Approved Changes to the PDG Blueprint v1.0

Requirement-Cred-001 (Manufacturers):

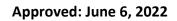| PDG Blueprint v1.0 Text	Revised Blueprint Text *(effective June 6, 2022)*
The Accreditor must ensure that an Accredited Credential Issuer issues credentials that allow a trading partner to: 1. Confirm the authorized status of a manufacturer as part of the systems and processes for tracing; and 2. Confirm the authorized status of a manufacturer as part of the systems and processes for verification. The Accreditor must also ensure that an Accredited Credential Issuer, as a condition of issuing such credentials: 1. Uses the FDA's establishment registration database to confirm registered status of the manufacturer; 2. Confirms that, if the manufacturer has multiple registered establishments, they will have at least one current valid registration for a registered packaging site; and 3. Validates that the manufacturer uses both their ATP credential and identity credential when engaging in the PDG ecosystem.	The Accreditor must ensure that an Accredited Credential Issuer issues credentials that allow a trading partner to: 1. Confirm the authorized status of a manufacturer as part of the systems and processes for tracing; and 2. Confirm the authorized status of a manufacturer as part of the systems and processes for verification. The Accreditor must also ensure that an Accredited Credential Issuer, as a condition of issuing such credentials: 1. Uses the FDA's establishment registration database to confirm registered status of the manufacturer; 2. Confirms that, if the manufacturer has multiple registered establishments, they will have at least one current valid registration for a registered packaging site.

Requirement-Cred-002 (Repackagers):

PDG Blueprint v1.0 Text	Revised Blueprint Text *(effective June 6, 2022)*
The Accreditor must ensure that an Accredited Credential Issuer issues credentials that allow a trading partner to: 1. Confirm the authorized status of a repackager as part of the systems and processes for tracing; and 2. Confirm the authorized status of a repackager as part of the systems and processes for verification. The Accreditor must also ensure that an Accredited Credential Issuer, as a condition of issuing such credentials: 1. Uses the FDA's establishment registration database to confirm the current valid registered status of the repackager; and 2. Validates that the repackager uses both their ATP credential and identity credential when engaging in the PDG ecosystem.	The Accreditor must ensure that an Accredited Credential Issuer issues credentials that allow a trading partner to: 1. Confirm the authorized status of a repackager as part of the systems and processes for tracing; and 2. Confirm the authorized status of a repackager as part of the systems and processes for verification. The Accreditor must also ensure that an Accredited Credential Issuer, as a condition of issuing such credentials: 1. Uses the FDA's establishment registration database to confirm the current valid registered status of the repackager.

Requirement-Cred-003 (Virtual Manufacturers):

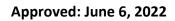| PDG Blueprint v1.0 Text	Revised Blueprint Text *(effective June 6, 2022)*
The Accreditor must ensure that an Accredited Credential Issuer issues credentials that allow a trading partner to: 1. Confirm the authorized status of a virtual manufacturer as part of the systems and processes for tracing; and 2. Confirm the authorized status of a virtual manufacturer as part of the systems and processes for verification. The Accreditor must ensure that an Accredited Credential Issuer, as a condition of issuing such credentials: 1. Confirms/validates the product labeler code or obtain clear evidence that the manufacturer holds an NDA, ANDA, or BLA for a product; 2. Confirms/validates that a CMO78 or CLP79 used by the virtual manufacturer to manufacture at least one product has a valid registration in accordance with Sec. 510 of the FDCA;80 and 3. Confirms/validates that the virtual manufacturer uses both their ATP credential and identity credential when engaging in the PDG ecosystem.	The Accreditor must ensure that an Accredited Credential Issuer issues credentials that allow a trading partner to: 1. Confirm the authorized status of a virtual manufacturer as part of the systems and processes for tracing; and 2. Confirm the authorized status of a virtual manufacturer as part of the systems and processes for verification. The Accreditor must ensure that an Accredited Credential Issuer, as a condition of issuing such credentials: 1. Confirms/validates the product labeler code or obtain clear evidence that the manufacturer holds an NDA, ANDA, or BLA for a product; 2. Confirms/validates that a CMO78 or CLP79 used by the virtual manufacturer to manufacture at least one product has a valid registration in accordance with Sec. 510 of the FDCA;80.

Requirement-Cred-004 (Wholesale Distributor):

PDG Blueprint v1.0 Text	Revised Blueprint Text *(effective June 6, 2022)*
The Accreditor must ensure that an Accredited Credential Issuer issues credentials that allow a trading partner to: 1. Confirm the authorized status of a wholesale distributor as part of the systems and processes for tracing; and 2. Confirm the authorized status of a wholesale distributor as part of the systems and processes for verification. The Accreditor must also ensure that an Accredited Credential Issuer, as a condition of issuing such credentials: 1. Uses a database or similar source of relevant licensure information operated and maintained directly by a State licensing authority (e.g., a State Board of Pharmacy) to confirm licensure of the wholesale distributor; 2. Confirms the wholesale distributor is registered with FDA's self-reported database, as required by DSCSA; 3. With regard to tracing and verification, if a wholesale distributor is licensed in multiple states, confirms current valid licensure in at least one state; and 4. Validates that the wholesale distributor uses both their ATP credential and identity credential when engaging in the PDG ecosystem.	The Accreditor must ensure that an Accredited Credential Issuer issues credentials that allow a trading partner to: 1. Confirm the authorized status of a wholesale distributor as part of the systems and processes for tracing; and 2. Confirm the authorized status of a wholesale distributor as part of the systems and processes for verification. The Accreditor must also ensure that an Accredited Credential Issuer, as a condition of issuing such credentials: 1. Uses an externally accessible system of record or similar source of relevant licensure information operated and maintained directly by a State licensing authority (e.g., a State Board of Pharmacy) to confirm licensure of the wholesale distributor; 2. Confirms the wholesale distributor is registered with FDA's self-reported database, as required by DSCSA; 3. With regard to tracing and verification, if a wholesale distributor is licensed in multiple states, confirms current valid licensure in at least one state.

Requirement-Cred-005 (Dispensers):

PDG Blueprint v1.0 Text	Revised Blueprint Text *(effective June 6, 2022)*
The Accreditor must ensure that an Accredited Credential Issuer issues credentials that allow a trading partner to:	The Accreditor must ensure that an Accredited Credential Issuer issues credentials that allow a trading partner to:
1. Confirm the authorized status of a dispenser as part of the systems and processes for tracing; and 2. Confirm the authorized status of a dispenser as part of the systems and processes for verification.	1. Confirm the authorized status of a dispenser as part of the systems and processes for tracing; and 2. Confirm the authorized status of a dispenser as part of the systems and processes for verification.
The Accreditor must also ensure that an Accredited Credential Issuer, as a condition of issuing such credentials:	The Accreditor must also ensure that an Accredited Credential Issuer, as a condition of issuing such credentials:
1. Uses a database or similar source of relevant licensure information operated and maintained directly by a State licensing authority (e.g., a State Board of Pharmacy) to confirm valid licensure as a dispenser; 2. With regard to tracing and verification, if a dispenser is licensed in multiple states, confirms current valid licensure in at least one state; and 3. Validates that the dispenser uses both their ATP credential and identity credential when engaging in the PDG ecosystem.	1. Uses an externally accessible system of record or similar source of relevant licensure information operated and maintained directly by a State licensing authority (e.g., a State Board of Pharmacy) to confirm valid licensure as a dispenser; 2. With regard to tracing and verification, if a dispenser is licensed in multiple states, confirms current valid licensure in at least one state.

Requirement-Cred-007:

PDG Blueprint v1.0 Text	Revised Blueprint Text *(effective June 6, 2022)*
An Accredited Credential Issuer shall have systems and processes in place to demonstrate and prove the orderly implementation of the requirements as specified by Req-Cred-001 – Req-Cred-006 and appropriately secure management of the information required to carry out such requirements. Such demonstration and proof includes: a record of each confirmation of authorized status, the source documentation utilized to validate authorized status, including any changes to source documentation (e.g., renewed license, revoked license), and a record of modifications, if any, that are made to the record of a trading partner's authorized status (e.g., grace period exemptions). This information shall be maintained in a manner that would allow for periodic and/or impromptu inspections.	An Accredited Credential Issuer shall have systems and processes in place to demonstrate and prove the orderly implementation of the requirements as specified by Req-Cred-001 – Req-Cred-006 and appropriately secure management of the information required to carry out such requirements. Such demonstration and proof includes: records maintained to demonstrate conformance to the PDG Blueprint requirements, the source documentation utilized to validate authorized status, including any changes to source documentation (e.g., renewed license, revoked license), and a record of modifications, if any, that are made to the record of a trading partner's authorized status (e.g., grace period exemptions). This information shall be maintained in a manner that would allow for periodic and/or impromptu inspections.

Requirement-Cred-008:

PDG Blueprint v1.0 Text	Revised Blueprint Text *(effective June 6, 2022)*
Systems and processes for validating ATP status shall allow state regulators and FDA to push alerts and updates to licensure/registration information. State regulators and FDA may therefore opt in to push updates or may continue with their current systems and processes.	**Replace all text with:** State regulators and FDA may develop systems to push updates of license and registration data. Once available, PDG may set governance rules for use and timetable for implementation.

Requirement-Cred-009:

PDG Blueprint v1.0 Text	Revised Blueprint Text *(effective June 6, 2022)*
For credentialing source documentation that originates in a state, or with FDA, where the regulator has implemented systems and processes to push updates to the Accredited Credential Issuer, an Accredited Credential Issuer shall verify authorized status with the source data upon expiry of a current license.	For credentialing source documentation that originates in a state, or with FDA, where the regulator has implemented systems and processes to push updates to the Accredited Credential Issuer, PDG may set governance rules for using the systems by credential issuers and a timetable for implementation.

Requirement-Cred-010:

PDG Blueprint v1.0 Text	Revised Blueprint Text *(effective June 6, 2022)*
For credentialing source documentation that originates in a state, or with FDA, where the regulator has not implemented systems and processes to push updates, an Accredited Credential Issuer shall verify authorized status at least weekly and upon expiry of a current license; provided however, if a state updates its database less frequently than weekly, the Accredited Credential Issuer shall verify authorized status as frequently as the state database is updated (e.g., if a state only updates their database month, the check can occur monthly) and upon expiry of a current license.	For credentialing source documentation that originates in a state, or with FDA, where the regulator has not implemented systems and processes to push updates, an Accredited Credential Issuer shall verify authorized status at least weekly and upon expiry of a current license; provided however, if a state updates its externally accessible system of record less frequently than weekly, the Accredited Credential Issuer shall verify authorized status as frequently as the state externally accessible system of record is updated (e.g., if a state only updates their externally accessible system of record month, the check can occur monthly) and upon expiry of a current license.

Requirement-Cred-014:

PDG Blueprint v1.0 Text	Revised Blueprint Text *(effective June 6, 2022)*

The Accreditor must ensure that an Accredited Credential Issuer, as a condition of issuing an organization identity credential verifies one of the following sets of information, at the discretion of the trading partner being credentialed:
 	
1. Confirms that the organization has: (1) Articles of Incorporation, (2) IRS EIN Letter, and (3) DUNS Number;
2. Confirms the organization has a valid LEI number from a valid LOU organization accredited by GLEIF (https://www.gleif.org/en/about-lei/introducing-the-legal-entity-identifier-lei), which would confirm that the organization has at a minimum:
    A. Articles of Incorporation
    B. IRS EIN Letter
    C. DUNS Number; or
3. Uses the DEA signing certificate to verify the organizational elements that were validated through the DEA registration process.
	Replace all text with:
	
	The Accreditor must ensure that an Accredited Credential Issuer, as a condition of issuing an organization identity credential, conforms to section 4.2 General Requirements for Identity Proofing of The National Institute of Standards and Technology (NIST) SP800-63A and meets Section 4.4.1.2 Identity Assurance Level 2 (IAL2) Evidence Collection Requirements of NIST when performing identity proofing.
	
	IMPORTANT NOTE: Simply collecting documents or identification numbers does not constitute identity proofing. Due diligence is required to thoroughly validate the collected documents and identification numbers.
	• The full set of standards can be found in Section 2 of NIST Special Publication 800-63A.
	• Core concepts and application of NIST IAL2 for DSCSA can be found in Sections 3-4 of the Open Credential Initiative (OCI) Credential Issuer Conformance Criteria.
	
	According to Section 4.4.1 of NIST Special Publication 800-63A, IAL2 proofing requirements requires that an Accredited Credential Issuer collects sufficient evidence to prove the:
	• Existence of the Organization;
	• Identity of the Organization;
	• Identity of the Organization's Representative; and
	• Authority of the Representative to act on behalf of that Organization.
	
	Section 4.4.1.2 (IAL2 Evidence Collection Requirements) of NIST Special Publication 800-63A states:
	
	The Credential Issuer SHALL collect the following from the applicant:
	• One piece of SUPERIOR or STRONG evidence IF the evidence's issuing source, during its identity proofing event, confirmed the claimed identity by collecting two or more forms of SUPERIOR or STRONG evidence AND the Accredited Credential Issuer validates the evidence directly with the issuing source; OR
	• Two pieces of STRONG evidence; OR
	• One piece of STRONG evidence plus two pieces of FAIR evidence.
	
	The above rules apply to both the Organization and its Representative.

Requirement-Ser-023:

PDG Blueprint v1.0 Text	Revised Blueprint Text *(effective June 6, 2022)*
	[*added footnote 1*] **Footnote 1:** It is not uncommon for FDA to extend the expiration date for certain products in the event of a drug shortage. In those instances, the "functional" expiration date differs from the expiration date in the product identifier affixed to the package. The Expiration Date presented in the TI is the expiration date in the product identifier affixed to the product.