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2 February 2018

Care Quality Commission
Health and Social Care Act 2008

Reference number: ENQ1-4529953707

Re: Stephen George Coulson (deceased)

Dear Dr.Sohal

Thank you for the Regulation 28: Report to Prevent Future Deaths dated 14 November 2017 regarding Mr Stephen George Coulson (deceased). Your letter has been forwarded to me for response as I have regulatory responsibility for acute health care in the north west of England.

In your report, you raised concerns regarding the care of Mr Stephen George Coulson at Manchester Royal Infirmary on the 30 and 31 December 2015, prior to his unfortunate death on 1 January 2016. In particular, you were concerned about:

- the system in place for the administration, documentation and audit processes associated with the use of controlled drugs
- the lack of escalation of the need to admit patients for observation and review should they fulfil the criteria to require continued observation or review prior to discharge, and
- the high level investigation with particular concern that the witness did not accept that any lessons could be learnt from the investigation surrounding the death of the deceased

I would like to thank you for bringing these matters to our specific attention.

As you are aware, Manchester Royal Infirmary is part of Manchester University NHS Foundation Trust Central (formerly Manchester NHS Foundation Trust). This NHS

trust became a new legal entity on 1 October 2017. It is registered with the Care Quality Commission ("the Commission") to provide regulated activities in accordance with the Health and Social Care Act 2008.

Manchester Royal Infirmary was last inspected on 3 to 6 November 2015 and 26 November 2015. The report was published on 13 June 2016. The overall rating for the hospital was 'good.' There were no regulatory breaches identified regarding medicines management at that time, which was prior to the death of Mr Coulson.

A requirement of registration is that organisations notify the Commission about certain changes, events and incidents that affect their service or the people who use it. NHS trusts can send most types of notification through the National Reporting and Learning System (NRLS). This includes incidents resulting in serious harm or death. However, the NRLS does not contain person identifiable information and we are not able to confirm if, and when Mr Coulson's death was reported to the Commission. We do monitor trends and mortality data and include these in regular engagement meetings with the Trust.

I will now respond to each of the concerns raised within the Regulation 28 report and action the Commission has taken in response to these.

1. **Controlled drugs – the system in place for the administration, documentation and audit of processes associated with the use of controlled drugs.**

As you are aware, the Trust have a controlled drugs policy in place. The pharmacy team within the Commission has reviewed this policy. The policy is of an acceptable standard, with some suggestions for improvements, such as making it clear who has responsibility for investigating medicines incidents, which occur outside of pharmacy. We will share these with the trust.

The policy was updated in November 2017 to include reference to an opioid patch monitoring form. The use of the form should minimise the risk of a similar incident experienced by Mr Coulson being repeated. The trust managers have informed the Commission that they plan to audit implementation of the form. We will monitor this through our quarterly engagement meetings and subsequently consider this at the next inspection, which is likely to take place between October and December 2018.

The trust must also have in place a controlled drug Standard Operating Procedures (SOPs). We will review these as part of our ongoing engagement with the trust. For your information, we have recently implemented a system of having a named pharmacist inspector who has responsibility for the Trust and who meets with the head pharmacist. They are aware of this Regulation 28 report and will include this as part of their next meeting.

2. **Observation policy – the lack of escalation of the need to admit patients for observation and review should they fulfil the criteria to require continued observation / review prior to discharge.**

As you are aware, the Trust has an observation policy in place. The most recent version is dated June 2017. This includes the policy statement that observations must be recorded on the day of discharge home. There is also an associated early warning score policy that supports escalation to more senior or medical staff for review.

During the inspection in 2015, it was noted that staff monitored patients by using an electronic early warning score system that automatically notified medical staff and some non-medical staff (such as the surgical lead pharmacist) if there was deterioration in a patient's medical condition. This process was considered to be fully embedded across the main site and all the staff we spoke with were positive about using this system.

That said, we will ensure that the use of the early warning score and escalation is considered at the next inspection. We will also continue to monitor through our quarterly engagement with the Trust.

3. **High Level Investigation – the witness did not accept that any lessons could be learnt from the investigation surrounding the death of the deceased.**

In light of the Regulation 28 report, the Commission obtained the revised action plan regarding this tragic incident, which has been submitted directly to you. This does now identify a number of lessons for the Trust.

As with other significant concerns, we will monitor the action plan through our regular quarterly engagement meetings with the Trust. We will also take into account the action plan and the implementation of these actions at the next inspection.

In addition, in light of the Regulation 28 report, we have also considered whether there is sufficient evidence to take further regulatory action regarding this matter. We have concluded, based on the information we currently hold, that there is no evidence there is a systemic issue. However, please be assured we will continue to monitor the issues you have raised from a regulatory perspective and use the information to inform future regulatory activity at the Trust.

I hope my response has been helpful in outlining the response of the Commission to the Regulation 28 report.

If you have any questions about this letter, you can make contact through our National Contact Centre using the details below:

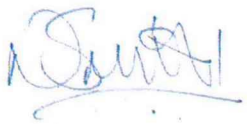
Telephone: 03000 616161

Email: Enquiries@CQC.org.uk

Write to: Care Quality Commission
Citygate
Gallowgate
Newcastle upon Tyne
NE1 4PA

It is helpful to have the reference number (above) to hand. This will help avoid any delays in responding to you.

Yours sincerely



Nicholas Smith
Head of Hospital Inspections (North West)