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AND BY POST

Dr. Liliane Field,
Assistant Coroner for London Inner South
1 Tennis Street
London
SE1 1YD

9 December 2025

Dear Madam,

Re: <u>Response to Regulation 28 Report to Prevent Future Deaths dated 14 October 2025</u>

1. This is Oracle Corporation UK Limited's (formerly Cerner Limited) ("**Oracle Health**") response (the "**Response**") to the Regulation 28 Report to Prevent Future Deaths dated 14 October 2025 (the "**Report**"). The Report was issued by Assistant Coroner Dr. Liliane Filed (the "**Assistant Coroner**") following an Inquest opened on 20 January 2022 into the death of Paula Doreen Hughes (the "**Deceased**") on 1 January 2022 (the "**Inquest**"). Oracle Health was not invited to participate in the Inquest or given an opportunity to make representations and was not aware of it, or the findings of the Assistant Coroner, until receiving the Report.

A. EXECUTIVE SUMMARY

2. Oracle Health was saddened to learn of, and deeply regrets, the various medical omissions at the Queen Elizabeth Hospital ("**QE Hospital**") and extends its condolences to the family of the Deceased and others bereaved. Oracle Health assures the Deceased's family that the contents of the Report are taken extremely seriously. While there is no suggestion that Oracle Health's Millennium software deployed at the QE Hospital was in any way at fault or contributed to the Deceased's death, Oracle Health has conducted a detailed review of that software in response to the Report and concludes as follows (key findings are highlighted in **bold** throughout):

    2.1. Oracle Health was invited to comment on one specific issue in the Report, out of a number of identified issues, which issue related to concurrent prescriptions of paracetamol and duplicate checking functionality. Further to its review, Oracle Health has not identified any evidence of any defect or deficiency in its software.

    2.2. Millennium's United Kingdom ("**UK**") default configuration has had the functionality to display alert notifications to protect against paracetamol overdosing at the stage it: (i) is ordered or prescribed, since before go-live at Lewisham and Greenwich NHS Trust ("**LGT**")*;* and (ii) is administered to patients, since August 2022, although this functionality had been used in United States of America ("**USA**") deployments previously.

2.3.   Whether NHS Trust ("**Trust**") clients choose to enable these features, or develop their own solutions independently, involves consideration of how alert notifications integrate with Trust clinical workflows. There is also a general need to guard against 'alert fatigue'.

2.4.   Oracle Health has no record of LGT raising any relevant service or test issues as part of the deployment testing process or subsequent to the systems going live. Approaches to safeguard against paracetamol dosing incidents were discussed with a number of Trust clients, including LGT, at a regular quarterly meeting in June 2024.

2.5.   Oracle Health does not consider that any further code development of alert notifications is required, but it continues to augment the content and function of all alert notifications and Millennium in general. Oracle Health will continue to work closely with its Trust clients to inform and educate them on the available functionality.

B. ORACLE HEALTH AND MILLENNIUM

3.   Oracle Health's Millennium software has been successfully deployed globally, first in the USA in 1984 and, since 1986, internationally. Oracle Health has licensed its solution at 28,000 facilities around the world, and has adapted Millennium to various types of facilities, including 3,000 hospitals, 3,500 physician practices, 200 home health facilities and 200 employer sites. Oracle Health's clients include over 40 NHS Trusts.

4.   Oracle Health designed Millennium as an electronic patient record ("**EPR**") solution. The solution creates an electronic medical record through which physicians can access near real time data. By organising the data around the patient, rather than the patient encounter, Millennium eliminates duplication and places data only once in a central repository. Millennium enables information from disparate clinical domains and multiple facilities to be seamlessly integrated.

5.   The Millennium solution currently comprises nine solution and service sets with sub-modules. The relevant sub-modules for the purposes of this Response are **PowerChart** and **Discern Expert**. As explained in more detail below, these sub-modules manage patient information, streamline workflows, and improve clinical decision-making. Common uses include the creation of workflows and rules for documenting patient encounters, ordering medications and tests, reviewing lab results, and supporting clinical documentation.

C. CONFIGURATION AND DEPLOYMENT AT LGT

6.   On 21 March 2013, LGT signed an agreement to implement Oracle Health's Millennium solution. Millennium went live at LGT, including the QE Hospital in around 2018.

7.   There are no specific Government or NHS regulations, or guidance, governing duplicate checking functionality for prescriptions in electronic healthcare systems. However, as an experienced industry leader in electronic healthcare, Oracle Health has developed content, workflows, and decision support to help meet the potential needs of its client base.

8.   The initial steps in the deployment of the Millennium solution involves an assessment of a client's existing systems, an evaluation of their objectives and a demonstration of the relevant solutions in default configuration. Following the initial consultation process, Oracle Health typically hosts a series of design and configuration workshops ("**D&C Workshops**"), covering key aspects of the Millennium software.

8.1. These D&C Workshops are generally attended by subject matter experts empowered to make design decisions on behalf of the particular client and afford an opportunity to tailor certain aspects of the system's functionality to the specific needs and workflows of the particular client. It is critical to the success of deployments that appropriate decision-makers attend these sessions and they are required to have a solid understanding of the workflow processes within their areas of expertise.

8.2. The D&C Workshops cover, and provide an opportunity to customise, specific sub-modules such as Discern Expert, which contains configurable rules through which certain alert notifications within Millennium can be enabled and the circumstances defined in which they are triggered ("**Rules**"). They also cover other sub-modules, such as PowerChart, which contains other types of alert notifications that can be customised and generated, based on clinical information provided to Oracle Health, relating to, e.g. Drug-Allergy, Drug-Drug Interaction, and Duplicate checking.

9. As described below, Oracle Health continuously engages in ongoing dialogue with its clients regarding potential software code and configuration enhancements to its Millennium solutions. Post go-live, it is also common for Trust clients, including LGT, to develop enhancements or adjust configurations in conjunction with internal I.T. teams. Oracle Health does not always have visibility over these 'in house' developments and cannot therefore comment on them.
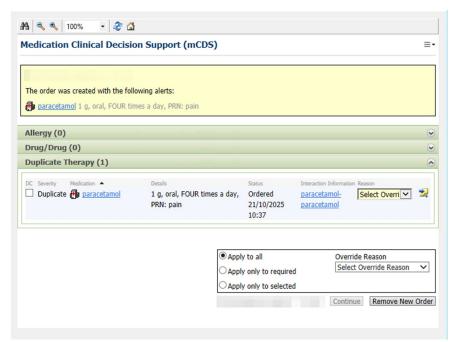
D. DOSAGE ALERT NOTIFICATIONS IN DEFAULT CONFIGURATION

10. Oracle Health understands that the Assistant Coroner was provided with screenshots and an oral description of certain aspects of Millennium as configured at LGT. However, the Assistant Coroner may not have had the benefit of a description of the relevant functionality that exists within Millenium in UK default configuration, without any pre or post deployment overlay by LGT.

11. In UK default configuration, Millennium is capable of displaying two main types of alert notifications to protect against overdosing:

11.1. **Prescription Duplicate Alert Notification:**

11.1.1. **The duplicate checking functionality, if enabled, can generate an alert notification at the stage medicines are <u>ordered, or prescribed</u>, by a user such as a clinician. This functionality was available before LGT went live in 2018.**

11.1.2. Medication, including paracetamol, is generally prescribed by clinicians using the 'order' tab within a patient's EPR. After selecting the relevant medicine, prescribers are directed to complete order entry details before signing the order to complete the prescription.

11.1.3. The system has the ability, or functionality, to display an alert notification during the ordering process, warning the user that the medicine sought to be prescribed is a duplicate of a prescribed medicine that already appears within the patient's record ("**Prescription Duplicate Alert Notification**").

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Screenshot 1: Prescription Duplicate Alert Notification

11.1.4. **As noted above, this functionality was available at the time Millennium went live at LGT, but historically Trust clients have chosen not to enable it at deployment.** Trust clients can make this decision for various reasons. This includes, for example, a desire to avoid 'alert fatigue'[1] where there may be good clinical reasons for exceeding certain standard prescription parameters, including the needs and characteristics of a particular patient. Excessive alerting can render alert notifications ineffective and also interfere with clinical workflows. The number, type and frequency of alerting is typically something that is discussed extensively during the design and configuration workshops. However, Trust clients may also choose to wait until after go-live to determine what type of alert notifications would best support their particular needs.

11.1.5. Millennium's alert notification functionality has been enhanced over the years so that it is now possible, for example, for Trust clients to specify the circumstances in which the alert notification will be displayed. For example, a Trust client can adjust the settings so that the alert notification only fires during specific stages of a patient's journey in hospital, to avoid the alert being over-inclusive and capturing prescriptions that are not relevant at that particular stage of treatment. However, even with the enhancements, clients still need to consider the risks of 'alert fatigue' and this is one reason why many clients are yet to utilise this functionality.

11.1.6. The Report states that "*The Cerner prescribing system offers a duplicate checking functionality that is not a standard feature. It is hard stop and can be overridden and was not adopted by the LGT when the system was introduced*". By way of clarification: (a) **the Prescription Duplicate Alert Notification is a standard feature within Millennium's UK default configuration, but it is not always enabled by Trust clients including for the reasons identified at paragraph 11.1.4 above**; and (b) in this context, "*hard stop*" has a specific meaning and refers to alert notifications that cannot be dismissed and which require specific action or
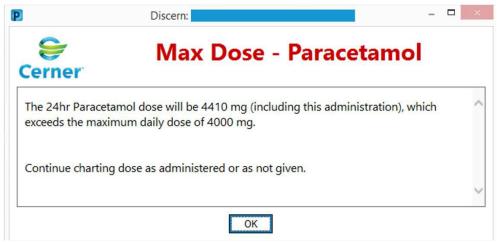
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[1] Broadly defined as a high volume of alert notifications causing users, including clinicians, to become desensitised and ignoring, or failing to respond appropriately to such, alert notifications.

confirmation by a user there and then: they cannot be "*overridden*". This is one of the configuration options available within Millennium's prescribing system but is not mandated, and other configuration options do exist, which allow alerts to be overridden (often with the need to document an override reason which gives visibility of the clinical reasoning behind the decision to override).

11.2. **Administration Alert Notification:**

11.2.1. *Second*, **since August 2022, the Rules in the UK have been capable of generating an alert notification at the stage paracetamol is actually <u>administered</u> to patients.** The implementation of this functionality in the UK followed the introduction of a similar alert notification for equivalent medication in the USA several years previously.

11.2.2. To administer medicine, the recommended workflow is that users, such as nurses: (i) access a patient's 'Medication Administration Record' within PowerChart to conduct a holistic review of that patient's drug chart; (ii) proceed to the 'Medication Administration Wizard' and scan a patient's wristband to verify identity; and (iii) use the Medication Administration Wizard to administer the medication. It is recommended that the user also scans the individual medications within the Medications Administration Wizard to ensure a match to the prescription held on the system before administering the medicine. Users are also able to perform these same checks by manually selecting the medication to be administered and performing a visual check of the medication.

11.2.3. Whether using the scanner or manually, the Rules can generate an alert to warn a user that the proposed administration of paracetamol would result in a dose exceeding the maximum recommended daily limit for that particular patient within a 24-hour window ("**Administration Alert Notification**"):

Screenshot 2: Administration Alert Notification

11.2.4. Similar to the Prescription Duplicate Alert Notification functionality, the Administration Alert Notification functionality has also been enhanced and updated subsequent to its original implementation. **Oracle Health has not been asked by LGT to assist with the implementation of the Administration Alert Notification, and it is not known whether it has introduced the alert notification itself**. Oracle Health notes that the reference in the Report to "*refinements of the system significantly reduced therapeutic excesses of paracetamol based on weight*" tends

to suggest that LGT has introduced the Administration Alert Notification, or a similar variant, in some form.

E. TESTING, TRAINING AND ONGOING MONITORING

12. Oracle Health has no record of LGT raising any relevant service or test issues as part of the deployment testing process or subsequent to the systems going live.

13. Oracle Health holds Special Interest Group ("**SIG**") meetings approximately every quarter, which enable Oracle to share enhancements, upgrades, and best practices with regard to Millennium functionality. They also enable clients to come together and present on any issues encountered within particular fields. At a SIG meeting in September 2022, Oracle Health introduced the Administration Alert Notification in the UK, including details about its form, how the alert is triggered, and how Trusts could seek to implement it. Trust clients in attendance also provided feedback on how the alert notification might be refined in the future. At a SIG meeting in June 2024, LGT raised in general terms paracetamol dosing incidents as a topic for discussion among other Trust clients, including whether any additional alert notifications may have been implemented by those Trusts internally. At the same meeting, Oracle Heath presented updates to the Administration Alert Notification, including functionality that would take into account the patient's weight in calculating the maximum dose before triggering the alert notification.

F. POTENTIAL ENHANCEMENTS

14. As noted above, Oracle Health continuously engages in ongoing dialogue with its clients regarding software code and configuration enhancements to its Millennium solutions. Such enhancements can arise at the global, or national, level in response to the knowledge and experience gained by Oracle Health from working with its extensive client base. They can also arise in response to specific issues at the level of local deployments. In each case, Oracle Health will discuss with its client the appropriateness of taking a potential upgrade and its impact on existing workflows and the user interface. Ultimately, the decision on whether to take a particular code or configuration enhancement remains with the client and can involve clinical and commercial considerations.

15. **Oracle Health considers that the Millennium prescribing system features are appropriate and functioning as designed in respect of the risk of duplicate paracetamol doses, including the Prescription Duplicate Alert Notification and the Administration Alert Notifications. Oracle Health will continue to review and monitor awareness of this functionality among its Trust clients.**

Yours faithfully,

, Vice President, and General Manager
For and on behalf of Oracle Corporation UK Limited

Copy to:

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(ii) , Chief Executive, Lewisham and Greenwich NHS Trust, University Hospital Lewisham, Lewisham High Street, London SE13 6LH.

(iii)   █████████████, Chief Executive NHS England, Trust Office, 4ᵗʰ Floor Gassiot House, St Thomas' Hospital, Westminster Bridge Road, London SE1 7EH.

(iv)   ██████████, Chief Executive Officer, Royal Pharmaceutical Society (RPS), 66-68 East Smithfield, London E1W 1AW.

(v)   █████████████, Chief Executive Medicines and Healthcare Products Regulatory Agency (MHRA), 10 South Colonnade, Canary Wharf, London E14 4PU.

(vi)   █████████████, Chief Executive Officer, Royal College of Physicians, 11 St Andrews Place, Regents Park, London NW1 4LE.