# Field Safety Notice

## Patient Safety Escalation

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## Summary

We have identified an issue relating to the use of our software that may potentially affect patient safety at your organization. Please read this document closely and work with your Epic Technical Services representative to determine if your organization is affected by this issue and to identify an appropriate resolution plan.

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| **Title** | Duplicate Medication and Duplicate Therapy Warnings Might Not Appear for Certain Medications That Lack a Generic Product Indicator |
| **Reference #** | 9254595 |
| **Products** | Willow Inpatient |
| **Versions** | August 2024, May 2024, February 2024, November 2023, August 2023, May 2023, February 2023, November 2022, May 2022, November 2019 |

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# Description

## Field Safety Notice

This issue affects Epic's Regulated Decision Support Framework (RDSF), which is CE Marked as a Class I medical device under the Council Directive 93/42/EEC on Medical Devices (MDD). In accordance with its obligations, Epic is informing the relevant regulatory authorities of this issue.

## Background Information

### *Third-Party Medication Data Loads*

Medication information is loaded into Epic from a third-party medication data vendor. In Switzerland, the third party that supplies this data is HCI Solutions.

### *Duplicate Medication Warnings*

The system performs duplicate medication checking to identify when the same order has been placed multiple times for the same patient. To be considered duplicates, medication orders must have equivalent routes, the same PRN status, and equivalent chemicals as specified in the Active Ingredients (I ERX 1507) field of the medication record. The system checks for potential duplicate medications whenever orders are signed by a clinician or verified by a pharmacist. To determine whether an order would be a duplicate, the system evaluates both the orders being ordered or verified, and the orders that are currently active for the patient.

### *Duplicate Therapy Warnings*

The system performs duplicate therapy checking when multiple medication orders have the same drug class. In Switzerland, the system uses the value in the Pharmaceutical Subclass (I ERX 112) field to determine whether a duplicate therapy warning should appear. The pharmaceutical subclass data is generally populated in each medication record by information from the third-party medication vendor. The system checks for potential duplicate therapies whenever orders are signed by a clinician or verified by a pharmacist. The system is expected to evaluate both the orders being ordered or verified, and the orders that are currently active for the patient.

## Issue Overview

When a medication is ordered or verified, and either that medication or a currently-active medication for the patient is configured as described in the Configuration section below, the system does not include that medication for potential duplicate medication and duplicate therapy warnings. As a result of this behavior, warnings that should otherwise appear might not appear, and clinicians might place orders that they otherwise wouldn't have if a warning had appeared.

## Configuration

This issue affects systems for which both of the following are true:

- The Medication Data Vendor (I LSD 4200) field in EMR System Definitions is set to HCI.
- The system has at least one medication record for which all of the following criteria are true:
    - The medication is imported from HCI, which is the case if there is a value in the Product number (I ERX 1050) field on the HCI Medication Identifiers screen in the medication record.
    - Either or both of the following conditions are true:
        - The medication has a value in the Active Ingredients (I ERX 1507) field on the HCI Medication Identifiers screen. With this field populated, the system can check for duplicate medication warnings for the medication.
        - The medication has a pharmaceutical subclass, which is the case if there is a value in the Subclass (I ERX 112) field on the Clinical Medication Information screen. With this field populated, the system can check for duplicate therapy warnings for the medication.
    - The medication does not have a Generic Product Indicator, which is the case if the GENGRP (I ERX 210) field is blank in the Generic Product Information section of the Interaction Related Information screen.

## Example Workflow

This issue occurs in a variety of workflows, including the following example:

1. A patient has an active medication order for komplexon III ophthalmic solution, for which the medication record is configured as described above.
2. For that same patient, a clinician signs a second medication order for komplexon III ophthalmic solution.
3. The clinician clicks Sign.

At this point in the workflow, the system does not include the medication orders from steps 1 and 2 when it checks for duplicate medication and duplicate therapy warnings, and no duplicate medication warning appears.

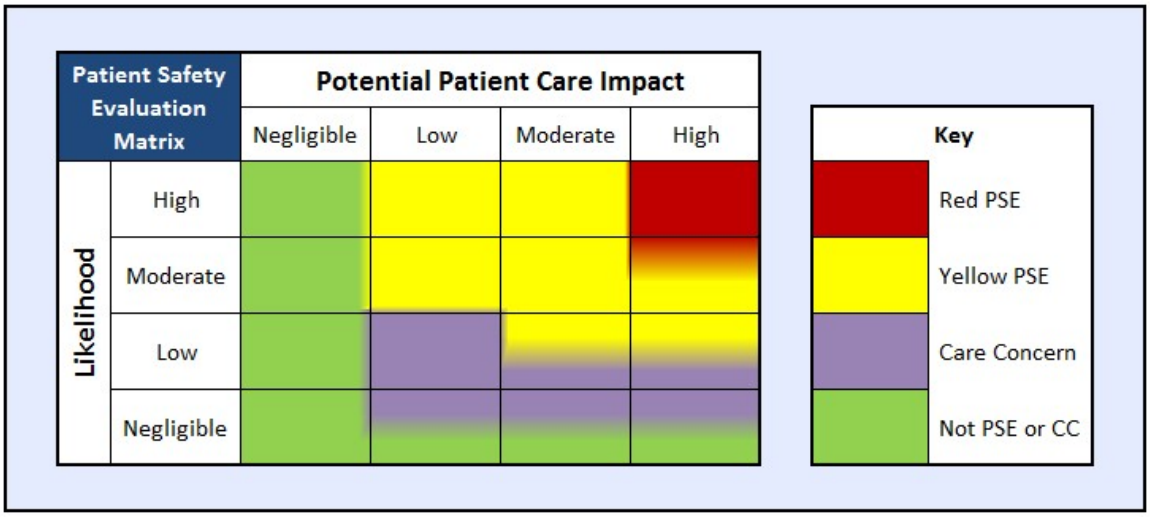
# Resolution

The following special updates are available to address this issue:

- August 2024: E11105545
- May 2024: E10910760
- February 2024: E10813676
- November 2023: E10714118
- August 2023: E10613977
- May 2023: E10518458

Until you install the special updates that address this issue, contact your Epic representative to discuss potential workaround options.

# Patient Safety Evaluation Matrix




*If you have questions or concerns about the content of this notification, or if you'd like to report a patient safety concern, please contact one of your Epic technical representatives.*

## Important Notice

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