

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.

Title	In a Specific Scenario Involving Multiple Order Modifications, a Weight-Based or BSA-Based Medication Order Can Be Signed Without a Calculated Administration Dose, Which Makes Dose Checking Warnings for that Order Unavailable During Administration
Reference #	8588391
Products	Willow Inpatient, EpicCare Inpatient (Clinical Documentation), EpicCare Inpatient (Orders), EpicCare Ambulatory, ASAP
Versions	February 2024 November 2023 August 2023 May 2023 February 2023 November 2022 May 2022 February 2022 November 2021

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Description

CE Marked Medical Device – Urgent 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

Weight and BSA-Based Doses and Weight or BSA Types

Medication orders can be dosed based on a patient's body weight or body surface area (BSA). There are multiple types of weights that can be used to calculate doses, including:

- The patient's actual recorded weight or BSA
- The patient's ideal or adjusted body weight or BSA
- An order-specific weight or BSA that is entered by a clinician at the time of ordering

When a clinician signs a medication order with a weight-based or BSA-based dose, the system calculates the corresponding administration dose using the specified weight and weight type. The calculated administration dose is stored in the Calculated Administer Dose (I ORD 34115) item in the order record for the weight-based or BSA-based medication order. All active weight-based and BSA-based medication orders are expected to have a calculated administration dose in this item.

Significant Weight Changes

If a clinician documents the patient's weight and that documented weight increases or decreases from the currently documented weight by more than a certain threshold, a warning appears to the clinician documenting the weight, prompting them to confirm that the newly documented weight is accurate. The threshold is determined by the value in the Weight Change Warning Percentage (I LSD 34154) field in EMR System Definitions (Age, Height, Weight > Weight Settings screen). This threshold can be overridden in profiles by entering a value in the Weight Change Warning Percentage (I LPR 2138) field (Age, Height, Weight > Weight Validation screen). If both fields are left blank, the system uses a default threshold of 10%.

Live-Edit Modifications

When a clinician modifies an active inpatient medication order and signs their changes, the system typically cancels the original order and creates a new order behind the scenes to replace it. However, you can configure the system to preserve the original order if only certain kinds of modifications are made, such as changing the end time or administration instructions. An edit that doesn't cause the original order to be replaced with a new order is called a live-edit modification. The modifications that result in a live-edit modification are determined by the Allowed Medication Modifications field (I LSD 25000) in EMR System Definitions (Medication, Allergy, Imm, etc. > Reorder, Modify, Discontinue > Inpatient Allowed Order Modifications screen).

Pharmacy Verification and Autoverification

Before medications are dispensed, a pharmacist typically reviews the medication orders and verifies that the medication orders are accurate, complete, and safe. Alternatively, you can configure the system to autoverify certain medication orders that meet configurable conditions. When a medication order is autoverified, it does not require manual pharmacist review.

If a pharmacist clicks Verify for a weight-based or BSA-based order that is missing either a weight or weight type or BSA or BSA type, respectively, a warning appears and prevents the pharmacist from completing the verification action. Likewise, autoverification for a medication can't be completed for a weight-based or BSA-based medication order that is missing either a weight or weight type or BSA or BSA type, respectively.

However, neither the Verify Orders activity nor the autoverification feature programmatically checks for the presence of a calculated administration dose when a weight-based or BSA-based medication order is verified or autoverified.

Dose Validation During Administration

When a clinician documents the administration of a weight-based or BSA-based medication order in the Medication Administration Record (MAR), they can refer to the calculated administration dose that appears for the medication's due time. When a clinician scans

a medication barcode during administration workflows, the calculated administration dose is compared to the dose populated from the barcode scan to inform the clinician whether they are administering the expected dose of medication to the patient. Alternatively, if a clinician manually clicks a due time instead of scanning, the calculated administration dose is populated by default in the Dose field in the MAR Administration form.

Issue Overview

In a system configured as described below, when the following workflow is performed, the system clears the Calculated Administer Dose (I ORD 34115) item for a weight-based or BSA-based medication order, and that order might be documented in the MAR without the dose being validated to match the ordering provider's intended dose:

1. A clinician signs an order with a weight-based or BSA-based dose (hereafter referred to as the weight-based order).
2. The same clinician or another clinician modifies the order from step 1 by changing the dose to a non-weight-based or non-BSA-based dose. In doing so, the clinician either manually clears the weight type or BSA type (hereafter referred to as the weight type) before they change the dose, or the weight type is automatically cleared because of a significant weight change having been documented for the patient after the signing of the order in step 1. The clinician signs the modification.
3. The same clinician or a different clinician modifies the weight-based order again, this time changing the dose back to a weight-based dose. When the clinician closes the Order Composer, the system clears the calculated administration dose, the selected weight, and the selected weight type for the weight-based order.
4. The clinician does either of the following in the same ordering session as step 3, both of which cause the system to re-add the selected weight and selected weight type from step 3 to the version of the weight-based order waiting to be signed. However, these actions don't cause the system to recalculate an administration dose:
 - Modifies an order other than the weight-based order.
 - Reopens and closes the Order Composer for the weight-based order.
5. The clinician signs the modification. While the weight and weight type from step 3 are saved to the order because they were re-added by the system in step 4, no dose is saved to the Calculated Administer Dose (I ORD 34115) item in the weight-based order.

At this point in the workflow, the weight-based order no longer has a calculated administration dose. If the system has been configured to send the weight-based order to the verification queue, and a pharmacist opens the order in the Verify Orders activity, no warning appears to indicate that the order is missing a calculated administration dose, and the pharmacist can proceed to verify the order without adding one because the order does have a weight, weight type, and order dose. If the order is configured to be autoverified, the order is autoverified without a calculated administration dose.

If a nurse opens the MAR administration form by scanning the medication, the Dose field is populated with the size of the medication package the nurse scanned. If only a portion of the package should be administered instead of the entire package, the nurse is not presented with a warning to indicate that they might be administering a different dose than the ordering clinician might have intended.

If a nurse clicks a due time for the weight-based medication order in the MAR instead of scanning the medication barcode, the Dose field in the administration form is blank. If they enter a dose, no validation occurs to check that the dose they entered matches the dose the ordering clinician might have intended.

Configuration

This issue affects systems that allow live-edit modifications, which is the case if there is at least one value in the Allowed Medication Modifications field (I LSD 25000) in EMR System Definitions (Medication, Allergy, Imm, etc. > Reorder, Modify, Discontinue > Inpatient Allowed Order Modifications screen).

Note that this issue does not occur for persistent clinic-administered medication orders, because clinicians can't perform live-edit modifications for these orders. Whether a clinic-administered medication order is persistent or non-persistent depends on several layers of configuration, as described in the [Support Clinic-Administered Medications That Need to Be Administered Multiple Times](#) topic. Because of the variety of relevant settings and because of the many possible details that can be entered for different individual medication orders, only certain orders placed from a given ambulatory department might be affected. The fixes described in the Resolution section resolve the issue for non-persistent clinic-administered medication orders that would previously have been affected.

Example Workflow

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

1. A clinician signs an order for oxycodone solution, selecting a dose of 0.1 mg/kg. The patient's recorded weight is 3 kg. This patient also has an order for acetaminophen solution.

Dose: mg/kg

Weight Type:

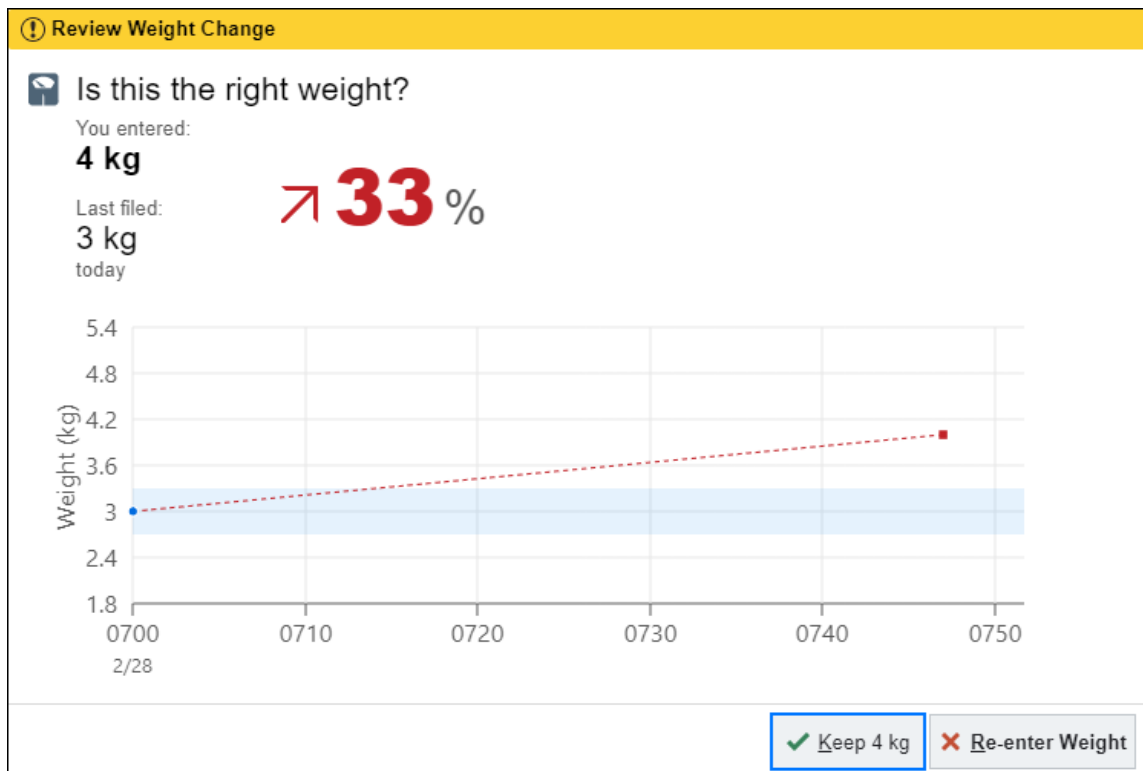
Additional Details: Weight: 3 kg (less than 1 hour ago)

Calculated dose: 0.3 mg = 0.3 mL ⓘ

New Orders

oxyCODONE (Roxicodone) solution 0.3 mg
0.3 mg (0.1 mg/kg × 3 kg), Oral, Every 6 hours PRN, severe pain, Starting today at 1502
Maximum MME/Day: 1.8 MME/Day for this order

2. In the Flowsheets activity, a clinician updates the patient's weight from 3 kg to 4 kg, and the Significant weight change warning appears. The clinician overrides this warning and files the updated weight value.



3. A clinician modifies the oxycodone solution order, changing the dose from the weight-based dose of 0.1 mg/kg to a dose of 0.3 mg. The clinician closes the Order Composer and signs the modified order.

Dose:

Calculated dose: 0.3 mL

Orders to Modify

oxyCODONE (Roxicodone) solution 0.3 mg
 0.3 mg, Oral, Every 6 hours PRN, severe pain, Starting today at 1510
 Maximum MME/Day: 1.8 MME/Day for this order

- A clinician modifies the oxycodone solution order again, changing the dose from 0.3 mg to the weight-based dose of 0.1 mg/kg.

Dose:

Weight Type:

Additional Details:
 Weight: 4 kg (less than 1 hour ago)

Calculated dose: 0.4 mg = 0.4 mL ⓘ

Orders to Modify

oxyCODONE (Roxicodone) solution 0.4 mg
 0.4 mg (0.1 mg/kg × 4 kg), Oral, Every 6 hours PRN, severe pain, Starting today at 1514
 Maximum MME/Day: 2.4 MME/Day for this order

- When the clinician closes the Order Composer for the modification in the previous step, the Summary Sentence for the oxycodone solution order is updated, and while the weight-based dose remains, the calculated administration dose, the weight, and the weight type are removed from the order.

Orders to Modify

oxyCODONE (Roxicodone) solution 0.1 mg/kg
 0.1 mg/kg, Oral, Every 6 hours PRN, severe pain, Starting today at 1514
 Maximum MME/Day: Unknown for this order

- In the same ordering session, the clinician modifies the acetaminophen solution order from step 1, changing the dose from 12 mg/kg to 10 mg/kg. This causes the weight and weight type the clinician selected in step 4 to be re-added, but the system doesn't recalculate the administration dose.

Dose:

Weight Type:

Additional Details:
 Weight: 4 kg (less than 1 hour ago)

Calculated dose: 41.6 mg = 1.3 mL ⓘ

Orders to Modify

oxyCODONE (Roxicodone) solution 0.1 mg/kg
0.1 mg/kg, Oral, Every 6 hours PRN, severe pain, Starting today at 1529
Maximum MME/Day: Unknown for this order

acetaminophen (Tylenol) solution 41.6 mg
41.6 mg (rounded from 40 mg = 10 mg/kg × 4 kg), Oral, Every 6 hours PRN, fever, Starting today at 1530
ADMIN

7. The clinician signs both modified orders.
8. In the Verify Orders activity, a pharmacist verifies the order. The order dose, weight, and weight type are present on the order, which allows the pharmacist to verify the order without a calculated administration dose.

oxyCODONE (Roxicodone) solution 0.1 mg/kg New

0.1 mg/kg, Oral, Every 6 hours PRN, Starting on Mon 2/26/24 at 1529, Until Discontinued, severe pain

Clinical details were modified from **oxyCODONE (Roxicodone) solution 0.4 mg**

Interactions Edit i-Vents New i-Vent Order Hx Show Charge Label Preview Inventory

Clinical Details

Order Dose 0.1 mg/kg	Route Oral	Frequency Every 6 hours PRN
Admin Dose Not calculated	Volume 0.4 mL	PRN Reasons severe pain
Weight Recorded (4 kg)	<input checked="" type="checkbox"/> Calculate Volume	For Until discontinued
		Starting Today 1529

Additional Details

9. A nurse scans a 5 mg cup of oxycodone solution in the MAR. The Dose field is populated with the package size of 5 mg, rather than the ordering clinician's intended calculated administration dose of 0.4 mg. The order name and ordered dose appear with the intended weight-based dose.

oxyCODONE (Roxicodone) solution 0.1 mg/kg
Dose: 0.1 mg/kg × 4 kg : Oral : Every 6 hours PRN : severe pain

Order Information

Dispense Location: EMH Central Pharmacy
Frequency: Every 6 hours PRN
Route: Oral
Ordered Dose: 0.1 mg/kg × 4 kg
Priority: Routine
Order ID: 1062205
Order Start Time: Today 02/26/24 at 1529
PRN Reasons: severe pain

Administration Details

Action Given	Date 02/26/2024	Time 1534	Comment
Route Oral	Site		
Dose 5 mg			
Order Concentration: 1 mg/mL Scanned Concentration: 1 mg/mL			

Resolution

The following special updates are available to resolve this issue:

- February 2024: E10803289
- November 2023: E10707888
- August 2023: E10611136
- May 2023: E10516693
- February 2023: E10418246
- November 2022: E10319364
- May 2022: E10231674

Until you validate and install the special updates resolving this issue, you can limit the potential impact of this issue by building a BestPractice Advisory to detect instances of the issue and warn pharmacists and nurses when the issue occurs. We have created two BestPractice Advisories for this purpose, one for nurses documenting administration in the MAR and one for pharmacy users. Your Technical Services representative can deliver these records to you in a Turbocharger package.

If you detect an instance of this issue occurring, pharmacists can resolve the issue for the affected weight-based or BSA-based order by reverifying the order and clicking the Recalculate Dispense Details button in the Verify Orders activity. When they click this button, the system automatically calculates the appropriate administration dose and populates the Calculated Administer Dose (I ORD 34115) item for the order.

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oxyCODONE (ROXICODONE) 5 mg/5 mL solution 0.1 mg/kg (Dosing Weight) New
0.1 mg/kg (Dosing), Oral, Every 6 hours PRN, Starting on Wed 2/21/24 at 1833, Until Wed 3/6/24 at 1830, other, QAN Test

Clinical details were modified from oxyCODONE (ROXICODONE) 5 mg/5 mL solution 0.1 mg

Interactions Edit i-Vents New i-Vent Order Hx Show Charge Label Preview Order: 1995860620

Inventory Report Messages Dispense

Clinical Details

Order Dose 0.1 mg/kg	Route Oral	Frequency Every 6 hours PRN
Admin Dose Not calculated	Volume 5 mL	PRN Reasons other, QAN Test
Weight Dosing (4.5 kg)	✓ Calculate Volume	For 335 Hours
		Starting Today 1833
		Ending 3/6/2024 1830

Products to Dispense

Product	Order Dose	Admin Dose	Dispense	Package
OXYCODONE 5 MG/5 ML ORAL SOLUTION	0.1 mg/kg	--	5 mL	5 mL Cup

Dispense Details

Dispense From
UNCH 6CH PYXIS 2

First Doses
UNCH 6CH PYXIS 2

Dispense Code
Unit Dose

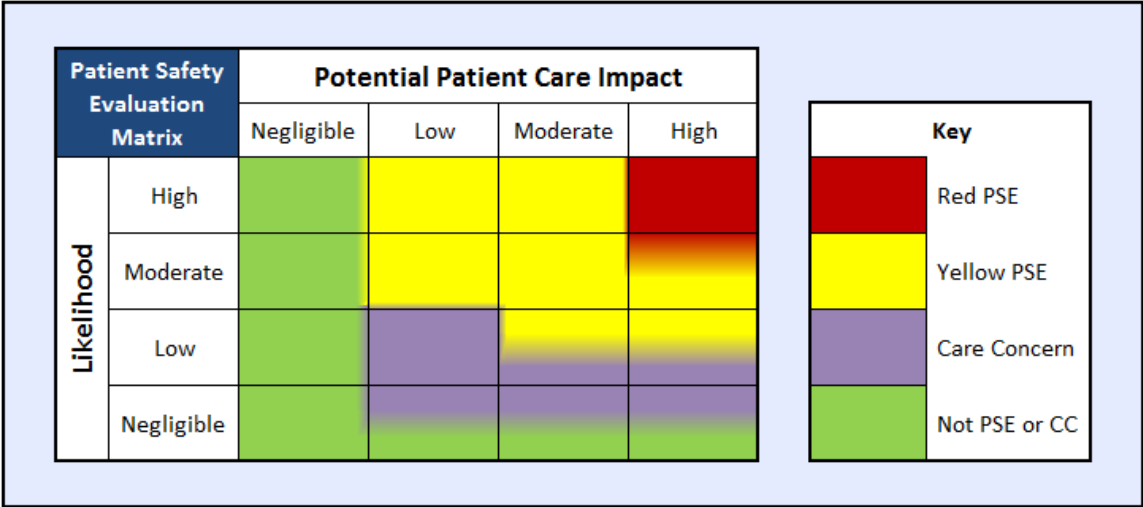
Other Details

Ordered by
Guerra, Peter J Today 1834

Reference Links
NC Controlled Substance Reporting System NC STOP Act Lexicomp Lexicomp Pediatric UNC Health Medication Formulary

Interactions
Drug-Drug (Severe Interaction)

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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