



*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*

*Fresenius Kabi USA*

*Genentech*

*Inmar*

*Johnson & Johnson*

*Medline Industries*

*Merck*

*Mylan*

*Novartis*

*Pfizer*

*Upsher-Smith Laboratories*

## White Paper 1:

# A Proposal: Governance for DSCSA Phase II Interoperability

March 25, 2019

## White Paper 1: A Proposal: Governance for DSCSA Phase II Interoperability

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.<sup>1</sup> Phase II interoperability will require a level of cooperation, coordination, and interconnection at the unit level not present today, and stakeholders throughout the supply chain have broadly recognized that an independent, balanced, sector-neutral governance body is important to guide or provide that coordination.<sup>2</sup> Additionally, such a governance body will also be positioned to address technical issues related to interoperability that continue to arise throughout the implementation process. Stakeholders, including FDA, have broadly recognized that governance is critical to the successful implementation of Phase II interoperability.

A formal governance body that is independent, balanced, and sector-neutral would also provide certainty and longevity that benefits the effective, efficient implementation of the DSCSA. As with the original development of the DSCSA construct, no individual sector representative should serve as the governing body because they will be, or will be perceived as, inherently biased. A sector-neutral body with clear rules for engagement is needed.

Furthermore, efficient implementation requires an intentional implementation plan that builds toward a shared vision of Phase II. A formal entity with governance responsibility will demonstrate such commitment.<sup>1</sup> Each trading partner will be committing significant resources to Phase II implementation. A formal structure with well-understood, agreed upon rules for governance will provide confidence and predictability in the allocation of those resources. To this end, the governance body should be expressly tasked with developing the vision to which it will advance commitment with input from various stakeholders, including PDSA.

This paper sets forth a proposal for one possible **structure** for the establishment of an independent, balanced, sector-neutral governance body and the functions it would be anticipated to perform in executing the vision set out in this White Paper. PDSA is publishing this white paper as a well-thought-out starting point for consideration by stakeholders broadly, with the hope that a diverse set of stakeholders will form a governance body. It is recognized that revisions to the structure may be needed in order to develop the breadth of stakeholder support needed to ultimately establish the governance body. Although PDSA hopes this proposal will stimulate action toward establishment of a governance body, PDSA does not intend to act as the governance body. As noted, independence will be a critical attribute of successful governance, and to that end, we believe it is important that the governance body be established—by both PDSA members and non-members alike—as a new, independent legal entity.

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***Vision Cornerstone:**  
Independence will be a critical attribute of successful governance, and to that end, we believe it is important that the governance body be established—by both PDSA members and non-members alike—as a new, independent legal entity.*

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The structure proposed in this White Paper is not dependent on any one specific technical vision for how interoperability should be achieved. Although PDSA intends to publish recommendations regarding a technical

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<sup>1</sup> PDSA intends to publish an additional White Paper that describes a vision for how interoperable exchange of TI and TS could occur, but such exchange is generally anticipated to be a peer-to-peer business practice. Regulatory clarity or direction on certain issues related to interoperable exchange may be needed, and we hope the forthcoming White Paper will inform that regulatory activity. The interoperable exchange of TI and TS will, however, generally be outside the scope of governance. Instead, governance will generally focus on establishing shared rules or expectations for the connection or link between the various networks for purpose of verification and tracing.

<sup>2</sup> This view was repeatedly expressed by stakeholders at a listening session convened by FDA on December 7, 2018 to solicit input on the appropriate role for governance and the appropriate process to establish governance.

## White Paper 1: A Proposal: Governance for DSCSA Phase II Interoperability

vision through additional White Papers for consideration by all stakeholders (including FDA), the specific technical vision to be advanced by the governance body should be determined by the governance body using its decision-making mechanisms intended to promote balance, sector-neutrality, and equitability.

### A. Scope of Governance

Consideration of the appropriate structure for a governance body for DSCSA interoperability can, at times, be difficult to divorce from the more technical consideration of the substance of the specific technical vision the governance body will seek to advance. We believe that the design and establishment of a governance body is a necessary first step because the governance body should provide the balanced, sector-neutral decision-making mechanisms necessary to make reasonable and appropriate decisions about the technical vision to be advanced by the governance body. Stated differently, the governance body itself—through mechanisms to ensure balance and equitability—should determine the specific technical vision it will advance. Nonetheless, we do believe it is necessary to articulate the general purpose of the governance body as part of consideration of the appropriate structural design of the governance body.

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. Ultimately, the development and evolution of such systems and networks is a positive and should be encouraged through the open market, but governance is needed to provide the direction necessary to ensure those distinct, independent systems and networks are interoperable. Therefore, we believe 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. Stated differently, the governance body should have responsibility for an overarching approach to interoperability of systems and networks for DSCSA compliance, but should not control or govern the systems and networks themselves (much less the economic terms for users of such systems or networks).

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*Vision Cornerstone: 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.*

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It is also acknowledged that other governance activities may take place. First, the governance body proposed in this White Paper 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. The governance proposed in this White Paper is intended to sit a layer above, and be complementary to, such activities. Second, it is possible that other governance efforts may emerge over time with the same or overlapping scope and objective. While it is neither possible nor appropriate to restrict the emergence of such effort, it is recognized that multiple divergent approaches could hamper trading partners' ability to be interoperable, as required by the DSCSA. Therefore, as described in the guiding principles below (see principle 2.d.), it should be the goal of the governance body to develop and advance a vision for interoperability that is inclusive of the views and goals of divergent stakeholders and is attractive to the broadest possible set of stakeholders.

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*Vision Cornerstone: It should be the goal of the governance body to develop and advance a vision for interoperability that is inclusive of the views and goals of divergent stakeholders and is attractive to the broadest possible set of stakeholders.*

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## White Paper 1: A Proposal: Governance for DSCSA Phase II Interoperability

### B. Guiding Principles

The proposed governance body structure described in this paper is grounded in several fundamental 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.**
  - a. 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.
  - b. Engagement of all trading partner sectors of the supply chain is critical to achieving supply chain security and improving patient safety.
  - c. Each sector should bear an equitable share of the responsibility for achieving interoperability and supply chain security.
2. **2023 system architectures should be governed by trading partners<sup>3</sup> through a balanced, independent, sector-neutral legal entity.**
  - a. The governance body's activities should be equitable for all trading partners (*i.e.*, should not favor any sector).
  - b. The governance body should promote balanced participation/representation among all trading partners—all sectors, company sizes, and business models—in carrying out its objectives.
  - c. 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).
  - d. 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.
  - e. The governance body's vision should maximize efficiency, scalability, and cost-effectiveness for all trading partners without regard to company size.
  - f. The governance body must comply with all applicable laws and regulations, including applicable antitrust requirements.
3. **The governance body's activities should support interoperable exchange, interoperable verification, and interoperable tracing, as required by the DSCSA.**
  - a. The model and architecture(s) (*i.e.*, vision) advanced by the governance body should be focused on **feasible methods of meeting the Phase II statutory requirements**, though it may note additional benefits that could be considered in the future.

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<sup>3</sup> 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.

## White Paper 1: A Proposal: Governance for DSCSA Phase II Interoperability

- i. 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.
  - ii. The governing body should preserve (*i.e.*, should not impede) the autonomy of individual trading partners that choose to subscribe to the 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.
- b. 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.<sup>4</sup>

### 4. Rules for membership and use will incent participation.

- a. Membership in the governance body should be open to all (i) authorized trading partners<sup>5</sup> (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.
  - i. 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.
- b. The minimum set of policies, procedures, and/or technical specifications for interoperability will require that:
  - i. 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
  - ii. 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).

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<sup>4</sup> 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.

<sup>5</sup> This includes trading partners not legally required to be licensed/registered, such as DOD dispensers, virtual manufacturers, etc.

## White Paper 1: A Proposal: Governance for DSCSA Phase II Interoperability

### C. Purpose and Functions

The overarching purpose and function of the governance body is to develop a vision<sup>6</sup> for full implementation of DSCSA interoperability and advance commitment to that vision. To do so, the governance body is expected to:

1. Define use cases and guidelines for communication between trading partner networks to facilitate interoperability, as required by DSCSA.
2. Assess the need for any assets to be shared by the membership, and develop and manage those assets if needed.
3. Define the terms and conditions for authorized trading partner access to the interoperable systems and processes being governed.
4. Support the long-term sustainability of interoperability.

Additional purpose and functions of the governance body will depend on the specific vision that is ultimately developed and advanced by the governance body. Depending on that vision, the body might also perform functions such as:

1. Develop minimum requirements for qualification (*i.e.*, credentialing or accreditation to the minimum requirements) of, and qualify, providers of interoperable systems and processes being governed.
2. Identify existing technical standards or the need for additional standards and call on standards bodies to develop those standards.

Additional general-operating functions (*e.g.*, opening a bank account) will also be necessary to carry out those objectives and should be detailed in the governance body's bylaws. Specific detailed governance body responsibilities will also be described in White Paper 3: The Interoperable Verification and Tracing of Pharmaceuticals (*forthcoming*). Ultimately, the goal is to define areas of responsibility that will be undertaken by the governance body and to establish a governance body structure that allows those responsibilities to be undertaken in an open, balanced manner. PDSA does not seek to define the outputs of the governance body as we recognize that those specific outputs should be developed through the broad input and procedural safeguards that the governance body intends to provide.

### D. General Structure

As reflected in Figure 1, below, the proposed governance body would be a membership-based organization with heavy reliance on committee activity. Executive management of the governance body would be vested in a 14-member Board elected by the general membership. However, tactical work and other non-executive functions should be pushed to committees that are open to all general members. Committees would be established by the Board, and participation

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*Vision Cornerstone: The proposed governance body would be a membership-based organization with heavy reliance on committee activity.*

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<sup>6</sup> As noted in the cover statement accompanying this White Paper, PDSA uses the term "vision" broadly to mean an overarching approach to interoperability. In that way, PDSA recognizes that multiple methods of compliance (*i.e.*, multiple models, systems, solutions, technologies, architectures, etc.) may emerge. PDSA believes that it should be the role of a governance body to establish and support the implementation of one vision for interoperability and connectivity among those multiple methods of compliance.

## White Paper 1: A Proposal: Governance for DSCSA Phase II Interoperability

in the committees would be open to all members.<sup>7</sup> This is essential to ensure the broadest set of member representatives have input to the tactical work of the governing body.

As necessary, the Board may hire or contract staff to carry out the day-to-day management, but doing so should not undermine the importance of the committee structure. Outside stakeholders (non-members) should also be able to engage with the governance body in three general ways:

1. As shown on the left side of the graphic in Figure 1, the governance body should have routine engagement with FDA and other appropriate Federal or State officials. Regulators 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 during recalls and illegitimate product investigations. Their engagement with the governance body will provide valuable feedback on governance activities and should help the governance body be assured its activities and plans are consistent with regulators' expectations. Dialogue with regulators is needed to help determine the exact method of engagement for regulators, but (i) routine engagement with regulators with decision making authority is highly desirable, and (ii) regulator engagement should not include formal voting board membership in the governance body in recognition that the governance body is expected to be trading partner-funded.
2. As shown on the bottom axis of the graphic in Figure 1, committees may establish Advisory Groups comprised of technical or process experts (*e.g.*, thought leaders, standards bodies, service providers) to provide input to committee activities.<sup>8</sup> While we believe membership should be limited to those with legal compliance obligations (*i.e.*, trading partners), these technical experts will be able to provide valuable insights and advice, and their participation in technical discussions should be encouraged.
3. As shown on the right side of the graphic in Figure 1, any interested stakeholder should be able to provide recommendations to the governance body, and the governance body should fairly and objectively consider those recommendations. While the objective of the governance body is to establish and advance a vision for interoperability, it is recognized that outside stakeholders will have valuable ideas and recommendations for components of such a vision, and the governance body should welcome those ideas and recommendations.

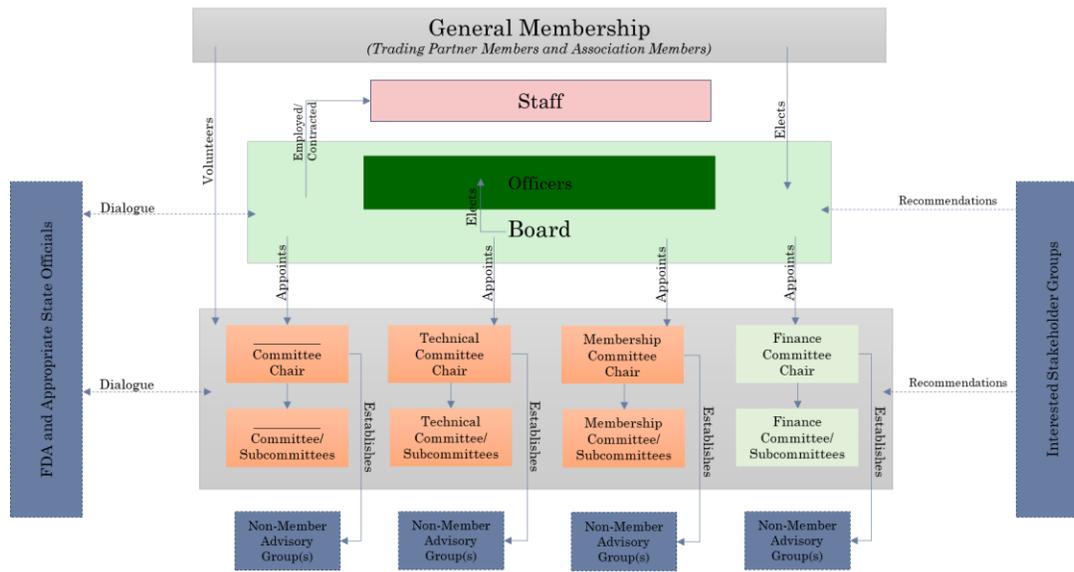
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<sup>7</sup> As noted later in this paper, the final scope of activity to be undertaken by the governance body may require changes to the scope of parties included in this activity. For example, if the governance body were to undertake certain standards-setting activities, broader participation (*i.e.*, non-member participation) might be needed.

<sup>8</sup> Here again, the final scope of activity to be undertaken will inform decisions on the final structure for the governance body.

# White Paper 1: A Proposal: Governance for DSCSA Phase II Interoperability

Figure 1. Governance Body Structure



## E. Membership

There should be two classes of general members: (1) trading partner members, and (2) association members.

1. **Trading Partner** membership would be open to any trading partner (as defined in DSCSA) that is authorized (as defined in DSCSA) and chooses to subscribe to the model(s) and architecture(s) for interoperability advanced by the governing body.
2. **Association** membership would be open to (i) any trade association or society the membership of which consists primarily of trading partners (as defined in the DSCSA), and (ii) professional societies representing health care providers.

Certain voting and other structures should be based on sector. Therefore, each member would, upon application for membership, designate itself as a manufacturer, wholesale distributor, dispenser, repackager, or third-party logistics provider (each category being referred to as a “sector”). A member should be permitted to designate itself as a member of any sector in which it operates and is subject to related DSCSA requirements. The designated sector should **not** have to be the member’s primary (e.g., highest revenue, highest volume) sector; it is a business decision for the member to determine the sector in which it would like its membership. However, to prevent the gaming of voting structures by continually changing sectors, a trading partner member would be required to obtain approval from the governing body (specifically, by the Membership Committee, as discussed below) to change its designated sector.

**Vision Cornerstone:** *There should be two classes of general members: (1) trading partner members, and (2) association members.*

Additional complications arise with regard to commonly controlled entities within a corporate family (e.g., multiple subsidiaries under the same corporate umbrella). In the interest of flexibility and permitting trading partners to advance their business interests, commonly controlled entities should have two options for membership. First, commonly controlled entities may choose to maintain a single membership for the corporate family and designate the sector for that membership (as explained above). Second, commonly controlled

## White Paper 1: A Proposal: Governance for DSCSA Phase II Interoperability

entities may choose to maintain separate memberships, up to one membership per sector. The Membership Committee would have the authority to admit more than one commonly controlled entity per sector if it determines the prospective members operate independently and have independent business interests with regard to the DSCSA.<sup>9</sup> The following examples illustrate this structure.

1. Company 1 operates as both a wholesale distributor and as a dispenser. Company 1 may have one membership in the governance body, and must designate that membership as either a wholesale distributor membership or as a dispenser membership.
2. Wholesaler A and Repackager Z are commonly owned by Company 2. Company 2 may maintain a single membership as either a wholesale distributor or as a repackager. Alternatively, Wholesaler A and Repackager Z may each maintain separate membership as a wholesale distributor and repackager, respectively.
3. Manufacturer A and Manufacturer B are commonly owned by Company 3. Company 3 may only maintain one membership (whether at the corporate level or subsidiary level) as a manufacturer, unless the Membership Committee determines that Manufacturer A and Manufacturer B operate independently and have independent business interests with regard to DSCSA.

Subject to the laws of the state in which it is incorporated, the general membership would meet annually, and at other times as deemed necessary or appropriate as described below. Virtual attendance (phone or video) should be permitted to minimize the burden of participation. Additional meetings of the general membership may be called by a simple majority of the Board or upon petition by 25% of the general membership. Although only one annual meeting would be *required*, it is generally expected that multiple meetings per year will likely be needed (particularly through 2023). General members would have the following 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.<sup>10</sup>

1. Request the formation of a committee.
2. Participate in committees, as established by the Board.
3. Participate and vote in general meetings.
4. Ratify changes to existing membership classes proposed by the Board.
5. Call a special meeting of the full membership and/or call a question to be put to the general membership for vote.
6. Call a question for the Board by petition of 25% of members.
7. Approve, upon proposal by the Board, an annual budget, including annual membership dues and any expenditures requiring the assumption of debt by simple majority of the voting quorum.
8. Make additional expenditures that, in aggregate, exceed ten percent of the annual budget approved by the general membership with approval by simple majority of the voting quorum.
9. Approve, upon proposal by the Board, special assessments to be paid by the general members by simple majority of the voting quorum.
10. Request the development of, or revision to any policy, procedure, or technical specification with 25% support of the full membership or a simple majority of one membership category/sector.

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<sup>9</sup> While premature at this time, this is an example of where it may be valuable for the governance body to adopt a non-discrimination policy to guide decisions in an appropriate, legally compliant, manner.

<sup>10</sup> Voting thresholds in this section refer to proportions of the full general membership, not specific sectors.

## White Paper 1: A Proposal: Governance for DSCSA Phase II Interoperability

11. Approve by 2/3 majority of the voting quorum new policies, procedures, and technical specifications that significantly or fundamentally impact secure, electronic, interoperable exchange, tracing, and/or verification.
12. Revise or revoke policies, procedures, and technical specifications, the revision or revocation of which significantly or fundamentally impact secure, electronic, interoperable exchange, tracing, and/or verification with approval by 2/3 majority of the voting quorum.
13. Approve, upon proposal by the Board, guidelines for determining whether a policy, procedure, or technical specification fundamentally impacts interoperability.
14. Amend the articles and bylaws, with approval by the Board, with support of a ¾ majority of the full membership.
15. Request an independent audit of the security and performance of any assets of the Governing Body, provided such audits are carried out at reasonable intervals and at the expense of the requesting members, by simple majority of the voting quorum.
16. Exercise all other corporate powers not otherwise reserved to the Board or a committee.

Except where specifically noted, action by the general membership would require a simple majority.

As noted above, the membership structure will be dependent on the activities to be undertaken by the governance body, and as understanding of those anticipated activities evolves, the membership structure may also need to evolve. We encourage any organizations that come together to establish a governance body to carefully consider and assess the membership structure accordingly.

### ***F. Board Structure***

A 14-member Board<sup>11</sup> elected by the general membership would carry out the executive functions of the governance body. Although substantive work would be pushed to the committee level to the maximum extent possible, the Board would have the authority to set the direction and strategy of the governance body. Additional responsibilities of the Board would include, among other things:

1. Fill Board vacancies by simple majority vote.
2. Remove Board members by three-fourths majority vote.
3. Call a special Board meeting by simple majority vote.
4. Approve additional expenditures not in excess of 10% of the budget by simple majority vote.
5. Approve emergency expenditures (outside budget) in excess of 10% of the budget by three-fourths majority vote.
6. Create and terminate committees, appoint committee chairs, define committee jurisdiction, and manage coordination across committees by simple majority vote.

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<sup>11</sup> We recognize that an even number of Board members creates the possibility of ties in voting; however, we were ultimately comfortable with this proposal because (i) many decisions are made by three-fourths majority, and (ii) where a simple majority is used, the necessary vote of 8 out of 14 Board will further support sector neutrality/balance. We also note there may be a need to scale down the size of the initial Board depending on the number of initial Board members. If that is done, care should be taken to retain balanced representation.

## White Paper 1: A Proposal: Governance for DSCSA Phase II Interoperability

7. Determine whether a policy, procedure, or technical specification significantly or fundamentally impacts secure, electronic, interoperable exchange, tracing, and/or verification by three-fourths majority vote.
8. Create and adopt policies and procedures, including, but not limited to antitrust policies and conflict of interest policies by simple majority vote.
9. Issue internal rules of procedure by simple majority vote.
10. Delegate the daily management to a director or third party by three-fourths majority vote.
11. Approve policies, procedures, and technical specifications that do not significantly or fundamentally impact secure, electronic, interoperable exchange, tracing, and/or verification by simple majority vote.
12. Revoke or revise policies, procedures, and technical specifications, the revision or revocation of which does not significantly or fundamentally impact secure, electronic, interoperable exchange, tracing, and/or verification by simple majority vote.

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***Vision Cornerstone:***  
*The structure of the Board is critical to provide appropriate balance among the various trading partners, and we therefore propose a 14-member Board divided by sector.*

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The structure of the Board is critical to provide appropriate balance among the various trading partners. Accountability to the general membership via the annual election process is also a critical attribute of the structure. The 14 Board seats would be allocated as follows:

1. Four Board seats would be open to, and elected by, general members (both trading partner members and association members) who are manufacturers or repackagers. These seats are referred to as **manufacturer/repackager board members**.
2. Four Board seats would be open to, and elected by, general members (both trading partner members and association members) who are wholesale distributors or 3PLs. These seats are referred to as **wholesaler/3PL board members**.
3. Four Board seats would be open to, and elected by, general members (both trading partner members and association members) who are dispensers. These seats are referred to as **dispenser board members**.
4. Two Board seats would be considered **at-large board members**. These seats would be open to any general member regardless of sector; provided that both at-large seats may not be held by members from the same sector. Unlike the other Board seats (which are elected by a vote of only the members from the respective sector) all members would vote for at-large candidates.

Board members would serve staggered two-year terms. Therefore, two of each sector's seats would be open for election each year, and one at-large seat will be open for election each year.<sup>12</sup> Terms limits would not be imposed, recognizing that Board members would have to stand for election every two years.

Any general member—both trading partner members and association members—would be eligible to run for its sector's Board seats or an at-large seat; provided, however, commonly controlled entities within a corporate

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<sup>12</sup> To establish this staggered structure, half of the Board seats would be designated for one-year terms for the first term only.

## White Paper 1: A Proposal: Governance for DSCSA Phase II Interoperability

family may not hold more than one Board seat at a given time.<sup>13</sup> Board nominees would be self-nominated or nominated by a peer and would be elected by simple ballot with the top vote-getter obtaining the seat. Any ties in voting for Board members would be broken by the remainder of the Board whose seats are not standing for election in that cycle. If there are no nominees for a seat, the Association Members from the respective sector(s) would recommend a representative from the relevant sector to fill the seat. The Board would approve that recommended replacement if he or she meets basic criteria to serve.

Each Board seat would be held by an individual in his or her capacity as a sponsored representative<sup>14</sup> of a specific Trading Partner Member or Association Member. As a result, if the individual elected to a Board seat leaves his or her organization—or is otherwise unable to serve—the individual would not retain the seat. Instead, the member organization will recommend a replacement for approval by the remainder of the Board. The Board would approve that recommended replacement if he or she meets basic criteria to serve. If such replacement cannot be identified, the Board would select a replacement (from any member organization in the sector) to serve for the remainder of the term. Regardless, each Board member has a responsibility to act in the best interest of the governance body (*i.e.*, the Board member owes a fiduciary duty to the 501(c) entity, consistent with the 501(c) entity's conflict of interest policy).<sup>15</sup> A Board member may be removed for cause upon three-fourths majority vote of the Board.

The Board would select a Chair, Vice Chair, Treasurer, and Secretary to serve one-year terms as officers. Term limits will not be applied to officers. The Chair would preside at all meetings of the general membership and of the Board and is responsible for Board logistics, such as setting meeting dates and establishing meeting agendas. The Vice Chair would preside at all meetings for which the Chair is absent and perform other duties that may be requested by the Board. The Treasurer would have or provide for the custody of funds, assets, and other property of the governance body and will provide for accurate records and accounts. The Secretary would attend all meetings and provide for the recording of minutes and votes of the Board.

This proposed structure is intended to provide balance among sectors and long-term flexibility. Numerous alternative structures were considered, but ultimately a more simple, flexible, election-centric approach was preferred. Among the variations considered was the notion of designating or reserving Board seats within sectors. This could take numerous forms. For example, a certain number of seats could be reserved for small businesses. Alternatively, seats could be designated or reserved for trading partner members versus association members. Within sectors, seats could also be further sub-allocated for specific business types (*e.g.*, manufacturer seats could be allocated between research-based manufacturers and generic manufacturers; wholesaler seats could be allocated between primary and secondary distributors; dispensers seats could be allocated among chain, independent, hospital, specialty, and other dispenser types). These various structures provide the benefit of predictable diversity of representation, but ultimately, we believe that particular benefit

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<sup>13</sup> As noted above, entities within a corporate family may operate in different sectors and have distinct interests in DSCSA implementation. There is great interest in permitting those distinct entities to engage through distinct membership, as noted. However, it is also recognized that a corporate family with multiple memberships could be positioned to have excessive influence. To balance these competing considerations, a corporate family could maintain multiple memberships as explained above, but the corporate family would be limited to one Board seat.

<sup>14</sup> The individual may be an employee, a dedicated contractor, a consultant, etc. of the organization. The individual should not, however, be a representative of numerous organizations (*e.g.*, a consultant that represents numerous trading partners).

<sup>15</sup> See Section J for additional discussion of legal status.

## White Paper 1: A Proposal: Governance for DSCSA Phase II Interoperability

is outweighed by other negatives. Allocating seats would add significant complexity to the voting structure. Additionally, it would create risk that no members are available to fill a particular type of seat or a particular type of entity would have unequal access to a Board seat<sup>16</sup>. By not further allocating seats, the general membership would have the flexibility to evolve the composition of the Board over time to meet the needs of the industry. For example, a particular type of entity may provide increasingly or decreasingly important perspective over time, and the membership could elect those respective types of organizations to the Board.

The at-large seats are also important to provide both long-term flexibility and a safeguard for underrepresented types of trading partners. As with the flexibility in not sub-allocating seats, the at-large seats allow various types of entities to be represented over time. For example, if dispenser perspective is particularly important early on, a dispenser could be elected to an at-large seat. That could then vary over time. Additionally, if a particular type of entity is underrepresented within its sector and unsuccessful in obtaining a Board seat as a result, that entity could run for an at-large seat and leverage the full, more diverse membership for election.

### G. Committee Structure

Committees would be used to carry out most substantive and tactical work of the governance body, including development of a framework to communicate between trading partner networks to facilitate interoperability and definition of use cases and guidelines for communication between trading partner networks. Three initial committees will be established upon formation of the governance body: a Membership Committee, a Finance Committee, and a Technical Committee. The Board would be responsible for appointing a chair of each committee, but membership/participation in each committee would be open to any/all general members (with the exception of the Finance Committee, as noted below).<sup>17</sup>

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**Vision Cornerstone:**  
*Committees would be open to all general members and would carry out most substantive and tactical work of the governance body.*

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The **Membership Committee** would be responsible for the development, recruitment, and retention of membership. This includes:<sup>18</sup>

1. The development of policies and procedures for membership application, subject to Board approval.
2. The review and approval or denial of membership applications, including confirmation of authorized (as defined in the DSCSA) status, consistent with those policies and procedures.
3. Approval of any change to a member's designated sector.
4. Advising the Board on any proposed changes to membership classifications.
5. Member relations (including recruitment and retention).
6. Termination of memberships for non-payment of membership dues.
7. The development and application of policies and procedures, subject to Board Approval, for member removal.

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<sup>16</sup> For example, assume one seat was allocated to research-based manufacturers and one seat was allocated to generic manufacturers and there were 15 research-based manufacturer members and 3 generic manufacturer members. In that instance, 15 members would be vying for one seat, while only 3 members would be vying for another.

<sup>17</sup> We also note that flexibility is important and committee structures may need to evolve over time. For example, if the governance body grows to a significant size (in terms of number of members), other structures, such as an Executive Committee, may be needed.

<sup>18</sup> This is another example of where it may be advisable for the governance body to adopt policies and procedures to ensure this activity remains legally compliant.

## White Paper 1: A Proposal: Governance for DSCSA Phase II Interoperability

8. Recommending, to the Board, removal of members for cause.

Appeal processes should be established for adverse decisions by the Membership Committee.

The **Finance Committee** would be responsible for financial planning for the governance body, including the development of an annual budget for Board consideration and approval. The Finance Committee would also be responsible for recommending, to the Board, the sale or disposal of an entity asset not contemplated in the annual budget as well as other financial responsibilities that may be designated by the Board. Unlike other committees, the Finance Committee would be structured as a subcommittee of the Board, recognizing it should consist primarily of persons with fiduciary responsibility to the governance body. Transparency to, and input from, the general membership will be paramount given this structure.

The **Technical Committee** would be responsible for substantive, tactical, and technical work related to interoperability.

The Board would have the authority to establish and terminate additional committees as needed. In doing so, the Board would appoint a chair of each committee and may, if necessary, set rules of procedure for the committee. Additional committee management would be left to each committee chair, including the appointment of any additional officers it determines necessary (provided, however, no more than one representative per sector shall serve as an officer of each committee).

The Board would be responsible for establishing the general direction and strategy of the governance body, including coordination among the committees. Committee chairs would have significant latitude, however, to operate within the general framework set by the Board, including the authority to set and manage the agenda and work plan for each committee. All committee activity would be conducted by simple majority of committee members, unless otherwise necessary.

### ***H. Other Procedural Safeguards***

As the specific activities of the governance body are further defined, additional or alternative procedural safeguards may be needed to ensure legal compliance. Stakeholders who come together to form the governance body should be diligent in their review of the final structure on which they agree so as to ensure compliance. For example, if the governance body will engage in standards setting activities, it will be essential that appropriate procedural safeguards are in place to ensure openness, balance, due process, appeals processes, and consensus development. Additionally, the governance body should immediately develop and adopt appropriate policies and procedures, such as policies for identifying and assessing potential conflicts of interest.

### ***I. Funding Model***

The precise funding model for the governance body should be determined by the trading partners and associations that establish it (“founding members”). The level of funding needed to sustain the governance body will depend on the vision for interoperability ultimately adopted by the governance body and on the specific role of the governance body in interoperability. At a minimum, funding will be needed to cover administrative and overhead functions of the governance body. Depending on the vision and role of the governance body, funding may also be needed to support the technical expertise necessary to identify, recognize, or develop technical policies, procedures, and/or technical specifications for interoperability, and to develop and maintain any technical assets the governance body determines are necessary.

## White Paper 1: A Proposal: Governance for DSCSA Phase II Interoperability

In developing a funding model, the founding members of the governance body should follow three 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).

It is also important to note that the member rights and responsibilities described above provide for member approval of annual budgets, including membership dues. This, in effect, provides that members are approving their dues annually.

One key initial question the founding members must answer is whether the governance body will be solely funded by member dues or whether other revenue streams are anticipated, such as fees charged to users of the governance body's outputs. The following concepts are proposed for consideration by the founding members of the governance body as it seeks to develop a funding model that aligns with the principles above:

1. All members should generally pay equal membership dues (*i.e.*, all sectors pay equal dues and Trading Partner Members and Association Members pay equal dues),<sup>19</sup> but a small business reduction should be available to members with 25 or fewer full-time employees.<sup>20</sup>
2. Any member that joins prior to November 27, 2023 should commit to membership through November 27, 2023 in order to provide stability and certainty through Phase II implementation.
3. Members should make an upfront lump sum contribution to fund governance body assets, if any. Tax implications need to be understood, but this could take the form of a loan, a pre-payment of membership dues, a capital contribution, or collateral for a loan.
4. Upfront contributions should have "rate of return" to incent early membership.
5. The rate of return on upfront contributions should decrease over time (*e.g.*, if it is treated as a pre-payment of dues, contributions in the first year of [\$Z] cover [\$Z x 1.25] of dues, and contributions in the second year of [\$Z] cover [\$Z x 1.20] of dues).
6. Members that join after a certain date should be required to pay a reasonable upfront initiation fee to cover/prevent freeriding, but this needs to be carefully structured to avoid deterring membership.<sup>21</sup>

### **J. Legal Structure**

The governing body will be established as a formal nonprofit legal entity to provide necessary continuity and legal structures. The governing body will likely be structured as a 501(c)(3) or 501(c)(6) entity, but legal representation for the trading partners and associations that form the governance body should advise on the precise structure to be used.

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<sup>19</sup> The dues amounts ultimately established by the Board could create a tension between this recommendation and the principle that dues should not dis-incent membership. Ultimately, the overarching principle of not dis-incenting membership may override the recommendation that all members pay equal dues or other concepts here.

<sup>20</sup> This threshold is taken from the small business study required under the DSCSA.

<sup>21</sup> Exceptions may be needed, such as for new companies that did not previously exist.

## **White Paper 1: A Proposal: Governance for DSCSA Phase II Interoperability**

### ***K. Conclusion***

The governance structure proposed in this white paper is intended to promote independent, balanced, sector-neutral governance and to implement the structures and process necessary for industry to come together in an appropriate, open, balanced manner to undertake the collaborative work needed to implement DSCSA interoperability. We are hopeful that the proposal serves as a constructive starting point for further stakeholder dialogue. We urge all stakeholders to consider the proposed structure, engage in dialogue regarding ways in which it can be improved, and rapidly come to consensus as to a structure that can be broadly supported and established.

## **White Paper 1: A Proposal: Governance for DSCSA Phase II Interoperability**