



To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 240 dated 19/11/2023 Regarding NCMDR field safety corrective action of Change Healthcare Radiology Solutions from (mfr: Change Healthcare).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information





Circular No. 240/2023

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2040
Vision

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19 -11-2023

Field Safety Corrective Action of Change Healthcare Radiology Solutions from Change Healthcare.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=19766
Product	Change Healthcare Radiology Solutions.
Description	PACS.
Manufacturer	Change Healthcare.
The affected products	Change Healthcare Radiology Solutions 14.0: (01)17540262030020(10)140000 Change Healthcare Radiology Solutions 14.1: (01)17540262030037(10)140100 Change Healthcare Radiology Solutions 14.2: (01)17540262030044(10)140200.
Reason	If study information from the CHRS database includes certain special characters (<, >, &, ", ') and is used for creating outgoing messages, sent using the CHRS PACS event notification service, the notification will fail when a special character has been included in at least one of the outgoing fields (see attached) which are not checked for special characters.
Action	1. Users are advised to check the CHRS Exception Tracker on a regular basis, as failed updates will be listed with details on the failure. 2. A software update has been developed by Change Healthcare that will address this issue for all impacted versions. 3. Contact the local agent for remedial action.
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General



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Urgent Field Safety Notice

October 18, 2023

To: Change Healthcare customers with Change Healthcare Radiology Solutions 14.0, 14.1, 14.2

Re: Update messages from Change Healthcare Radiology Solutions (CHRS) may not update patient or study records in external applications

If study information from the CHRS database includes certain special characters (<, >, &, ", ') and is used for creating outgoing messages, sent using the CHRS PACS event notification service, the notification will fail when a special character has been included in at least one of the following outgoing fields which are not checked for special characters:

- Patient Gender
- Deleted Patient Last Name
- Deleted Patient First Name
- Deleted Patient Middle Name
- Original Target Patient Public ID
- Original Target Patient Context Code
- Modality
- Study Procedure Code
- Study Procedure Description
- Requesting Physician

The PACS Event Notification service is one of several methods used to sync data values on interfaced systems. This issue only impacts interfaced applications that receive PACS event notification communications from CHRS.

Products affected:

Change Healthcare Radiology Solutions 14.0: (01)17540262030020(10)140000

Change Healthcare Radiology Solutions 14.1: (01)17540262030037(10)140100

Change Healthcare Radiology Solutions 14.2: (01)17540262030044(10)140200

Circumstances under which the issue occurs:

Currently Change Healthcare systems leveraging the PACS event notification service for messaging include Change Healthcare Workflow Intelligence (CHWI) and Change Healthcare Image Repository (CHIR). Other applications, such as secondary PACS, RIS systems, other overlay products and third-party VNA's may be impacted if they are configured to use the PACS event notification service. These systems will only be impacted if study information from the CHRS database includes certain special characters (<, >, &, ", ') and is used for creating outgoing messages sent using the CHRS PACS event notification service.

This failure can cause data quality issues in any system that receives PACS Event Notifications from CHRS. This failure has the potential to result in data values, in interfaced applications, that are not in sync with actions performed on CHRS data. For example, a patient is merged in CHRS and the non-surviving patient record (deleted patient last name value) has a last name of O'Brian. The special character in the deleted patient name causes the merge message to fail to send to the interfaced system. Therefore, the intended non surviving patient record would be deleted in the PACS database but would persist in the interfaced database. This creates a situation where the interfaced database contains a patient record that is missing studies.

Risk to patient:

The most serious potential impact to a patient would result from accessing incorrect data (data that is out of sync with the CHRS database) from an interfaced system to inform patient management. If content viewed in an enterprise viewer is adversely affected by this issue, routine critical results communication workflows should prevent this issue from causing serious impact to patients; however, incorrect data interpreted in a secondary PACS could lead to misdiagnosis.

Although an incorrect radiology interpretation worklist is also a potential source of an impact, department quality processes and clinical awareness and heightened communication for care of critically ill patients are environmental controls that can mitigate against patient impact.

Immediate actions to take to reduce patient impact:

Users are advised to check the CHRS Exception Tracker on a regular basis, as failed updates will be listed with details on the failure.

Product updates that will address the issue:

Change Healthcare has developed a software update that will address this issue for all impacted versions.

Recommended actions to take on potentially affected data:

Impacted data can be identified by using the CHRS Exception Tracker. Customers are advised to review records of recent updates from CHRS to external systems and manually update any changes to study records that may have been missed.

This notice must be distributed to all personnel within your organization who need to be aware of this Urgent Field Safety Notice. Customers should alert other affiliated parties that may be affected by this Urgent Field Safety Notice.

To ensure effectiveness of any required corrective actions, please maintain awareness of this Urgent Field Safety Notice until the issue has been fully resolved.

To acknowledge your understanding of this urgent field safety notice please complete and return the acknowledgement letter. To request the installation of the product update on your system, please contact our Customer Support department. You can find the toll-free number for your region at <https://iwcrm.changehealthcare.com>.

If you have any questions or need further clarification about this notice, please do not hesitate to reach out to our Customer Support department using the toll-free number provided in the link above.

Once again, until the product update is installed at your site, Change Healthcare recommends that the immediate actions to avoid the issue by reviewing updates from CHRS to downstream systems be taken.

A copy of this field safety notice has been submitted to the appropriate regulatory agency.

Thank you.

Sincerely,

Ketan Paranjape
COO, Enterprise Imaging, Optum