PDSA
Pharmaceutical Distribution Security Alliance

Association for Accessible Medicines (AAM)

Biotechnology Innovation Organization (BIO)

Pharmaceutical Research and Manufacturers of America (PhRMA)

Healthcare Distribution Alliance (HDA)

International Warehouse Logistics Association (IWLA)

American Society of Health-System Pharmacists (ASHP)

National Association of Chain Drug Stores (NACDS)

Abbvie

Allergan

AmerisourceBergen

AstraZeneca

Bayer

Bristol-Myers Squibb

CardinalHealth

Celgene

CVSHealth

Fresenius Kabi USA

Genentech

Inmar

Johnson & Johnson

Medline Industries

Merck

Mylan

Novartis

Pfizer

Upsher-Smith Laboratories

An Overview: PDSA Vision for Phase II Interoperability and Governance

MARCH 25, 2019

The Drug Supply Chain Security Act (DSCSA) mandates the development and implementation of systems and processes for the "interoperable, electronic tracing of [pharmaceutical] product at the package level" no later than November 27, 2023. In order to reach that milestone efficiently and effectively, it is critical that stakeholders,[1] including industry and FDA, have a shared vision for Phase II. The Pharmaceutical Distribution Security Alliance (PDSA),[2] an alliance of more than 30 companies and trade associations from every sector of the pharmaceutical supply chain, seeks through this series of white papers to stimulate and advance the stakeholder dialogue related to, and development of, that shared vision. Specifically, PDSA intends to release three white papers for such consideration and advancement:

1. **White Paper 1: A Proposal: Governance for DSCSA Phase II Interoperability**
2. **White Paper 2: The Interoperable Exchange of Transaction Information and Transaction Statements**
3. **White Paper 3: The Interoperable Verification and Tracing of Pharmaceuticals**

Each of these white papers will be written to stand on its own, but read together, the series of white papers is intended to provide a comprehensive vision for DSCSA interoperability. Each paper reflects significant input and discussion among trading partners from all sectors of the supply chain—manufacturers, repackagers, wholesalers, third-party logistics providers, and dispensers.

It is important to note that we use the term "vision" broadly to mean an overarching approach to interoperability. In that way, PDSA recognizes such overarching approach may encompass multiple methods of compliance (*i.e.*, multiple models, systems, solutions, technologies, architectures, etc.) that emerge and may compete with each other. PDSA believes that it should be the role of a governance body to establish and support the implementation of one vision for interoperability and connectivity among those multiple methods of compliance.[3] The PDSA vision articulated in these white papers is simply one vision we suggest be considered by a governance body (once formed).

The process of transitioning from current Phase I (*i.e.*, the requirements in effect as of January 1, 2015) tracing requirements to Phase II (*i.e.*, the requirements effective November 27, 2023) systems and processes will require significant, shared, collaborative efforts from all sectors of the supply chain, including regulators. Although Phase II is almost five years away, it is critical that industry and regulators immediately begin movement toward a consensus vision/approach[4] to Phase II for many reasons:

1. Any conceptual systems and processes for Phase II will require significant development activities, potential standard development and adoption,[5] testing, and piloting.

[1] We use "stakeholder" to include all interested parties, including trading partners, regulators, and other interested parties. We use "industry" and "trading partners" interchangeably to mean trading partners, as defined in the DSCSA.

[2] PDSA is a multi-stakeholder coalition with membership that spans the entire spectrum of the U.S. pharmaceutical distribution system, including manufacturers, repackagers, wholesale distributors, third-party logistics providers, and pharmacies. More than 30 companies are formal members of PDSA, while many other external stakeholders provide additional policy and technical support through industry trade associations. Our primary goal is ensuring patients have uninterrupted access to safe, authentic, FDA-approved medicine.

[3] This would also include the identification, recognition, or development (as needed) of policies, procedures, and/or technical specifications for interoperability by which other methods that emerge outside of the governance body's vision may be interoperable with methods that are within the governance body's vision.

[4] A consensus approach may incorporate multiple methods of compliance.

[5] Likely/often by a third-party standards development organization.

2. A significant amount of time is needed for industry dialogue and discussion in order to align behind a vision for interoperability.
3. Capital investments and planning for any Phase II systems or processes could require several years' lead time.
4. Certain systems and processes that may be needed for Phase II may inform and help to sustain the systems and processes that will be used to meet the requirements for enhanced verification and verification of saleable returns in 2019.
5. Regulator understanding and recognition of any Phase II solution will require ongoing communication (among industry members and with regulators) and continuous testing of assumptions and operational capabilities against statutory requirements.
6. There are a tremendous number of companies that must be "on boarded" to any Phase II system and, as we saw in Phase I, this process of compliance can be lengthy and the large number of connections can add exponential complexity.[6] Obtaining feedback, refinements, and buy in from industry partners—particularly those not represented within PDSA—can bolster adoption efforts.

We believe the vision for Phase II described in this series of white papers is a significant step forward on the path to implementation and will advance the collective dialogue regarding Phase II. **The proposed vision in this series of white papers does not represent an absolute commitment by PDSA members to implement Phase II in the manner set out; rather, the vision in this series of white papers reflects PDSA's best current thinking and is intended to stimulate conversation among all stakeholders, including FDA.** There may well be pathways to implementation and compliance different from what is set forth in these white papers. The vision in these white papers represent one possible high-level framework for implementation, but identifies numerous areas where additional detail, research, or piloting will be needed. Callout boxes are used to highlight specific areas where such additional work will be essential. Furthermore, the governance body structure proposed in White Paper 1 is not dependent on adoption of/support for the vision for interoperability articulated in forthcoming White Papers 2 and 3.

PDSA recognizes that it is unlikely every trading partner will adopt and implement systems and processes that are based on the same vision for Phase II. In fact, the DSCSA bars FDA from requiring "the adoption of specific business systems" and requires that FDA "provide for alternative methods of compliance" with the Phase II requirements.[7] As a result, it is recognized that multiple approaches to Phase II may be adopted. It is, however, also recognized that broadly divergent approaches to Phase II will present challenges to statutorily required interoperability. Therefore, alignment of a critical mass of industry (along with regulatory engagement) to a shared vision for Phase II, which as noted above may include multiple competing models, is critical to implementation of the statutory requirements for interoperability. Early and robust industry and regulator dialogue—hopefully building upon the vision outlined in this series of white papers—will support broad stakeholder alignment and interoperability.

[6] There are estimated to be hundreds of manufacturers, dozens of wholesale distributors, and tens of thousands of dispensers in the supply chain today.

[7] Federal Food, Drug, and Cosmetic Act (FDCA) § 582(g)(4).

I. DSCSA Phase II Requirements[8]

The DSCSA construct recognizes the operational complexity of unit-level tracing and phases in the related requirements over a 10-year period. The traceability requirements in effect from January 1, 2015 to November 26, 2023 (Phase I) require pharmaceutical products to be traceable at the lot level, and the statute provides relatively clear direction as to how such traceability is to be achieved. The statute provides *much* less detail with regard to the Phase II requirements (effective November 27, 2023) for the tracing of products at the package level.[9] Collaborative stakeholder engagement to help develop a shared vision for how those Phase II requirements could be implemented will help advance the statutory objectives and benefit all stakeholders. The views set forth in the PDSA white papers will be used to help inform government rulemaking and actions and will represent one way (but not the only way) to satisfy the requirements of DSCSA.

Phase II is comprised of three specific, but highly interrelated statutory components. These three components are referenced and addressed throughout these papers. Each goes into effect on November 27, 2023.

1. **Interoperable Exchange.** Trading partners must exchange required transaction information (TI) and transaction statements (TS) in a secure, electronic, interoperable manner, and the TI must include the product identifier at the package level.[10]
2. **Interoperable Verification.** Trading partners must be able to verify the product identifier on a package or sealed homogenous case in a secure, electronic, interoperable manner.[11]
3. **Interoperable Tracing.** Trading partners must maintain secure, electronic, interoperable systems and processes to provide TI and TS in response to a request for it and to promptly facilitate gathering the information necessary to produce the TI for each transaction going back to the manufacturer.[12]

Some Phase I requirements continue to apply in Phase II. However, other Phase I requirements sunset (*i.e.*, end) on November 27, 2023, including the Phase I requirement that each transfer of a product be accompanied by the full transaction history (TH) of the product back to the manufacturer.[13] The sunset of TH is consistent with the understanding that the DSCSA is a "one up and one back" model in which each trading partner has record of the entity from which it purchased a product and the entity to which it sold the product. However, FDA has made clear that, while it recognizes the exchange of TH ends in Phase II, it believes interoperable tracing systems and processes should be capable of providing information that is functionally equivalent to a unit-level TH.[14]

A complete detailed listing of the statutory Phase II requirements (categorized by the three components above) is included in Appendix B.

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[8] These papers assume general familiarity with the DSCSA, including DSCSA terminology and the substantive requirements. Background on the DSCSA is available at https://pdsaonline.org/dscsa-information/ and from other resources that can be found at https://pdsaonline.org/resources/.

[9] The statutory text of Phase II is included in Appendix A for reference.

[10] FD&C Act § 582(g)(1)(A), (B). The requirement to exchange transaction history (TH) sunsets in 2023.

[11] FD&C Act § 582(g)(1)(C), (F).

[12] FD&C Act § 582(g)(1)(D), (E). Such request may be made by a regulatory authority or authorized trading partner on account of a recall or for investigating suspect or illegitimate product.

[13] FD&C Act § 582(k)(1).

[14] *See* https://www.fda.gov/NewsEvents/Speeches/ucm598719.htm, FD&C Act § 582(g)(1)(E).

It is also important to consider that legal and regulatory requirements separate and apart from the DSCSA may significantly impact how Phase II is implemented. For example, cGMP requirements and 21 CFR Part 11 requirements related to electronic records and FDA's related guidance on data integrity[15] may impact the way in which TI data is generated, stored, and managed. Similarly, antitrust laws may restrict certain activities or solutions.

Phase II requirements are self-effectuating, but FDA is required to publish guidance and/or regulations clarifying the Phase II requirements. Pursuant to the express requirements of the DSCSA, these guidance documents are expected to address, at a minimum, the system attributes necessary to enable secure tracing at the package level and standards of interoperable data exchange necessary to enhance the security of the pharmaceutical distribution supply chain.[16] It is essential that industry work collaboratively with FDA and other regulatory stakeholders to ensure alignment on expectations that are operationally practical, technically feasible, and achieve appropriate public health objectives. It is our hope that these papers will be central to such collaboration with FDA and inform FDA's guidances and regulations.

II. Scope and Objectives of Appropriate Phase II Systems and Processes

The statutory provisions describing Phase II are intentionally vague, which presents both opportunities and challenges for industry. The vagueness in the statutory requirements reflects a recognition that the detailed complexities of traceability and the related technologies that may emerge could not be fully accounted for in statute. However, the lack of clear specificity in the statute leaves a broad, highly diverse set of stakeholders throughout the supply chain to develop their vision—some components of which must necessarily be aligned in order to achieve DSCSA interoperability—for implementation of the statute. Other components need not necessarily align. This vision must balance and account for a number of important factual and policy considerations:

1. The breadth, diversity, and complexity of the supply chain is immense. Operational implementation of even basic, immature, systems and processes for traceability will be challenging and resource-intensive, and nearly every company will have unique circumstances that exacerbate the challenge.
2. Serialization is being implemented in markets around the globe,[17] and domestic trading partners and regulators are monitoring that activity and will be influenced by it. However, Congress deliberately selected and enacted a traceability model that differs in important respects from those of many other global markets.[18]
3. The statute expressly calls for the flexibility to allow different trading partners to implement different methods of compliance based on their business models.[19] However, certain

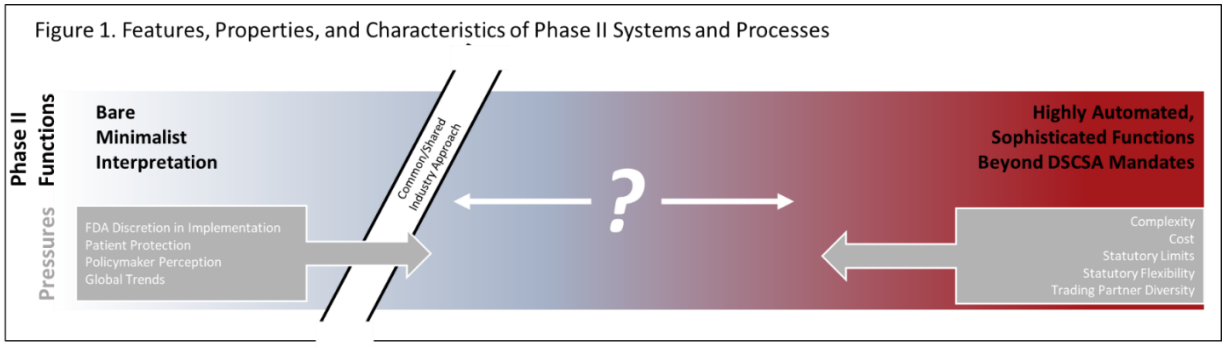
[15] *See* https://www.fda.gov/downloads/drugs/guidances/ucm495891.pdf.
[16] FD&C Act § 582(h).
[17] There is no consensus as to the optimal regulatory model for using serialization data, and nearly every country with requirements has faced significant implementation challenges and delays.
[18] For example, the European Union's point-of-dispense verification system is frequently referenced in industry and regulator discussions. While the EU implementation may provide some valuable lessons, it must also be recognized that Congress, through the DSCSA, deliberately selected a very different serialization model—a tracing model focused on the ability to recreate a product's path of ownership, not a verification model. In fact, the EU had not even published its technical requirements at the time the DSCSA was enacted.
[19] FD&C Act § 582 (g)(4)(A)(ii).

components of Phase II systems and processes must necessarily be aligned across the industry to enable interoperability.

4. When statutory requirements are vague, regulatory agencies can have broad latitude to interpret and effectuate those requirements through rulemaking.[20] Where the DSCSA may lack specificity, it is critical that industry work collaboratively with FDA to develop reasonable, achievable expectations for Phase II implementation.
5. The core policy objectives of the DSCSA—supply chain security and patient safety—are paramount. As new policy issues arise, there is risk that Congress will look to enhance DSCSA Phase II requirements as a solution to such policy issues if it does not believe industry has effectively implemented Phase II systems and processes.
6. Technology and business practices will continue to evolve prior to and after 2023, and DSCSA systems and process must be flexible enough to keep pace.

All stakeholders must balance these competing considerations in developing a vision to be presented to regulators for practical, reasonable, cost-effective, flexible Phase II systems and processes. Figure 1, below, presents this delicate balance graphically. As shown, there is a wide spectrum of functionalities that could be incorporated in Phase II systems and process. To the far left of the spectrum is a "bare minimalist" type of approach that seeks to implement only the most basic, explicitly articulated requirements of Phase II. We believe the considerations or "pressures" such as those described above (and shown in gray in the graphic) make this bare minimalist approach unviable. To the far right are highly automated, sophisticated, fully integrated systems and processes, such as those that have been identified by FDA for discussion and consideration (*e.g.*, enable trading partners to verify product identifiers accurately and efficiently to facilitate investigations of suspect or illegitimate product, recalls, and saleable returns; verify that a trading partner is an "authorized" trading partner; improve the ability of FDA and trading partners to prevent distribution of suspect or illegitimate product; signals that a product has been determined to be illegitimate).[21] However, some of those functions go beyond our perceived intent of the statute, and we believe such systems and processes are infeasible due to pressures such as complexity and cost, as well as statutory limitations. The question for regulators and industry, therefore, is how far to the left or right of the spectrum are the systems and processes that strike an appropriate balance of all these considerations, recognizing that such systems and processes may be time-oriented (some functionalities may be reasonable for 2023, and others may be feasible only on a longer time horizon). The papers being released by PDSA will help stakeholders answer that question.

Figure 1. Features, Properties, and Characteristics of Phase II Systems and Processes



[20] *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).

[21] *See* Drug Supply Chain Security Act (DSCSA) Public Meeting Series, *Enhanced Drug Distribution Security* (February 28, 2018), *available at* https://www.fda.gov/downloads/Drugs/NewsEvents/UCM602534.pdf.

III. Background: Understanding Distribution Processes

It is essential that each trading partner have flexibility to design and use its own internal operational processes for DSCSA compliance that are tailored to its business needs. With that recognition, however, it is also important to recognize that, particularly in Phase II, internal processes can impact the content and reliability of the data available downstream for statutorily required tracing and ultimately, the ability to provide an accurate chain of ownership for a particular unit. Therefore, it is useful for stakeholders, including the FDA, to at least have a common baseline *understanding* of the processes for DSCSA compliance that are *anticipated*[22] to be used. This section is not intended to establish requirements, expectations, or recommendations, nor is it an assessment or endorsement of the processes described. Rather, this section describes examples of—*solely for purposes of common understanding and as background for discussion of interoperability*—the processes for DSCSA compliance that many trading partners currently anticipate using. Other processes may be used, and these anticipated processes may continue to evolve or change, but at this time, we believe it is the best current background for helping FDA and others understand how interoperability may be considered. We believe this factual explanation of current/anticipated supply chain processes for DSCSA compliance can provide useful background for industry and regulators as both move to the next phase of DSCSA implementation.

Under the DSCSA (particularly in Phase II), there are effectively two supply chains, which do not always move in the same manner. The ***physical supply chain*** consists of the physical movement and handling of product among trading partners, which has historically happened and continues. The ***virtual supply chain*** consists of DSCSA-mandated data (and potentially other data), including TI and TS, that are intended to mirror the physical supply chain. To aid in understanding how supply chain processes will impact Phase II implementation, the process flows in Appendix C represent the anticipated[23] supply chain processes. These process flows represent the most common anticipated use cases for each sector.

Specifically, Appendix C diagrams the anticipated physical and virtual supply chain processes for DSCSA compliance by sector for 15 of the most common use cases.

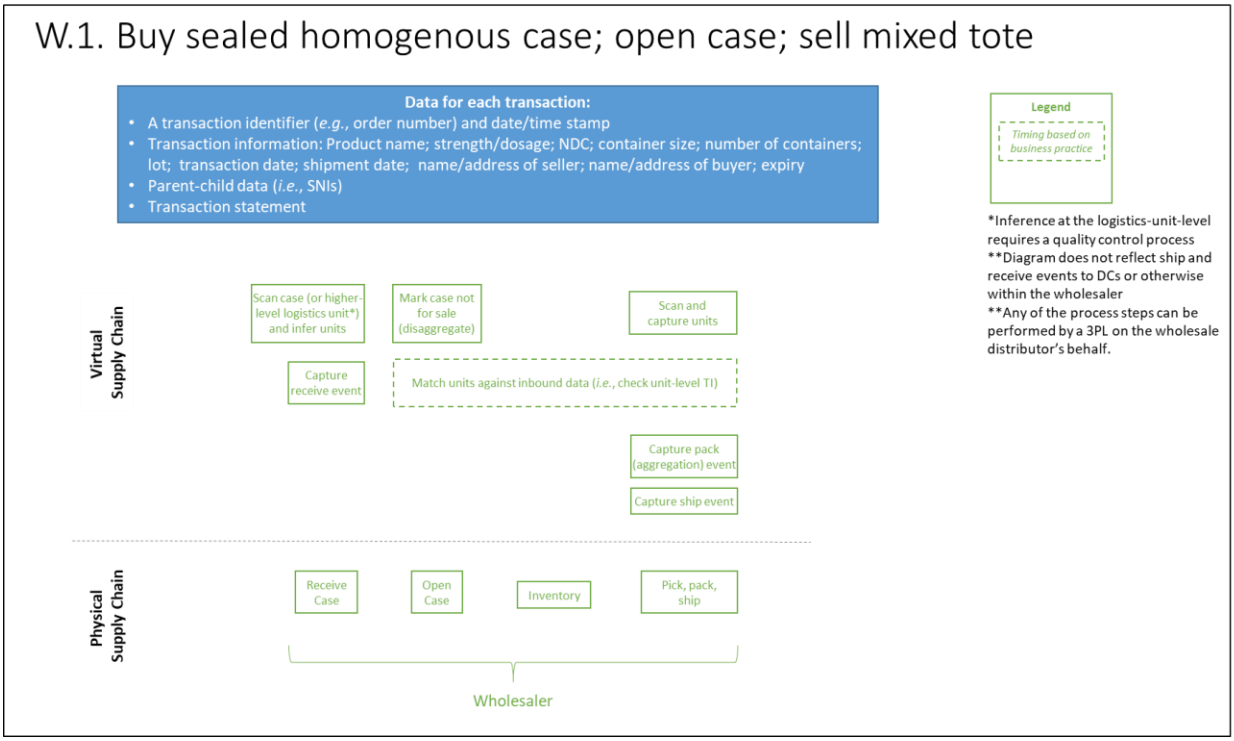
Manufacturers	Wholesalers	Repackagers	Dispensers
Use Case 1: Sale of a sealed homogenous case	*Use Case 1:* Purchase of a sealed homogenous case; open that case; sell a mixed tote of packages	*Use Case 1:* Purchase of a sealed homogenous case; open that case; repackage the units; sale of a sealed homogenous case	*Use Case 1:* Purchase of a sealed homogenous case; open that case; dispense the product
Use Case 2: Sale of a non-homogenous case (*i.e.*, a mixed case or repack of multiple NDCs)	*Use Case 2:* Purchase of a sealed homogenous case; sale of that sealed homogenous case	*Use Case 2:* Purchase of a sealed homogenous case; open that case; repackage the units; sale of a non-homogenous case	*Use Case 2:* Purchase of a non-homogenous case/mixed tote; dispense the product
Use Case 3: Receipt of a sealed homogenous case as a saleable return; sale of that sealed homogenous case	*Use Case 3:* Purchase of a non-homogenous case/ mixed tote; Open that case/tote; sale of a mixed tote		*Use Case 3:* Return a sealed homogenous case as a saleable return
Use Case 4: Receipt of a package as a saleable return; sale of that package in a non-homogenous case	*Use Case 4:* Receipt of a sealed homogenous case as a saleable return; sale of that sealed homogenous case		*Use Case 4:* Return a package as a saleable return
	Use Case 5: Receipt of a package as a saleable return; sale of that package in a mixed tote		

[22] Throughout this paper we use the word "anticipated" as a predictive statement of future fact. It is not intended as a requirement that must be followed; it is merely an explanation of what trading partners—at this time—generally believe may be voluntarily implemented by many or most trading partners.

[23] Some trading partners may choose to use alternative processes. The process flows in Appendix C are intended only to represent—for educational purposes—the processes that many trading partners anticipate using.

As an example of the process flows included in **Appendix C**, one use case (Wholesaler Use Case 1) is shown below in Figure 2. The diagram shows the physical (bottom) and virtual (top) supply chains for the use case in which a wholesale distributor purchases a sealed homogenous case, opens the case, and sells the individual packages from the case as part of multiple mixed totes (*i.e.*, non-homogenous cases or totes containing packages of multiple products).

Figure 2. Example Process Flow



In the physical process for this use case, the wholesale distributor first receives the sealed homogenous case into its warehouse; second, it opens the case; third, it places the individual packages from the case into its inventory; and fourth, the individual packages are placed into mixed totes for sale to another trading partner as part of the wholesaler's pick, pack, and ship operation.

The anticipated process steps shown above the physical supply chain will generate and manage the data that comprises the virtual supply chain. In the anticipated virtual supply chain process, upon physical receipt, the wholesale distributor scans the case to infer (using aggregation and inference practices) the individual packages[24] contained in the sealed homogenous case.[25] Inference can also be based on a higher-level logistics unit, such as a pallet, using an SSCC (Serial Shipping Container Code) if sound quality processes are in place. At this point, the wholesaler's systems and processes generate an Electronic Product Code Information Services (EPCIS)[26] "receive" event that identifies each inferred unit as having been received.

When the physical case is opened, systems and process indicate that the opened case is no longer available for trade as a case. This process is often referred to as "disaggregation" because aggregation

[24] "Package," "saleable unit," and "unit" are used interchangeably in this paper to mean the package, as defined in FD&C Act § 581(11).

[25] This is not intended create an obligation to scan or rely on inference. This is merely the process that we predict many wholesalers may choose to follow.

[26] EPCIS is a global GS1 Standard for creating and sharing visibility event data.

and inference become invalid once the case is opened. At this time, this disaggregation step is anticipated to occur within the wholesaler's operations; it is not currently anticipated that this information would be communicated to prior trading partners, such as the manufacturer based on trading partner agreements (though such communication would not be restricted).

As part of the wholesaler's pick, pack, and ship operations, it is anticipated the wholesaler will aggregate the various packages to the mixed tote by scanning those packages, creating an EPCIS packing event, and then creating an EPCIS shipping event for the units/mixed tote.

For reasons discussed in greater detail in White Paper 2: The Interoperable Exchange of Transaction Information and Transaction Statements (*forthcoming*), aggregation and inference have the potential to create inconsistencies between the data presented in the physical and virtual supply chain if proper controls are not in place. As one such control, it is anticipated that many wholesale distributors will have a process in place to ensure that the physical saleable units (no longer in a sealed homogenous case) it sells were among the inferred saleable units (*i.e.,* virtual supply chain) it received in a sealed homogenous case. How and when that process occurs is a matter of business process that will be decided by each company (it is therefore shown in a dotted green box to represent such variability).

The remaining 14 uses cases are diagramed in Appendix C and provide the baseline understanding upon which the three components of Phase II—interoperable exchange, verification, and tracing—will be built.

IV. Stakeholder Feedback

As noted above, the series of white papers is intended to advance the collective industry dialogue regarding DSCSA interoperability and industry's dialogue with FDA. We urge all stakeholders to consider the ideas and proposals in these white papers, engage in dialogue regarding the pros and cons of those ideas and proposals, and rapidly move toward a consensus vision through that dialogue.

APPENDIX A—DSCSA Phase II Statutory Text

SEC. 203. ENHANCED DRUG DISTRIBUTION SECURITY.

Section 582, as added by section 202, is amended by adding at the

end the following:

``(g) Enhanced Drug Distribution Security.--

``(1) In general.--On the date that is 10 years after the date of enactment of the Drug Supply Chain Security Act, the following interoperable, electronic tracing of product at the package level requirements shall go into effect:

``(A) The transaction information and the transaction statements as required under this section shall be exchanged in a secure, interoperable, electronic manner in accordance with the standards established under the guidance issued pursuant to paragraphs (3) and (4) of subsection (h), including any revision of such guidance issued in accordance with paragraph (5) of such subsection.

``(B) The transaction information required under this section shall include the product identifier at the package level for each package included in the transaction.

``(C) Systems and processes for verification of product at the package level, including the standardized numerical identifier, shall be required in accordance with the standards established under the guidance issued pursuant to subsection (a)(2) and the guidances issued pursuant to paragraphs (2), (3), and (4) of subsection (h), including any revision of such guidances issued in accordance with paragraph (5) of such subsection, which may include the use of aggregation and inference as necessary.

``(D) The systems and processes necessary to promptly respond with the transaction information and transaction statement for a product upon a request by the Secretary (or other appropriate Federal or State official) in the event of a recall or for the purposes of investigating a suspect product or an illegitimate product shall be required.

``(E) The systems and processes necessary to promptly facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer, as applicable, shall be required--

``(i) in the event of a request by the Secretary (or other appropriate Federal or State official), on account of a recall or for the purposes of investigating a suspect product or an illegitimate product; or

``(ii) in the event of a request by an authorized trading partner, in a secure manner that ensures the protection of confidential commercial information and trade secrets, for purposes of investigating a suspect product or assisting the Secretary (or other appropriate Federal or State official) with a request described in clause (i).

``(F) Each person accepting a saleable return shall have systems and processes in place to allow acceptance of such product and may accept saleable returns only if such person can associate the saleable return product with the transaction information and transaction statement associated with that product.

``(2) Compliance.--

``(A) Information maintenance agreement.--A dispenser may enter into a written agreement with a third party, including an authorized wholesale distributor, under which the third party shall confidentially maintain any information and statements required to be maintained under this section. If a dispenser enters into such an agreement, the dispenser shall maintain a copy of the written agreement and shall not be relieved of the obligations of the dispenser under this subsection.

``(B) Alternative methods.--The Secretary, taking into consideration the assessment conducted under paragraph (3), shall provide for alternative methods of compliance with any of the requirements set forth in paragraph (1), including--

``(i) establishing timelines for compliance by small businesses (including small business dispensers with 25 or fewer full-time employees) with such requirements, in order to ensure that such requirements do not impose undue economic hardship for small businesses, including small business dispensers for whom the criteria set forth in the assessment under paragraph (3) is not met, if the Secretary determines that such requirements under paragraph (1) would result in undue economic hardship; and

``(ii) establishing a process by which a dispenser may request a waiver from any of the requirements set forth in paragraph (1) if the Secretary determines that such requirements would result in an undue economic hardship, which shall include a process for the biennial review and renewal of any such waiver.

``(3) Assessment.--

``(A) In general.--Not later than the date that is 18 months after the Secretary issues the final guidance required under subsection (h), the Secretary shall enter into a contract with a private, independent consulting firm with expertise to conduct a technology and software assessment that looks at the feasibility of dispensers with 25 or fewer full-time employees conducting interoperable, electronic tracing of products at the package level. Such assessment shall be completed not later than 8 1/2 years after the date of enactment of the Drug Supply Chain Security Act.

``(B) Condition.--As a condition of the award of the contract under subparagraph (A), the private, independent consulting firm shall agree to consult with dispensers with 25 or fewer full-time employees when conducting the assessment under such subparagraph.

``(C) Content.--The assessment under subparagraph (A) shall assess whether--

``(i) the necessary software and hardware is readily accessible to such dispensers;

``(ii) the necessary software and hardware is prohibitively expensive to obtain, install, and maintain for such dispensers; and

``(iii) the necessary hardware and software can be integrated into business practices, such as interoperability with wholesale distributors, for such dispensers.

``(D) Publication.--The Secretary shall--

``(i) publish the statement of work for the assessment under subparagraph (A) for public comment prior to beginning the assessment;

``(ii) publish the final assessment for public comment not later than 30 calendar days after receiving such assessment; and

``(iii) hold a public meeting not later than 180 calendar days after receiving the final assessment at which public stakeholders may present their views on the assessment.

``(4) Procedure.--Notwithstanding section 553 of title 5, United States Code, the Secretary, in promulgating any regulation pursuant to this section, shall--

``(A) provide appropriate flexibility by--

``(i) not requiring the adoption of specific business systems for the maintenance and transmission of data;

``(ii) prescribing alternative methods of compliance for any of the requirements set forth in paragraph (1) or set forth in regulations implementing such requirements, including--

``(I) timelines for small businesses to comply with the requirements set forth in the regulations in order to ensure that such requirements do not impose undue economic hardship for small businesses (including small business dispensers for whom the criteria set forth in the assessment under paragraph (3) is not met), if the Secretary determines that such requirements would result in undue economic hardship; and

``(II) the establishment of a process by which a dispenser may request a waiver from any of the requirements set forth in such regulations if the Secretary determines that such requirements would result in an undue economic hardship; and

``(iii) taking into consideration--

``(I) the results of pilot projects, including pilot projects pursuant to this section and private sector pilot projects, including those involving the use of aggregation and inference;

``(II) the public meetings held and related guidance documents issued under this section;

``(III) the public health benefits of any additional regulations in comparison to the cost of compliance with such requirements, including on entities of varying sizes and capabilities;

``(IV) the diversity of the pharmaceutical distribution supply chain by providing appropriate flexibility for each sector, including both large and small businesses; and

``(V) the assessment pursuant to paragraph (3) with respect to small business dispensers, including related public comment and the public meeting, and requirements under this section;

``(B) issue a notice of proposed rulemaking that includes a copy of the proposed regulation;

``(C) provide a period of not less than 60 days for comments on the proposed regulation; and

``(D) publish in the Federal Register the final regulation not less than 2 years prior to the effective date of the regulation.

APPENDIX B—Detailed Phase II Statutory Requirements

	Topic	Applicable Sectors	Statutory Requirement
1	Interoperable Exchange	Manufacturers Wholesalers Dispensers Repackagers	*Outbound transactions:* TI that includes the product identifier at the package level for each package in the transaction must be provided to the subsequent owner (excludes patient sales and dispenser-to-dispenser sales for a specific patient need)
2	Interoperable Exchange	Manufacturers Wholesalers Dispensers Repackagers	TI must be provided in an electronic manner
3	Interoperable Exchange	Manufacturers Wholesalers Dispensers Repackagers	TI must be provided in an interoperable manner
4	Interoperable Exchange	Manufacturers Wholesalers Dispensers Repackagers	TI must be provided in a secure manner
5	Interoperable Exchange	Manufacturers Wholesalers Repackagers	*Outbound transactions:* TI for each outbound transaction must be captured and maintained for 6 years
6	Interoperable Exchange	Dispensers	*Outbound transactions:* Dispensers must capture and maintain (6yrs) TI for each outbound transaction as necessary to investigate suspect product *(may contract with third-party to maintain)*
7	Interoperable Exchange	Manufacturers Wholesalers Dispensers Repackagers	*Outbound transactions:* TS must be provided to the subsequent owner (excludes patient sales and dispenser-to-dispenser sales for a specific patient need)
8	Interoperable Exchange	Manufacturers Wholesalers Dispensers Repackagers	TS must be provided in an electronic manner
9	Interoperable Exchange	Manufacturers Wholesalers Dispensers Repackagers	TS must be provided in an interoperable manner

10	Interoperable Exchange	Manufacturers Wholesalers Dispensers Repackagers	TS must be provided in secure manner
11	Interoperable Exchange	Manufacturers Wholesalers Repackagers	*Outbound transactions:* TS for each outbound transaction must be captured and maintained for 6 years
12	Interoperable Exchange	Dispensers	*Outbound transactions:* Dispensers must capture and maintain (6yrs) TS for each outbound transaction as necessary to investigate suspect product *(may contract with third-party to maintain)*
13	Interoperable Exchange	Wholesalers Dispensers Repackagers	*Inbound transactions:* TI from prior owner that includes the product identifier at the package level for each package in the transaction must be received (i.e., prior owner must "provide") before accepting ownership
14	Interoperable Exchange	Wholesalers Dispensers Repackagers	TI must be provided in an electronic manner
15	Interoperable Exchange	Wholesalers Dispensers Repackagers	TI must be provided in an interoperable manner
16	Interoperable Exchange	Wholesalers Dispensers Repackagers	TI must be provided in a secure manner
17	Interoperable Exchange	Wholesalers Repackagers	*Inbound transactions:* TI for each inbound transaction must be captured and maintained for 6 years
18	Interoperable Exchange	Dispensers	*Inbound transactions:* Dispensers must capture and maintain (6yrs) TI for each inbound transaction as necessary to investigate suspect product *(may contract with third-party to maintain)*
19	Interoperable Exchange	Wholesalers Dispensers Repackagers	*Inbound transactions:* TS from the prior owner must be received (i.e., prior owner must "provide") before accepting ownership
20	Interoperable Exchange	Wholesalers Dispensers Repackagers	TS must be provided in an electronic manner
21	Interoperable Exchange	Wholesalers Dispensers Repackagers	TS must be provided in an interoperable manner

22	Interoperable Exchange	Wholesalers Dispensers Repackagers	TS must be provided in secure manner
23	Interoperable Exchange	Wholesalers Repackagers	*Inbound transaction*: TS for each inbound transaction must be captured and maintained for 6 years
24	Interoperable Exchange	Dispensers	*Inbound transactions:* Dispensers must capture and maintain (6yrs) TS for each inbound transaction as necessary to investigate suspect product *(may contract with third-party to maintain)*
25	Interoperable Exchange	Manufacturers Repackagers	Product identifier information must be maintained for 6 years
26	Interoperable Exchange	Repackagers	Repackagers must maintain records to associate its product identifier with MFR's product identifier for 6 yrs
27	Requests for Information	Manufacturers Wholesalers Dispensers Repackagers	TI must be provided to the Secretary (or other appropriate Federal or State official) upon request within 24 hours (2 business days for dispensers) (limited to recalls or investigation of suspect and illegitimate product)
28	Requests for Information	Manufacturers Wholesalers Dispensers Repackagers	TS must be provided to the Secretary (or other appropriate Federal or State official) upon request within 24 hours (2 business days for dispensers) (limited to recalls or investigation of suspect and illegitimate product)
29	Requests for Information	Manufacturers Wholesalers Dispensers Repackagers	Trading partners must have systems and processes to promptly provide TI to the Secretary (or other appropriate Federal or State official) upon request in the event of recall or suspect or illegitimate product
30	Requests for Information	Manufacturers Wholesalers Dispensers Repackagers	Trading partners must have systems and processes to promptly provide TS to the Secretary (or other appropriate Federal or State official) upon request in the event of recall or suspect or illegitimate product
31	Interoperable Verification	Manufacturers	Upon request for verification from an authorized repackager, wholesaler, or dispenser with possession of a product, manufacturers must verify the PI of the product within 24 hrs *(may satisfy via secure electronic database)*
32	Interoperable Verification	Repackagers	Upon request for verification from an authorized manufacturer, wholesaler, or dispenser with possession of a product, repackagers must verify the PI of the product within 24 hrs *(may satisfy via secure electronic database)*
33	Interoperable Verification	Manufacturers Wholesalers Dispensers Repackagers	As part of a suspect product investigation, the product identifier at the package level, including SNI, must be verified (dispensers only required to verify for 3 packages or 10%) *(may satisfy via secure electronic database)*

34	Interoperable Verification	Dispensers	For suspect product, dispensers must verify the lot number *(may satisfy via secure electronic database)*
35	Interoperable Verification	Wholesalers	For saleable returns, wholesalers must verify the product identifier, including SNI, for saleable returns *(may satisfy via secure electronic database)*
36	Saleable Returns	Manufacturers Wholesalers Dispensers Repackagers	Trading partners that accept a saleable return must associate the saleable return with the TI and TS for the returned product
37	Other	Manufacturers Wholesalers Dispensers Repackagers	For suspect product, TI in the trading partner's possession must be validated to determine whether suspect product is an illegitimate product *(may satisfy via secure electronic database)*
38	Interoperable Tracing	Manufacturers Wholesalers Dispensers Repackagers	Trading partners must have systems and processes to promptly facilitate gathering the information necessary to produce the TI for each transaction going back to the manufacturer, as applicable
39	Interoperable Tracing	Manufacturers Wholesalers Dispensers Repackagers	If the request is from an authorized trading partner, the facilitation of the gathering must be in a secure manner that protects confidential information

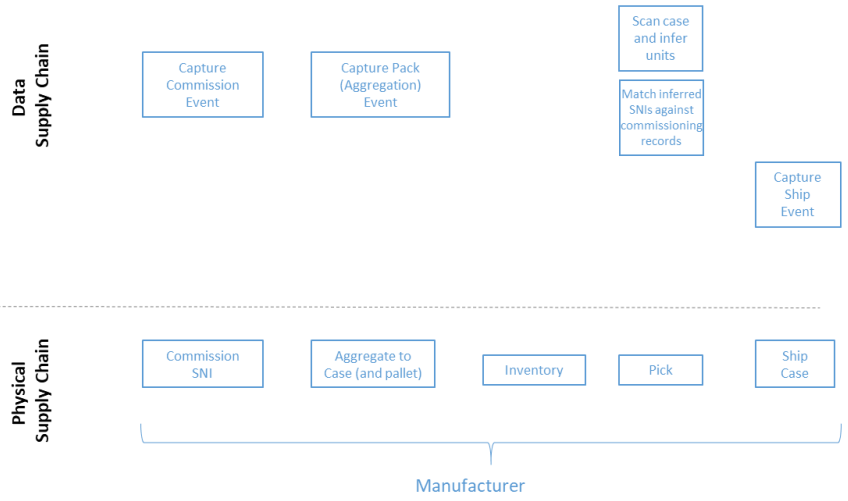
APPENDIX C—Anticipated Supply Chain Process Flows

M.1. Sell sealed homogenous case

**When shipping multiple cases, cases should be aggregated to the SSCC-18 per GS1 US standards
** Does not include ship and receive events to distribution centers (DCs), contract manufacturing organizations (CMOs), or otherwise within the manufacturer (MFR)
**Any of these process steps can be performed by a third-party logistics provider (3PL) on the MFR's behalf

Data for each transaction:

- A transaction identifier (*e.g.*, order number) and date/time stamp
- Transaction information: Product name; strength/dosage; NDC; container size; number of containers; lot; transaction date; shipment date (if >24 hours); name/address of seller; name/address of buyer; expiry
- Parent-child data (*i.e.*, Serialized Numerical Identifiers (SNIs))
- Transaction statement

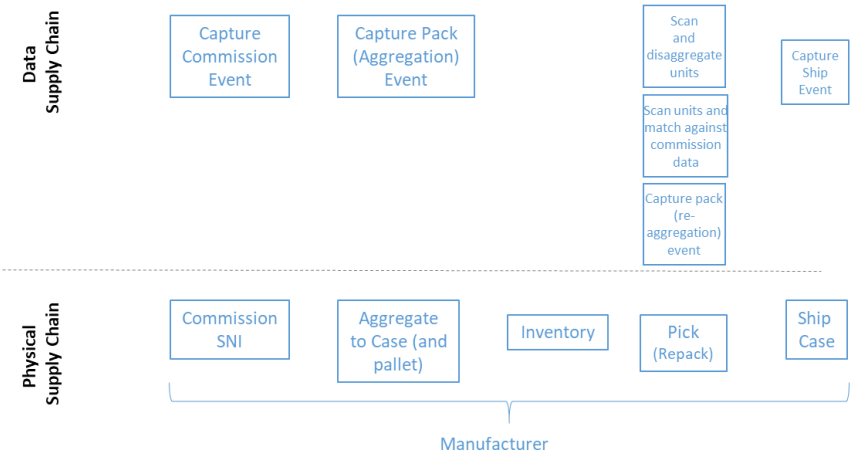


M.2. Sell mixed case (repack)

**When shipping multiple cases, cases should be aggregated to the SSCC-18 per GS1 US standards
** Does not include ship and receive events to DCs, CMOs, or otherwise within the MFR
** "Mixed case" is any set of salable units sold by the MFR to a wholesale distributor (WD) that is not in a sealed homogenous case.
**Any of these process steps can be performed by a 3PL on the MFR's behalf

Data for each transaction:

- A transaction identifier (*e.g.*, order number) and date/time stamp
- Transaction information: Product name; strength/dosage; NDC; container size; number of containers; lot; transaction date; shipment date (if >24 hours); name/address of seller; name/address of buyer; expiry
- Parent-child data (*i.e.*, SNIs)
- Transaction statement

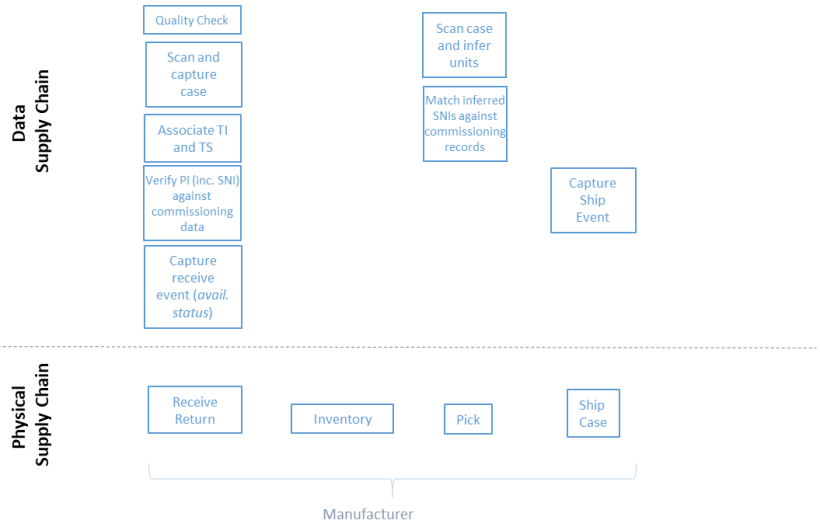


M.3. Receive case saleable return; sell case

**When shipping multiple cases, cases should be aggregated to the SSCC-18 per GS1 US standards
** Does not include ship and receive events to DCs, CMOs, or otherwise within the MFR
** "Mixed case" is any set of salable units sold by MRF to WD that is not in a sealed homogenous case
**Any of these process steps can be performed by a 3PL on the MFR's behalf

Data for each transaction:

- A transaction identifier (*e.g.*, order number) and date/time stamp
- Transaction information: Product name; strength/dosage; NDC; container size; number of containers; lot; transaction date; shipment date (if >24 hours); name/address of seller; name/address of buyer; expiry
- Parent-child data (*i.e.*, SNIs)
- Transaction statement

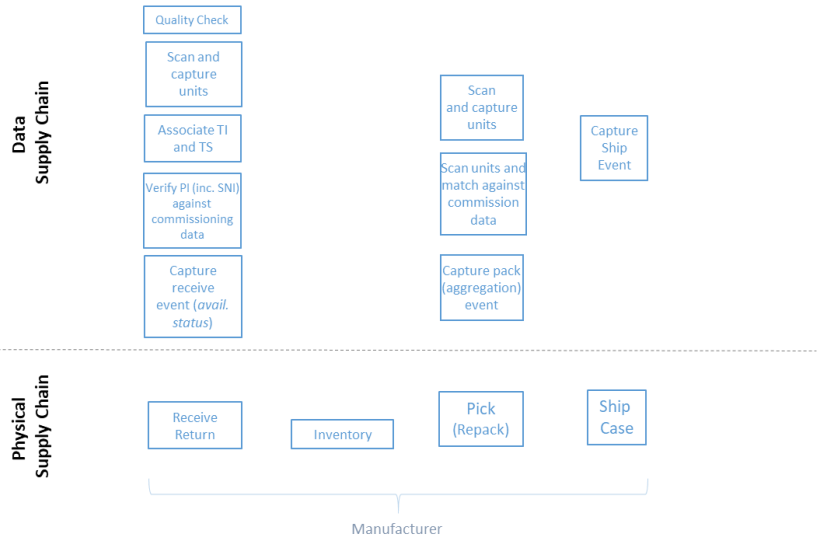


M.4. Receive saleable return of units; sell mixed case

**When shipping multiple cases, cases should be aggregated to the SSCC-18 per GS1 US standards
** Does not include ship and receive events to DCs, CMOs, or otherwise within the MFR
** "Mixed case" is any set of salable units sold by MRF to WD that is not in a sealed homogenous case
**Any of these process steps can be performed by a 3PL on the MFR's behalf

Data for each transaction:

- A transaction identifier (*e.g.*, order number) and date/time stamp
- Transaction information: Product name; strength/dosage; NDC; container size; number of containers; lot; transaction date; shipment date (if >24 hours); name/address of seller; name/address of buyer; expiry
- Parent-child data (*i.e.*, SNIs)
- Transaction statement



W.1. Buy sealed homogenous case; open case; sell mixed tote

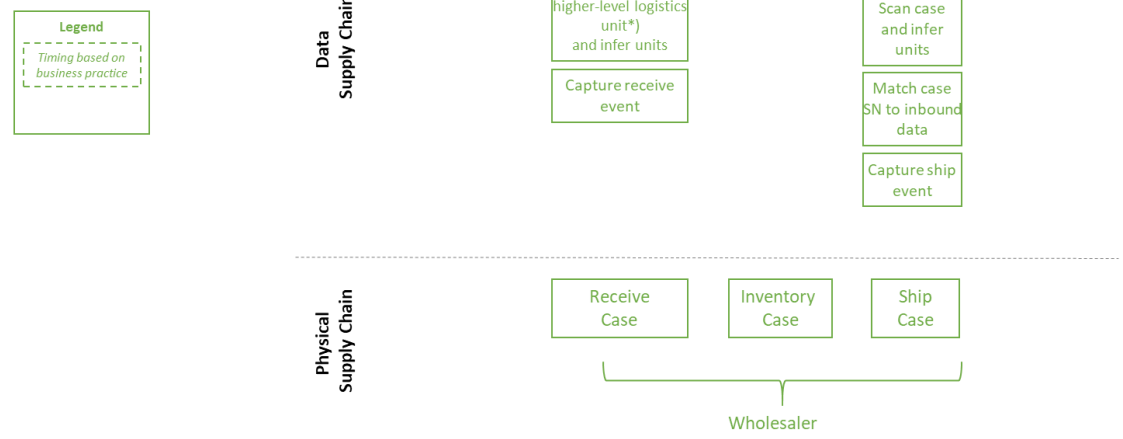
** Does not include ship and receive events to DCs or otherwise within the wholesaler
**Any of these process steps can be performed by a 3PL on the WD's behalf
** Inference at the logistics-unit-level requires some quality control process (business decision)

Data for each transaction:
- A transaction identifier (*e.g.*, order number) and date/time stamp
- Transaction information: Product name; strength/dosage; NDC; container size; number of containers; lot; transaction date; shipment date (if >24 hours); name/address of seller; name/address of buyer; expiry
- Parent-child data (*i.e.*, SNIs)
- Transaction statement

W.2. Buy sealed homogenous case; sell sealed homogenous case

** Does not include ship and receive events to DCs or otherwise within the wholesaler
**Any of these process steps can be performed by a 3PL on the WD's behalf
** Inference at the logistics-unit-level requires some quality control process (business decision)

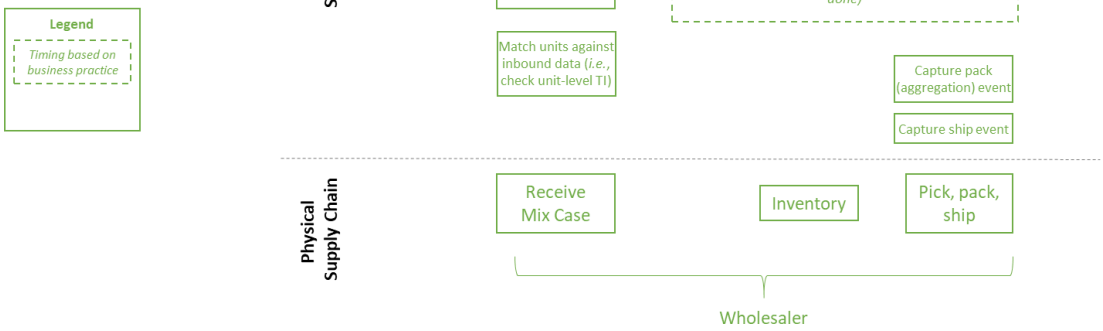
Data for each transaction:
- A transaction identifier (*e.g.*, order number) and date/time stamp
- Transaction information: Product name; strength/dosage; NDC; container size; number of containers; lot; transaction date; shipment date (if >24 hours); name/address of seller; name/address of buyer; expiry
- Parent-child data (*i.e.*, SNIs)
- Transaction statement



W.3. Buy mixed case/tote; sell mixed tote

** Does not include ship and receive events to DCs or otherwise within the wholesaler
** "Mixed case" is any set of salable units sold by the MFR to a WD that is not in a sealed homogenous case
**Any of these process steps can be performed by a 3PL on the WD's behalf
** Inference at the logistics-unit-level requires some quality control process (business decision)

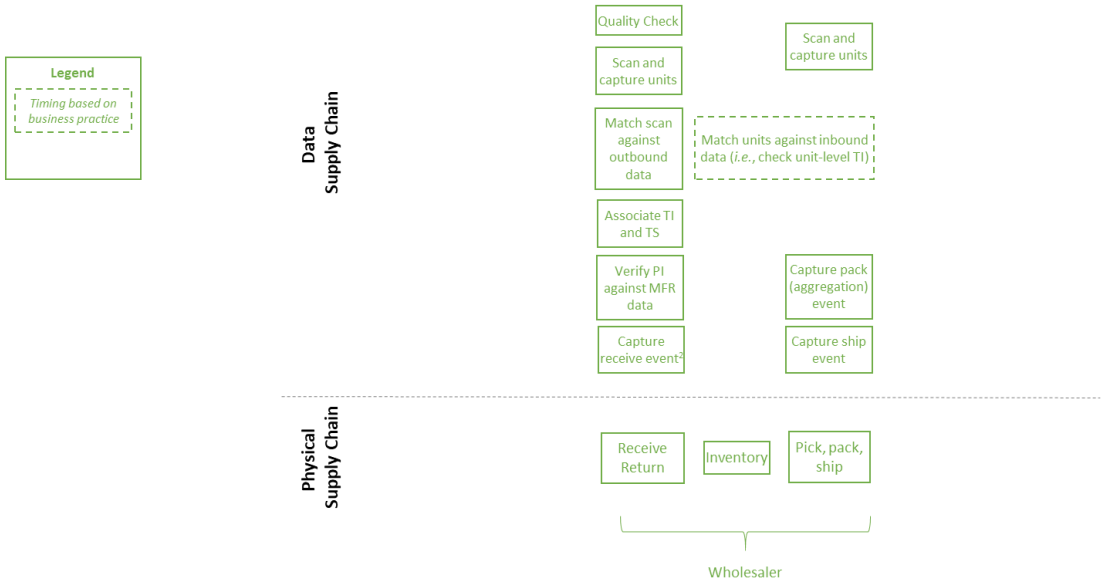
Data for each transaction:
- A transaction identifier (*e.g.*, order number) and date/time stamp
- Transaction information: Product name; strength/dosage; NDC; container size; number of containers; lot; transaction date; shipment date (if >24 hours); name/address of seller; name/address of buyer; expiry
- Parent-child data (*i.e.*, SNIs)
- Transaction statement



W.4. Receive saleable return of units; sell mixed tote

** Does not include ship and receive events to DCs or otherwise within the wholesaler
**Any of these process steps can be performed by a 3PL on the WD's behalf

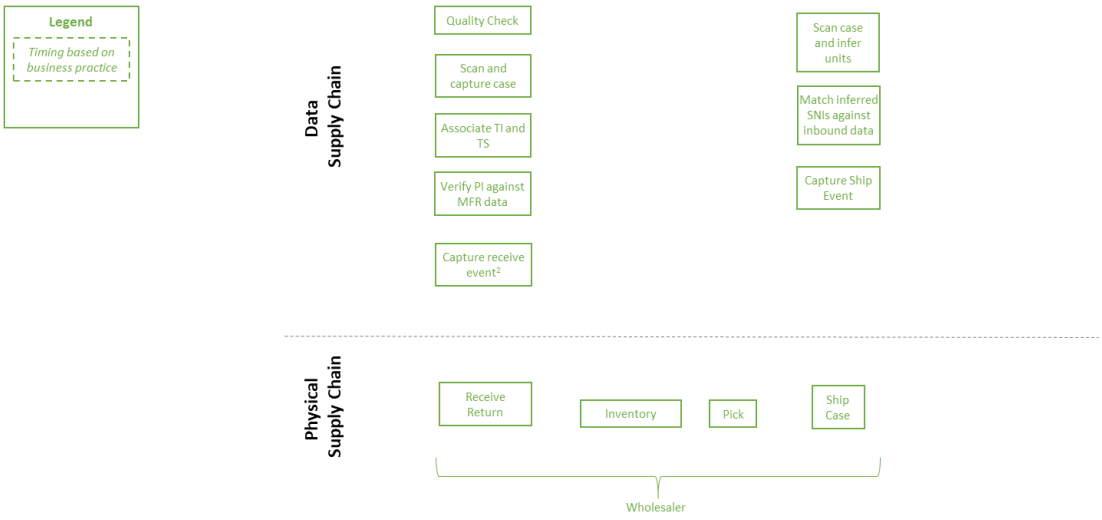
Data for each transaction:
- A transaction identifier (*e.g.*, order number) and date/time stamp
- Transaction information: Product name; strength/dosage; NDC; container size; number of containers; lot; transaction date; shipment date (if >24 hours); name/address of seller; name/address of buyer; expiry
- Parent-child data (*i.e.*, SNIs)
- Transaction statement



W.5. Receive case saleable return; sell case

** Does not include ship and receive events to DCs or otherwise within the wholesaler
**Any of these process steps can be performed by a 3PL on the WD's behalf

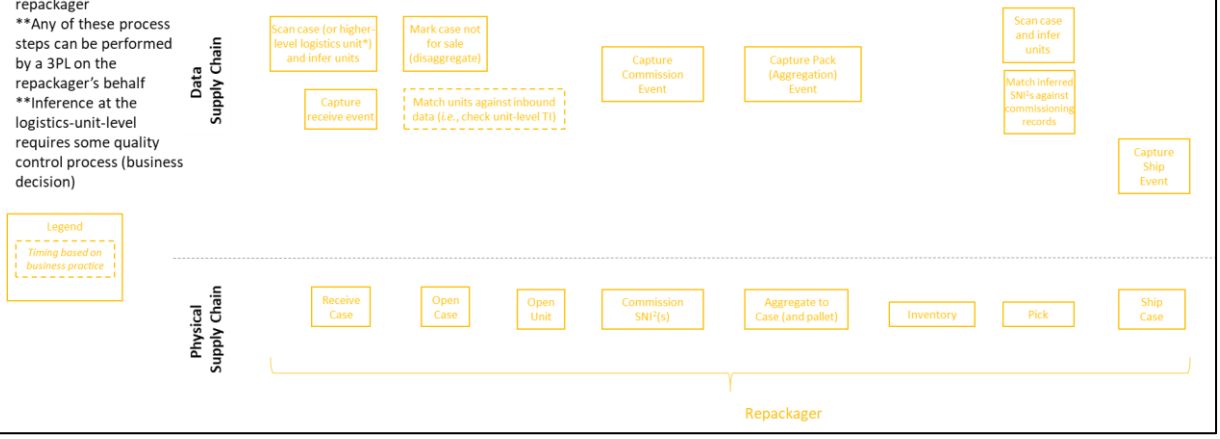
Data for each transaction:
- A transaction identifier (*e.g.*, order number) and date/time stamp
- Transaction information: Product name; strength/dosage; NDC; container size; number of containers; lot; transaction date; shipment date (if >24 hours); name/address of seller; name/address of buyer; expiry
- Parent-child data (*i.e.*, SNIs)
- Transaction statement



R.1. Buy sealed homogenous case; open case; repackage; sell sealed homogenous case

**When shipping multiple cases, cases should be aggregated to the SSCC-18 per GS1 US standards
** Does not include ship and receive events to DCs or otherwise within the repackager
**Any of these process steps can be performed by a 3PL on the repackager's behalf
**Inference at the logistics-unit-level requires some quality control process (business decision)

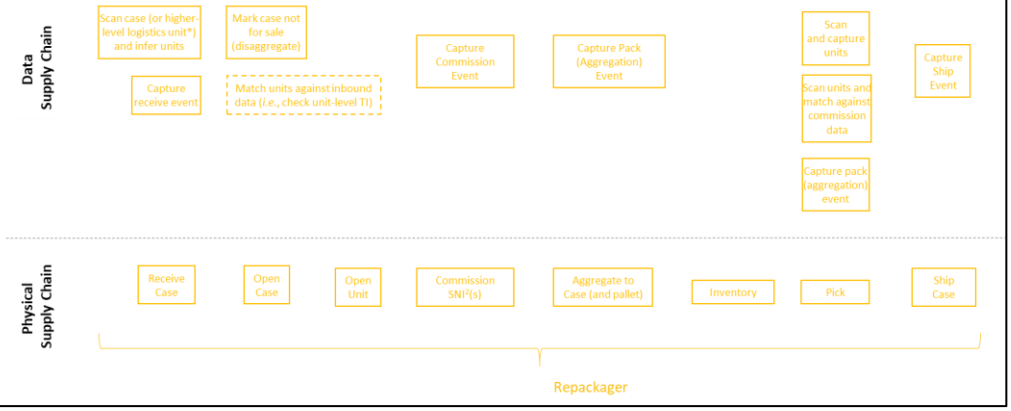
Data for each transaction:
- A transaction identifier (*e.g.*, order number) and date/time stamp
- Transaction information: Product name; strength/dosage; NDC; container size; number of containers; lot; transaction date; shipment date (if >24 hours); name/address of seller; name/address of buyer; expiry
- Parent-child data (*i.e.*, SNIs)
- Transaction statement



R.2. Buy sealed homogenous case; open case; repackage; sell mixed case

**When shipping multiple cases, cases should be aggregated to the SSCC-18 per GS1 US standards
** Does not include ship and receive events to DCs or otherwise within the repackager
**Any of these process steps can be performed by a 3PL on the repackager's behalf
**Inference at the logistics-unit-level requires some quality control process (business decision)

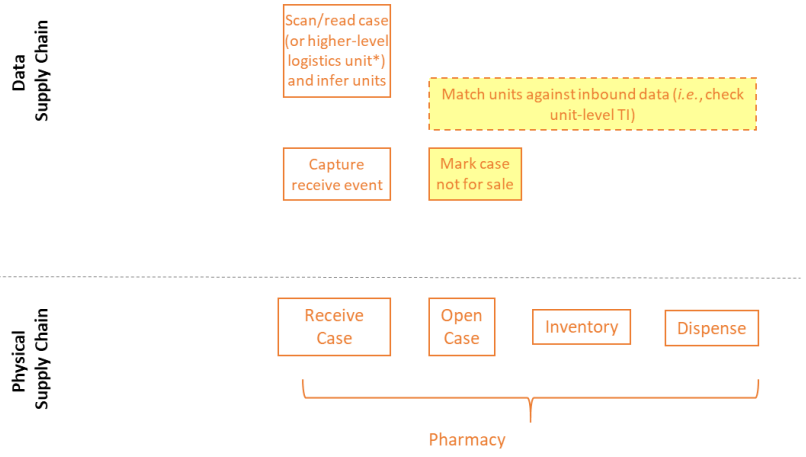
Data for each transaction:
- A transaction identifier (*e.g.*, order number) and date/time stamp
- Transaction information: Product name; strength/dosage; NDC; container size; number of containers; lot; transaction date; shipment date (if >24 hours); name/address of seller; name/address of buyer; expiry
- Parent-child data (*i.e.*, SNIs)
- Transaction statement



D.1. Buy sealed homogenous case; open case; dispense *(Internal Data Repository)*

** Does not include ship and receive events from DCs or otherwise within the dispenser
**Any of these process steps can be performed by a 3PL on the dispenser's behalf
** Inference at the logistics-unit-level requires some quality control process (business decision)

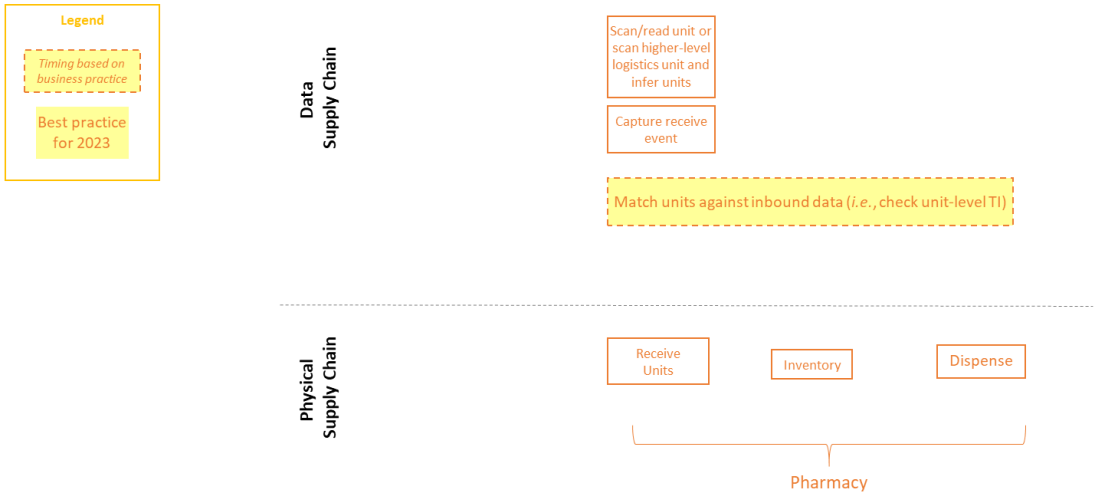
Data for each transaction:
- A transaction identifier (*e.g.*, order number) and date/time stamp
- Transaction information: Product name; strength/dosage; NDC; container size; number of containers; lot; transaction date; shipment date (if >24 hours); name/address of seller; name/address of buyer; expiry
- Parent-child data (*i.e.*, SNIs)
- Transaction statement



D.2. Buy mixed tote; dispense *(Internal Data Repository)*

** Does not include ship and receive events from DCs or otherwise within the dispenser
**Any of these process steps can be performed by a 3PL on the dispenser's behalf

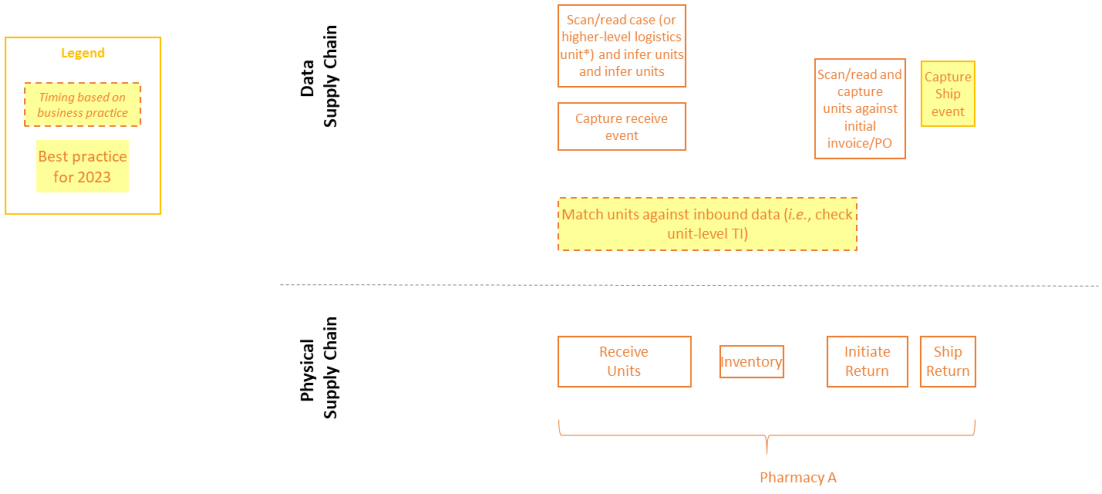
Data for each transaction:
- A transaction identifier (*e.g.*, order number) and date/time stamp
- Transaction information: Product name; strength/dosage; NDC; container size; number of containers; lot; transaction date; shipment date (if >24 hours); name/address of seller; name/address of buyer; expiry
- Parent-child data (*i.e.*, SNIs)
- Transaction statement



D.3. Make saleable return *(Internal Data Repository)*

** Does not include ship and receive events from DCs or otherwise within the dispenser
**Any of these process steps can be performed by a 3PL on the dispenser's behalf
** Inference at the logistics-unit-level requires some quality control process (business decision)

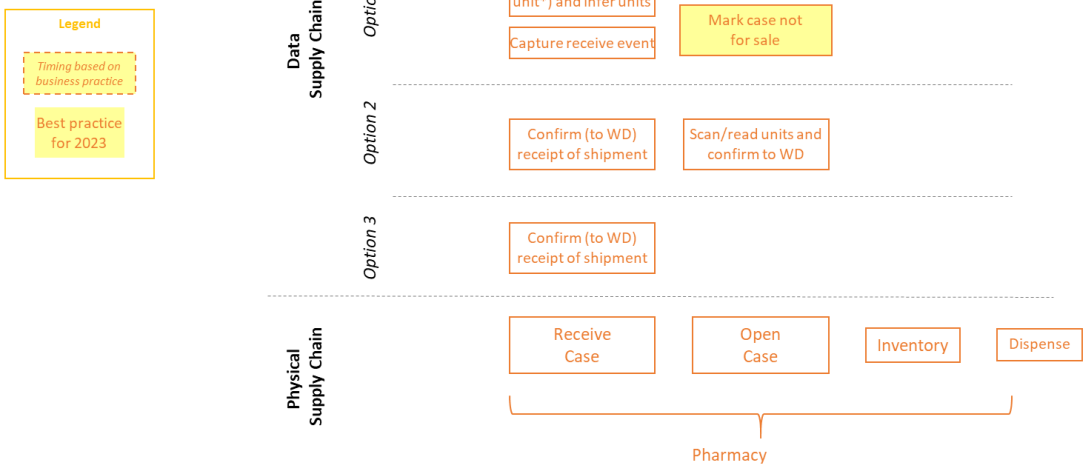
Data for each transaction:
- A transaction identifier (*e.g.*, order number) and date/time stamp
- Transaction information: Product name; strength/dosage; NDC; container size; number of containers; lot; transaction date; shipment date (if >24 hours); name/address of seller; name/address of buyer; expiry
- Parent-child data (*i.e.*, SNIs)
- Transaction statement



D.1. Buy sealed homogenous case; open case; dispense *(Wholesaler Data Repository by Contract)*

** Does not include ship and receive events from DCs or otherwise within the dispenser
**Any of these process steps can be performed by a 3PL on the dispenser's behalf
** Inference at the logistics-unit-level requires some quality control process (business decision)

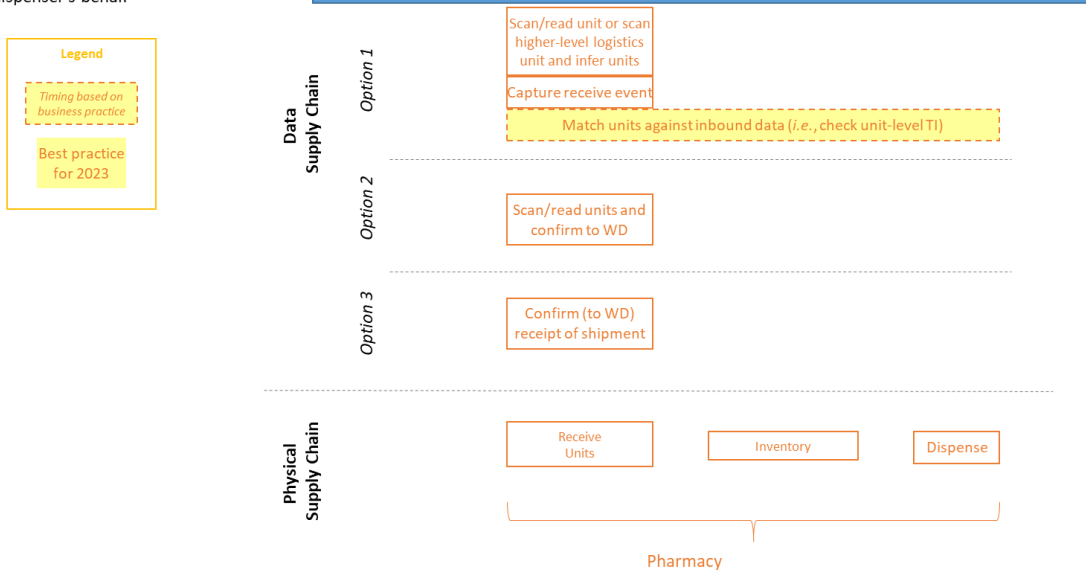
Data for each transaction:
- A transaction identifier (*e.g.*, order number) and date/time stamp
- Transaction information: Product name; strength/dosage; NDC; container size; number of containers; lot; transaction date; shipment date (if >24 hours); name/address of seller; name/address of buyer; expiry
- Parent-child data (*i.e.*, SNIs)
- Transaction statement



D.2. Buy mixed tote; dispense *(Wholesaler Data Repository by Contract)*

** Does not include ship and receive events from DCs or otherwise within the dispenser
**Any of these process steps can be performed by a 3PL on the dispenser's behalf

Data for each transaction:
- A transaction identifier (*e.g.*, order number) and date/time stamp
- Transaction information: Product name; strength/dosage; NDC; container size; number of containers; lot; transaction date; shipment date (if >24 hours); name/address of seller; name/address of buyer; expiry
- Parent-child data (*i.e.*, SNIs)
- Transaction statement



D.3. Make saleable return *(Wholesaler Data Repository by Contract)*

** Does not include ship and receive events from DCs or otherwise within the dispenser
**Any of these process steps can be performed by a 3PL on the dispenser's behalf
*Inference at the logistics-unit-level requires some quality control process (business decision)