delivers the prescription) should do everything they can to ensure the patient is protected. In other words, Providers should take advantage of this opportunity not only to comply with the letter of the law, but instead to ensure all drugs that are administered to patients are safe.

Solutions Summary

Moving from paper to automated solutions that help manufacturers, distributors and dispensers comply with the regulation (and more importantly its intent) is critical. Tracking and tracing drugs from the

point of manufacturer to the point of receipt, comes with its own set of hurdles to navigate for all trading partners. Under DSCSA requirements, the manufacturer, distributor and dispenser need technology to receive, track and trace where each drug has changed custody.

Customers and commercial manufacturers around the globe use software to ship, track and trace products all over the world. In our mobile and digital technology world, many thought it should be easy enough to purchase a software solution to manage all requirements from the early stage phases of DSCSA through serialization in 2023.

Vendors in the shipping space were the first to jump in, offering what was touted as an end to end software solution. However, to date, dropships, recalls and faulty or incomplete GTIN data remain a challenge, even with software automation. Many healthcare organizations and U.S. pharmacies are waiting for the "right" software solution and proof that is can automate the serialization aspect of the law.

The solution marketplace is dominated by four vendors (TraceLink, ConstortiEx, RxTransparent and RxScan). All have their merits and drawbacks. Following are a few of our observations pertaining to these solutions as well as other options that may be considered:

1. Software implementation will not guarantee successful completion of a federal audit. Software implementation and ongoing drug tracking/tracing management will always require some level of manual intervention to assure all aspects of the Act are met.
2. Master data management is critical to both implementing, maintaining and securing a successful federal audit. The time and resources involved in identifying the actual supply chain flow from delivery to dispense, the naming convention for each dispensing location and actual drug named are significant.
3. Many healthcare organizations are facing slim margins in today's heavily regulated healthcare environment, and expect the software, regardless of the cost, to alleviate the necessity of adding incremental FTE to meet the letter of the law.
4. Software vendors are scrambling to improve the user experience, assist with drop-ship issues and build the serialization component into their respective software platforms.
5. Value add, when 2023 is 3.5 years is always are hard sell. If the 2023 deadline is not delayed, assessing the length of time it takes to implement software across a large organization and assure the solution meets information technology and security requirements can take 6-12 months or more.

Assessment, Observations and Predictions

Below is a summary of our current viewpoints associated with the various industry stakeholders.

FDA: The FDA is actively moving the initiative through its many government agencies. They have been effective in getting final actions to establish the law. That said, there is a lack of clarity as to certain requirements, timeframes and enforcement. They recognize the need for clarity and as a result have requested voluntary pilots that would be overseen by the FDA. While there is a lot of merit in their intentions it is our experience that the manufacturer and software vendors generally dominate these pilots. As the pilots progress over the next 12-18 months we expect their own interests will continue to control the conversation and prevail in decisions around best possible outcomes, any updates to regulations etc. Some useful information is likely to result but likely not a lot of input from Providers.

Pilots: Blockchain is new technologies that has gotten a lot of attention in the track and trace space and has been speculated by some as a natural fit for DSCSA. We have been monitoring a pilot under the direction of the "Center for Supply Chain Studies". While a lot of progress has been made in modeling the detailed end to end requirements for the law, two things are apparent. Blockchain, while promising remains immature and is not ready for the robust and complex use cases associated with DSCSA. Additionally, simultaneously designing for all stakeholders is painfully slow. We anticipate that timelines will force Healthcare to abandon blockchain for now. Most recently we were introduced to another track and trace pilot in the foods industry. Their scope and complexity of their pilot is more manageable and they seem to be making some progress.

Work Groups: We have personally been participating in two track and trace work groups, both being driven by DSCSA requirements. The first is with the Center for Supply Chain Studies (mentioned previously), with a specific focus on the potential for blockchain. Participants include vendors offering general blockchain solutions (none have an end to end solution). To date, the largest hurdle with blockchain is the lack of maturity both in the technology as well as success with complex use cases such as DSSCA. For this reason progress is slow and while longer term DSSCA might be a sweet spot for blockchain, at this time it is not likely. The second DSCSA workgroup activity is a much smaller consortium of health care organizations that have pharmacies within their healthcare system, in multiple locations throughout the U.S. This is a workgroup that sits under the Healthcare Transformation Group (HTG). Mayo, Kaiser Permanente, Mercy Healthcare and a few others, meet bi-weekly to discuss overall progress and challenges with the current DSCSA requirements. There is consensus that the current vended solutions in the marketplace do not truly offer an end-to-end solution. The group also believes collaboration with commercial industry to build a better, less complex software solution is necessary. Both groups are watching the Federal DSCSA pilot projects closely.

Recommendations

We believe that the industry needs Provider leadership in regards to DSCSA. For that reason, we recommend Providers continue to participate in FDA and Industry workgroups as time and resources permit. We also recommend that we all share our perspective and learnings.

However, given the current landscape, we also recommend that Providers to take action internally and pursue a DSCSA project including Pharmacy, Supply Chain and Compliance (as well as others as necessary). Following would be our recommended scope of functionality/objectives:

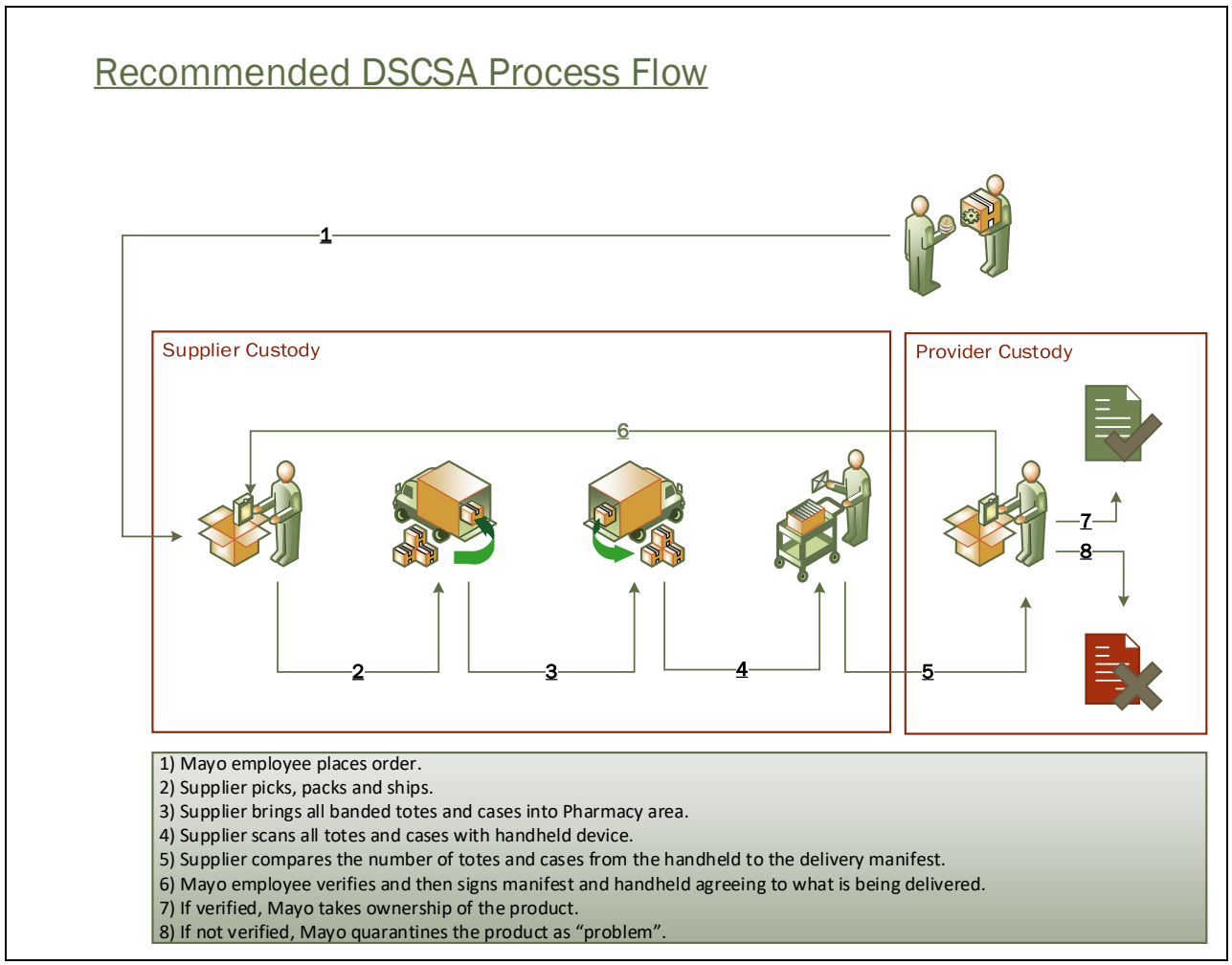
By November 2020:

- All pharmaceutical suppliers must provide labels at the smallest purchase unit (serialization).
- TI, TS and TH data transmitted and stored (through a data collection service partner).
- At the point of receipt, the Provider (or authorized party) will scan and verify each package (auto verification), against the TI/TH data (stored by the data collection service).
- If the auto verification is successful, the Provider will provide an update, attesting that verification has been completed (this proof will be stored by the data collection service). *Note: Inference is not preferred but acceptable, if the container is sealed and if each unit within has been prior verified (upon seal by our supplier).*
- If the auto verification fails, the Provider will work with the supplier to research the issue. If parties conclude that product is found to be suspect, the product will be quarantined and FDA will be notified. Otherwise, as with auto-verification, the Provider will provide an update, attesting that verification has been completed (this proof will be stored by the data collection service).

By November 2023:

- Only auto verification will be used. If auto verification fails, product will be quarantined and FDA will be notified.

Below is a simplified representation of how the system would work with verification.



Important Notes:

1) Providers, most likely, scan at point of dispense for other reasons. It may be a good time to make sure we have TI and whether there might be other reasons (recall, temp issue, etc.) that we don't want to use the product. However, our opinion is that this is not currently required in the U.S. as the regulations are to track and trace change of custody between trading partners.
2) The DSCSA system will likely be used to communicate other states of the product (recall, damage, etc.). At this point we recommend focusing on request through receive functions.
3) Real time location technology solutions are changing rapidly and becoming far more affordable and feasible. Exploring real-time location services to gain potential synergy for supply chain verification may be beneficial. Once again, this may help DSCSA, but at this time RFID is not in scope nor required.
4) A Provider may also be considered as a distributor and/or manufacturer. These requirements should be assessed in parallel to the dispenser recommendations outlined in this document.

As for the various software solutions, there is no perfect system and we feel vendors are likely over engineering processes and promises. For this reason, we recommend that the Provider partner (joint

development) with one of the market leaders previously mentioned to develop an effective and efficient solution. If a likeminded vendor is not quickly determined, we recommend seeking other solutions that might be repurposed from other industries or that a custom solution or cloud platform provider could be approached with this opportunity.

References

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3) https://www.healthcaretransformationgroup.com/
4) https://www.c4scs.org/
5) https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/dscsa-pilot-project-program