



EXCEPTIONS DATA CORRECTION GUIDE FOR DSCSA

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The Healthcare Distribution Alliance (HDA) represents primary pharmaceutical distributors — the vital link between the nation’s pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently. The HDA Research Foundation, HDA’s nonprofit charitable foundation, serves the healthcare industry by providing research and education focused on priority healthcare supply chain issues.

INTRODUCTION

The “HDA Exceptions Data Correction Guide for the Drug Supply Chain Security Act (DSCSA)” was prepared by the Healthcare Distribution Alliance’s (HDA) Exceptions Handling Work Group. The Work Group recommends standardizing the steps to correct data in trading partners’ systems to reflect complete and accurate package-level transaction data. This guide describes how trading partners can correct the data exceptions identified in the more comprehensive [Exceptions Handling Guidelines for the DSCSA](#).

This guide is voluntary and does not constitute and is not intended to represent legal advice. The following recommendations are based on an evolving understanding of DSCSA requirements. As such, the recommendations presented here may change as the Food and Drug Administration (FDA) issues and finalizes guidance documents, as well as releases regulations. Each company must make its own business decisions about how it will procedurally handle transaction data corrections. Companies should consult their legal counsel, regulatory compliance specialists and trading partners for further guidance in correcting transaction information.

Exceptions Data Correction: General Recommendations

Currently, the Work Group believes exceptions data correction will primarily be manual, sometimes involving sending incremental data and other steps. The Work Group makes the following general recommendations:

- **Resolve Exceptions as Quickly as Possible:** The data correction efforts applicable to the exceptions category should be undertaken as soon as possible as quarantine space is limited. Following the [FDA’s guidance](#), which recommends up to 10 business days to resolve exceptions, could quickly result in quarantine area overflow.
- **Determine Scope:** Establish whether this is a file-level exception covering an entire shipment or a more limited exception covering only a portion.
- **Trust but Verify:** Confirm if the incident reported can save time in resolving the exception. For example, when a trading partner reporting an overage receives both product and data, first scan the file sent to make sure the sGTIN(s) reported missing were not overlooked for some reason. These files can be large, and the problems associated with them can be very insidious.
- **Check Serial Numbers:** Check if the serial numbers reported missing were included in an Electronic Product Code Information Services (EPCIS) file directed to another trading partner. This might indicate another data issue that needs to be resolved.

- **Communicate With Trading Partners:** Establish preferences with your trading partners regarding how to handle supplemental EPCIS files typically sent to correct for data that has no product categories or exceptions:
 - **Purchase Order (PO) Numbers:** Some may prefer a new manual PO to be created and listed in the EPCIS file but not transacted as an EDI PO. Others may want the existing PO to continue to be used to transact the overage.
 - **Despatch Advice:** Some system configurations look for unique, new despatch advice as they do duplicate checking. However, others may want the overage transacted using the original despatch advice.
 - **Shipment and SSCC Numbers:** A preference for Shipment and SSCC numbers should also be established.
- **Take Preventative Measures To Help Guard Against Exceptions.**
 - Trading partners initiating a transaction should follow Section V.B. of the final EDDS Guidance issued by FDA, ["The Selling Trading Partner Should Reconcile the Transaction Information With the Product It Sells to a Purchasing Trading Partner."](#) Following this final guidance will help prevent data exceptions before the product is given to the carrier for delivery.
 - Adhere to global [EPCIS standards](#) and healthcare industry [implementation guidelines](#) for the DSCSA.
 - Implement systems processes to ensure data were successfully transmitted to the trading partner.



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