

Detailed Explanation of Changes:

Request 1 - Changes to the DSCSA ATP Credential and specifications:

The existing ATP Credential contains the claim “Organization Type”. “Section 7.2 Claim: Organization Type” provides a definition of this claim and states that “Dispenser”, “Wholesaler” and “Manufacturer” are the only valid values.

PDG is requesting that the schema documentation and associated documents be changed to:

- Define “Organization Type” as the main type of operation that the associated entity is known as.
- Reflect that an organization MAY have separate ATP Credentials reflecting their Organization Type, but MAY also have only one ATP Credential based on the main type of operation that the entity chooses to be known as.
- The credential Issuer MUST verify the licenses, registrations and other proofs based on the chosen Organization Type (ex: State Licenses are verified for Dispensers and FDA registrations are checked for Manufacturers).
- Add “Repackager” as a valid value for Organization Type. o Issuer Verification steps for Repackagers follow the same criteria as Manufacturers.
- Add “3PL” as a valid Organization Type. o Issuer Verification steps:
  - Verify Identity Credential
  - If the State of operation licenses 3PLs, verify the license
  - If the State does not license 3PLs, do not issue an ATP credential until the FDA 3PL licensing or registration system is available.

**Affected PDG Interoperability Areas:** Credentialing, PI Verification, TI Trace

Requirement-Ser-033 and Requirement-Ser-034, Change Request 5:

Request:

Ch. 1 of the Blueprint identifies and defines 13 elements of TI. In the context of a drop shipment, 582(f) A wholesale distributor that does not physically handle or store product shall be exempt from the provisions of this section, except the notification requirements under clauses (ii), (iii), and (iv) of subsection (c)(4)(B), provided that the manufacturer, repackager, or other wholesale distributor that distributes the product to the dispenser by means of a drop shipment for such wholesale distributor INCLUDES ON THE TRANSACTION INFORMATION and transaction history TO THE DISPENSER THE CONTACT INFORMATION OF SUCH WHOLESALE DISTRIBUTOR and provides the transaction information, transaction history, and transaction statement directly to the dispenser.

A 14th element should be added to the definition of TI in the Blueprint, specifically that in the event of a drop shipment, the contact information for the wholesale distributor is a 14th element. That element should be defined as the name and business address of the wholesale distributor and should be defined the same as in Req-Ser-019 and -020.

## Resolution:

Change Request 5 asks for a 14<sup>th</sup> element to be added to the TI in the event of a **drop shipment** to hold the Business Name and Address of the Wholesale Distributor. This is already specified in Recommendation-Ser-019 and Recommendation-Ser-020 (see below). The Serialized TI/TS Work Group understood the requester's intent to provide a means of documenting the Dispenser's participation in the drop ship transaction as the "person **to** whom ownership is **indicated**", that is, the person or entity to whom ownership is ultimately transferred to once the Wholesale Distributor triggers the transfer through other processes (ex: invoicing).

### **Current TI elements usage for Drop Shipments:**

- Recommendation-Ser-017 and Recommendation-Ser-018: Manufacturer's (transfer **from** entity) Business Name and Address
- Recommendation-Ser-019 and Recommendation-Ser-020 recommend the details of the Wholesale Distributor's (transfer **to** entity) Business Name and Address

### **Recommendation for Drop Shipments under Section 582(f):**

When a product is drop shipped from a manufacturer or repackager to a dispenser, FDCA 582(f) defines an exemption that allows the TI for the drop ship to be provided by the manufacturer or repackager to the dispenser. To qualify for this exemption, the TI provided by the manufacturer or repackager must include contact information of the wholesale distributor. It is recommended that such contact information of the wholesale distributor include the business name and address of the wholesale distributor and be formatted in the same manner as the business name and address of the selling and purchasing trading partners, as defined in Recommendations-Ser-017 to -020. In effect, when the drop ship exemption under Section 582(f) is utilized, a fourteenth element is added to the TI so that the TI includes the business name address for each the manufacturer/repackager, wholesale distributor, and dispenser.