Executive Summary

The Partnership for DSCSA Governance (PDG) Governance Pilot Project was designed to test and improve organizational systems and processes of a Drug Supply Chain Security Act (DSCSA) interoperability governance body. This Pilot was therefore predicated on the ability of industry members from across the pharmaceutical supply chain to come together and successfully establish a governance body to support implementation of the DSCSA 2023 requirements.

First and foremost, successful completion of PDG formation demonstrated industry's ability to form and operate an independent, balanced, sector-neutral nonprofit industry governance body. Further, completion of the Pilot Project, including evaluation of the established PDG structure and governance systems, showed that the PDG governance structure is sound, that PDG members are effectively engaged, that meaningful progress toward 2023 interoperability can be made within PDG, and that PDG has been successful in abiding by the four key principles of governance:

1. All supply chain sectors should work collaboratively to establish efficient, viable, and effective systems and processes to protect patients through compliance with the DSCSA 2023 requirements.
2. 2023 system architectures should be governed by trading partners through a balanced, independent, sector-neutral legal entity.
3. The governance body's activities should support interoperable exchange, interoperable verification, and interoperable tracing, as required by the DSCSA.
4. Rules for membership and use should incent participation.

Therefore, in response to the question of whether the creation of PDG been a successful experiment in governance, the pilot results indicate a resounding *yes*; industry can collectively and collaboratively govern the DSCSA interoperability environment as needed to support successful implementation.

Overall success of the governance model does not indicate that the current structure is perfect, and PDG is dedicated to learning from the key findings of the pilot and continuing to learn and evaluate the governance structures and processes as PDG work progresses to make PDG as effective as possible. Key pilot learnings that PDG will incorporate moving forward include:

- Exploring opportunities to increase the required input to a proposed solution before it can be considered a consensus policy;
- Structuring future work plans in a way that balances substance with speed and allows time for discussions of appropriate depth and detail;
- Continuing to leverage voting mechanisms as a way to come to conclusion on consensus solutions, but finding ways to ensure the votes are not taken prematurely;
- Utilizing semi-frequent, but lengthy meetings to allow sufficient prep time as well as sufficient depth of conversation to achieve the desired goals;
- Grounding specific substantive conversations in the broader context of the many ongoing, concurrent conversations that will be occurring; and
- Agreeing upon high-level structural principles and technical assumptions for a 2023 solution upon which specific issue-areas conversations can be based.

I. Description

Overview

For multiple years, stakeholders throughout the supply chain have broadly recognized that an independent, balanced, sector-neutral governance body is important to guide and support interoperable verification and tracing at the salable unit level, as required by the Drug Supply Chain Security Act (DSCSA) in 2023. The Pilot has successfully demonstrated industry's ability to collectively and collaboratively govern the DSCSA interoperability environment as needed to support successful implementation.

The Pharmaceutical Distribution Security Alliance (PDSA) worked for over a year to develop a proposed structure for such a governance body. In March 2019, PDSA published that proposed structure and began to engage trading partners beyond PDSA in discussion of the proposed structure. Although the Pilot proposal was submitted to the Food and Drug Administration (FDA) by PDSA, responsibility for the Pilot transitioned to the Partnership for DSCSA Governance (PDG) upon successful formation in November 2019.

Once a critical mass of supply chain entities agreed to a governance body structure (using the PDSA proposal as a starting point for developing such agreement), the governance body was established. The process of developing broad stakeholder support for a governance structure (including a funding model) and legal formation of the governance body took approximately 8 months. It is these agreed upon organizational structures that were piloted by PDG.

The goal of the PDG Pilot was to test, learn from, and refine the organizational structure and processes of a DSCSA interoperability governance body (now formally PDG). A variety of governance metrics were established at the outset of the pilot for formal evaluation of 11 governance processes and PDG structural elements. Testing these structural elements and processes to evaluate the ability of PDG to successfully govern the DSCSA interoperability environment required PDG to formally exercise each process within the context of a substantive use case. Therefore, the Pilot WG was tasked with the development of proposed systems and processes (*e.g.*, business requirements) for confirming the "authorized" (as defined in the DSCSA) status of trading partners.[1]

The substantive use case was purposefully limited in scope to support experiential learning related to *governance processes* for collaboration between the governance body and FDA, collaboration between the governance body and technology providers, the role of committees within the governance body, documenting and publishing use case outputs, and other processes. Through the testing of governance, however, the pilot also examined and solved for the best ways to determine if an entity is an authorized trading partner (*i.e.*, manufacturer, repackager, wholesaler, third party logistics provider, dispenser). Details of the deliberations and conclusions related to this use case will become an input to the PDG Interoperability Committee as it develops a blueprint for interoperability in 2023.

[1] Any trading partner connecting into an interoperable electronic system used for the purpose of verification or tracing must be "authorized" as defined under FD&C Act 581(2). To support an interoperable system, users of an interoperable system for verification or tracing must demonstrate they (or if a service provider, the clients on behalf of which they are acting) are authorized.

Background

Prior to the start of the pilot, trading partners came together to form PDG. This process involved continued conversations around key details of the governance body (*e.g.*, funding model; role of services providers, standards bodies, and other technical stakeholders; scope of governance).

Key industry conversations leading to the formation of PDG included:

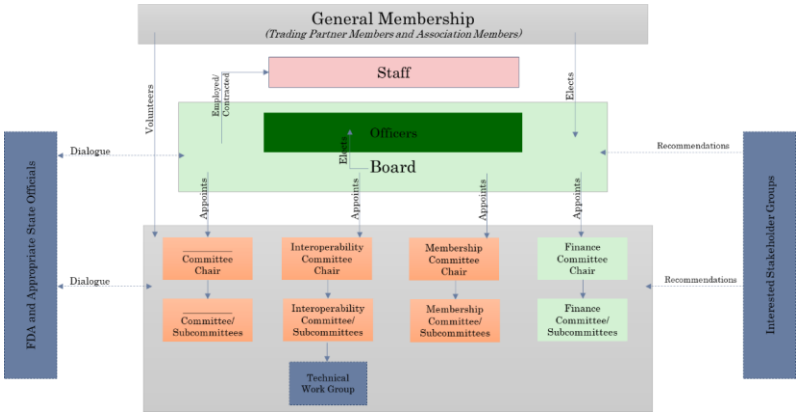
- May 1st, 2019 – an industry stakeholder workshop held in Washington, D.C. to present and discuss a potential governance structure.
- June 26th and 27th, 2019 – prospective members of the governance body held follow-up conversations to refine governance body structure and formation process. Discussions specifically addressed the two key outstanding issues identified during the May 1st workshop: (i) the role of technical experts, such as service providers, in the governance body, and (ii) funding of the governance body.
- August 8th, 2019 – an industry stakeholder follow-up meeting to ultimately determine and agree upon the membership role of service providers and technical experts, and the tier structure and definitions. In addition, perspective members of the governance body discussed options for initial and longer-term payment arrangements for membership dues, including the timing of such options.

Key formation activities included:

Date	Activity
September 30, 2019	Non-binding Membership Commitments Due*
October 4, 2019	Entity Officially Incorporated
October 11, 2019	Expression of Intent to Run for Board Seats Due
October 14, 2019	Governance Body Kick-Off Meeting
October 15 – October 30, 2019	Board Elections
November 13, 2019	Board Officially Seated; Entity Officially Named the Partnership for DSCSA Governance (PDG)
November 21, 2019	Board Meeting; Committee Chairs Appointed
December 12, 2019	Board Meeting
December 13, 2019	PDG Membership & Prospects Meeting
December 16, 2019	Public Rollout of PDG
January 2020	Committee Activity Begins

*Non-binding membership commitments were solicited to determine whether there was sufficient interest to move forward with formation of a governance body. The commitments received by September 30, 2019 indicated that there was sufficient cross-sector industry interest in establishing a governance body to move forward with formal incorporation of the entity.

As indicated above, PDG was successfully formed and work began in earnest in November 2019. The structure of PDG is shown below. The Pilot Work Group was created as a sub-group of the Interoperability Committee.



Successful completion of the formation activities above proved that industry could come together to form an independent, balanced, sector-neutral nonprofit industry governance body. The Pilot Project work was undertaken to improve and assess the governance structure shown above and the governance processes established in the PDG bylaws. An overview of the PDG structure, including a breakdown of the PDG membership categories, can be found in the PDG prospectus, included as Appendix A and at https://dscsagovernance.org/wp-content/uploads/2020/04/Governance-Prospectus-Document_Final.pdf.

II. Objectives

The PDG pilot project had three core objectives:

1. Ensure that the structural and organizational aspects of the governance body allow the organization to meet the goals of governance (described below).
2. Improve governance systems and processes at the outset of governance body formation.
3. Identify challenges with the operation of the governance body's initial systems and processes for governance.

The goals of governance as referenced above were a fundamental set of guiding principles on which PDG was based. These are:

- All supply chain sectors should work collaboratively to establish efficient, viable, and effective systems and processes to protect patients through compliance with the DSCSA 2023 requirements.

- The pharmaceutical supply chain is highly complex, encompassing a range of entity types and companies, and the perspectives of all sectors of the supply chain are critical.
- Engagement of all trading partner sectors of the supply chain is critical to achieving supply chain security and improving patient safety.
- Each sector should bear an equitable share of the responsibility for achieving interoperability and supply chain security.

- 2023 system architectures should be governed by trading partners[2] through a balanced, independent, sector-neutral legal entity.
  - The governance body's activities should be equitable for all trading partners (*i.e.*, should not favor any sector).
  - The governance body should promote balanced participation/representation among all trading partners—all sectors, company sizes, and business models—in carrying out its objectives.
  - The governance body should be structured as an independent legal entity to provide necessary continuity and legal structures (*e.g.*, ownership and protection of jointly developed intellectual property, financial liability).
  - The governance body's vision should be designed to maximize opt-ins (*i.e.*, encourage broad voluntary adoption) to the vision from all trading partners, sectors, business sizes, etc., while recognizing that alternative approaches may be adopted by some trading partners.
  - The governance body's vision should maximize efficiency, scalability, and cost-effectiveness for all trading partners without regard to company size.
  - The governance body must comply with all applicable laws and regulations, including applicable antitrust requirements.

- The governance body's activities should support interoperable exchange, interoperable verification, and interoperable tracing, as required by the DSCSA.
  - The model and architecture(s) (*i.e.*, vision) advanced by the governance body should be focused on feasible methods of meeting the 2023 statutory requirements, though it may note additional benefits that could be considered in the future.
    - The model and architecture(s) should allow trading partners to create their own arrangements for particular business needs in a manner that differs from the minimum set of policies, procedures, and/or technical specifications for interoperability recognized or outlined by the governance body, provided that such arrangements do not undermine/interfere with the model and architecture.
    - The governing body should preserve (*i.e.*, should not impede) the autonomy of individual trading partners that choose to subscribe to the

[2] This document uses "trading partners" to mean all supply chain companies that are subject to DSCSA requirements, which includes manufacturers, wholesale distributors, dispensers, repackagers, and third-party logistics providers (each category of which is referred to as a "sector"). The term "stakeholder" is used to refer to all organizations that have an interest in/are impacted by DSCSA implementation, including trading partners, FDA, state regulators, standards bodies, and service providers.

governing body's model and architecture to develop and maintain internal systems and processes used to comply with the DSCSA, provided that such systems and processes do not undermine/interfere with the model and architecture.

- The governing body should recognize or establish the minimum set of policies, procedures, and/or technical specifications for interoperability by which other system architectures may interoperably communicate with the model and architecture(s) advanced by the governing body.[3]

- Rules for membership and use will incent participation.
  - Membership in the governance body should be open to all (i) authorized trading partners[4] (as defined in DSCSA) who subscribe to the model and architecture for interoperability advanced by the governing body, and (ii) trade associations of authorized trading partners.
    - Non-member participation should be open to, at a minimum, (i) regulators, and (ii) technical or process experts, such as standards bodies, solutions/service providers, and technology providers.
  - The minimum set of policies, procedures, and/or technical specifications for interoperability will require that:
    - all users (*i.e.*, trading partners) of model and architecture(s) advanced by the governing body are authorized trading partners (*i.e.*, direct users are authorized, as required by DSCSA), and
    - all users (*i.e.*, trading partners) of other system architecture(s) that connect to the model and architecture(s) advanced by the governing body are authorized (*i.e.*, indirect users are authorized, as required by DSCSA).

III. Methods

On January 17, the PDG FDA Pilot Work Group (a sub-group of the Interoperability Committee; "the Work Group") held an initial kick-off meeting. Work Group members met weekly, by phone, for one hour for the duration of the pilot. A work plan was established at the outset of pilot work for both the substantive use case as well as the Pilot Project itself. The work plan set purposefully aggressive timelines given the time-limited nature of the pilot and to encourage as much substantive progress on the selected use case as possible.

Participants

[3] For example, assume the governance body recognizes policies, procedures, and technical specifications for the interoperability of technologies A, B, and C. This does not preclude trading partners from using technology D, even though technology D is outside of the governance body's visions. The governance body should, however, provide policies, procedures, and/or technical specifications that describe how other technologies, including technology D, can be interoperable with the technologies A, B, and C.

[4] This includes trading partners not legally required to be licensed/registered, such as DOD dispensers, virtual manufacturers, etc.

Brian Lee, Board member affiliated with Bristol Myers Squibb, was appointed Chair of the PDG Interoperability Committee. Brian was therefore also Chair of the PDG Pilot Work Group (as a sub-group of the Committee). Matthew Price, Board member affiliated with Medline Industries, was appointed as Co-Chair of the Pilot Work Group.

FDA representatives were invited to join all weekly Pilot Work Group meetings.

PDG members who volunteered as members of the PDG Pilot Work Group were:

Manufacturers/Repackagers:
- Bristol Myers Squibb
- Endo Pharmaceuticals
- Genentech
- Johnson & Johnson
- Pfizer
- Sanofi

Wholesale Distributors/3PLs:
- Hercules Pharmaceuticals
- The International Warehouse Logistics Association (IWLA)
- Inmar Intelligence
- McKesson
- Medline Industries

Dispensers:
- CVS Health
- Uptown Pharmacy
- Walgreens

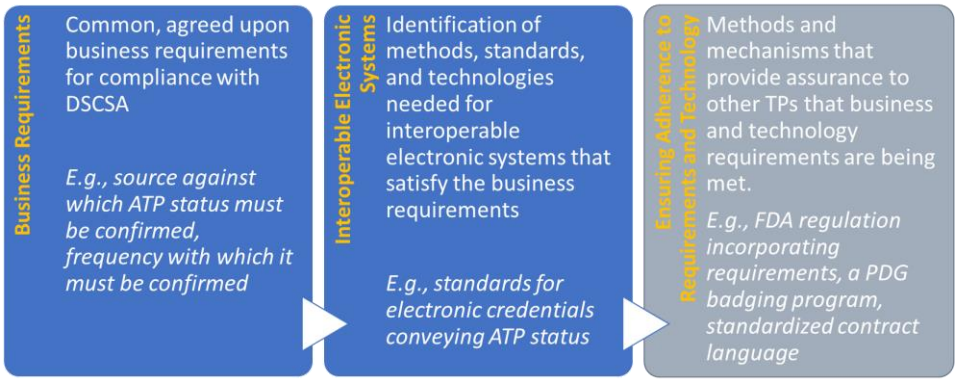
Technical Experts:
- Chronicled
- TraceLink
- rfxcel
- Providence Health Technologies
- Second Generation/.med

Pilot Use Case

Testing the structural elements and processes to evaluate the ability of PDG to successfully govern the DSCSA interoperability environment required PDG to formally exercise each process within the context of a substantive use case. Therefore, the Pilot WG engaged in the development of proposed systems and processes (*e.g.*, business requirements) for confirming the

"authorized" (as defined in the DSCSA) status of trading partners.[5] This substantive use case was purposefully limited in scope to support experiential learning related to *governance processes*. Through the testing of governance, however, the pilot also examined and solved for the best ways to determine if an entity is an authorized trading partner.

The first task of the Pilot Work Group was to further define the scope of the Pilot use case. The Work Group agreed that the scope of the use case would include developing common, agreed upon business requirements for compliance with DSCSA, and could possibly include identification of methods, standards, and technologies needed for interoperable electronic systems that satisfy the business requirements. The Work Group agreed that methods and mechanisms that provide assurance to other trading partners that business and technology requirements are being met are out of scope for this pilot. This scope is captured in the image below (blue = in scope; gray = out of scope):



The Work Group identified five business requirements to be defined within the pilot use case:

1. Reliable demonstration/documentation of authorized status (*e.g.*, What is the source documentation of authorized status?)
2. Responsibility for confirmation of authorized status (*e.g.*, Who is responsible for confirmation, and how can that be delegated?)
3. Frequency of confirmation of authorized status (*e.g.*, How frequently must authorized status be confirmed/updated?)
4. Resolution of exceptions and non-confirmation authorized status (*e.g.*, How are other "network" participants notified if there is a failure of authorized status?)
5. Relationship with user authentication (*e.g.*, How can authorized status be incorporated into systems and processes for user authentication?)

[5] Any trading partner connecting into an interoperable electronic system used for the purpose of verification or tracing must be "authorized" as defined under FD&C Act 581(2). To support an interoperable system, users of an interoperable system for verification or tracing must demonstrate they (or if a service provider, the clients on behalf of which they are acting) are authorized.

Governance Structures & Processes

The Work Group identified 11 governance structural elements and processes to be tested and engaged in a number of activities to test each element/process. The Work Group prioritized activities that would allow Work Group members to glean sufficient insight on how well PDG was functioning across the almost 50 pre-identified metrics corresponding to the 11 structural elements and processes. Examples of the activities that the Work Group undertook to test and evaluate PDG structural elements and governance processes include:

- To evaluate *methods/mechanisms for engagement with FDA and regulators*, the Work Group invited FDA representatives to observe weekly Work Group meetings. When Work Group members felt there were specific questions related to the use case on which FDA could provide clarity or insight, those questions were posed to the FDA representatives on the call. While PDG fully recognizes and respects the Agency's limited ability to respond to such inquiries,[6] the questions were presented to FDA to illustrate the types of issues and questions for which it would be helpful to have FDA feedback in the future.

- As described in Appendix A, solutions providers, thought leaders, and other experts can join PDG as non-voting "technical experts." These technical experts are able to engage in PDG committee work in an advisory function. In order to ensure that both PDG general members (*i.e.*, trading partners) and technical experts (*e.g.*, service providers) felt that the established *methods/mechanisms for engagement with technical experts* were successful (informative, unbiased, etc.), PDG ensured that multiple technical experts were engaged in the Work Group activities. When substantive votes occurred, technical experts were not permitted to vote (per PDG bylaws and Committee rules).

- To evaluate *methods/mechanisms for engagement with non-members*, the Work Group invited Bob Celeste from the Center for Supply Chain Studies to present on two topics related to the use case discussion of verifying ATP status: (1) the Digital Trust Framework, and (2) the Credentialized DSCSA Authorized Trading Partner Proof of Concept and Pilot.

- In addition to the work that Bob Celeste presented to the Work Group, evaluation of PDG's *incorporation of, and ability to leverage, existing/prior non-PDG efforts* included evaluation of how the work group leveraged the information provided by Justine Freisleben of the Healthcare Distribution Alliance regarding the business requirements for VRS users for verifying authorized trading partner status.

[6] Statutory and regulatory restrictions limited FDA's ability to engage in more than an "observer" role. These limitations were communicated in advance by FDA, and we do not view limitations on FDA's engagement as a negative outcome of the pilot. Rather, FDA's consistent participation as a pilot observer provided a valuable opportunity to demonstrate the types of discussions occurring within PDG and highlighted issues that would benefit from FDA engagement in the future, subject to necessary procedural structures and safeguards. PDG looks forward to working with FDA to develop and implement such structures that may be mutually beneficial to all stakeholders, including FDA.

- To evaluate *Work Group structure and participation*, and specifically to evaluate the PDG committee voting processes and procedures, the Work Group ensured that multiple substantive votes were taken. The Work Group took a vote on the appropriate frequency for confirming ATP status against source information and also took a vote on the appropriate grace period for lapsed or expired licenses. As noted, votes were limited to general members.

IV. Evaluation

PDG Formation

While the PDG Pilot Project was executed by members of the PDG Pilot Work Group around a use case for verifying authorized trading partner status, a precondition of the pilot work was successful formation of an independent, balanced, sector-neutral nonprofit industry governance body, founded in the established principles of governance outlined above, that supports the secure, electronic, interoperable tracing, and verification of prescription drugs in the U.S. supply chain, as required by the DSCSA.

PDSA (and the broader governance formation team as time went on) provided updates during the formation phase of the governance body. Key outputs/outcomes that were assessed during the formation phase included:

- Did the governance body successfully incent sufficient membership across sectors, Y/N?
- Was the governance body successfully formed within the proposed timeline, Y/N?
- Were the initial financial commitment of the founding members sufficient to cover the costs of formation of the governance entity, Y/N?

Governance Pilot Metrics

The Work Group agreed that the pilot project would test the following PDG systems and processes:

1. Methods/mechanisms for engagement with technical experts
2. Methods/mechanisms for engagement with non-members
3. Methods/mechanisms for engagement with FDA and regulators
4. Incorporation of, and ability to leverage, existing/prior non-PDG efforts
5. Allocation of responsibilities between the Board, Interoperability Committee, and Work Groups
6. Handoffs and relationship between Board, Committees, and Work Groups
7. Board participation
8. Work Group structure and participation
9. Meeting (Board and Committee) cadence and organization
10. Execution of project plan
11. Outputs/documentation

These systems and processes were evaluated across approximately 50 distinct metrics that are detailed in Appendix B. The Work Group gathered qualitative feedback from participants on an ongoing basis as well as formally through a mid-pilot survey and an end-of-pilot survey.

The Work Group completed the mid-pilot survey on March 31 to assess the governance metrics on which the Work Group felt it had the ability to provide valuable feedback at that time. In all, 33 metrics were assessed (11 quantitative metrics and 22 qualitative metrics). The metrics were used to evaluate the following governance systems and processes: (1) methods/mechanisms for engagement with FDA and regulators; (2) methods/mechanisms for engagement with non-members; (3) handoffs and relationship between Board, Committees, and Work Groups; (4) board participation; and (5) distribution and socialization of outputs/documentation with non-members.

The Work Group completed the end-of-pilot survey on May 1 to assess the full set of governance metrics. In all, 37 metrics were assessed (11 quantitative metrics and 27 qualitative metrics). The metrics were used to evaluate the following governance systems and processes: (1) methods/mechanisms for engagement with FDA and regulators; (2) methods/mechanisms for engagement with non-members; (3) handoffs and relationship between Board, Committees, and Work Groups; (4) board participation; and (5) distribution and socialization of outputs/documentation with non-members.

V. Costs

Cost was not a significant component of the pilot. The pilot was successfully executed within the existing PDG budget. PDG membership dues funded the legal and managerial aspects of operation of the 501(c)(6) organization. Participation of Work Group members was strictly voluntary.

VI. Key Findings

PDG Formation

Through formation of an independent, balanced, sector-neutral nonprofit industry governance body, PDG successfully demonstrated industry's ability to collectively and collaboratively govern the DSCSA interoperability environment as needed to support successful implementation.

Significant "stop gaps," such as non-binding membership commitments were incorporated into the formation of PDG to ensure that the new governance body was formed according to the pre-established governance principles and that in short order the membership and operations of PDG also reflected the governance principles that industry had agreed upon. For example, the founding members of PDG were intent on ensuring membership recruitment that enabled PDG to live up to the principles that *engagement of all trading partner sectors of the supply chain is critical to achieving supply chain security and improving patient safety* and that *the governance body should promote balanced participation/representation among all trading partners—all*

sectors, company sizes, and business models—in carrying out its objectives. In fact, PDG formation was predicated on receiving sufficient membership commitments by September 20, 2019. Specifically, formation of the governance body was only initiated upon commitment of one half of the targeted number of members across sectors (initial targets shown in the chart below).

	Targeted Number of Members				
	Manufacturers	**Wholesalers**	**Dispensers**	**Associations**	**Technical Experts**
Tier 1	12	3	4	6	10
Tier 2	7	2	8		
Tier 3	3	2	6		
Small Business	0	0	5		
Total	22	7	23	6	10

Successful formation of PDG demonstrated that:

- Yes, the governance body did successfully incent sufficient membership across sectors.

As of May 13, 2020 PDG has 45 formal membership commitments from across all trading partner sectors as well as solutions providers and technical experts. For a full list of member organizations, see https://dscsagovernance.org/members/.

- Yes, the governance body was successfully formed within the proposed timeline.

In the PDSA pilot application on behalf of PDG, PDSA indicated that formation of the governance body was anticipated in Fall 2019. While the administrative and logistical efforts required to form PDG and establish the necessary governing structures and processes to begin substantive work was significant, PDG formation did successfully occur within the proposed timeline. This is a testament to the industry leaders and staff who acknowledged the looming 2023 DSCSA compliance deadline and were determined to take on risk and put in the necessary work to ensure that governance was properly established.

- Yes, the initial financial commitment of the founding members of PDG was sufficient to cover the costs of formation of the governance entity.

PDG established a budget at the outset of governance activity, which was predicated on yet to be acquired membership dues. Initial investments were sufficient to cover the costs of the formation of the governance entity, and within six months of operation, PDG achieved sufficient membership to sustain operations for the first year.

Governance Pilot Metrics

Assessment of the governance pilot metrics in Appendix B showed that overall, the PDG governance structure is sound, that PDG members are effectively engaged, that meaningful progress toward 2023 interoperability can be made within PDG, and that PDG has been successful in abiding by the principles of governance. Important and notable successes across both the mid- and end-of-pilot surveys include:

- Technical Experts participated in meaningful and valuable ways without biasing general members (*i.e.*, trading partners) toward specific solutions.
- FDA participation in Work Group calls as an observer was consistent and valuable.
- PDG effectively identified and leveraged prior work and outside experts to inform Pilot Work Group discussions of the use case.
- Prior work and existing efforts were timely identified and described to the Work Group by representatives of those efforts, yet importantly were seen as informative rather than binding recommendations.
- All Work Group members felt that they had a fair and equal opportunity to participate in governance discussions.
- All Work Group members viewed the PDG decision-making processes (including voting structures) to be fair and balanced.
- Major process issues were not experienced and any minor process issues were resolved efficiently and effectively.

In addition, evaluation of the PDG governance structures and processes yielded some valuable learnings that PDG leveraged to improve the success of PDG.

Some of the key learnings from the mid-pilot survey include:

- To better evaluate the incorporation and use of prior work, the Pilot Work Group should discuss/leverage prior work in additional ways.
- Roles and responsibilities of the Work Group, Committee, and Board should be made more explicit and are not yet well-understood by Work Group members.
- PDG should provide additional clarity to Work Group members around which portions of substantive work product should be elevated to the Board.
- To better evaluate Work Group/Committee operations, the Work Group should find additional opportunities to leverage and assess the voting process.
- Materials and recaps should be distributed sooner.
- The majority of work plan items have not been completed on time. PDG should seek to balance speed/efficiency of output and depth of discussion over time.
- Pilot Work Group output should be disseminated with additional context for those not involved in the conversations.

Full results of the mid-pilot survey are included in Appendix C.

Some of the key learnings from the end-of-pilot survey include:

- Participants have varying levels of technical expertise. PDG should be intentional about recognizing this diversity and using it to its advantage.
- Conversations to-date have not required deep technical expertise. PDG should explore and find the best ways to “deep-dive” into technical solutions.

- PDG members need more clarity on the roles and responsibilities of each part of the organization. PDG should consider creating an explanatory document on governance roles and responsibilities.
- For efficiency and participation purposes, PDG should consider utilizing tools for real-time feedback/voting rather than taking offline polls.
- PDG should continue to work on ensuring continuity of conversations and explore tools in addition to meeting recaps to assist those who miss a call.
- PDG should continue to explore the appropriate role of the Board in substantive conversations.
- Active participation across all sectors and organizations continues to be a concern. PDG should consider the use of tools such as real-time polling or cold calling to improve participation.
- PDG should continue to promote membership and participation in the dispenser sector.[7]

Full results of the end-of-pilot survey are included in Appendix D.

VII. Lessons Learned

Ensuring Respect for Output

If PDG output is to represent an industry recommendation on how to implement electronic, interoperable, unit-level tracing in 2023, the output must be well-regarded, respected, and seen as a fair and balanced consensus position by all PDG members as well as industry representatives outside of PDG. PDG has multiple systems and processes in place to ensure that substantive decisions are representative positions that represent the diverse voices of PDG members. One such set of processes are the conditions of voting within PDG.

In the Pilot Work Group, votes were called for two main reasons: (1) to test the systems and processes for voting within a PDG committee/work group, and (2) to accelerate the consensus process and help the Work Group move forward more expeditiously. Votes were taken in the Work Group on two occasions: once to come to a conclusion on a recommendation for how frequently source data must be checked to verify ATP status (frequency poll) and once to determine a recommendation for an appropriate grace period with regard to lapsed or pending licenses.

Although a voting quorum was present for each vote, Work Group members ultimately raised concern about the voting response rates and therefore the consensus nature of a voting result. For example, although the frequency poll had a 64% response rate, only 5 voting members chose the response with the highest vote total. While it is expected that future substantive votes at the committee level will involve more PDG voting members and therefore will require more voters

[7] Dispenser membership and participation has been recognized as a priority not just by PDG Pilot Work Group members, but also by the PDG Board. PDG is already acting on this finding by creating a time-limited pathway for dispenser expert participation as non-voting committee representatives without formal membership in PDG/payment of PDG member dues. PDG hopes that this opportunity will increase the dispenser voice in important interoperability discussions.

to reach a quorum, it is worth noting that presence of a quorum as currently defined may not be sufficient to ensure full respect for the result of the vote. As such, **PDG should explore opportunities to increase the required input to a proposed solution before it can be considered a consensus policy**. One possible solution would be for PDG to consider raising voting thresholds (e.g., 66% or 75% agreement) within committees and work groups.

Speed vs. Substance

While there is always an inherent tradeoff between speed of conversation and the level of detail addressed, the pilot use case emphasized that this tradeoff, and the need to strike an appropriate balance, is even more acute when the timeframe of discussion is limited. The use case that was chosen for the pilot, while concrete and limited in scope, remained a complex conversation. The original work plan that was constructed envisioned a very aggressive timeline for discussion and finalization of the group's positions across each of the business requirements. What became clear quickly is that allocating two weeks (*i.e.*, two hours) per discussion of each business requirement was insufficient. Early in the process, members agreed that allocating time for robust discussion was necessary for the group to come to the best and most informed positions and conclusions. As one member pointed out during the mid-pilot survey, "I think I expected to be further along in the process than we are today, but again, there was a lot of discussion that led us to be at the point that we are currently." Given the recognized benefit of in-depth discussions as well as the inherent need for efficiency given the looming 2023 deadline, **PDG should structure future work plans in a way that balances substance with speed and allows time for discussions of appropriate depth and detail**.

In order to improve efficiency, as the pilot went on members agreed that holding more votes might be a tool to speed the processes of reaching consensus conclusions. As one member indicated in the mid-pilot survey, "I still believe there is an opportunity to get more efficient with the process issues. We are behind on the execution of the project plan but have had a lot of fruitful discussions. Maybe we can start voting on issues sooner rather than later?" However, as noted in the previous learning there are risks associated with taking a premature vote or basing conclusions on a vote rather than true consensus. Therefore, **PDG should continue to leverage voting mechanisms as a way to come to conclusion on consensus solutions, but should find ways to ensure the votes are not taken prematurely.** One possible solution is to wait to hold a formal vote until there is full alignment around the alternatives and sufficient discussion of each alternative has been completed. Another possible solution, as noted by multiple members during the end-of-pilot survey, may be to elicit real-time, informal feedback via live voting during committee conversations. Informal, real-time feedback could prevent surprises during formal voting, speed up conversations in anticipation of a formal vote, or even obviate the need for a formal vote.

An additional learning with regard to balancing speed and substance is the appropriate length of discussions. As indicated, the Pilot Work Group was meeting for one hour once per week. While meeting each week helped to maintain the momentum of the discussion, the quick turnaround and limited duration of meetings hindered the ability of the Work Group to "deep dive" into particular issues. As one member noted in the mid-pilot survey, "The meeting cadence is appropriate but does not allow enough prep time." It will be important that the PDG

Interoperability learn from this experience given the aggressive timeline, considerable complexity, and deep content required to complete a full interoperability blueprint by end of year. **The Committee should look toward semi-frequent, but lengthy meetings to allow sufficient prep time as well as sufficient depth of conversation to achieve the desired goals**. As one member indicated in the end-of-pilot survey, it "may be good to occasionally have a longer meeting to cover more (*e.g.*, one [longer] meeting per month)."

Difficulty of isolating one use case

Out of necessity, given the time constraints and the focus on governance, the pilot use case was constructed as a limited, concrete discussion. While the benefits of carving off one specific set of business requirements was the ability to test governance processes and isolate the substantive focus of the group, the drawback of such a limited scope was that the natural interconnectedness of the issues and challenges that must be addressed to achieve interoperable verification and tracing under DSCSA make it difficult to truly isolate a single use case. As such, the Work Group was not able to complete discussion of all five business requirements. In fact, two of the five business requirements were deemed to be too inter-related to other aspects of interoperability and the technology to effectuate interoperability (yet unknown and not yet discussed) to be able to come to meaningful conclusions as a Work Group. As one member pointed out during the mid-pilot survey, "some of this work is very technical and requires a lot more discussion to understand and assess its applicability to the ATP use case, specifically on verifiable credentialing." It was quite difficult to the Work Group to envision answers to some of the challenges related to verifying Authorized Trading Partner status without an understanding of the systems and technology that would be used in 2023. As the Interoperability Committee takes over this work, it will be important to **ground specific substantive conversations in the broader context of the many ongoing, concurrent conversations that will be occurring** to establish a 2023 Interoperability Blueprint. Especially as the Interoperability Committee expands its work to multiple work groups, **the Committee should be sure to establish good cross-work group communication**. This could also mean ensuring some consistent participation of specific individual member company representative across multiple topic areas and work groups.

The lack of discussion or awareness of the technology to be leveraged also limited the ability of solutions providers engaged in the discussions from engaging to their full extent or potential. As one member pointed out during the mid-pilot survey, "The solution providers have been participating, but until more requirements are set, there has not been a lot of opportunity to provide technical insight." Another member indicated that, "I just feel we need a deeper dive into this issue as it feels were only at the surface. As for solutions, we have yet to discuss and put forward a meaningful solution." These observations indicate an important learning that it is difficult to isolate certain components of interoperability without a broader vision. The Pilot Work Group experience also raises the question of whether business requirements and technology should be discussed consecutively or simultaneously, as it was challenging to understand the ability of industry to adhere to a business requirement without having an (even surface level) understanding of the technology that industry will have at its disposal. As such, **PDG should consider agreeing upon high-level structural principles and technical assumptions for a 2023 solution upon which specific issue-areas conversations can be based**.

VIII. Conclusion

Successful completion of PDG formation proved that industry could come together to form an independent, balanced, sector-neutral nonprofit industry governance body. Further, completion of the Pilot Project, including evaluation of the established PDG structure and governance systems, showed that the PDG governance structure is sound, that PDG members are effectively engaged, that meaningful progress toward 2023 interoperability can be made within PDG, and that PDG has been successful in abiding by the key principles of governance.

Further, PDG successfully utilized the pilot to pilot to further examine and solve for the best ways to determine if an entity is an authorized trading partner. The results of the pilot use case conversations have been compiled into draft business requirements that are included in Attachment E. These substantive findings will be handed off and presented to the PDG Interoperability Committee to serve as a foundation for their continued discussion of the methods, standards, and technologies that will be needed to satisfy the draft business requirements, as well as the methods and mechanisms to provide assurance to other trading partners that the business and technology requirements to ensure authorized status are being met.

While the PDG Pilot Project determined that governance is feasible and that the structures and processes that PDG has established can operate effectively, the Pilot Project also helped PDG understand where governance processes can be marginally modified to improve PDG operation and effectiveness. PDG is dedicated to learning from the key findings of the pilot and to continuing to learn and evaluate the governance structures and processes as PDG work progresses to make PDG as effective as possible.

Key recommendations from the PDG Pilot Work Group include:

1. Explore opportunities to increase the required input to a proposed solution before it can be considered a consensus policy.

2. Structure future work plans in a way that balances substance with speed and allows time for discussions of appropriate depth and detail.

3. Continue to leverage voting mechanisms as a way to come to conclusion on consensus solutions, but find ways to ensure the votes are not taken prematurely.

4. Utilize semi-frequent, but lengthy meetings to allow sufficient prep time as well as sufficient depth of conversation to achieve the desired goals.

5. Ground specific substantive conversations in the broader context of the many ongoing, concurrent conversations that will be occurring, in-particular emphasizing cross-work group communication.

6. Agree upon high-level structural principles and technical assumptions for a 2023 solution upon which specific issue-areas conversations can be based.

We thank the Agency for the opportunity to participate in the FDA DSCSA Pilot Program and are grateful to the meaningful contributions of PDG members and staff to complete the pilot project.

Appendix A.

Overview
Partnership for DSCSA Governance (PDG)

The Partnership for DSCSA Governance (PDG) is an independent, balanced, sector-neutral nonprofit industry governance body that supports the secure, electronic, interoperable tracing, and verification of prescription drugs in the U.S. supply chain, as required by the Drug Supply Chain Security Act (DSCSA).

PDG's membership includes leading authorized manufacturers, repackagers, wholesalers, third-party logistics providers, and dispensers (hospitals and retail and independent pharmacies), as well as leading industry trade associations and technical experts. Together, these members are working to establish a comprehensive vision for industry's implementation of secure, electronics systems and processes for drug traceability in the U.S.

For additional information, visit www.DSCSAgovernance.org.

What is the purpose of the governance body?

The ability to gather and use serialization data among trading partners is essential to the effective and efficient implementation of the DSCSA requirements for electronic interoperable verification and tracing. Phase II interoperability will require a level of cooperation, coordination, and interconnection at the unit level not present today. Stakeholders throughout the supply chain, including FDA, have broadly recognized that governance is critical to the successful implementation of Phase II interoperability.

Efficient implementation requires an intentional implementation plan that builds toward a shared vision for Phase II interoperability. As an independent, balanced, and sector-neutral governance body, PDG is best positioned to establish such an implementation plan and will provide certainty and longevity that benefits the effective, efficient implementation of the DSCSA. No individual sector representative can serve as the governing body because they will be, or will be perceived as, inherently biased; PDG is a sector-neutral body with clear rules for engagement. Each trading partner will be committing significant resources to Phase II implementation. The formal structure of PDG, with well-understood, agreed upon rules for governance provides confidence and predictability in the allocation of those resources.

PDG's work is not dependent on any one specific technical vision for how interoperability should be achieved. The specific technical vision to be advanced by PDG will be determined by PDG using its decision-making mechanisms that promote balance, sector-neutrality, and equitability. At a general level, however, PDG will govern interoperable verification and tracing (as required by DSCSA) and practices and processes that impact the integrity and reliability of interoperable verification and tracing.8 This includes the practices and processes to create, store, and transmit data intended to be exchanged under DSCSA, but excludes internal company processes and practices. Collectively, the technical vision that includes these practices and processes, as well as the technology for accomplishing them, are referred to as the "blueprint for interoperability." The primary deliverable of PDG within the first year is this blueprint for

[8] It is acknowledged that other governance activities may take place. First, PDG is intended to govern interoperability among systems and networks. Specific systems and networks and distinct technologies (*e.g.*, blockchain) may require their own governance activities within their own network or system. Second, it is possible that other governance efforts may emerge with the same or overlapping scope and objective. While it is neither possible nor appropriate to restrict the emergence of such effort, multiple divergent approaches could hamper trading partners' ability to be interoperable, as required by the DSCSA. Therefore, PDG strives to develop and advance a vision for interoperability that is inclusive of the views and goals of divergent stakeholders and attracts the broadest possible set of stakeholders.

interoperability, the establishment of which will help to further define the scope of governance moving forward. More specifically, it is expected that the blueprint for interoperability will:

- Define a database architecture (*e.g.*, centralized, semi-centralized, distributed) for DSCSA interoperability.
- Define necessary governance body activities (*e.g.*, whether the body will issue best practices or will identify technical specifications to support interoperability).
- Define the vision for interoperability (*e.g.*, a model for credentialing tracing services, establishment of technical systems to support interoperability)
- Define the use cases and business requirements for DSCSA interoperability.
- Identify standards and/or functional specifications needed for DSCSA interoperability.
- Identify any infrastructure that may be needed for DSCSA interoperability.

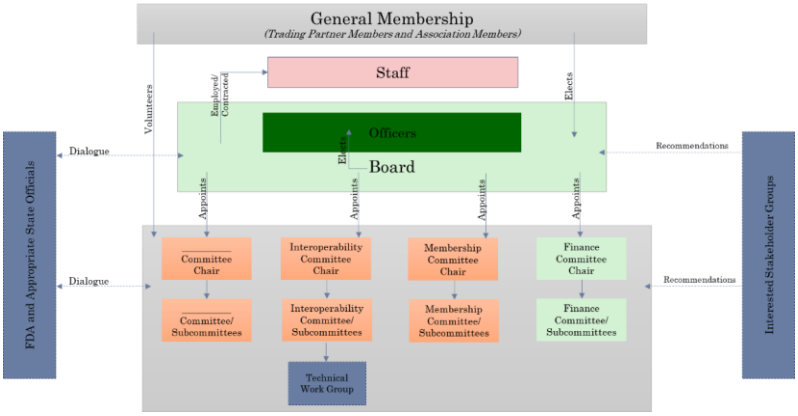
Regulators also play an essential role both in helping to define the requirements of the DSCSA and as a potential recipient of information from DSCSA systems and processes. FDA has acknowledged the importance of governance and has shown a willingness to engage in dialogue regarding the method by which FDA will engage with PDG. FDA has called for governance at public meetings, has attended an industry workshop where industry members discussed the specifics of governance, and has accepted into the official FDA Pilot Program an application for a governance pilot that is being conducted by PDG. The pilot accepted by FDA is specifically intended to determine and refine methods of regular engagement between the governing body and FDA. FDA's engagement with PDG will provide valuable feedback on governance activities and should help the governance body be assured its activities and plans are consistent with regulators' expectations.

Who can participate in the governance body?

Full membership in PDG (and therefore decision-making/voting authority) is reserved for authorized manufacturers,[9] repackagers, wholesalers, third-party logistics providers, and dispensers (*i.e.*, "trading partners," as defined in the DSCSA) with legal obligations under the DSCSA. A 14-member Board **elected by the general membership** is responsible for executive management of the governance body, and contracts staff to carry out day-to-day management.[10] PDG **relies heavily on committee activity** to carry out the tactical/substantive work (*e.g.*, creation of a blueprint for interoperability) of the body. Committees are **open to all general members**. Technical or process experts (*e.g.*, thought leaders, service providers) are encouraged to participate in the Interoperability Committee's Technical Work Group, in which participation is **not limited** to general members. Further, any interested stakeholder may provide recommendations to PDG. This structure is detailed in the graphic below.

[9] Contract manufacturing organizations (CMOs) may join PDG as a full member if they are a "manufacturer" (i.e., hold an NDA/ANDA/BLA) and/or are considered a "3PL" as defined in the DSCSA. In instances where a CMO is not considered a manufacturer or 3PL, CMOs may join PDG as Technical Expert members.

[10] A 10-member board was elected for the initial six months of PDG activity (*i.e.*, until April 1, 2020). Appropriate ratios were maintained.



What are the benefits to/roles of governance body participants?

General Members

The general membership of PDG has the authority to elect board members, approve budgets, and ratify significant technical documents. General members also have the opportunity to participate in committees, which undertake the tactical/substantive work of PDG, including the creation of a blueprint for interoperability. There are two types of general membership:

1. **Trading Partner Members** – any trading partner (as defined in DSCSA) that is authorized (as defined in DSCSA).
2. **Association Members** – any trade association or society the membership of which consists primarily of trading partners (as defined in the DSCSA), and professional societies representing health care providers.

Upon application for membership, each organization will designate itself as a manufacturer, wholesale distributor, dispenser, repackager, or third-party logistics provider. The designated sector does not need to be the member's primary (e.g., highest revenue, highest volume) sector, but must be a sector in which the organization operates and is subject to related DSCSA requirements.

Board Members

The Board has the authority to set the direction and strategy of the governance body, but the activities of the Board are limited to executive functions of the governance body. The 14 Board seats[11] are held by individuals serving staggered two-year terms in their capacity as a sponsored representative of a specific general member (trading partner or association) (*i.e.*, if the elected individual leaves his/her organization, the individual would not retain the seat). Board seats are allocated as follows:

1. **Four manufacturer/repackager board seats** – open to, and elected by, general members who are manufacturers or repackagers.
2. **Four wholesaler/3PL board seats** – open to, and elected by, general members who are wholesale distributors or 3PLs.
3. **Four dispenser board seats** – open to, and elected by, general members who are

[11] A 10-member board was elected for the initial six months of PDG activity (*i.e.,* until April 1, 2020). Appropriate ratios were maintained.

dispensers.

4. **Two at-large board seats** – open to any **general member** regardless of sector; provided that both at-large seats may not be held by members from the same sector. At-large board members are elected by the full general membership (as opposed to a specific sector).

Committee Members

Committees are used to carry out the substantive and technical work of PDG. Three initial committees were established: a Membership Committee, a Finance Committee, and an Interoperability Committee. Committees are open to all general members, with the exception of the Finance Committee, which is made up of Board members. The Membership Committee is responsible for the development, recruitment, and retention of membership. The Finance Committee is responsible for financial planning, including the development of an annual budget.

Members of the Technical Work Group

The Interoperability Committee is responsible for substantive, tactical, and technical work needed to establish a blueprint for interoperability. The Interoperability Committee also has a Technical Work Group in which both general members and non-member thought leaders, such as service providers and other experts, can participate. The Work Group meets regularly to ensure service providers and other technical experts have continuity of information and early awareness of, and input to, the blueprint for interoperability. The Work Group also serves an advisory function making recommendations to the Interoperability Committee on technical matters (e.g., recommendations on reasonably expected response times).

What is the cost of membership in the governance body?

Projecting the long-term funding model for PDG is very difficult given that the technical blueprint for interoperability is not currently known and will be established by PDG over the course of 2020. During this first year of operation, while the blueprint for interoperability is being developed, the governance body will be funded by membership dues.

Beyond the first year of operation, the funding will be highly dependent on the specific blueprint PDG pursues. For example, the cost of operating PDG will be relatively low if it simply develops a set of high-level best-practices documents, but the cost will be relatively high if PDG determines that significant shared asset or services (e.g., databases, registries) are needed to achieve interoperability. Such assets or services would, however, open the possibility for funding streams other than membership dues. While this will need to be determined—and approved—by the membership, it is expected that long-term membership dues will use a similar structure to the initial year's dues, even if the amounts vary or supplemental revenue streams are established.

Membership dues for 2020 were established so as to (i) not dis-incent membership by any trading partner, (ii) incent early, diverse membership, and (iii) incent long-term membership commitment. Accordingly, the membership dues set out below are proposed to be similar (but not identical) among sectors and account for ability-to-pay by through three tiers of dues within each sector, based on annual **U.S. pharmaceutical revenue**. In addition, a small-business rate is available to trading partners with 25 or fewer full-time employees. A single fee applies to Association Members as well as technical experts in the technical work group.

	ANNUAL MEMBERSHIP DUES				
	Manufacturers/ Repackagers	**Wholesalers/ 3PLs**	**Dispensers**	**Associations**	**Technical Experts**
Tier 1	$ 50,000	$ 50,000	$ 50,000	$ 10,000	$ 15,000
Tier 2	$ 30,000	$ 30,000	$ 15,000		$7,500
Tier 3	$ 10,000	$ 5,000	$ 2,500		
Small Business	$ 1,000	$ 1,000	$ 250		$1,000

	TIER DEFINITIONS				
	Manufacturers/ Repackagers	**Wholesalers/ 3PLs**	**Dispensers**	**Associations**	**Technical Experts**
Tier 1	> $10 B	> $10 B	> $10 B	N/A	101+ EEs
Tier 2	$1 B - $10 B	$1 B - $10 B	$1 B - $10 B		26-100 EEs
Tier 3	< $1 B	< $1 B	< $1 B		
Small Business	25 or fewer full-time employees				25 or fewer EEs

Initial membership dues will cover the period from commencement of membership through December 31, 2020. It is generally expected that annual membership dues will be paid in full at the beginning of the year.

What is the value of PDG?

The risk to trading partners from a void of governance is that systems and networks for DSCSA compliance will emerge and evolve without the foresight and coordination needed to ensure interoperability of those systems and networks, as required by DSCSA. Membership in PDG will support operation of an independent, balanced, sector-neutral mechanism to ensure the development of an effective, efficient path to DSCSA interoperability, and it will afford members the opportunity to shape the blueprint and thereby minimize the impact of interoperability on their business.

Appendix B.

PDG System/Process to be Tested	Metric(s)	Evaluation Method(s)
1. Methods/mechanisms for engagement with FDA and regulators	FDA participation in at least 80% of Work Group meetings	Quantitative tracking and analysis
	At least one consistent individual FDA participant in at least 75% of Work Group meetings	Quantitative tracking and analysis
	FDA participants in Work Group meetings meaningfully engaged in Work Group discussions	Qualitative survey of Work Group members Qualitative survey of FDA (if willing)
	FDA feedback/input on critical regulatory aspects of the use case within two weeks of request for feedback	Qualitative survey of Work Group members Qualitative survey of FDA (if willing)
	Substantive FDA feedback on final use case deliverables within four weeks of submission	Qualitative survey of Work Group members Qualitative survey of FDA (if willing)
2. Methods/mechanisms for engagement with technical experts	Adequate, timely, and appropriate input from technical experts	Qualitative survey of Technical Expert Work Group members Qualitative survey of General Work Group members
	General member independence in setting business requirements	Qualitative survey of Technical Expert Work Group members Qualitative survey of General Work Group members
	Technical expert input fairly considered and incorporated	Qualitative survey of Technical Expert Work Group members Qualitative survey of General Work Group members
	Lack of vendor bias in technical discussions	Qualitative survey of Technical Expert Work Group members Qualitative survey of

		General Work Group members
3. Methods/mechanisms for engagement with non-members	Opportunities to engage non-members fairly considered	Qualitative survey of Work Group members
	Non-members engaged in effective manner	Qualitative survey of Work Group members
	Identified and solicited non-member participation/expertise when appropriate	Qualitative survey of Work Group members
4. Incorporation of, and ability to leverage, existing/prior non-PDG efforts	Existing/prior efforts timely identified	Qualitative survey of Work Group members
	Formal Representative of existing/prior efforts effectively engaged	Qualitative survey of Work Group members
	Outputs of existing/prior efforts effectively presented to and understood by Work Group members	Qualitative survey of Work Group members
	Outputs of existing/prior efforts fairly considered and leveraged, but not viewed as binding	Qualitative survey of Work Group members
5. Allocation of responsibilities between the Board, Interoperability Committee, and Work Groups	Board, Committee, and Work Group roles were clear	Qualitative survey of Work Group, Committee, and Board members
	No significant disagreement over which body has responsibility for a given item	Qualitative survey of Work Group, Committee, and Board members
6. Handoffs and relationship between Board, Committees, and Work Groups	Portions of substantive work to be elevated were clear	Qualitative survey of Work Group members
	Substantive work elevated through Committee and to Board for consideration within one week of completion	Quantitative tracking and analysis
	Substantive work voted on by Board or referred to general	Quantitative tracking and analysis

	membership for vote within one week of receipt	
7. Board participation	Board viewed as fair, balanced, and sector-neutral in its participation in the use case	Qualitative end-of-pilot survey of Work Group members
8. Work Group structure and participation	At least 2 representatives per sector participated in every Work Group meeting	Quantitative tracking and analysis
	At least 1 representative per member tier participated in every Work Group meeting	Quantitative tracking and analysis
	At least of 80% of Work Group member companies participated in every Work Group meeting	Quantitative tracking and analysis
	All Work Group members had fair and equal opportunity to participate in meeting discussions	Qualitative survey of Work Group members
	Work Group decision making process (consensus, voting, etc.) viewed as fair and balanced	Qualitative survey of Work Group members
	Number of decisions requiring a vote and voting response rates were seen as appropriate	Qantitative tracking and analysis of votes; qualitative survey of Work Group members
9. Meeting (Board and Committee) cadence and organization	Meeting cadence provided sufficient time for Work Group prep outside of meetings	Qualitative survey of Work Group members
	Duration of meetings provided sufficient time for Work Group Discussion	Qualitative survey of Work Group members
	Meeting materials distributed 48 hours in advance	Quantitative tracking and analysis
	Meeting follow-up distributed within 24 hours after meeting	Quantitative tracking and analysis
10. Execution of project plan	Pilot Work Plan finalized by February 5	Quantitative tracking and analysis

	Updated Work Plan presented each meeting	Quantitative tracking and analysis
	90% of Work Plan items completed on time according to Work Plan	Quantitative tracking and analysis
	Efficient resolution of process issues	Qualitative survey of Work Group members
11. Outputs/documentation	Drafts available for at least one week of review by Work Group, FDA, Board, and General Membership	Quantitative tracking and analysis
	Documents organized and easily accessible to Work Group Members	Qualitative survey of Work Group members
	Outputs digestible by members and non-members	Qualitative survey of Work Group, Committee, and Board members
	Outputs perceived as product of a fair, balanced, transparent process	Qualitative survey of Work Group, Committee, and Board members

Appendix C.

Mid-Pilot Survey Results

Response Rate: 63% (12/19 organizations)

Key Learnings

- To better establish engagement with FDA, the Pilot Work Group should provide a more direct ask of FDA for feedback on the use case to-date.
- To better evaluate the incorporation and use of prior work, the Pilot Work Group should discuss/leverage prior work in additional ways.
- Roles and responsibilities of the Work Group, Committee, and Board should be made more explicit and are not yet well-understood by Work Group members.
- PDG should provide additional clarity to Work Group members around which portions of substantive work product should be elevated to the Board.
- To better evaluate Work Group/Committee operations, the Work Group should find additional opportunities to leverage and assess the voting process.
- Materials and recaps should be distributed sooner.
- The majority of work plan items have not been completed on time. PDG should seek to balance speed/efficiency of output and depth of discussion over time.
- Pilot Work Group output should be disseminated with additional context for those not involved in the conversations.

Methods/mechanisms for engagement with FDA and regulators

FDA participation in at least 80% of Work Group meetings	FDA joined 8/10 (80%) WG Meetings
At least one consistent individual FDA participant in at least 75% of Work Group meetings	Consistent FDA observer joined 7/10 (70%) WG Meetings
FDA participants in Work Group meetings meaningfully engaged in Work Group discussions	50% - FDA participation has been highly productive and helpful 42% - FDA participation has been consistent, but lacking in substance 8% - FDA participation has not been meaningful
FDA feedback/input on critical regulatory aspects of the use case within two weeks of request for feedback	25% - True 8% - False 67% - Do not have sufficient information to assess
Substantive FDA feedback on final use case deliverables within four weeks of submission	Not Assessed

Methods/mechanisms for engagement with technical experts

Adequate, timely, and appropriate input from technical experts	33% - Robust feedback/input from technical experts 58% [100% of technical expert respondents] - Some feedback/input from technical experts 8% - Insufficient feedback/input from technical experts
General member independence in setting business requirements	92% [100% of technical expert respondents] - General members have independence in setting business requirements 8% - Do not have sufficient information to assess
Technical expert input fairly considered and incorporated	83% [100% of technical expert respondents] - Technical expert input has been valued, assessed, and incorporated 8% - Technical expert input has not been fairly considered and/or incorporated 8% - Do not have sufficient information to assess
Lack of vendor bias in technical discussions	92% [100% of technical expert respondents] - Technical discussions have been vendor agnostic 8% - Do not have sufficient information to assess

Incorporation of, and ability to leverage, existing/prior non-PDG efforts

Existing/prior efforts timely identified	50% - Yes 8% - No 42% - Do not have sufficient information to assess
Formal Representative of existing/prior efforts effectively engaged	92% - Yes 8% - Do not have sufficient information to assess
Outputs of existing/prior efforts effectively presented to and understood by Work Group members	58% - Yes 33% - No 8% - Do not have sufficient information to assess
Outputs of existing/prior efforts fairly considered and leveraged, but not viewed as binding	83% - Yes 17% - Do not have sufficient information to assess

Allocation of responsibilities between the Board, Interoperability Committee, and Work Groups

Board, Committee, and Work Group roles were clear	67% - Yes 33% - No
No significant disagreement over which body has responsibility for a given item	8% - There has been disagreement 67% - Everyone seems generally on the same page 25% - Do not have sufficient information to assess

Handoffs and relationship between Board, Committees, and Work Groups

Portions of substantive work to be elevated were clear	42% - Yes 58% - No
Substantive work elevated through Committee and to Board for consideration within one week of completion	Progress to-date was presented to the Board at the first Board meeting following completion of substantive conversations (but not within one week)
Substantive work voted on by Board or referred to general membership for vote within one week of receipt	Not Assessed

Work Group Structure and Participation

At least 2 representatives per sector participated in every Work Group meeting	Yes
At least 1 representative per member tier participated in every Work Group meeting	There is only one Tier 2 participant in the WG, therefore, at least 1 representative per tier participated in 7/10 (70%) of WG meetings
At least of 80% of Work Group member companies participated in every Work Group meeting	No; at least 80% (15/19) of Work Group member companies participated in 3/10 (30%) WG meetings
All Work Group members had fair and equal opportunity to participate in meeting discussions	100% - Yes

Work Group decision making process (consensus, voting, etc.) viewed as fair and balanced	100% - Yes
Number of decisions requiring a vote and voting response rates were seen as appropriate	33% - The number of votes taken was appropriate 17% - The number of votes taken was too low 50% - Do not have sufficient information to assess

Meeting (Board and Committee) cadence and organization

Meeting cadence provided sufficient time for Work Group prep outside of meetings	83% - Cadence is appropriate and allows time for prep 8% - Cadence is too spaced out and conversations lose momentum 8% - Other
Duration of meetings provided sufficient time for Work Group Discussion	75% - Duration is sufficient for productive discussion 25% - Meetings should be longer
Meeting materials distributed 48 hours in advance	Meeting materials were distributed 48 hours in advance 10% of the time. 90% of the time meeting materials were distributed 24 hours in advance.
Meeting follow-up distributed within 24 hours after meeting	Meeting follow-up was distributed within 24 hours 20% of the time.

Execution of Project Plan

Pilot Work Plan finalized by February 5	Yes; the Work Plan was finalized by February 5
Updated Work Plan presented each meeting	Yes; the Work Plan was updated and presented at each meeting
90% of Work Plan items completed on time according to Work Plan	Approximately 46% (12/26) of Work Plan items have been completed on time to-date
Efficient resolution of process issues	33% - Yes, issues were resolved efficiently 17% - No, issues still exist/were not resolved efficiently

	17% - N/A there have not been any process issues 33% - Do not have sufficient information to assess

Outputs/documentation

Drafts available for at least one week of review by Work Group, FDA, Board, and General Membership	Not Assessed
Documents organized and easily accessible to Work Group Members	100% - Yes, documents well-organized and easily-accessible
Outputs digestible by members and non-members	83% - Output is easily digestible 8% - Output is confusing without additional context 8% - Do not have sufficient information to assess
Outputs perceived as product of a fair, balanced, transparent process	83% - Yes 8% - Other (Too early to tell) 8% - Do not have sufficient information to assess (Too early to tell)

Appendix D.

End-of-Pilot Survey Results

Response Rate: 74% (14/19 organizations)

Key Learnings

- Participants have varying levels of technical expertise. PDG should be intentional about recognizing this diversity and using it to its advantage.
- Conversations to-date have not required deep technical expertise. PDG should explore and find the best ways to "deep-dive" into technical solutions.
- PDG members need more clarity on the roles and responsibilities of each part of the organization. PDG should consider creating an explanatory document on governance roles and responsibilities.
- For efficiency and participation purposes, PDG should consider utilizing tools for real-time feedback/voting rather than taking offline polls.
- PDG should continue to work on ensuring continuity of conversations and explore tools in addition to meeting recaps to assist those who miss a call.
- PDG should continue to explore the appropriate role of the Board in substantive conversations.
- Active participation across all sectors and organizations continues to be a concern. PDG should consider the use of tools such as real-time polling or cold calling to improve participation.

Methods/mechanisms for engagement with FDA and regulators[12]

FDA participation in at least 80% of Work Group meetings	FDA joined 11/14 (79%) WG Meetings
At least one consistent individual FDA participant in at least 75% of Work Group meetings	The same FDA observer joined 10/14 (71%) WG Meetings
FDA observers meaningfully engaged in Work Group discussions[13]	31% - FDA participation has been highly productive and helpful 57% - FDA participation has been consistent, but lacking in substance 7% - FDA participation has not been meaningful

[12] **Red** indicates decrease from mid-pilot survey; **green** indicates increase from mid-pilot survey; **no color change** indicates no change in response rate or the option/metric was not tested in the mid-pilot survey

[13] As noted in the Report above, PDG recognizes and respects significant limitations that FDA faces in actively engaging in pilot activities, and therefore, we do not interpret FDA's engagement as representative of potential future engagement.

FDA feedback/input on critical regulatory aspects of the use case within two weeks of request for feedback	43% - True 14% - False 43% - Other
Substantive FDA feedback on final use case deliverables within four weeks of submission	Not Assessed

Methods/mechanisms for engagement with technical experts

Adequate, timely, and appropriate input from technical experts	64% [66% of technical expert respondents] - Robust feedback/input from technical experts 29% [33% of technical expert respondents] - Some feedback/input from technical experts 7% - Insufficient feedback/input from technical experts
General member independence in setting business requirements	100% [100% of technical expert respondents] - General members have independence in setting business requirements
Technical expert input fairly considered and incorporated	93% [100% of technical expert respondents] - Technical expert input has been valued, assessed, and incorporated 7% - Technical expert input has not been fairly considered and/or incorporated
Lack of vendor bias in technical discussions	100% [100% of technical expert respondents] - Technical discussions have been vendor agnostic

Methods/Mechanisms for Engagement with Non-Members

Opportunities to engage non-members fairly considered	77% - Yes 23% - No
Non-members engaged in effective manner	86% - Yes 14% - Other
Identified/solicited non-member participation/expertise when appropriate	79% - There was an appropriate amount of non-member participation 21% - Non-member participation should have been sought more frequently

Incorporation of, and ability to leverage, existing/prior non-PDG efforts

Existing/prior efforts timely identified	100% - Yes
Formal Representative of existing/prior efforts effectively engaged	100% - Yes
Outputs of existing/prior efforts effectively presented to and understood by Work Group members	93% - Yes 7% - No
Outputs of existing/prior efforts fairly considered and leveraged, but not viewed as binding	100% - Yes

Allocation of responsibilities between the Board, Interoperability Committee, and Work Groups

Board, Committee, and Work Group roles were clear	57% - Yes 43% - No
No significant disagreement over which body has responsibility for a given item	7% - There has been disagreement 93% - Everyone seems generally on the same page

Handoffs and relationship between Board, Committees, and Work Groups

Portions of substantive work to be elevated were clear	64% - Yes 36% - No
Substantive work elevated through Committee and to Board for consideration within one week of completion	Progress to-date was presented to the Board at the first Board meeting following completion of substantive conversations (but not within one week)
Substantive work voted on by Board or referred to general membership for vote within one week of receipt	Not Assessed

Board Participation

Board viewed as fair, balanced, and sector-neutral in its participation in the use case	57% - Yes 7% - No 36% - Do not have sufficient information to assess

Work Group Structure and Participation

At least 2 representatives per sector participated in every Work Group meeting	Yes
At least 1 representative per member tier participated in every Work Group meeting	There is only one Tier 2 participant in the WG, therefore, at least 1 representative per tier participated in 11/14 (79%) of WG meetings
At least of 80% of Work Group member companies participated in every Work Group meeting	No; at least 80% (15/19) of Work Group member companies participated in 6/14 (43%) WG meetings
All Work Group members had fair and equal opportunity to participate in meeting discussions	100% - Yes
Work Group decision making process (consensus, voting, etc.) viewed as fair and balanced	100% - Yes
Number of decisions requiring a vote and voting response rates were seen as appropriate	86% - The number of votes taken was appropriate 7% - The number of votes taken was too low 7% - The number of votes taken was too high

Meeting (Board and Committee) cadence and organization

Meeting cadence provided sufficient time for Work Group prep outside of meetings	93% - Cadence is appropriate and allows time for prep 7% - Cadence is too quick and does not provide sufficient time for prep
Duration of meetings provided sufficient time for Work Group Discussion	93% - Duration is sufficient for productive discussion 7% - Meetings should be longer
Meeting materials distributed 48 hours in advance	Meeting materials were distributed 48 hours in advance 21% of the time. 86% of the time meeting materials were distributed 24 hours in advance.

Meeting follow-up distributed within 24 hours after meeting	Meeting follow-up was distributed within 24 hours 36% of the time.

Execution of Project Plan

Pilot Work Plan finalized by February 5	Yes; the Work Plan was finalized by February 5
Updated Work Plan presented each meeting	Yes; the Work Plan was updated and presented at each meeting
90% of Work Plan items completed on time according to Work Plan	Approximately 46% (12/26) of Work Plan items have been completed on time to-date
Efficient resolution of process issues	77% - Yes, issues were resolved efficiently 23% - N/A there have not been any process issues

Outputs/documentation

Drafts available for at least one week of review by Work Group, FDA, Board, and General Membership	Not Assessed
Documents organized and easily accessible to Work Group Members	100% - Yes, documents well-organized and easily-accessible
Outputs digestible by members and non-members	86% - Output is easily digestible 7% - Output is confusing without additional context 7% - Other
Outputs perceived as product of a fair, balanced, transparent process	100% - Yes

Appendix E.

The following are non-binding recommendations from the PDG Pilot Work Group to the PDG Interoperability Committee regarding the business requirements to verify Authorized Trading Partner Status.

Requirements to verify Authorized Trading Partner (ATP) status

Any trading partner connecting into an interoperable electronic system used for the purpose of verification or tracing must be "authorized" as defined under FD&C Act 581(2). Further clarification is provided in FDA's Guidance for Industry entitled, "Identifying Trading Partners Under the Drug Supply Chain Security Act." To support an interoperable system, users of an interoperable system for verification or tracing must demonstrate they (or if a service provider, the clients on behalf of which they are acting) are authorized.

Business Requirement	Req. #	Description
Reliable demonstration/documentation of authorized status: Manufacturer/Repackager	R-001a	Each trading partner initiating a verification or tracing request to a manufacturer or repackager must ensure that the manufacturer (*i.e.*, either the labeler or the NDA/ANDA holder at option of purchasing entity) is authorized as defined by DSCSA prior to making a verification or tracing request. Examples of evidence of authorized status include evidence of a valid/current registration under Section 510 through confirmation of registration directly from the FDA Establishment database. Information may be obtained directly from FDA by the trading partner, or a trading partner may contract with a third party to acquire such evidence for them. For a manufacturer with more than one Federal Establishment Identification (FEI) number, a trading partner should confirm registration of a site that is a packaging site. For a virtual manufacturer, a trading partner should utilize a labeler code.
	R-001b	Each manufacturer must ensure that evidence of their authorized status is available to trading partners initiating verification or tracing request. This can be accomplished through registration with the FDA. [PLACEHOLDER FOR CREDENTIALING OBLIGATION]
Reliable demonstration/documentation of authorized status: Wholesaler	R-002a	Each trading partner initiating a tracing request to or responding to a verification or tracing request from a wholesale distributor ensure that the wholesale distributor is authorized as defined by DSCSA.

Commented [A1]: The Pilot Work Group recognizes the need to tie verification of ATP status to user authentication/credentialing, but did not engage in a discussion of such a requirement.

		Examples of evidence of authorized status include evidence of a valid/current state license through one of the following methods: obtain a copy of license or confirm with a state licensing board or use a license aggregator. Neither a DEA license nor the FDA website are valid documentation for this purpose. Information may be obtained directly from the wholesaler by the trading partner or the trading partner may contract with a third party to acquire such evidence for them. The trading partner must *also* obtain confirmation of registration status with the FDA. Information may be obtained directly from FDA by the trading partner, or a trading partner may contract with a third party to acquire such evidence for them. ATP status must be verified in the state the wholesaler is located for a given transaction.
	R-002b	Each wholesaler must ensure that evidence of their authorized status is available to trading partners initiating a tracing request with the wholesaler or responding to a verification or tracing request from the wholesaler. This is accomplished by obtaining a valid state license and registering directly with the FDA. [PLACEHOLDER FOR CREDENTIALING OBLIGATION]
Reliable demonstration/documentation of authorized status: 3PL	R-003a	Each trading partner initiating a tracing request to or responding to a verification or tracing request from a 3PL must ensure that the 3PL is authorized as defined by DSCSA. If the state in which the 3PL is based has a state licensure requirement, examples of evidence of authorized status include evidence of a valid/current state license through one of the following methods: obtain a copy of license or confirm with a state licensing board or use a license aggregator. Information may be obtained directly from the 3PL by the trading partner or the trading partner may contract with a third party to acquire such evidence for them. If the state in which the 3PL is based does not have a state licensure requirement, examples of evidence of authorized status include evidence of a valid/current federal license through confirmation of registration directly from the FDA database. Information may be

Commented [A2]: The Pilot Work Group recommends that the Interoperability Committee consider whether a wholesaler should be required to verify authorized status in both the state where the wholesaler is located AND the state where the wholesaler is distributing product.

Commented [A3]: The Pilot Work Group recognizes the need to tie verification of ATP status to user authentication/credentialing, but did not engage in a discussion of such a requirement.

		obtained directly from FDA by the trading partner, or a trading partner may contract with a third party to acquire such evidence for them. ATP status must be verified in the state the 3PL is located for a given transaction. *(Note: federal licensure program pending; FDA database is currently incomplete; not all authorized 3PLs will have state licenses due to state variability; currently no consistently valid source of 3PL licensure information exists)*
	R003b	Each 3PL must ensure that evidence of their authorized status is available to trading partners initiating a tracing request with the 3PL or responding to a verification or tracing request from the 3PL. This is accomplished by obtaining a valid state license (if the state in which the 3PL is based has a state licensure requirement) or a valid federal license (if the state in which the 3PL is based does not have a state licensure requirement). [PLACEHOLDER FOR CREDENTIALING OBLIGATION]
Reliable demonstration/documentation of authorized status: Dispenser (Pharmacy)	R-004a	Each trading partner initiating a tracing request to or responding to a verification or tracing request from a pharmacy must ensure that the pharmacy is authorized as defined by DSCSA. Examples of evidence of authorized status include evidence of a valid/current state license through one of the following methods: obtain a copy of license, confirm with the State Board of Pharmacy. Information must be obtained directly from the State Board of Pharmacy by the trading partner, or a trading partner may contract with a third party to acquire such evidence for them. ATP status must be verified in the state where the product is being received.
	R-004b	Each pharmacy must ensure that evidence of their authorized status is available to trading partners initiating a tracing request with the pharmacy or responding to a verification or tracing request from the pharmacy. This is accomplished by obtaining a valid state license. [PLACEHOLDER FOR CREDENTIALING OBLIGATION]

Commented [A4]: The Pilot Work Group recognizes the need to tie verification of ATP status to user authentication/credentialing, but did not engage in a discussion of such a requirement.

Commented [A5]: The Pilot Work Group recognizes the need to tie verification of ATP status to user authentication/credentialing, but did not engage in a discussion of such a requirement.

Reliable demonstration/documentation of authorized status: Dispenser (Practitioner)	R-005a	Each trading partner initiating a tracing request to or responding to a verification or tracing request from a practitioner must ensure that the practitioner is authorized as defined by DSCSA. Examples of evidence of authorized status include evidence of a valid/current state license through one of the following methods: obtain a copy of license, confirm with the State Medical Board (MD, PA) or State Nursing Board (NP). Information must be obtained directly from the State Medical Board (MD, PA) or State Nursing Board (NP) by the trading partner, or a trading partner may contract with a third party to acquire such evidence for them. ATP status must be verified in the state where the product is being received/dispensed.
	R-005b	Each practitioner must ensure that evidence of their authorized status is available to trading partners initiating a tracing request with the practitioner or responding to a verification or tracing request from the practitioner. This is accomplished by obtaining a valid state license. [PLACEHOLDER FOR CREDENTIALING OBLIGATION]
Reliable demonstration/documentation of authorized status: Audit Trail	R-006	All trading partners must have systems and processes in place to maintain a record of each confirmation of authorized status once completed as required by R-001-005 and to maintain a record of modifications, if any, that are made to the trading partner's internal database of authorization information (if applicable).
Frequency of confirmation of authorized status	R-007	A trading partner must ensure authorized status as required by R-001-005 for each verification or tracing request received or initiated. Trading partners are permitted to operate an internal database of authorization information, which they may reference for the purposes of this request-based confirmation.
	R-008	Each trading partner must verify authorized status with the source data identified in R-001-005 with a frequency no less than once per month or upon expiry of a current license.

Commented [A6]: The Pilot Work Group recognizes that this business requirement may need to take into account the distinction between authorization for dispensing physicians and authorization for administering physicians. The Work Group offers this as a further topic of conversation.

Commented [A7]: The Pilot Work Group recognizes the need to tie verification of ATP status to user authentication/credentialing, but did not engage in a discussion of such a requirement.

Commented [A8]: This conclusion was reached via a voting process and does not reflect Pilot Work Group consensus. Pilot Work Group members agree that this topic should be discussed further.

		If a trading partner is operating an internal database of authorization information, that database must be updated consistent with the source data identified in R-001-R005 with a frequency no less than once per month and upon expiry of a current license.
Resolution of exceptions and non-confirmation authorized status	R-009	Should an authorized entity initiating a request for verification or tracing data or receiving a request for verification or tracing data be alerted that their ATP status is "not confirmed" by the trading partner confirming their authorized status, the entity for which authorized status is in question must obtain and present a letter from the authorizing entity as described in R-001-R-005 confirming valid licensure as described in R-001-005. The trading partner must then update their database to reflect the accurate licensure information. [NOTE: if a centralized source of licensure information is created, there will need to be a means by which that database is updated to reflect accurate licensure information should there be an error]
	R-010	An entity with a valid license that is expired or pending inspection or renewal may be deemed authorized for a period of no longer than X days provided that they are able to demonstrate that their renewal request is in process. After X days the entity should be deemed not authorized.
	R-011	Upon receipt of a verification or tracing request by a non-authorized entity, the trading partner receiving the request must [PLACEHOLDER FOR FUTURE DISCUSSION AT COMMITTEE LEVEL].

Commented [A9]: The Pilot Work Group understands that license renewal processes vary by sector and state. As such, consensus was not yet reached on an appropriate grace period.

Commented [A10]: Depending on the technology and system architecture that is ultimately used for this purpose, it may be unnecessary to notify others of a non-authorized entity. Further, user authentication requirements will impact this requirement as well.