Partnership for DSCSA Governance

Work Group: **Credentialing and User Authentication**

Document Status: Interoperability Committee approved (2022-09-20), for review by the General Membership

Issue: Change requests to the Open Credentialing Initiative (OCI) for the DSCSA ATP Credential and request to develop ATP-Equivalent and DSCSA Authority Credentials and Conformance criteria.

Timeline: PDG recommends OCI complete Requests 1 through 3 (Credential changes and development) by the end of 2022 to allow testing and implementations to take place ahead of the November 27, 2023, implementation date. The Work Group recommends OCI complete Request 4 ("Evidence" claim exploration) by the end of the first quarter, 2023.

Background: OCI has developed specifications, schemas, and conformance criteria to support the credentialing and user authentication needs of the industry in alignment with the PDG blueprint requirements for credentialing. The Work Group has also explored the use of credentials for PI Verification and TI Tracing interactions and is requesting changes to the existing OCI DSCSA ATP Credential specifications and the development of an ATP-Equivalent credential and DSCSA Authority credential.

References:
PDG Blueprint[1]
OCI Credential Schema Version 1.0[2]
Credential Issuer Conformance Criteria[3]
Digital Wallet Conformance Criteria[4]
Digital Wallet Provider OpenAPI Specification[5]
Integration with VRS[6]
Verifiable Credentials Data Model v1.1[7]

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.

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[1] *https://dscsagovernance.org/wp-content/uploads/2021/07/PDG_Blueprint-v1.0-Final_071221.pdf*

[2] https://open-credentialing-initiative.github.io/schemas/specification/v1.0.0/

[3] https://open-credentialing-initiative.github.io/Credential-Issuer-Conformance-Criteria/

[4] https://open-credentialing-initiative.github.io/Digital-Wallet-Conformance-Criteria/lates

[5] https://open-credentialing-initiative.github.io/api-specifications/latest/index.html

[6] https://open-credentialing-initiative.github.io/Digital-Wallet-Conformance-Criteria/latest/#integration-with-vrs-providers

[7] https://www.w3.org/TR/vc-data-model/

- 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.
  - Issuer Verification steps for Repackagers follow the same criteria as Manufacturers.
- Add "3PL" as a valid Organization Type.
  - 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

Request 2 - ATP-Equivalent Credentials:

The Credentialing WG recognizes that there are trading partners that are not required to register with the FDA or obtain a State license and as such will not be able to qualify for an ATP Credential. The following is a representative, but not exhaustive list of organizations anticipated:

- The Veterans Administration
- The Department of Defense
- Federal Prisons
- The Bureau of Indian Affairs
- Administration for Strategic Preparedness and Response (ASPR)/Strategic National Stockpile
- Tribal-operated dispensers

The Credentialing WG is recommending that PDG maintain a list (in collaboration with industry and the FDA) of recognized entities that qualify as an ATP-Equivalent. If at any point the Secretary or Secretary's designee publishes a list of recognized ATP-Equivalents, we will defer to that list.

The PDG maintained list of ATP-Equivalents should be auditable, easily maintainable and secure. Additionally, the removal or addition of ATP-Equivalent parties should not influence **already issued** and transacted credentials or their **verifiability.** Changes to the list must be trackable and auditable. Issuers of these credentials MUST monitor the list, review changes to the list and revoke credentials of entities not on or represented by entities on the list.

PDG requests OCI to develop "ATP-Equivalent" Credential specifications with identical claims as the ATP Credential. Issuer verification steps include:

- Verify Identity Credential
- Verify the entity identified in the Identity Credential is also on the PDG ATP-Equivalent published list.
- Continued monitoring of the PDG ATP-Equivalent list.
- Revocation of the ATP-Equivalent credential if the entity is removed (not found) on the PDG ATP-Equivalent list.

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

Request 3 – DSCSA Authority Credentials:

The Credentialing WG recognizes that the Secretary and "other appropriate Federal or State officials" are allowed to perform PI Verifications and TI Traces, however, there is no credential that these types of organizations can use to allow trading partners to verify the authority's identity or access authorization during the PI Verification and TI Trace processes. The following is a representative, but not exhaustive list of organizations anticipated:

- The FDA
- State Licensing Authorities (ex: State Boards of Pharmacy)
- The DEA

The DSCSA refers to authorities making information requests of trading partners as "the Secretary or other appropriate Federal or State official". The Credentialing WG is recommending that PDG maintain a list (in collaboration with industry and the FDA) of authorities that are recognized as meeting the DSCSA definition. If at any point the Secretary or Secretary's designee publishes a list of recognized DSCSA Authorities, that list will be the official, recognized list.

The PDG maintained list of DSCSA Authorities should be auditable, easily maintainable and secure. Additionally, the removal or addition of DSCSA Authorities should not influence **already issued** and transacted credentials or their **verifiability.** Changes to the list must be trackable and auditable. Issuers of these credentials MUST monitor the list, review changes to the list and revoke credentials of entities not on or represented by entities on the list.

PDG requests OCI to develop "DSCSA Authority" Credential specifications with identical claims as the ATP Credential (excluding Organization Type). Issuer verification steps include:

- Verify Identity Credential
- Verify the entity identified in the Identity Credential is also on the PDG DSCSA Authority published list.
- Continued monitoring of the PDG DSCSA Authority list.
- Revocation of the DSCSA Authority credential if the entity is removed (not found) on the PDG DSCSA Authority list.

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

Request 4 – Exploration of credential use of "Evidence" Claim:

The Credentialing WG recognizes that trust in credentials is supported by clear specifications, conformance criteria and a conformance program. In understanding the W3C specification for Verifiable Credentials, the WG became aware of the "Evidence" property listed in the Advanced Concepts section of the W3C Verifiable Credential specification. The WG recommends OCI investigate the use of this property to add transparency to the evidence or proof verified during the issuing process. Provide PDG with output of this exploration.

Key considerations include:

- Providing transparency to the actual checks made by the Issuer to the verifier (receiver of the credential).
- Mitigating exposure of confidential information (either credential Subject's or Issuer's).

This is a research request only. PDG will establish if there is a need for the use of this claim type in the future.

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

Issue: Change requests to the PDG Blueprint

Background: A change requests was received by PDG and assigned to the Serialized TI/TS Exchange Work Group for analysis and resolution. The work group explored the request carefully and makes the following recommendations. These recommendations were approved by the Interoperability Committee in their 5/17/2022 call.

References:
PDG Blueprint[8]

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 14th element to 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:**

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[8] *https://dscsagovernance.org/wp-content/uploads/2021/07/PDG_Blueprint-v1.0-Final_071221.pdf*

- 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.