

The attached Prospectus details the proposed structure and membership terms of an industry governance body to support interoperability, as required by the Drug Supply Chain Security Act (DSCSA). It has been developed collaboratively by dozens of stakeholders throughout the supply chain.

All stakeholders are encouraged to participate in the governance body. A diversity of members (sectors, sizes, business models) is expressly desired. Please review the attached document carefully in considering your willingness to participate as a member of the governance body. Any questions can be directed to [PDSA@leavittpartners.com](mailto:PDSA@leavittpartners.com).

**Please complete the following survey by September 30, 2019 to indicate your interest in participating in the governance body:**

<https://forms.office.com/Pages/ResponsePage.aspx?id=zXMTvDFi7UqzqsJ87OlvMW5p4WKwAh9KhAxzDPHn8RUNFINSzJOWFdCQjgzVkFSMUFLVUdSWUtJMS4u>. An expression of commitment to join the membership body in the attached survey will be treated as a good faith commitment that your organization has approved membership in the governance body and is able to pay the related membership dues. Additional details for formal processing of membership and payment of dues (e.g., a formal membership agreement, invoicing details) will follow, and it is recognized that there is some potential that process will impact your organizations ability to follow through with formal membership, but we expect such circumstances are unlikely.

If the minimum number of commitments to establish the governance body is obtained, a meeting will be promptly scheduled (please tentatively hold **October 15<sup>th</sup>**) to formalize establishment of the governance body, including election of the initial Board. Additional members will be admitted after that date on a prorated basis.

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## For Establishment of a DSCSA Governance Body

Various stakeholders have worked in recent months to propose and design a balanced, sector-neutral governance body to support the interoperable electronic tracing of pharmaceuticals, as required by the Drug Supply Chain Security Act (DSCSA). This document is intended to provide stakeholders with the information necessary to evaluate their interest and willingness to formally participate in those governance activities through formal membership in the governance body being established.

### 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. A formal governance body that is independent, balanced, and sector-neutral will be 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 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. 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.

Formation of the governance body is not dependent on any one specific technical vision for how interoperability should be achieved. The specific technical vision to be advanced by the governance body should be determined by the governance body using its decision-making mechanisms that promote balance, sector-neutrality, and equitability. At a general level, however, 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.<sup>1</sup> 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 the governance body within the first year is this blueprint for 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.

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<sup>1</sup> It is acknowledged that other governance activities may take place. First, the governance body 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, the governance body 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.

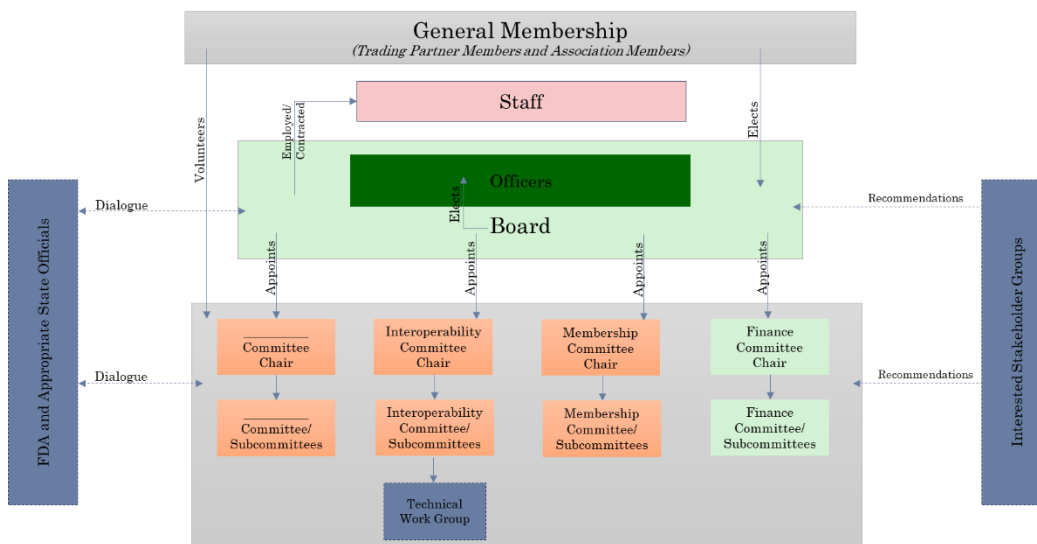
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- Identify any infrastructure that may be needed for DSCSA interoperability.

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 in the governance body. 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 will be conducted by the to-be-formed governance body. 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 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.

## Who can participate in the governance body?

Full membership in the governance body (and therefore decision-making/voting authority) is reserved for authorized manufacturers, 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** will be responsible for executive management of the governance body, and may hire or contract staff to carry out day-to-day management.<sup>2</sup> The governance body will **rely 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 the governance body. This structure is detailed in the graphic below.



<sup>2</sup> Board seats may need to be scaled back proportionate to the size of the governance body early on. Appropriate ratios should be maintained.

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

### General Members

The general membership of the governance body 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 will undertake the tactical/substantive work of the governance body, 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 will be 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 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 will be used to carry out the substantive and technical work of the governance body. Three initial committees will be 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 will be 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 will also have 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 will meet 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 will serve an advisory function making recommendations to the

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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 the governance body is very difficult given that the technical blueprint for interoperability is not currently known and will be established by the governance body. During the 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 the governance body pursues. For example, the cost of operating the governance body will be relatively low if it simply develops a set of high-level best-practices documents, but the cost will be relatively high if the governance body 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.

The proposed membership dues model was developed 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
<b>Tier 1</b>	\$ 50,000	\$ 50,000	\$ 50,000	\$ 10,000	\$ 15,000
<b>Tier 2</b>	\$ 30,000	\$ 30,000	\$ 15,000		
<b>Tier 3</b>	\$ 10,000	\$ 5,000	\$ 2,500		
<b>Small Business</b>	\$ 1,000	\$ 1,000	\$ 250		

	TIER DEFINITIONS				
	Manufacturers/ Repackagers	Wholesalers/ 3PLs	Dispensers	Associations	Technical Experts
<b>Tier 1</b>	> \$10 B	> \$10 B	> \$10 B	N/A	N/A
<b>Tier 2</b>	\$1 B - \$10 B	\$1 B - \$10 B	\$1 B - \$10 B		
<b>Tier 3</b>	< \$1 B	< \$1 B	< \$1 B		
<b>Small Business</b>	25 or fewer full-time employees				

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Initial membership will cover a 12-month membership period (*e.g.*, if the governance body is launched October 15, 2019, the membership year would be October 15, 2019 to October 14, 2020). A member that joins after the initial launch of the governance body will pay prorated (by month) membership during the initial year of membership. It is generally expected that annual membership dues will be paid in full at the beginning of the year. However, recognizing challenges associated with varying fiscal years, two alternative payment arrangements could be considered *for the first year of the governance body*:

**Alternate Structure 1:** Instead of paying the full annual amount up front, members would have the option to pay monthly dues. To incent early payment and support cash flow, monthly dues would be equal to 110% of annual dues, divided by 12. The remainder of the annual dues could be paid off at any time during the year.

*Example: A Tier 2 manufacturer could pay \$2,750 per month during the first year.*

**Alternate Structure 2:** Instead of paying the full annual amount up front, members could make two payments. The first payment would be at least 20% of the annual amount and would be paid up front. The second payment would be made at the beginning of the member's next fiscal year and would be equal to the remainder of the annual amount plus 1% per month.

*Example: Assume the governance body is established on October 1, 2019, and a Tier 2 manufacturer has an April 1<sup>st</sup> fiscal year. The manufacturer could pay \$6,000 up front and \$25,440 on April 1, 2019.*

The budget supported by these dues rates is detailed in Appendix A. This dues structure is dependent upon securing sufficient funding to support the budget detailed in Appendix A and founding membership consistent with founding principles of balanced, sector-neutral governance.

## When will the governance body be formed?

Formation of the governance body will occur upon membership commitments from approximately half of the targeted membership outlined in Appendix A, which is *approximately* 26 trading partner members, with relative balance across the three sectors.<sup>3</sup> The necessary level of commitments is targeted to support an October 2019 launch. ***Therefore, initial members of the governance body are asked to express their formal commitment by emailing the attached survey sheet to [PDSA@leavittpartners.com](mailto:PDSA@leavittpartners.com) by September 30, 2019.***<sup>4</sup>

Following the creation of the governance body, there are several key milestones that must be reached and deliverables that must be created within the first year of governance body operations. These milestones include:

- **Board elections** – Target date: October 2019
- **Approval and adoption of bylaws** – Target date: October 2019

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<sup>3</sup> Commitments will not be binding if fewer than the targeted number of commitment are received.

<sup>4</sup> PDSA is providing an administrative support service by collecting these responses on behalf of the entities interested in founding membership. PDSA is not expected to support the formation of the governance body beyond the administrative collection of these responses.

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- **Complete FDA pilot** – Target date: April 2020
- **Approve a business plan** – Target date: July 2020
- **Establish a high-level blueprint for interoperability** – Target date: September 2020

A more detailed overview of milestones for the first year is included in Appendix B.

## What is the value 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. Membership in the governance body will support the establishment 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 A

### Draft Budget

The membership dues structure was developed to provide sufficient funding for the following budget. As noted, the budget beyond the first year is unknown and could fluctuate significantly depending on the technical blueprint for interoperability that is developed by the governance body. Accordingly, the budget below for Years 2 and 3 should be used only as a point of reference subject to significant potential fluctuations.

<b>Draft Budget</b>				
	<b>Year 1</b>	<b>Year 2</b>	<b>Year 3</b>	<b>Notes &amp; Assumptions</b>
<b>Staff</b>	\$ 700,000	\$ 875,000	\$ 875,000	<i>For Year 1, this assumes an Executive Director at \$300k and two staff at \$200k each (fully loaded). These could be direct hires or outsourced FTEs.</i>
<b>Consultants/SMEs</b>	\$ 500,000	\$ 625,000	\$ 781,250	<i>This will fund issue-specific technical experts to support development of a blueprint for interoperability, and includes their travel.</i>
<b>Accounting</b>	\$ 75,000	\$ 56,250	\$ 56,250	<i>This assumes payroll support from any consultant that provides the staffing.</i>
<b>Legal</b>	\$ 150,000	\$ 112,500	\$ 84,375	<i>Covers review of SOPs and documents, antitrust advice, general corporate support, etc., but does not contemplate legal counsel in every meeting.</i>
<b>Facilities/Equipment</b>	\$ 50,000	\$ 62,500	\$ 78,125	<i>Office space, technology, and equipment, recognizing much of this is offloaded if staff are outsourced.</i>
<b>PR and Communications</b>	\$ 50,000	\$ 62,500	\$ 78,125	<i>Website, marketing materials, educational materials, etc.</i>
<b>Recruiting/education/membership services</b>	\$ 75,000	\$ 93,750	\$ 70,313	<i>Membership recruitment and general industry educational activities.</i>
<b>Travel</b>	\$ 50,000	\$ 62,500	\$ 78,125	<i>20 trips at \$2500 per trip, assuming approximately 6 industry functions and 12-14 recruiting/member visits.</i>
<b>Meetings</b>	\$ 100,000	\$ 100,000	\$ 75,000	<i>Cost of space and support for membership and committee meetings, assuming such is not provided by outsourced staff.</i>
<b>Insurance</b>	\$ 15,000	\$ 15,000	\$ 15,000	<i>General business liability and D&amp;O insurance.</i>
<b>Total Budget</b>	<b>\$ 1,765,000</b>	<b>\$ 2,065,000</b>	<b>\$ 2,191,563</b>	

The dues structure will support the above budget based on the following targeted number of members (52 trading partners, 6 association, and 14 technical experts). It is recognized that it will take time to reach or exceed these targets. Therefore, formation of the governance body would be initiated upon commitment from half of the targeted number of members and the budget will be managed fluidly over the course of the year to scale up to the budgeted levels as the full targeted number of members are added.

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



Appendix B

