Healthcare Distribution Alliance
PATIENTS MOVE US.

Verification Router Service
Governance Body Charter

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1. Governance Body Charter

1.1. Background on VRS

Healthcare Distribution Alliance (HDA) formed the Traceability Pilots Work Group in 2016 to focus on a pilot study of nine (9) potential methods or solutions to meet the 2019 Saleable Returns DSCSA requirements. Through the process of evaluating nine scenarios, the Work Group acknowledged no single solution for the supply chain existed, and put forward two preferred options, keeping in mind solution cost, implementation effort, process execution, exception handling, and other advantages and disadvantages.

One of the options studied in the pilot was a Verification Router Service (VRS). A proof of concept was successfully built and utilized during a live pilot, but it was a temporary system designed solely for the purposes of the pilot. (For the full pilots report, see https://healthcaredistribution.org/resources/hda-saleable-returns-pilots-report.) At the conclusion of the pilot study, the Work Group decided that the Verification Router Service was a verification method that should be pursued.

HDA subsequently formed a task force consisting of industry members and later expanded the team to include solution providers in order to mobilize efforts for defining the business requirements, high-level functionality, solution components, component interactions, minimal required data and recommended communications protocols. With assistance from KPMG LLP, HDA and the task force members conducted virtual meetings and in-person workshops throughout 2017. The resulting output was consolidated into two documents:

1. VRS Business Requirements Document (BRD)


VRS BRD.pdf

2. Solution Architecture Reference Document (SARD)


Verification Router Service_Solution Arc

The initial versions of these documents have been approved by the task force members, however, the group recognizes that further updates will be required throughout 2018 and over the VRS solution lifecycle.

In addition to the technical and functional activities resulting in the initial BRD and SARD documents, there was a recognized need to begin discussions and define requirements for VRS governance and stewardship. Based on HDA's poll of industry members and solution providers to indicate intentions to actively support and participate in VRS build, test, and pilot activities, a governance workstream was assembled.

This document will further define the group's intended objectives, proposed responsibilities, planned activities, expected deliverables, and overall operational parameters and logistics.

It is anticipated that this document will be frequently revised throughout 2018 based on additional experience and learnings from solution build, test, and pilot activities.

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1.2. **Purpose / Mission**

The main purpose of the VRS Governance Body is to provide direction to the VRS solution providers (who at this stage in early 2018 are developers) and VRS user community (who at this stage in early 2018 are prospective users). The VRS user community is comprised of the authorized distributors and dispensers who need to initiate verification requests, and the manufacturers responsible for responding to such requests.

The VRS Governance Body will provide guidance in various forms, including the following:

1) Coordination of stakeholder inputs for knowledge sharing, solution improvements, and general on-going communications;

2) Maintenance of reference and requirements documents such as the BRD and SARD;

3) Assessment of proposed requirement and proposed architecture document changes ;

4) Recommended usage and application of solutions developed to meet requirements and functionality (*e.g.* reason codes);

5) Suggested practice for error handling and exception management;

6) Further determine if needed and if required design a Registration Process for identification and authorization of entities and entity locations that will initiate requests or respond to requests;

7) Further determine if needed and if required design Registration Process for identification and authorization of entities providing VRS routing solutions; and

8) Recommended Governance Body structure throughout the multi-year existence of the VRS.

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1.3. Guiding Principles

The VRS stakeholder community, defined as the VRS Task Force, is currently in the development, build, and test phase with a target to implement production-ready VRS solutions in advance of the November 2019 DSCSA requirement to verify serialized product identifiers for saleable returns. As the stakeholder community evolves, the approach will be to document learnings as experience is gained throughout the integrated testing and pilot periods. This will allow the Governance Body to further assess the requirements and design of the VRS in order to provide and/or refine guidance and recommendations based on qualitative and quantitative data.

The VRS Governance Body will operate with a sufficient degree of flexibility so as to not impede the progress being made on solution build and test activities. The Governance Body will, however, monitor and measure VRS workstream activities and progress as an input for making updates to the BRD and SARD.

As the VRS stakeholder community evolves, the Governance Body should explore mechanisms for obtaining feedback on its service and performance. This will include defining Key Performance Indicators (KPIs) that can be used to measure the effectiveness of the governance body over time.

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1.4. **Scope**

1.4.1. The following processes and systems are in scope for the governance body in terms of providing guidance and recommendations:

- Interactions between the components described in the BRD and SARD:
  1. Connectivity Information (CI) provided by the Responder to VRS Provider(s).
  2. Exchange of VRS Provider ID used by Responder at GTIN level amongst VRS Providers for routing of VRs.
  3. Initiation of a Verification Request (VR) via Requestor using their own internal system interfaced to the Requestor's VRS or Requestor using their VRS Provider's system.
  4. Routing of a VR between two VRS Providers.
  5. Delivery of a VR from a VRS to a Responder.
  6. The reply to VRS from the Responder indicating whether the PI provided in the VR are valid.
  7. Routing of the Response to a VR between two VRSs.
  8. Delivery of the Response to a VR from the Requestor's VRS to the Requestor.

- Identification / Registration of VRS community participants. The Governance Body will determine if needed and if required document the recognized participants based on registration criteria. The registry is not an endorsement or recommendation of any individual organization.

1.4.2. The following processes and systems are <u>not</u> in scope for the Governance Body in terms of providing guidance and recommendations:

- Requestor systems and application design (*e.g.* WM/WMS)
- Responder systems and application design (*e.g.* PI repository)
- VRS solution provider technical design

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1.5. Members and Participant Roles & Responsibilities

1.5.1. The following organizations are currently participating in the effort to define the appropriate stewardship activities in support of VRS development and represent the interim Governance Body. These organizations have indicated their intent to support and participate in the VRS build, test, and pilot activities:

- AmerisourceBergen Corporation
- Cardinal Health
- CVS Health
- Genentech
- Gilead Sciences
- Johnson and Johnson Supply Chain
- McKesson
- Par Pharma
- Pfizer
- rfXcel
- SAP
- Sunovion
- TraceLink

1.5.2. It is expected that the Governance Body membership and members' individual and collective responsibilities will evolve over 2018 and 2019, particularly as VRS solutions progress from development to testing to implementation.

1.5.3. Near-term (2018-2019) Governance Body roles and responsibilities:

- Advance VRS efforts and support the overall purpose and mission as defined in this charter
- Understand the current business requirements and solution architecture; provide recommendations for improvement
- Provide relevant subject matter knowledge from relevant experience as a requestor (distributor/dispenser), manufacturer, or solution provider in support of the deliverables this group will oversee
- Suggest inputs and send feedback for meeting agendas and inputs
- Review meeting outputs and send feedback
- Monitor and measure implementations as an input to changes / improvements to deliverables managed by this Governance Body.

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- Make recommendations for objectives and structuring of any planned pilots
- Consult technical group on topics that require exploration of options or development of guidelines or standards

1.5.4. Solution Provider Responsibilities:

1. The VRS Provider shall have the ability to demonstrate a procedure(s) or other documentation that describes the process for verifying authorization of its customers for initiating verification requests; conducting periodic reviews; and documenting the results of this on-going activity.
2. The VRS Provider must obtain documented evidence that the wholesale distributor (requestor) is authorized to either distribute or dispense prescription products. Examples of documented evidence include valid/current state license through one of the following methods: obtain a copy of license, confirm with a state licensing board, or use a license aggregator, e.g. MedPro, Atlas Certified, Legisym or other similar. Information may be obtained directly from the entity or using a 3rd party service (e.g. MedPro, Atlas Certified, Legisym or other similar). It is only necessary to verify a single state license to confirm the distributor is "authorized". The license must be active. For states that extend expiration date, grace period needs to be considered If a license cannot be verified, the wholesale distributor should not be allowed access to the system until a valid license can be provided. Note: Neither a DEA license nor the FDA website are valid documentation for this purpose. .
3. The VRS Provider must obtain documented evidence in R-001 and R-002 with frequency no less than once a month so as to verify that the license is valid and has a non-expired status.
4. The VRS Provider must obtain documented evidence that the entity providing Connectivity Information (CI) is the authorized manufacturer responsible for providing responses for the GCP(s)/GTIN(s) identified. Examples of documented evidence could include trusted sources of data (e.g. FDA database, approved product labeling) and/or attestation from manufacturer and co-licensed partner as applicable
5. The VRS Provider will maintain and provide upon request or audit from a customer a listing of all entities for which they are providing requesting and/or responding services. Listing will include, at a minimum, company identifier (i.e. GLN), on-boarding date, contact information, license information, and next review date where applicable.
6. The VRS Provider will adhere to published VRS business requirements, specifications and GS1 Lightweight Messaging Standard for Verification of Product Identifiers unless otherwise indicated by VRS Provider.
7. The VRS Provider will route verification requests to other VRS Providers as needed based on manufacturer (responder) and wholesale distributor (requestor) solution set/scenario.
8. The VRS Provider will make available to other VRS Providers Look-up Directory (LD) information obtained directly from an authorized manufacturer (GCP/GTIN owner).
9. VRS providers will make a public statement that they follow the rules as outlined above. VRS providers make public an outline of their ATP check concepts. VRS providers are not required to audit each other but rely on the public statements.

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10. The VRS Provider and any network participant who intends to provide their own requesting or responding services will utilize a TLS mutual authentication approach, exchanging X.509 certificates. Certificates can either be self-signed or public issued by a certificate authority. Managing certificate validity and expiration dates is something that will need to be taken care of during onboarding between VRS Providers or those building their own requesting or responding services.

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1.5.5. Longer-term (2019 and beyond) Governance Body roles and responsibilities:

To be completed in future revision based on feedback and recommendations from working group and experience gained through industry testing.

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1.6. Deliverables

The following are the guidance / reference documents that this Governance Body has the responsibility to oversee:

1.6.1. Business Requirements Document (BRD). Version 3.0 is the current version and was approved April 2019. The original was approved in 2017 and revised.

1.6.2. Solution Architecture Reference Document (SARD). Version 2.0 is the current version and was approved April 2019. The original document was approved in 2017 and revised.

1.6.3. VRS Messaging Standard. This is a newly required document and will provide messaging content for requests and responses. This includes request and response types, error codes, and samples for reference. This document was issued by GS1 in 2019.

1.6.4. Identification Protocol. This is a newly required document and will describe the process for solution providers to identify and vet requestors and responders. It is expected that the VRS technical workstream will support the definition of this process in collaboration with the governance body.

1.6.5. Look-up Directory technical specification – This is a newly required document and will provide guidance for the exchange of CI amongst VRS providers. It is expected that the VRS technical workstream, particularly the solution provider members, will support the definition of this process in collaboration with the governance body. This document was last revised August 2018.

1.6.6. VRS Provider Registry / Process – This is a newly identified document and if required will provide relevant company information to the VRS providers and the contact information that others would subscribe to for connection information. This process is required to support LD sharing across providers and for processing verification requests that require VRS ←→VRS interaction.

In order to maintain version control and a planned revision cycle for deliverable documents, the Governance Body will oversee the change control process for the documents that are being managed, *i.e.* revision cycle, period for comment and review, approval process, and effective date. It is expected that the current working group will drive the content revisions of the document until disbanded

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and, thereafter, the Governance Body will maintain and make available the approved versions for use by the community at-large.

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1.7. VRS Activities and Milestones

1.7.1. The main activities and milestones have been identified for 2018. The scheduling and sequencing will be refined as needed. Any significant changes will be communicated to the VRS stakeholder community, currently defined as the VRS Task Force.

1.7.2. The following timeline depicts the major planned 2018 activities across all workstreams:

Activity	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
Teams Formed											
Governance Charter											
Specifications – new and rev											
Solution Provider Build											
SP Unit Test and Report											
Registry Process											
Connectivity Testing											
Pilot Scope, Use Cases											
Pilot Protocol and KPIs											
End to end Testing											
Pilot – round 1											
Pilot – round 2											
Pilot report											

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1.8. Meetings

1.8.1. Meeting Frequency

During 2018, meetings will be conducted once or twice monthly. Meetings will be scheduled by HDA. Meetings will be hosted and conducted by HDA with assistance from KPMG LLP.

1.8.2. Meeting Logistics

Meetings will mostly be conducted via web-ex / teleconference. In-person meetings may be conducted should a compelling need arise or an opportunity arises to leverage participants being co-located at another meeting or conference.

Meetings will be supported by an agenda and, as needed, supporting materials to facilitate discussion and recommendations.

HDA will issue output from the meetings to all meeting invitees.

1.8.3. Meeting Inputs

Meetings will include recurring agenda items in order to review pending action items and decisions needed in support of guidance and recommendations. Additionally, members will be asked to provide inputs in advance of meetings based on the topics to be discussed and documents to be reviewed. These may include responding to surveys and questionnaires.

1.8.4. Meeting Outputs

The following are the expected outputs from meetings and will depend based on the overall work plan schedule and specific topic(s) covered:

- Updated work plan
- RAID (Risks, Actions, Issues, Decisions) Log / Tracker
- Recommended content for deliverables and communication of content
- Recommended content for communications

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1.9. Coordination & Interactions with Other Groups

1.9.1. GS1 – standard format for verification query and response.

1.9.2. Blockchain solution provider community – potential for Look-Up Directory, Registry, or other functionality that might impact VRS.

1.10. Communications

HDA, with input from the Governance Body and technical/pilot workstreams, will issue communications throughout the build, test, and pilot phase in various forms such as blog posts, conference presentations, and webinar sessions.

The following table lists the planned communications for 2018:

#	Description	Timing	Format
1	VRS / Traceability 2018 Plans	February 2019	HDA Blog
2	VRS Overview, 2018 Work Plan, Call to Action	March 2019	Conference Presentation – DMC Tech Expo
3	BRD and SARD Updates and how to access	May/June 2019	HDA Blog and/or Other (*e.g.* HDA Weekly Digest)
4	VRS Pilot Schedule and Scope	June / July 2019	TBD
5	VRS Pilot Update – Preliminary Results	August 2019	TBD
6	VRS Report-out	October 2019	Conference Presentation – HDA Traceability Seminar
7	End of year Report	December 2019	TBD

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1.11. Finalizing Guidance & Recommendations

1.11.1. Process – near term.

In the near-term, it is expected that this interim Governance Body will operate in a consensus-style mode. Should it be determined that a more formal approach is needed, this will be re-evaluated.

1.11.2. Process – long term.

To be defined in a future version.

1.12. Membership Criteria and Process to Request Membership

1.12.1. Near-term:

Requestors and responder organizations who will be supporting and participating in the build, test, and pilot activities.

1.12.2. Long-term:

The content of this section will be determined at a later date. However, it is envisioned that it will cover items, such as: governance structure and make up, nomination, voting and decision making process, as well as fees.

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2. Appendix

2.1. Glossary

Term / Acronym	Definition
Connectivity Information (CI)	A general term used in this document to refer to the technical information (e.g. end-point URL, security certificates, authentication parameters) needed to establish connection with the responder's repository. The details of what this connectivity information entails will be further defined in the design phase.
DQSA	Drug Quality and Security Act
DSCSA	Drug Supply Chain Security Act, Title II of the DQSA. See full law here or information from the Food and Drug Administration (FDA) here.
GCP	Global Company Prefix, a unique GS1 identification code for your company obtained through GS1. For additional information see here.
GS1	GS1 is an international organization that develops and maintains standards for supply and demand chains across multiple sectors. For additional information see here.
GTIN	Global Trade Item Number, used to uniquely identify trade items that are priced, ordered, or invoiced at any point in the supply chain. For additional information see here. For U.S. Rx product, the National Drug Code or NDC number is embedded in the GTIN. For additional information on the NDC see here.
LD	Look-up Directory which contains the Connectivity Information of the Responders' Repositories. It is expected that the LD will be an integrated component of each VRS.
PI	Product Identifier, defined by DSCSA as a standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product. In this context it is used to reference its component data elements: 1) GTIN, 2) Serial Number, 3) Lot Number, and 4) Expiration Date (month/year).
Repository	Repository refers to the Responder's system that stores PI data and relevant data in order to provide responses to verification requests.
Requestor	Entity that initiates the verification requests (e.g. distributor, dispenser)
Responder	Entity responsible for providing response to verification requests (e.g. manufacturers, re-packagers) for specified FDA Labeler Code(s) and/or GTIN(s)
VR	Verification Request
VRS	Verification Router Service
VRS Provider / VRS Provider ID	Entity offering a Verification Router Service solution (which is expected to include a LD as an integrated component).

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