



# **Verification Router Service**

## **Policies for Control and Maintenance of Lookup Directory Records**

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## TABLE OF CONTENTS

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Revision History.....	2
<b>1. Introduction.....</b>	<b>3</b>
1.1. Background.....	3
1.2. Purpose.....	4
<b>2. Policy on Ensuring Synchronization of Individual Lookup Directory Records from Authoritative Source.....</b>	<b>5</b>
<b>3. Policy on Initiation and Refresh of VRS Lookup Directory Records.....</b>	<b>7</b>
<b>4. Policy on Plan to Permit Removal of Records from Defunct Authoritative Source Systems.....</b>	<b>7</b>

## REVISION HISTORY

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Version	Date	Revision Description
1.0	04-MAY-2026	Initial Publication

## 1. INTRODUCTION

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### 1.1. Background

#### 1.1.1. The Drug Supply Chain Security Act

The Drug Supply Chain Security Act (DSCSA), enacted on November 27, 2013 amends the federal Food, Drug and Cosmetic Act (FDCA) and establishes the requirement that for each change of ownership (referred to as a transaction) of a covered prescription drug product trading partners exchange product tracing data at the package level, in an interoperable, secure, electronic manner.<sup>1</sup> This interoperable electronic data exchange has been implemented in stages across the entire pharmaceutical supply chain. By November 27, 2025, most trading partners must be fully compliant with the DSCSA; all trading partners must be fully compliant by November 27, 2026.<sup>2</sup>

An important requirement in the DSCSA is the ability to “verify” the product identifier on a drug package. “Verification” or “verify” means “determining whether the product identifier affixed to, or imprinted upon, a package or homogeneous case corresponds to the [SNI] ... assigned to the product by the manufacturer or the repackager....”<sup>3</sup> Currently, a manufacturer or repackager who receives a verification request from an authorized repackager, wholesale distributor or dispenser that is in possession or control of a drug package must respond to that request within 24 hours, or one business day.<sup>4</sup> FDA and other government officials may also request that a trading partner provide information, including a request to verify a product identifier.<sup>5</sup>

Wholesale distributors and dispensers have additional verification requirements. Before a wholesale distributor may resell a return, it must verify the product identifier for each sealed homogeneous case and each package.<sup>6</sup> Dispensers must verify a certain number or percentage of packages during a suspect product investigation.<sup>7</sup> These requirements, originally effective in 2019 and 2020 respectively, will now be enforced in 2025 and 2026.<sup>8</sup>

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<sup>1</sup> § 582(g)(1).

<sup>2</sup> The original effective date for all DSCSA package-level requirements was November 27, 2023. The Food and Drug Administration (FDA) first granted a one-year period of enforcement discretion and now has issued exemptions for connected trading partner partners and for small business dispensers. More information on the final phase in of DSCSA requirements is available at FDA’s website, [here](#).

<sup>3</sup> See § 581(28) (definition of “verify” or “verification”).

<sup>4</sup> See § 582(b)(4)(C) (manufacturers); § 582(e)(4)(C) (repackagers). Though the DSCSA specifies 24-hours to respond, FDA has stated that a best practice would be no later than one business day. See [Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs Final Guidance for Industry](#) (Dec. 2023).

<sup>5</sup> See § 582(b)(1)(B), (c)(1)(C), and (e)(1)(C); [Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act Final Guidance for Industry](#) (January 2024).

<sup>6</sup> § 582(c)(4)(D).

<sup>7</sup> § 582(d)(4)(A)(ii)(II).

<sup>8</sup> More information on the final phase-in of DSCSA requirements is available at FDA’s website [here](#).

### 1.1.2. The History of the VRS Provider Network

The 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. One of the promising options studied was a Verification Router Service (VRS). A proof-of-concept was successfully built and used in a live pilot.<sup>9</sup> At the conclusion of the pilot study, the Work Group determined that the Verification Router Service was a verification method worth pursuing.

HDA subsequently formed a task force to further develop and collaborate with industry partners to build and expand the VRS Solution. In 2023, participating solution providers determined that, for the VRS's continued success, a governance structure was necessary to ensure network interoperability and functionality. In response to this request for governance, HDA established the VRS Provider Network, a membership body for all industry stakeholders developing and interested in VRS. The membership body is governed by an Advisory Board of core VRS solution providers who have demonstrated their commitment to the network's success through rounds of interoperability testing exercises, production cutover execution, and ongoing participation in connection and syncing activities.

### 1.1.3. Description of the VRS

The Business Requirements Document provides detailed information on what the VRS is and how it is intended to function.

In summary, an authorized trading partner in possession or control of a product captures the product identifier information on the product label and passes it to a qualified routing service, namely the VRS<sup>10</sup>. The VRS uses the associated Global Trade Identification Number (GTIN), contained in the DataMatrix barcode encoding the product identifier, to automatically query the appropriate manufacturer's database and return a real-time response indicating whether the product identifier is one the manufacturer assigned. The GS1 messaging standard can support additional information, including whether the product is expired, under a recall, or otherwise should not be distributed.

The responding manufacturers, through their service providers, are responsible for providing repository connectivity information to the VRS and providing appropriate responses to the verification requests by matching the product identifier received from the requester with the product identifier in their repositories.

A Look-up Directory (LD) contains connectivity information for a responding manufacturer's repository, essentially telling the verification request where to go and which manufacturer to query to return a timely response. Service Providers provide the systems necessary to enable manufacturers to maintain their lookup directory GTINs on an ongoing basis. The importance of LDs is explained further in Section 2, *Policy on Ensuring Synchronization of Individual Lookup Directory Records from Authoritative Source Systems*.

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<sup>9</sup> See full pilot report, [here](#).

<sup>10</sup> In addition, under the DSCSA and FDA implementing guidance, a trading partner's individual system and processes should permit FDA and other Federal and State officials, as applicable and appropriate, to submit a verification request and receive the response in an electronic, interoperable, and standardized manner. Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Final Security Act Guidance for Industry (January 2024).

## 1.2. Purpose of these Policies

The VRS Provider Network Advisory Board has adopted these policies to establish rules of engagement for the upkeep and maintenance of each VRS LD, promoting synchronization and functionality across the entire network of VRS lookup directories. The policies have expanded to include other use cases, including support of suspect product investigations.

The following policies are included here:

- Policy on Ensuring Synchronization of Individual Lookup Directory Records from Authoritative Source Systems
- Policy on Initiation and Refresh of VRS Lookup Directory Records
- Policy on Plan to Permit Removal of Records from Defunct Authoritative Source Systems

## 2. POLICY ON ENSURING SYNCHRONIZATION OF INDIVIDUAL LOOKUP DIRECTORY RECORDS FROM AUTHORITATIVE SOURCE SYSTEMS

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Solution providers facilitate the maintenance of GTINs for their responding customers in LDs. Maintaining accurate GTINs in LDs is critically important to the VRS's functionality, as the LD directs a user's verification request to the appropriate manufacturer's data repository for confirmation that the product identifier is verified. For the VRS to be interoperable and enable fast, accurate, and legally required verifications across the VRS network, these LDs must be synchronized. The VRS Provider Network Advisory Board has adopted this *Policy on Ensuring Synchronization of Individual Lookup Directory Records from Authoritative Source Systems* to ensure that participating service providers enable synchronization of the VRS LDs, which, in turn, is necessary for VRS users' legal compliance.

### 2.1 Ensure synchronization of individual LD records from authoritative source systems.

An authoritative source system is defined as the publisher of the LD entries for one or more responders—manufacturers, repackagers or their agents. The responder maintains their respective GTINs in their authoritative source system.

### 2.2 Maintenance

This section addresses how authoritative source systems share records with other LDs and ensure all updates are received. The authoritative source system will push records out and enable LD subscribers to pull records from the authoritative system lookup directories.

The push message is posted to each connected subscribing LD provider listed in the [VRS LD registry](#) whenever a modification is made to the LD record entry.

The push mechanism assumes that each VRS has an up-to-date list of other VRS LD connectivity information in the VRS LD Registry, and that each VRS LD has implemented an API method per [HDA VRS Technical Specifications](#) to receive this notification.

The “push synchronization” enables updating LD records across all VRS LD subscribers in real time.

The pull mechanism is used by subscribing LD systems to retrieve and synchronize authoritative LD entries and their changes from authoritative source systems.

Subscribing to LD systems should refresh LD content from the authoritative source system at least once per day and no more than once per hour.

For more details on the push-and-pull mechanism, please refer to the LD Technical Specifications.<sup>11</sup>

### **2.3 Resolution of conflicting LD records across solution providers.**

The VRS Provider Network Subgroup for LD Readiness is a subgroup of solution providers in the VRS Provider Network focused on lookup directory readiness that maintains high-level metrics on lookup directory records. The subgroup reviews a report of active record errors to facilitate authoritative source systems in analyzing and troubleshooting known errors.

Conflicts arise when two LDs list the same GTIN with overlapping expiry date ranges. To resolve this conflict, one of the two source lookup directories must set the record status to deleted or inactive, or set the expiry date to eliminate the conflict.

Dispute resolution occurs between LD source systems with overlapping LD record entries for the same GTIN. The respective customer LD record owner from each involved LD system is a stakeholder in the dispute resolution process. To resolve overlapping LD record conflicts, identify which source lookup directory will alter its record to remove the overlapping LD record condition.

The labeler associated with FDA registrations and the related NDC is the best evidence for determining who the source Authoritative Record owner is. If the conflict remains unresolved, other evidence sources must be consulted, such as the manufacturer, repackager, contract manufacturer, private-label distributor or solution providers involved.

### **2.4 Proper Control and Maintenance of Records**

Pursuant to the VRS Technical Specifications, there are expected activities that constitute proper control and maintenance of a connected and in-sync LD solution. LD Solution Providers are expected to participate in and follow the activities of the VRS Provider Network Subgroup for LD Readiness:

- (a) Adhere to the technical requirements of the VRS Technical Specification (latest version 1.11).
- (b) Participate in testing activities.
- (c) Share system updates and any anticipated downtimes with participating solution providers and users.
- (d) Engage in logging active records and developing any needed resyncing protocols.
- (e) Participate in Active Record Resync activities.
- (f) Follow steps for the removal of defunct records and develop internal clean-up protocols, as needed.
- (g) Communicate and address technical issues with other providers.
- (h) Communicate with HDA regarding the status and resolution of elevated issues, as well as outreach efforts, to ensure they remain fully informed. Communicate system updates and metrics to VRS end users

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<sup>11</sup> Verification Router Service Technical Specifications available [here](#).

### 3. POLICY ON INITIATION AND REFRESH OF VRS LOOKUP DIRECTORY RECORDS

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Certain events can trigger the need to initiate and refresh LD records. If solution provider participants in the VRS Provider Network do not initiate and refresh LD records (minimum daily, as referenced in the LD Technical Specifications), this may impede network interoperability, impair users' ability to successfully verify product identifiers and result in legal noncompliance with the DSCSA. The VRS Provider Network Advisory Board has adopted this *Policy on Initiation and Refresh of VRS Lookup Directory Records* to ensure that participating LD service providers know when and how to perform these functions in order to maintain the interoperability of the VRS.

These qualifying conditions include:

- A new LD solution provider.
- An individual LD solution provider is recalibrating LD content to resolve and resync LD content from the network.
- When active records are created and later abandoned by a source LD, and the source LD is unable or unwilling to reclaim or modify the specific LD entries

In addition to the conditions listed above, the group may reach a consensus to perform a coordinated refresh and a resync of LD content from the network across all LD solution providers. The steps a service provider should follow to initialize LD subscribing systems are:

1. **Verify Registry Entries:** Ensure the LD subscribing system and authoritative LD source systems are correctly registered in the VRS LD Registry.
2. **Retrieve & Resync Records:** Use the GET method to retrieve records from authoritative LD source systems and resync the LD subscribing system.
3. **Verify Data:** Log entries in the Active Record Log and compare counts to confirm accuracy and completeness.

For more details, please refer to the LD Technical Specifications.<sup>12</sup>

### 4. POLICY ON PLAN TO PERMIT REMOVAL OF RECORDS FROM DEFUNCT AUTHORITATIVE SOURCE SYSTEMS

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The VRS Provider Network enables users to comply with the DSCSA verification requirements. An impediment to this legally required interoperability arises when a manufacturer maintains its records in multiple sources. If the LD holding the duplicate record is defunct, or otherwise unwilling or unable to delete the duplicate record(s), the interoperability of the VRS Provider Network is potentially compromised and with it, the ability of users to comply with the law.

The VRS Provider Network Advisory Board has adopted this *Policy on Removing Records from a Defunct Authoritative Source* to establish a transparent process for removing duplicate records from the directories of defunct and unresponsive authoritative sources, thereby maintaining the interoperability of the VRS Provider Networks for all users. The Policy sets out 7 steps for HDA staff and the Advisory

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<sup>12</sup> Verification Router Service Technical Specifications available [here](#).

Board to follow in the event that an authoritative source is identified as holding a duplicate record and the authoritative source does not respond to communications and/or appears to be defunct.

Step 1: Identification of a potential defunct authoritative source.

Step 2: Communication to identify a potential defunct authoritative source.

Step 3: Confirmation that GTINs are active and have a new or corrected authoritative source through contact with the manufacturer.

Step 4: Consideration by Advisory Board regarding defunct authoritative source status and potential vote instructing other service providers to remove the duplicate record.

Step 5: HDA announcement of Advisory Board approval to remove record from defunct authoritative source.

Step 6: Service providers execute removal of records of defunct authoritative source.

Step 7: HDA sends notice of removal to defunct authoritative source.

### **Step 1: Identification of a potential defunct authoritative source**

A service provider or user of the VRS may notify HDA staff that they believe they have identified a duplicate record, and the LD holding the record has failed to respond to communications from the user or service provider requesting its removal. The following are factors HDA staff may consider in determining that a record may be held by an LD that is defunct:

- a. Certificates have expired, and the LD has made no attempts to share new certificates.
- b. The LD does not respond to weekly outreach from two or more LD service providers that are attempting to resolve issues with certificates or records for over 30 days.
- c. The LD is absent from all VRS Provider Network meetings for over 90 days.
- d. The LD has not provided updated data for the Active Records Log for over 90 days.
- e. GTIN owner does not acknowledge a business relationship with the potentially defunct LD.
- f. The LD does not respond when their participation and/or a duplicate record issue is raised during a Subgroup for VRS Lookup Directory Readiness meeting.
- g. The LD does not respond to email communications from HDA staff.

Using the above factors, HDA staff may conclude that the LD may be defunct. If HDA staff do so, they will document that conclusion and initiate Step 2.

### **Step 2: Communication to identify a potential defunct authoritative source**

HDA staff will communicate the following to the LD's last known email address, last known phone number, and last known mailing address in the following order of escalation at the following intervals:

#### **a. Initial Notification**

- *Template A, Initial Notification and Request for Response*
- *Notice is sent via email by HDA staff to the last known email addresses of LD.*
- *If HDA receives no response, after 10 business days, proceed to b.*
- *Initiate Step 3, communication with the GTIN(s) owner to confirm a business relationship with potentially defunct LD.*

#### **b. Warning**

- *Template B, Warning: Records At Risk of Removal*
- *A warning is sent via email by HDA staff to the last known email addresses of Lookup Directory.*

- *HDA staff shall also call the LD at the last known phone number.*
- *If HDA receives no response, after 10 business days, proceed to c.*

**c. Urgent Final Warning**

- *Template C, Urgent, Final Warning, Removal of Records Pending*
- *A warning is sent via email by HDA staff to the last known email addresses of Lookup Directory.*
- *HDA staff shall also call the LD at the last known phone number.*
- *HDA staff shall also send the Warning to the last known mailing address of the Lookup Directory.*
- *HDA also notifies the customer/GTIN record owner (Template D) by email that their record(s) are at risk of removal because their LD is not responsive to repeated requests and appears defunct.*
- *If HDA receives no response from the Lookup Directory after 10 business days, proceed to Step 4. HDA staff will refer the matter to the Advisory Board.*

If, at any point in the above process, the LD responds, they must resolve the problem within 10 business days. If they fail to do so, HDA staff will notify the LD by email that the matter has been referred to the VRS Provider Network Advisory Board for consideration and potential vote to delete the duplicate record.

**Step 3: Confirmation that GTINs are active and have a new or correct authoritative source through contact with the manufacturer**

Through communication with the customer/GTIN record owner, HDA will seek to establish if there is a business relationship with the potentially defunct LD.

- *Customer/GTIN record owner will need to provide details of their new LD or will be advised to establish a business relationship with a new LD in order to ensure their records are maintained. GTIN record owner should be advised that records that are removed as a result of the potentially defunct LD could result in 'GTIN Not Found' error (HTTP status code 404) when verification is made to a non-existing GTIN record.*

**Step 4: Consideration by the Advisory Board regarding defunct authoritative source status and potential vote instructing other service providers to remove the duplicate record**

- a. HDA staff will, at least seven calendar days in advance of a meeting of the VRS Provider Network Advisory Board, send an email to the Board informing members that potential deletion of records held by a potential defunct LD will be placed on the agenda of the next meeting.
- b. At least three business days prior to the noticed meeting, HDA staff will provide via email to the VRS Provider Network Advisory Board members the records of all communications with and regarding the LD and a short summary of the duplicative records that are the subject of the potential removal action. HDA staff shall also provide the Board with any communications received from other service providers regarding the matter, including any complaints and notifications regarding the potentially defunct LD and its duplicate records.
- c. If the LD has communicated with HDA staff, they may submit an explanation for why the records should not be deleted and provide their plan to maintain interoperability and synchronicity with other LDs.

- d. The Advisory Board shall consider the materials provided by HDA Staff pursuant to the noticed agenda item. After due consideration, any member of the Board may then make a motion to declare the LD is defunct. If the motion is seconded, the Board may then proceed to a vote on whether to declare the LD defunct. The motion must be carried by a majority of Board members voting. HDA staff shall record the vote. If the Board has declared the LD as defunct, any member of the Board may then make a motion to direct the removal of the record or records of the defunct LD. If the motion is seconded, the Board may then proceed to a vote to authorize the deletion of the record or records. The motion must be carried by a majority of Board members participating in the vote. HDA staff shall record the vote. The Board shall direct HDA staff to make the notifications required under this Policy. For all Board actions under this section, a quorum must be present.
- e. Matters before the Advisory Board are conducted pursuant to the Verification Router Service (VRS) Provider Network Membership Guidelines.

**Step 5: HDA Announcement Advisory Board approval to remove from record authoritative source**

HDA staff shall issue the following notifications of any vote taken by the Advisory Board to declare an LD as defunct and to direct the removal of a record or records held by that defunct entity.

- a. HDA staff shall send a notification to the last known email address, last known phone number, and last known mailing address of the defunct LD informing it of the Advisory Board decision.
- b. HDA staff shall send a notification by email to the customer/GTIN record owner informing them of the Advisory Board decision.
- c. HDA staff shall notify all members of the VRS Provider Network of the Advisory Board decision. This notification shall include, but is not limited to, oral communication and email, to the participants in the Subgroup for VRS Lookup Directory Readiness, directing them to delete the record or records of the defunct LD.

**Step 6: Service providers removal of records defunct authoritative source**

Members of the VRS Provider Network shall take the following steps to remove the record or records of a defunct LD as directed by HDA staff pursuant to the Advisory Board's decision.

- a. Find and confirm the sourceVrsId of the defunct LD Provider from the registry.
- b. The subscribing LDs will delete record(s) of the defunct LD Provider based on the sourceVrsId as identified in step a.

**Step 7: HDA sends notice of removal of defunct authoritative source**

Once LDs in the VRS provider network have removed the record or records, HDA staff will notify the defunct LD at the last known email address, phone number and mailing address, informing the LD of their removal.