HDA
Healthcare Distribution Alliance

NTS M

# Verification Router

# Service

Business Requirements Document

Version: 3
Date: 12-April 2019

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# Revision History

| Version | Date | Revision Description |
|---|---|---|
| 1.0 | 05-MAY-2017 | Initial Draft Version |
| 2.0 | 30-JUN-2017 | Final update from Task Force and HDA Review |
| 3.0 | 12- APR-2019 | Final Task Force edits and HDA Review |

# 1. Introduction

## 1.1. Background

The Drug Supply Chain Security Act (DSCSA), enacted on November 27, 2013 in Title II of the Drug Quality and Security Act (DQSA), aims to help combat the threat of pharmaceutical diversion by enhancing the traceability of prescription pharmaceutical products in the U.S. The DSCSA amends the federal Food, Drug and Cosmetic Act (FDC Act)[1] to establish an interoperable electronic system for the identification and tracing of individual units of certain prescription drugs. This legislation, which preempts state and local laws, mandates that all trading partners in the supply chain be authorized and hold appropriate licenses or registrations, details requirements for verification procedures and prescribes requirements for information necessary to identify and trace the distribution of prescription products down to the smallest unit intended for sale to a dispenser. This interoperable electronic system is to be implemented in stages over the next six years across the entire pharmaceutical supply chain. By November 27, 2023, each package of applicable prescription drug product must bear a product identifier[2], which includes a unique serial number[3] that will link each saleable product unit to the selling and purchasing sources of the product in a secure, interoperable, electronic system [See § 582(g)(1)]. **One important milestone in the progress towards the 2023 deadline and full product traceability begins on November 27, 2019.** Starting on that date, each wholesale distributor is required to "verify" the product identifier on each unit (or sealed homogenous case) returned that the wholesale distributor seeks to resell.

Beginning on November 27, 2019, before it may resell a returned product, "the wholesale distributor shall verify the product identifier, including the [SNI] … for each sealed homogeneous case or on each package" [§ 582(c)(4)(D)]. "Verification" or "verify" "means determining whether the product identifier affixed to, or imprinted upon on a package or homogeneous case corresponds to the [SNI] … assigned to the product by the manufacturer or the repackager…."[4] [§ 581(28)]. A manufacturer who receives a verification request from a repackager, wholesale distributor, or dispenser must respond to that request within 24 hours (or such other time FDA establishes) [§ 582(b)(4)(C)]. A repackager also has 24 hours to respond [§ 582(e)(4)(C)].

This requirement will be henceforth referred to as 2019 Saleable Returns DSCSA Requirement in this document.

[1] Citations that follow to sections 581 and 582 refer to sections of the FDC Act as amended by the DSCSA and are codified at 21 U.S.C. § 360eee and §360eee-1, respectively.

[2] The product identifier requirement begins November 27, 2017, by which time manufacturers must affix or imprint a product identifier to each package and homogenous case intended to be introduced in a transaction into commerce [§ 582(b)(2)(A)]. Repackagers must affix product identifiers a year later, by November 27, 2018. [§ 582(e)(2)(A)].

[3] The product identifier is a standardized graphic in human-readable form and on a machine-readable carrier that conforms to international standards and includes the product's unique standardized numerical identifier (SNI), lot number and expiration date [§ 581(14) (definition of product identifier); § 581(20) (definition of SNI)].

[4] Section 581(28) also permits verification of a product identifier by "lot number and expiration date." However, once all product is serialized, there would be no reason for trading partners to verify product by lot number and expiration date when the product identifier (which includes the SNI, lot number, and expiration date (§ 581(14)) would be more accurate and efficient.

## 1.2. Purpose

Healthcare Distribution Alliance (HDA) formed the Traceability Pilots Work Group 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, advantages and disadvantages, and sustainability implications from both the manufacturer and wholesale distributor perspective. One of the options studied in the pilot was a Verification Router Service. A proof of concept was successfully built and utilized during a live pilot, but it was only a temporary system for the purpose 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 believed the Verification Router Service was the most feasible external solution due to its speed and security.

As an outcome of the pilots work, HDA formed a task force consisting of pharmaceutical manufacturers and wholesale distributors to develop the business requirements and governance associated with the Verification Router Service solution. HDA, working with KPMG LLP and the task force members, conducted several workshops and meetings to collaborate on defining the business requirements and identifying governance needs to oversee and support on-going operation of the complete solution. The task force defined the requirements with the expectation that there will be multiple VRS providers operating in a distributed environment.

The purpose of this document is to present the business requirements defined by the task force for the Verification Router Service that will be able to support compliance with the 2019 Saleable Returns DSCSA Requirements, and is scalable to meet the business needs for a diverse network of Manufacturers and Wholesale Distributors. While the driver behind development of the Verification Router Service is to support 2019 Saleable Returns Requirements, there is the potential for Manufacturers to use such a solution to meet DSCSA requirements beginning November 27, 2017 requiring them to verify whether the product identifier, including the SNI, corresponds to the product identifier the manufacturer affixed or imprinted to the product, as well as the potential to include additional future capabilities for expanded use beyond 2023 when full product traceability goes into effect.

## 1.3. Solution overview

The Verification Router Service is envisioned to function in the following manner:

Upon receiving product as a potentially saleable return, the wholesale distributor (henceforth referred to as Requestors) captures the product identifier information and passes the data to a qualified routing service (henceforth referred to as Verification Router Service or VRS), which references the associated GTIN to automatically query the appropriate Manufacturer's (henceforth referred to as Responders) database and return a response in real-time. The Requestor is responsible for passing the appropriate product identifier data elements to the VRS. The VRS is responsible for maintaining and looking-up the appropriate repository information of the Responder and submitting appropriately formatted request message to the repository. The Responders 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.

The business requirements will be defined for the following high-level processes:

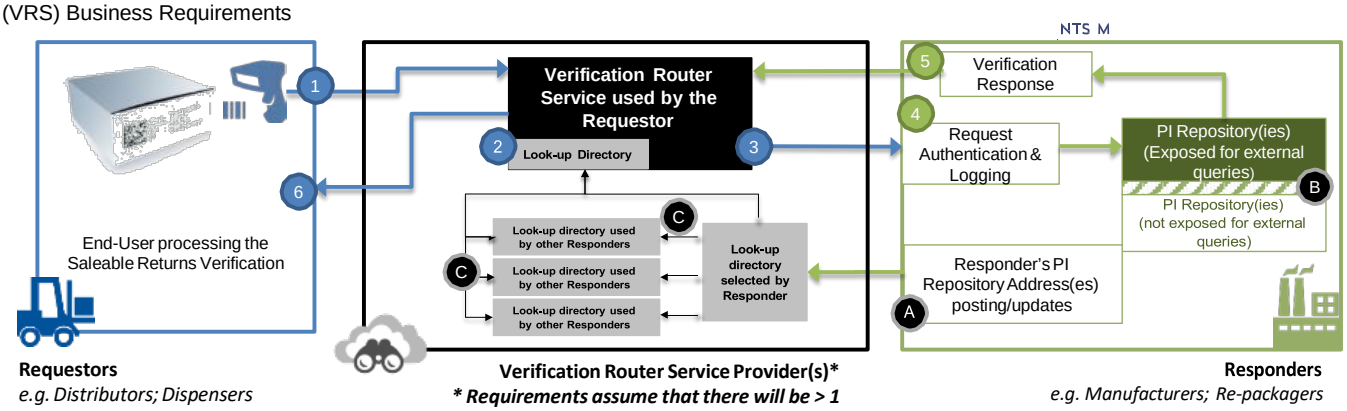
- **Requesting processes:**
  These include capabilities required to initiate a verification request, look-up the Responder's repository connectivity information and submit verification requests. These requirements would typically apply to Requestors and VRS solution providers.

- **Responding processes:**
  These include capabilities required to authenticate and log verification requests and respond to verification requests. These requirements would typically apply to Responders and VRS solution providers.

- **Enabling processes:**
  These include capabilities required to post and maintain product identifier repository information and to manage or expose product identifier data for external queries.

The following interaction diagram illustrates the various process steps and enabling activities for the overall Verification Router Service solution:

Verification Router Service
(VRS) Business Requirements




*e.g. Distributors; Dispensers*

**** Requirements assume that there will be > 1***

*e.g. Manufacturers; Re-packagers*

***Enabling Processes - Product Identifier (PI) Data Management Activities***

A. Product identifier (PI) repository information posting and maintenance
B. Manage and expose product identifier (PI) data for external query
C. Look-up directory synchronization between VRS providers

***Requesting Processes - Transaction Activities***

1. Initiate verification request
2. Look-up Responder's repository destination
3. Submit verification request
6. Receive and log response

***Responding Processes - Transaction Activities***

4. Receive, authenticate, and log verification request
5. Provide response for verification request

## 1.4. Glossary

| Term / Acronym | Definition |
|---|---|
| API | Application Program Interface |
| CBV | The Core Business Vocabulary (CBV) specifies the structure of vocabularies and specific values for the vocabulary elements to be utilized in conjunction with GS1 EPCIS for data sharing both within and across enterprises. It was designed to ensure a common understanding of data semantics and the use of the CBV is critical to the interoperability of EPCIS implementations. |
| Connectivity Information | 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. |
| csv file | Comma separated value file |
| 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. |
| DUNS number | Data Universal Numbering System, abbreviated as DUNS or D-U-N-S, is a proprietary system developed and regulated by Dun & Bradstreet (D&B) |
| EPCIS | Electronic Product Code Information Services, a messaging standard that enables trading partners to share information about the physical movement and status of products as they travel throughout the supply chain. For additional information see here. |
| FDC Act | Food, Drug and Cosmetic Act. See full law https://www.gpo.gov/fdsys/pkg/USCODE-2015-title21/pdf/USCODE- 2015-title21-chap9.pdf here. |
| GCP | Global Company Prefix, a unique GS1 identification code for your company obtained through GS1. For additional information see here. |
| GLN | Global Location Number, the GS1 identification key utilized to identify unique physical locations, operational locations, and legal entities. For additional information see here and for healthcare specific GLN information see here. GLNs will be used to identify the Requestor and Responder in the messaging standard. |
| GS1 | GS1 is an international organization that develops and maintains standards for supply and demand chains across multiple sectors. For additional information see here. |

| Term / Acronym | Definition |
|---|---|
| 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 pharmaceuticals, the product's National Drug Code or NDC number is embedded in the GTIN. For additional information on the NDC see here. |
| guid | globally unique identifier assigned to requests that are initiated within the VRS using 8-4-4-4-12 string format, e.g. 998CDC77-6860-4351-9277-6F3E6F870AC6 |
| LD | Look-up Directory (directory which contains the connectivity information of the Responder's repository fulfilling the verification request) |
| 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.<br>In this context it is used to reference its component data elements which include GTIN, Serial Number, Lot Number, and Expiration Date. |
| Repository | Repository refers to the Responder's systems that will minimally store the 4 PI data elements and provide the response to the verification request. |
| Requestors | Entities that will initiate the verification requests (e.g. distributors), Requestors can either utilize a VRS provider or build their own requesting capabilities. |
| Requestor ID | A unique identifier assigned to Requestor entities that are registered and authorized to use the VRS. |
| Responders | Entities that will provide response to the verification requests (e.g. manufacturers, re-packagers).<br>Responders can either utilize a VRS provider or build their own responding capabilities. |
| Responder ID | A unique identifier assigned to Responder entities that are registered and authorized to use the VRS. |
| SGTIN | Serialized Global Trade Item Number, which consists of the GTIN plus a unique serial number. |

| | |
|---|---|
| SNI | Standardized Numerical Identifier, defined by DSCSA as “a set of numbers or characters used to uniquely identify each package or homogenous case that is composed of the National Drug Code that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters.” § 581(20). For additional guidance, though it predates the DSCSA, see here. |
| Transaction ID | General term for the unique value assigned to requests that are initiated within the VRS. see guid definition. |
| txt file | Text file |
| VRS | Verification Router Service |
| VRS providers | Solution providers that will provide Verification Router Services. Note that requestors or responders can also build their own requesting or responding capabiltiies. |
| xls file | Microsoft Excel file |

# 2. Business Requirements

## 2.1. Requesting processes

The following requirements apply to the VRS solution providers:

| Req. ID | Requirement | Additional clarification |
|---|---|---|
| REQ-010 | The VRS shall require the following four Product Identifier (PI) data elements to initiate a verification request:<br>(1) GTIN<br>(2) Serial Number<br>(3) Lot Number<br>(4) Expiration Date | |
| REQ-020 | The VRS shall support multiple request types. | *Initially, the only request type planned is "Saleable Returns Verification". However, this functionality will allow for future types of requests (e.g. General Verification). The additional request types should not impact the functionality of how request/response is executed.* |
| REQ-030 | The VRS shall provide system integration capabilities (e.g. standard APIs) for Requestors to initiate verification requests and to receive responses. | |
| REQ-040 | The VRS shall provide a single access point (account) to each requesting entity for use of the verification routing services. | |
| REQ-050 | The VRS shall provide a web portal user interface to initiate verification requests and to receive responses. | |
| REQ-055 | The VRS web portal shall provide ability to download the requests and responses for the verifications initiated via the portal. | |
| REQ-060 | The VRS shall provide the ability to capture the four Product Identifier (PI) data elements via scan of the GS1 DataMatrix printed on the saleable unit in order to initiate requests. | |

| Req. ID | Requirement | Additional clarification |
|---|---|---|
| REQ-070 | The VRS shall provide the ability to manually enter the four Product Identifier (PI) data elements into the portal to initiate requests. | REQ-070 |
| REQ-080 | The VRS shall provide data validation for PI entered for initiating verification requests. | *e.g. GTIN is numeric, check digit verification; field lengths are correct* |
| REQ-120 | The VRS shall only permit registered and authorized Requestors and other authorized VRS providers to submit verification requests. | |
| REQ-130 | The VRS shall maintain a log of the verification requests received, including Date/Time, and identified with the unique Transaction ID. | |
| REQ-140 | The VRS shall submit the verification request to the appropriate Responder's repository based on the Connectivity Information (CI) associated to the GTIN and start/end date values in the look-up directory. | *The VRS would determine theCI associated to the GTIN based on the scanned PI data. The Verification Request may be submitted from the Requestor's VRS directly to Responder's PI repository or to Responder's PI repository via Responder's VRS provider.* |
| REQ-150 | The VRS shall follow the prescribed data formats and exchange standards to submit the verification request to the Responder's repository. | *The VRS Governance body will work with GS1 or other appropriate standards' organizations to establish or refine existing standards (e.g. EPCIS) for verification requests purposes.* |
| REQ-160 | The VRS shall follow the prescribed data formats and exchange standards to provide the verification response to the Requestor or the Requestor's VRS provider. | The GS1 Lightweight Messaging Standard for Product Verification defines the data formats in support of REQ-150 and REQ-160 |

| Req. ID | Requirement | Additional clarification |
|---|---|---|
| REQ-170 | The VRS shall follow the appropriate authentication and security protocols as established by the Responder when submitting the verification requests to the Responder's repository. | |
| REQ-180 | Requestors, who choose to build the LD and request capabilities, shall get a copy of the synchronized LD | |
| REQ-190 | Requestors, who choose to build the LD and request capabilities, shall be notified when a new GTIN is published (via an LD update) | |
| REQ-200 | Requestors, who choose to build the LD and request capabilities, shall be notified when a new GTIN ownership change is approved (via an LD update) | |

## 2.2. Responding processes

The following requirements apply to the Responders:

| Req. ID | Requirement | Additional clarification |
|---|---|---|
| RES-010 | The Responder shall provide one of the following responses for a verification request:<br>- Response – PI Data Elements Verified (T)<br>- Response – PI Data Elements Not Verified (F) | In DSCSA verification "means determining whether the product identifier affixed to, or imprinted upon, a package or homogeneous case corresponds to the standardized numerical identifier or lot number and expiration date assigned to the product by the manufacturer or repackager". If additional information is known about the status of a PI that would cause the Responder to not want the product to be resold, then the Responder should provide optional information in the response (see RES-030). Refer to the GS1 Lightweight Messaging Standard for Product Verification. |
| RES-030 | The Responder shall have the option to provide additional status attributes in the verification response for a PI record. | *Additional information can be provided by Responders for additional context to the verified product identifier (e.g. recalled lot, do not resell, etc.).* |
| RES-040 | The VRS shall follow the prescribed data formats and exchange standards to provide the verification response to the Requestor or the Requestor's VRS provider. | Refer to the GS1 Lightweight Messaging Standard for Product Verification. |

The following requirements apply to the VRS NTS M solution providers:

| Req. ID | Requirement | Additional clarification |
|---|---|---|
| | | |
| RES-080 | The VRS shall return an error if the Responder's repository is not found in the look- up directory. | |
| RES-090 | The VRS shall return an error if there are exceptions in reaching the Responder's repository: - No Response from Manufacturer / Product / GTIN Owner Repository | |
| RES-100 | The VRS shall return an error if the VRS service is down or not available | |
| RES-120 | The VRS shall add to the log of the verification requests maintained the response(s) received, the Responder ID(s), and the Date/Time stamp of the response. | |
| RES-140 | Responders, shall have the ability to initiate a GTIN ownership change when they take over ownership of a product. (to initiate a change in the LD) | |
| RES-150 | Responders, shall have the ability to approve a GTIN ownership change when requested. (to accept a request to change the LD) | |
| RES-160 | Only responders, who “own” the Labeler Code / GCP, shall have the default capability to add a new GTIN for that Labeler Code / GCP. | |

## 2.3. Enabling processes

The following requirements apply to the VRS solution providers, or those trading partners that decide to build the LD synchronization and request / response capabilities :

| Req. ID | Requirement | Additional clarification |
|---|---|---|
| ENB-010 | The VRS shall have the ability to accept the following data from Responders to maintain the Look-up Directory (LD):<br>- At the GTIN-level: Global Trade Item Number (GTIN), Responder's Company Name, Responder ID, Connectivity Information, StartDate, End Date (optional) | |
| ENB-020 | The VRS shall be able to obtain and store Responders' Repository connectivity information in the Look-up Directory (LD) from any of the following sources: the Responder, another VRS provider, or other external source. | |
| ENB-030 | The VRS shall make available to other qualified VRS providers the repository connectivity information that was submitted to them. | |
| ENB-040 | The VRS' Look-up Directory (LD) shall allow multiple Responder repositories for a single GTIN in order to accommodate scenarios such as product ownership changes (e.g. divestiture, M&A, co-licensed partnerships). | *However, the PI for a single GTIN will be active in one and only one Responder Repository. See Assumptions Section.* |
| ENB-050 | The VRS shall provide the ability to manage version control for Look-up Directory (LD) updates and to indicate if Repository Connectivity Information is active (e.g. via start/end date range). | |
| ENB-060 | The VRS shall provide the ability to ensure Look-up Directory (LD) updates can only be made by the authorized entity (i.e. GTIN owner). | |
| ENB-070 | The VRS shall provide system interfaces (e.g. standard APIs) for Responders to update/append the VRS Look-up Directory (LD). | |

| Req. ID | Requirement | Additional clarification |
|---|---|---|
| ENB-070 | The VRS shall provide system interfaces (e.g. standard APIs) for Responders to update/append the VRS Look-up Directory (LD). | |
| ENB-080 | The VRS shall provide a single access point (account) to each responding entity to post data to the Look-up Directory (LD). | |
| ENB-090 | The VRS shall have a process to register and authorize Responder entities with a valid Responder ID in order to use the verification routing services. | *GLN will be used.* |
| ENB-100 | The VRS shall allow ability to view and download the list of GTINs and the associated repository connectivity information and restrict view/access to the responding entity's own data. | |
| ENB-110 | A responder shall only be able to enter GTINs aligned to their GCP / Labeler Code | |
| ENB-120 | The VRS shall permit transfer of ownership of a GTIN between responders. | *In the event of mergers & acquisitions; product divestitures. This may need to be managed by Labeler Code or GCP* |
| ENB-130 | The VRS shall obtain approval from the original GTIN owner before transferring ownership of a GTIN or granting permission for a second, concurrent Responder. | *Systemic approval.* |

The following requirements apply to the NTS M Responders:

| Req. ID | Requirement | Additional clarification |
|---|---|---|
| ENB-140 | The Responder's PI repository shall use the four elements of the product identifier (GTIN, Serial Number, Lot Number & Expiration Date) as the selection criteria to determine if a matching record exists. | |
| ENB-150 | The Responder's PI repository may use the month and year portion of the expiration date only when determining if the expiration date data element matches the product being verified. | *This is to address false negatives when the encoded data may not contain day of the month.* |
| ENB-160 | The Responder's PI repository shall be accessible by any qualified VRS to submit verification requests. | *The VRS Governance body will establish guidelines to qualify VRS providers* |

## 2.4. Other requirements

The following requirements apply to the VRS solution providers:

| Req. ID | Requirement | Additional clarification |
|---|---|---|
| OTH-010 | The VRS shall return responses to the Requestor in less than one second for requests containing a single product identifier. | |
| OTH-020 | The VRS shall follow the system availability and maintenance standards as prescribed by the governing body. | *The VRS Governance body will prescribe these standards.* |
| OTH-030 | The VRS shall ensure the secure delivery of all requests and responses. | |
| OTH-040 | The VRS shall provide a service to ensure any connectivity or LD issues are resolved with the Responders. | |
| OTH-050 | The VRS shall provide issue resolution services in case of connectivity issues with Responders' repositories. | |
| OTH-060 | The VRS shall ensure that only Requestors and Responders can view/access their own request and response transactions. | |
| OTH-070 | The VRS shall log all changes to its LD for audit trail purposes. | |
| OTH-080 | The VRS shall provide appropriate security authentication mechanisms for Responder's to post data to the LD. | |

# 3. Appendix

## 3.1. Assumptions

1. The VRS may be provided by one or many VRS providers. The requirements do not define the ultimate architecture, but rather how the complete “solution” will function.

2. A to be determined VRS Governance body will be established to facilitate the VRS technical architecture definition.

3. A to be determined VRS Governance body will develop standard data exchange and technical specifications, including standard API specifications, for use by VRS providers.

4. Industry standards associations (e.g. GS1, ANSI, ISO) may participate in the governance body to define data exchange standards that support the business requirements.

5. The Look-up Directory (LD) is a component of the VRS solution. The sharing and synchronization of the LD records amongst VRS providers will be part of the defining governance and architecture.

6. The Look-up Directory (LD) will be managed by GS1 GTIN, a start date where all expiration date values of the PI must be >= in order to be routed, and an optional end date, where all expiration date values must be <= in order to be routed.

7. Data exchange protocols, technical connectivity methods and data security should be based on widely adopted industry standards and must provide interoperability amongst all VRS Solution providers and PI Repository solutions.

8. Entities will manage accounts and authentication of individual users within their organization. The VRS will manage entity-level accounts and authentication.

9. The Verification Request may be submitted from the Requestor’s VRS directly to Responder’s PI repository or to Responder’s PI repository via Responder’s VRS provider.

10. The Responder's repository will only verify the PI that was sent in the verification request and will not verify the children PIs (if the data is aggregated in the repository). e.g. If PI for a homogenous case is being verified, it will only verify if the PI for that case is valid/not valid and will not infer and verify the children PIs for the units packed in that case.

11. PI records for a single GTIN may reside in multiple repositories, however, one and only one repository can receive and respond to a verification request from a

VRS for an individual PI record. When multiple PI repositories exist in the LD for a single GTIN, the routing will be determined from the expiration date month/year from the scanned PI and the start date / end date values in the LD.