

A Proposal: Governance for DSCSA Phase II Interoperability

PDSA WHITE PAPER I: INFORMATIONAL WEBINAR

April 2, 2019



Antitrust Statement

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- limits on production or product lines;
- allocating customers or territories;
- individual company marketing strategies, projections, or assessments; and
- establishing a practice of dealing with customers or suppliers.

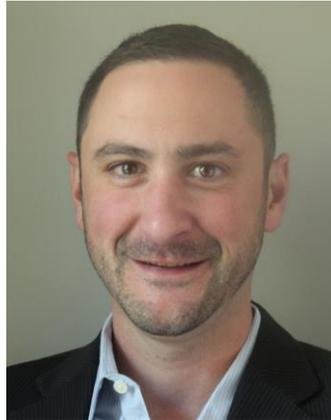
Please consult your counsel if you have any questions about your obligations or today's discussion.

PDSA's views are not legal interpretations or advice.

Speakers



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Association for Accessible
Medicines



Matt Sample
VP, Manufacturer
Operations
AmerisourceBergen



Tom McHugh
Sr. Strategist,
Supply Chain &
Technology
CVSHealth



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Pharmaceutical Distribution Security Alliance (PDSA)

Membership



CardinalHealth



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A Proposal: Governance for DSCSA Phase II Interoperability

DSCSA Governance Workshop

May 1, 2019

10:00 AM - 3:00 PM ET

601 New Jersey Ave. NW, Ste. 350

Visit www.PDSAonline.org to Register

The image shows two overlapping white paper covers for a white paper titled "An Overview: PDSA Vision for Phase I Interoperability and Governance". The top cover is slightly offset to the left and top, while the bottom cover is offset to the right and bottom. Both covers feature the PDSA logo at the top center, which consists of a blue square with a white vertical bar and the text "PDSA Pharmaceutical Distribution Security Alliance". Below the logo, there is a list of member organizations arranged in three columns. The date "MARCH 25, 2019" is printed at the bottom of each cover. The bottom cover also includes the text "White Paper 1:" and "A Proposal: Governance for DSCSA Phase II Interoperability" below the title, with the date "March 25, 2019" at the very bottom.

PDSA
Pharmaceutical Distribution Security Alliance

Association for Accessible Medicines (AAM)
Biotechnology Innovation Organization (BIO)
Pharmaceutical Research and Manufacturers of America (PhRMA)
Healthcare Distribution Alliance (HDA)
International Warehouse Logistics Association (IWLA)
American Society of Health-System Pharmacists (ASHP)
National Association of Chain Drug Stores (NACDS)

Abbvie
Allergan
AmerisourceBergen
AstraZeneca
Bayer
Bristol-Myers Squibb
CardinalHealth
Celgene
CVSHealth
Freseus Kabi USA

Genentech
Inmar
Johnson & Johnson
Medline Industries
Merck
Mylan
Novartis
Pfizer
Upsher-Smith Laboratories

**An Overview:
PDSA Vision for Phase I
Interoperability and
Governance**

MARCH 25, 2019

White Paper 1:
**A Proposal: Governance for DSCSA Phase II
Interoperability**
March 25, 2019

Need For & Scope of Governance

Structure vs. Function

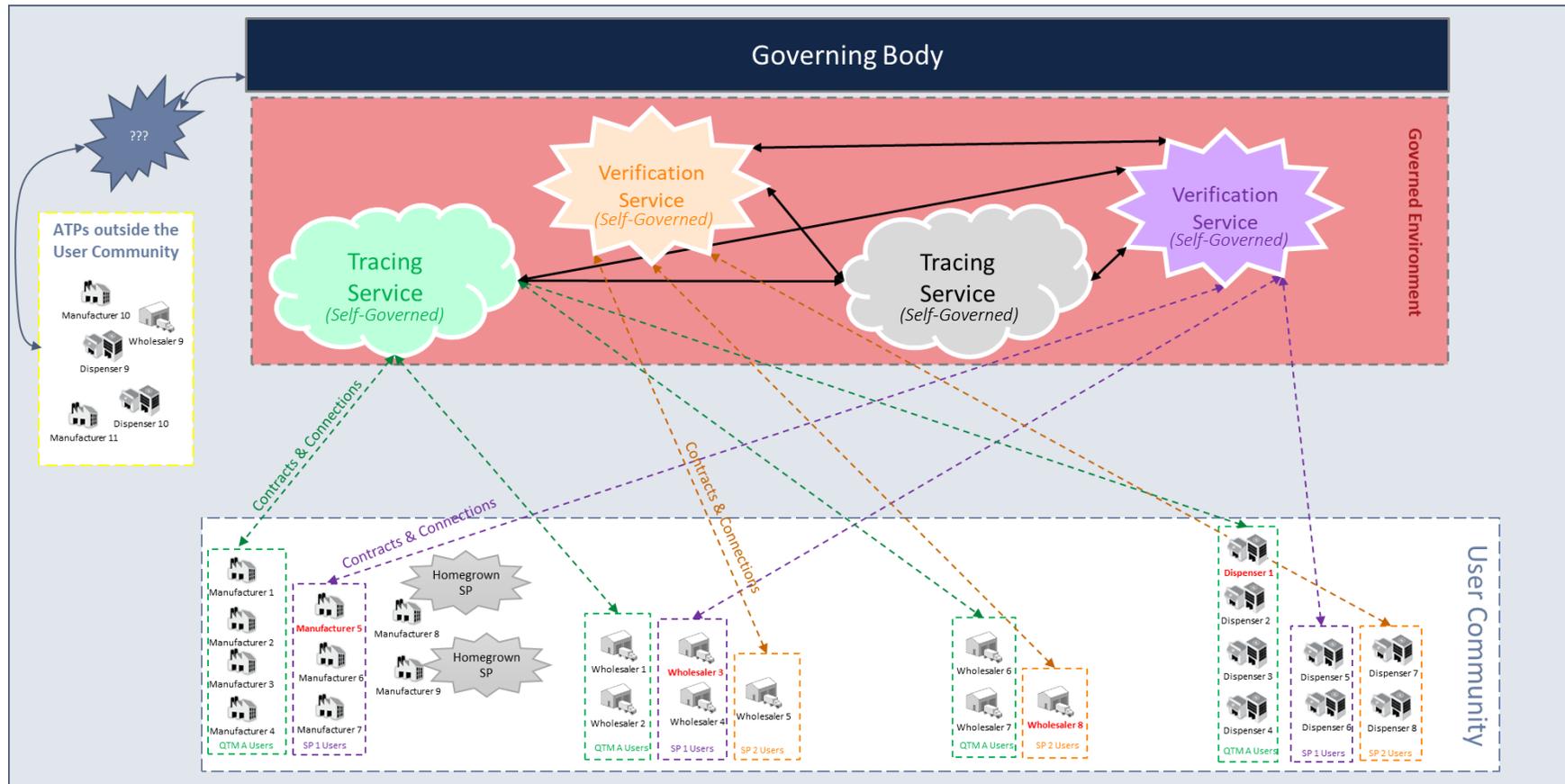


Governance Body Responsibilities

- We believe it is best for the governance body – with the appropriate legal structures and processes for decision making – to determine and set the vision and architecture it will pursue.
- The overarching purpose and function of the governance body is to develop a vision for full implementation of DSCSA interoperability and advance commitment to that vision.
- Specific detailed governance body responsibilities will also be described in White Paper 3: *The Interoperable Verification and Tracing of Pharmaceuticals (forthcoming)*.

Scope of Governance

- The proposed governance body should govern interoperable verification and tracing (as required by DSCSA) and practices and processes that impact the integrity and reliability of interoperable verification and tracing.

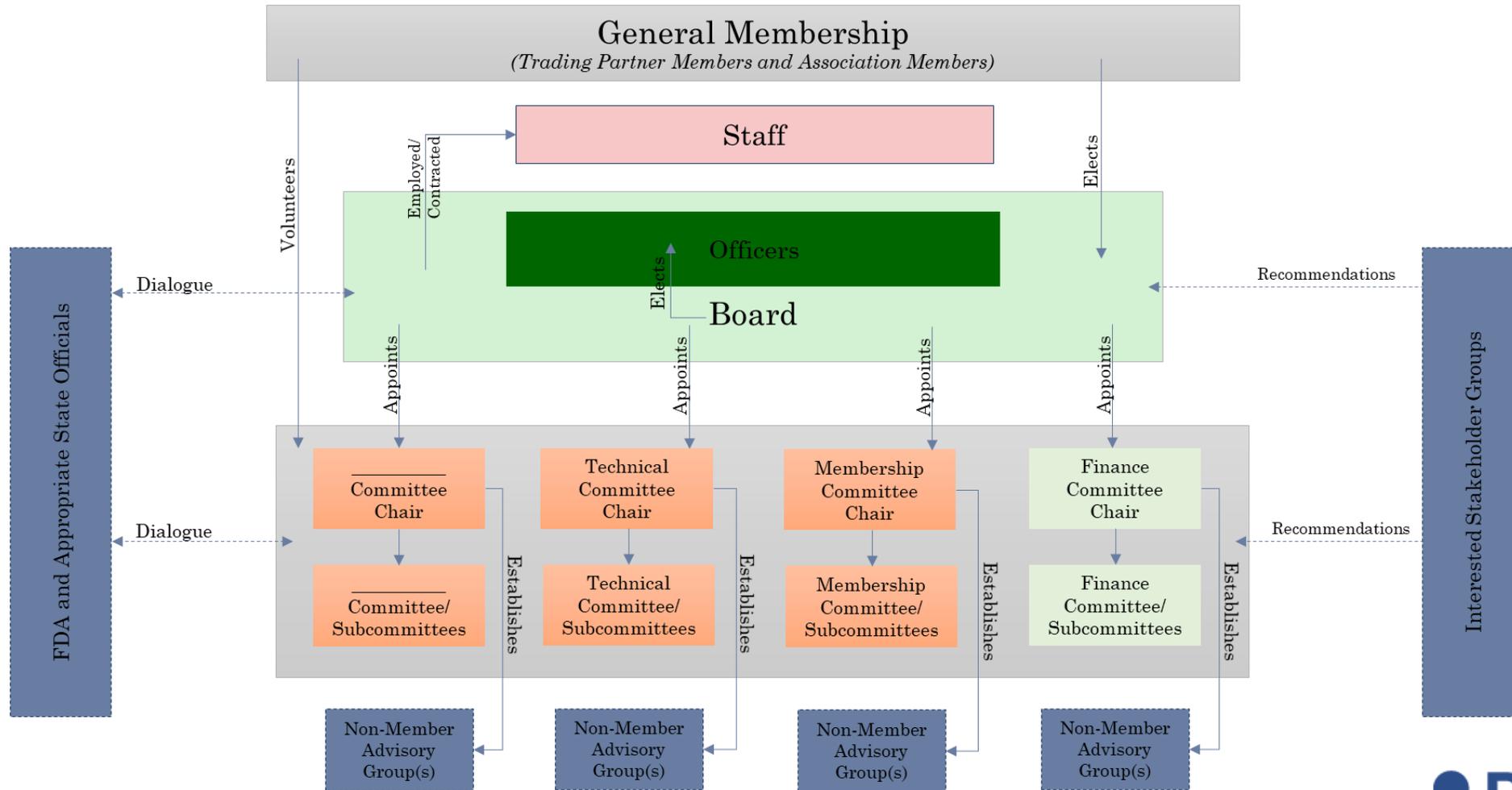


General Structure

Guiding Principles

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 Phase II 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 will incent participation.

General Structure



Key Recommendations

Membership

- There should be two classes of general members:
 - (1) trading partner members, and
 - (2) association members.
- **Commonly controlled entities should have two options for membership:**
 - Maintain a single membership for the corporate family and designate the sector for that membership.
 - Maintain separate memberships, up to one membership per sector.
- General membership have rights and obligations, the most important of which are the right to participate in committees, elect board members, approve budgets, and ratify significant technical documents.

Board

- A 14-member Board elected by the general membership would carry out the executive functions of the governance body.
- The Board would have the authority to set the direction and strategy of the governance body.
- **The 14 Board seats would be allocated as follows (4/4/4/2 Structure):**
 - Four Board seats open to manufacturer/repackager board members
 - Four Board seats open to wholesaler/3PL board members
 - Four Board seats open to dispenser board members
 - Two Board seats open to at-large board members
- Board members would serve staggered two-year terms.
- Board would elect a Chair, Vice Chair, Treasurer, and Secretary to serve one-year terms as officers.

Committees

- Committees would be used to carry out most substantive and tactical work of the governance body and generally would be open to all general members.
- Three initial committees will be established upon formation of the governance body and open to any/all membership:
 - Membership Committee
 - Finance Committee
 - Technical Committee

Funding Methodology

- The precise funding model for the governance body should be determined by the trading partners and associations that establish it (“founding members”).
- **Key Principles:**
 1. The funding model should not dis-incent membership.
 2. The funding model should incent early membership.
 3. The funding model should incent long-term commitment to membership (*i.e.*, an incentive not to terminate membership once interoperability is initially implemented).
- Membership dues will be established by the founding members of the governance body, and details will depend, in large part, on the vision pursued by the governance body.

Closing

Governance White Paper Feedback

We welcome and encourage any and all feedback on the proposed governance structure

- Please submit any comments and feedback to PDSA@leavittpartners.com.
- PDSA does not intend to independently evaluate the feedback or issue a revised paper; rather we will compile the feedback and make it available to all stakeholders interested in participating in the development and establishment of a governance body.

Governance White Paper Feedback

A **stakeholder workshop** to discuss and develop a broadly supported governance organization will be held on **May 1st** in **Washington D.C.**

- The workshop is **open to all** interested stakeholders.
- If interested, please register at www.PDSAonline.org.

Key Areas of Consideration

- Do you agree that an independent, balanced, sector-neutral governance body is needed?
- Does the PDSA proposal achieve its goals of balance and sector neutrality?
- Is the proposed membership model (mix of trading partners and associations) the optimal model?
- How should the governance body be funded? Should membership dues be the sole source of funding?

Q&A