

Urgent Field Safety Notice

Flash Number: FLASH21-0397-0

Solution Name: *i.s.h.med*

Subject: *i.s.h.med* Medication: After you import collective note number 3072109 and note number 3069051 the system does not correctly re-assign medication events during case revision (reassign visit)

Impact:  **Patient Care**

Summary: The system behavior during case revision has changed with regard to the medication due to the collective note 3072109 (code) and note number 3069051 (info) from July 2021.

August 10, 2021: This flash is no longer preliminary. All sections of this flash are updated with clarifying information including the subject and summary.

August 3, 2021: Original, preliminary flash publication date.

Release: *i.s.h.med* 6.18 EHP SP26.1
i.s.h.med 6.17 EHP SP37.1

Role Targeted: Management and employees of the IT department, physicians, nursing staff, system administrators

Publication Date: August 10, 2021

Description

Collective note 3072109 and note number 3069051 from July 2021 modified the system behavior during case revision, specifically reassigning a visit to another case of the patient, with regard to medication. If an order exists with events that are flagged as “administered”, or if an anamnestic order is saved for the case, the system will reject the case revision for patient safety reasons. However, if it is possible to execute case revision, and administration events exist that are “filled”, changed or canceled, the changes made are lost, as events are automatically re-generated according to the dosage regulations during case revision.

Impact Details

This affects the workflow because case revision can no longer be executed in many situations. Whenever there is at least one administered event, or if there is at least one anamnestic order saved for a patient, the system displays an error message during case revision, which means that the action cannot be continued.

The following effects occur if case revision can be executed:

- The patient can receive an unplanned dose of medication in the following example situations:
 - If a drug is suspended for one day during surgery preparation and the user has canceled all doses for this day, the system incorrectly re-generates these events as valid events, due to case revision. The patient could therefore receive this drug unintentionally.
 - If you modify the dose of a medication administration (increase or decrease it), this modification is lost after case revision, because the system incorrectly re-generates the events in accordance with the original dosage definition of the order. The intended dose may be lost, and the patient could receive an unintended dose.
- Furthermore, there is a risk that drugs may be distributed a second time. Drugs in status “filled” are generated in status “confirmed” (internal status 200) due to case revision. These therefore appear in medication event views as “not filled”. Clinical users could therefore unintentionally dispense the drug a second time, and the patient could receive a second dose of the drug.
The same applies to all other event statuses, e.g. “prepared” or “validated”.

Circumstances

In a test environment, where note number 3072109 has already been imported, create an outpatient case with an outpatient visit for a patient and generate an active medication order with several events.

Create an additional inpatient case for the same patient.

Proceed as follows:

1. Change the dose of a medication event.
2. Cancel a medication event by setting the dose to 0 in the Day's Events chapter.
3. Flag a medication event as “filled” or “validated” by setting a corresponding event status in the clinical work station.
4. Administer an event on the clinical work station.

Enter the transaction NP10 (IS-H Case Overview) for the patient, who just are currently creating. Select the outpatient visit of the outpatient case, and the inpatient case.

Select the function Menu -> Case Revision -> Move Visit.

Observation: The system displays an error message that it cannot execute case revision due to an administered event.

In the clinical work station toggle to a suitable view of the Medication Events view type and cancel the administered event.

Execute case revision as described above again.

Observation:

It is now possible to execute case revision, but the following effects are visible:

1. The status of all newly created events is “confirmed”.
2. Manual dose changes no longer exist.
3. Manually canceled events are re-generated.

Affected Sites

- **Other terms:** i.s.h.med Medication
- **Reason and Prerequisites:** Implementation of collective note 3072109 and note number 3069051, which are part of the Support Packages (see below).

This error occurs with the following Support Packages:

Release	Support Package
i.s.h.med 6.18	SP26.1
i.s.h.med 6.17	SP37.1

Note: If a Support Package contains an error, this exists until it is corrected in every subsequent Support Package as well as compatible Support Packages in previous releases. These Support Packages are not listed individually above.

Resolution

Check whether you have imported note numbers 3072109 and 3069051.

If you have imported the notes, we would ask you to remove the again from all environments (test, productive) using the translation SNOTE.

If removal from a productive environment is not possible, inform your users that they may no longer execute case revision, until we have provided a new note. Check all records to see if case revision has generated any incorrect events.

We have taken back the notes. You can no longer import them using SNOTE.

Cerner is still working on an error correction and will deliver this as soon as possible via a new correction note. Please also refer to the product documentation.

Reference

[Unique Device Identifier \(UDI\)](#)

Action

If you have imported the notes on a productive environment and have also executed case revisions during this time, we would ask you to check that the medication of these patients is correct and manually adjust this, if necessary.

In case of questions, please contact Cerner's i.s.h.med Support.

Forward this flash to the relevant employees as soon as possible.

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