HSCA Further Information
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HM Area Coroner Ms Emma Brown, for Birmingham and Solihull

[redacted]

12 April 2024

Care Quality Commission
[redacted]

Dear HM Coroner Brown

Prevention of future death report following inquest into the death of Steven Sanders

Thank you for addressing the Regulation 28 prevention of future deaths report to the Care Quality Commission (CQC) following the death of Steven Sanders This letter represents CQC's formal response to your Regulation 28 report.

Relevant regulatory context

The CQC was established on 1 April 2009 by the Health and Social Care Act 2008 ('the Act'). The CQC is the independent regulator of healthcare, adult social care, hospital and community trusts and primary care services in England. The CQC also protects the interests of vulnerable people, including those whose rights are restricted under the Mental Health Act.

The Act introduced a single registration system which applied to both healthcare and adult social services. Once registered with the CQC, providers such as St Andrew's Healthcare Birmingham (SAH) were required to comply with conditions placed on their registration, as well as the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 ('Regulated Activities Regulations 2010') and the Care Quality CQC (Registration) Regulations 2009 (RR 2009). The Regulations set out the essential standards of quality and safety that service users had a right to expect. The Regulated Activities Regulations 2010 were replaced by the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (RAR 2014), which came into effect from 1 April 2015.

While the essential standards contained in RAR 2014 set out the relevant standards that registered providers must meet, they do not prescribe how exactly and what precisely registered providers must do to meet them; those are things that the registered provider must determine in order to meet the standards and duties set out in Act, RAR 2014 and RR 2009. It is the primary responsibility of a registered provider such as SAH to develop and implement adequate policy and process to ensure that those duties, responsibilities, and standards are met. To assist providers, CQC have published details of our key lines of enquiry and rating characteristics and guidance for providers on meeting the regulations.

As a regulator the CQC looks look to ensure providers have effective systems and process in place to keep people safe. Under regulation 12 RAR 2014, for example, providers must do all that is reasonably practicable to mitigate risks. They should follow good practice guidance and must adopt control measures to make sure the risk is as low as is reasonably possible. They should review methods and measures and amend them to address changing practice. This duty to provide safe care and treatment must also be balanced against service users' human rights, and specifically with the provider's duties under Regulations 10 RAR 2014 (Dignity and respect) and 9 RAR 2014 (person centred care) to ensure both that service users' dignity is protected and that the care is person centred.

For all those providing health and social care, including those providing care in secure settings such as St Andrew's Healthcare Birmingham, we expect that people's needs are assessed and care and treatment delivered in line with current legislation, standards, and evidence-based guidance to achieve effective outcomes. Relevant legislation, standards and guidance in this context includes as follows:

1. Mental Health Act (MHA) 1983: Code of Practice and the Mental Capacity Act (MCA) 2005. Least restrictive care is a key feature and guiding principle of the MHA code of practice. For example, the first guiding principle at page 22 concerns "*least restrictive option and maximising independence: Where it is possible to treat a patient safely and lawfully without detaining them under the Act, the patient should not be detained. Wherever possible a patient's independence should be encouraged and supported with a focus on promoting recovery wherever possible.*"

2. Further to this, the Code of Practice includes specific guidance on 'personal and other searches' at chapter 8, page 69. This chapter sets out clear principles for search policies. For example, "*the authority to conduct a search of a person or their property is controlled by law, and it is important that hospital staff are aware of whether they have legal authority to carry out any such search. Searching should be proportionate to the identified risk and should involve the minimum possible intrusion into the individual's privacy, and all searches will be undertaken with due regard to and respect for the person's dignity and privacy*"

3. Where a provider puts a restriction/s in place, CQC expects providers to act in accordance with the principles set out in Positive and Proactive Care: reducing the need for restrictive interventions (publishing.service.gov.uk), and use to all restrictive interventions in line with the MHA Code of Practice 2015, Mental Capacity Act 2005, Human Rights Act 1998 and the common law.

We also expect providers to take account of national guidance when providing regulated activities. In this case CQC expects that St Andrew's healthcare will have regard to the following:

1. National Institute for Health and Care Excellence (NICE) guidance CG120 - Coexisting severe mental illness (psychosis) and substance misuse: assessment and management in healthcare settings The guidance states at page 9, as follows:

   "Substance misuse - All inpatient mental health services should ensure that they have policies and procedures for promoting a therapeutic environment free from drugs and alcohol that have been developed together with service users and their families, carers, or significant others. These should include search procedures, visiting arrangements, planning, and reviewing leave, drug and alcohol testing, disposal of legal and illicit substances, and other security measures. Soon after admission, provide all service users, and their families, carers, or significant others, with information about the policies and procedures."

2. NICE Quality standard [QS101] Learning disability: behaviour that challenges. Quality statement 10: Review of restrictive interventions | Learning disability: behaviour that challenges | Quality standards | NICE: The standard states as follows:

   "Restrictive interventions should be used as a last resort and decisions to use them should be based on the principle of using the least restrictive intervention necessary. Documented risk assessment and review of restrictive interventions helps to ensure learning. This will reduce the use of future restrictive practices, identify, and mitigate any risks associated with their use and ensure safety, dignity and respect for people with a learning disability and behaviour that challenges'.

CQC has produced guidance documents for inspectors to follow when inspecting and monitoring services such as St Andrew's Healthcare, including a brief guide relating to restraint (physical and mechanical) and on use of 'blanket restrictions' in mental health wards.

On 1 April 2015 the CQC assumed enforcement responsibility for health and safety related serious incidents concerning people using services in health and social care

settings in England. This includes where people using services have sustained avoidable harm including death or have been exposed to a significant risk of avoidable harm as a result of a failure by the Registered Person. The 'Registered Person' (RP) is the Registered Provider and/or Registered Manager. Where Registered Providers are corporate bodies (such as limited companies) or unincorporated associations (such as partnerships), individual office holders or members may in certain circumstances be criminally liable under sections 91 and 92 Health and Social Care Act 2008.[1]

CQC has a clear internal process to follow whenever a Regulation 28 report is received, including where CQC are named within report. In line with the CQC's enforcement and internal specific incident guidance, policies and procedures, a management review meeting (MRM) takes place. This MRM considers the matters of concern raised, reviews the facts, and gathers additional information where required to inform regulatory decision-making and identify if any potential breaches of regulation may have taken place, and undertakes an initial assessment using our specific incident guidance. In summary terms, this initial assessment enables the CQC to consider and/or determine any appropriate regulatory response in line with CQC's published enforcement policy[2]. More specifically, it enables CQC to consider and determine whether any formal and/or informal regulatory actions, for instance monitoring, inspection and/or civil enforcement action, may be required to further assess compliance of the provider or protect service users from ongoing risks; and to assess and determine whether there may be reasonable grounds to suspect that a service user(/s) may have sustained avoidable harm or been exposed to a significant risk of avoidable harm, as a result of registered person failure to provide safe care and treatment.

Actions taken by CQC following receipt of the information of concern concerning Steven Sanders' death

Considering the service had not been inspected since June 2018, an inspector carried out a formal annual regulatory review with the provider on 23 June 2022 and concluded no further regulatory activity was required at that time. Before receipt of your Regulation 28 report, and in line with its published inspection priorities CQC had already identified SAH Birmingham for a comprehensive inspection alongside other services that have not been inspected and rated for 5 years or more.

The initial assessment and specific incidents guidance processes identified above were initiated following receipt of information of concern following the death of Steven Sanders. That information included notification of his death and receipt of HM Coroner's concerns about the provision of care to Steven and others at St Andrews Healthcare Birmingham (SAH) arising from the coronial investigation. The assessments made are subject to continuing monitoring and review, taking account of

[2] https://www.cqc.org.uk/guidance-providers/regulations-enforcement/enforcement-policy

ongoing assessment of any new information coming to light, gathered by CQC, or shared by the coroner during the coronial investigation. A second process was initiated following receipt of the Regulation 28 report and linked to the on-going process opened in relation to the death of Steven Sanders. In the initial assessment following receipt of a regulation 28 report, and information of concern regarding a specific incident of harm that may be avoidable, we ask two key questions, the first of which is most relevant to our response to your Regulation 28 report:

- *Question 1: Does the information about the specific incident raise concerns about ongoing risk of harm to users of the service which CQC should inspect?*

    - As part of CQC's consideration of a response to this question, we have considered the on-going concerns regarding the supply and use of illicit drugs, and reviewed again all the information we hold in relation to SAH. This includes new information, such as, information within this Regulation 28 report, notifications received from SAH, engagement meetings with the provider following receipt of your Regulation 28 report, action plans received from the provider and discussions with Birmingham and Solihull Mental Health Foundation Trust.

    - Following a management review meeting in which we considered all the relevant information including a review of the action plan submitted by the provider and their implementation of ward lockdowns, we concluded that an urgent unannounced inspection would not take place at that time. We determined that it was proportionate to give the provider time to implement the action identified following their own urgent investigation. This position however remained under continuous review. SAH provided CQC with weekly reports, which included actions they were taking to prevent the supply of illicit drugs, additional staff training, review of security protocols, risk assessments and care plans, alongside joint work with local substance misuse services.

    - An inspector reviewed the notification submitted by the provider in relation to the death of patient C in line with our processes. The CQC requested and reviewed a 72-hour report from the provider, and the Initial Management Review, Serious Incidents and Deaths report that was received on 3 October 2024. CQC found that immediate actions had been taken by the provider and the CQC also concluded that there were not reasonable grounds to suspect an offence under Regulations 12(1) and 22(2) RAR 2014. The CQC did and will continue to monitor the extent to which appropriate actions have been implemented by the provider as part of on-going engagement and during the inspection of the service. The CQC will also review any further or new information that it receives or gathers.

- CQC undertook an unannounced, comprehensive inspection of the service in January 2024. The inspection focussed on all five key questions which are safe, effective, caring, responsive and well-led and specifically included consideration of the concerns expressed in your report about illicit drug supply.

- At the inspection undertaken in January 2024 we visited five wards which included both Hurst and Hawkesley ward. We identified breaches in regulations and rated SAH as requires improvement overall.

- At the inspection we also found that although staff knew patients' individual risks and took action, risk assessments were not always reviewed or updated to reflect this. Patients were not always involved in their care plans and there were gaps in information such as restrictions, plans for discharge and Do Not Attempt Cardio Pulmonary Resuscitation (DNACPR) decisions which had not been updated to ensure they were current. Patients were not always offered regular therapeutic activities as part of their care and treatment. There were policies and procedures to support staff to prescribe and administer medicines safely. However, this was not followed with controlled drugs (CDs). There were gaps in staffing levels and staff training. Overall, the governance systems to assess, monitor and improve the quality and safety of the service required strengthening.

- At the January 2024 inspection we also found that there were areas of good practice: the ward environments were safe and clean; staff had access to supervision and appraisal and worked together well; Patients were treated with care and compassion and had access to a full range of specialists to meet their needs; and there was evidence of quality improvement activity.

- At the January 2024 inspection we did not find evidence of illicit substances entering the service and found that action had been taken to mitigate risks and address the concerns identified in the prevention of future death report. This included continuing to improve the security arrangements and a review of the search procedures with positive changes implemented. There was now a full-time specialist substance misuse worker based at the service with a remit on prevention, education, and harm reduction for both staff and patients. The service had engaged with external substance misuse services to provide education to patients on the impact of substances on their mental and physical health and ensure support for patients leaving the hospital. Staff were provided training to help recognise signs of substance use and to understand addiction.

- A copy of the inspection report is published on the CQC website and can be found here: https://www.cqc.org.uk/location/1-121538294

In relation to HM Coroner's concerns in relation to information not being received from CQC following correspondence sent on 28 July 2023:

- The CQC wrote to HM Coroner on 6 September 2023 to acknowledge receipt of correspondence directly to a colleague in the CQC National Customer Service Centre dated 15 August 2023. At that stage the current CQC operational team with responsibility for SAH Birmingham was unaware of your correspondence dated 28 July 2023; the correspondence we believe was not passed through to the relevant operational team and/or handled appropriately in accordance with CQC processes and guidance on the handling of coronial correspondence. The CQC relationship owner for SAH has not been employed by CQC since 15 August 2023.

- To support the robust and systematic handling of coronial correspondence CQC has developed and improved clear and well-messaged internal processes and operational guidance products. Those processes and products signpost, and are based upon, the MoU with the Coroners Society which CQC understands to be in operation. For example, the dedicated inbox that is referenced at paragraphs 31, 34 and 35 of the MoU (CQCInquestsandCoroners1@cqc.org.uk) represents a key component of those processes: a team is responsible for overseeing that dedicated inbox and is required to catalogue, categorise and analyse all coronial correspondence that arrives into the inbox; it is then required to promptly and reliably distribute that correspondence in accordance with the relevant category and associated established process to designated operational colleagues for appropriate consideration and timely response.

- The CQC operational team now responsible for SAH Birmingham first became aware of HM Coroner's correspondence dated 28 July 2023 on 21 August 2023; and first had sight of that correspondence dated 28 July 2023 upon receipt of a copy of as an attachment to an email kindly sent from HM Coroner's office dated 6 October 2023. As set out in CQC's letter to HM Coroner dated 5 September 2023 it is a matter of genuine regret to the Commission that your letter dated 28 July was not handled, or responded to, in a timely and appropriate way: the CQC aims to provide prompt, considered and appropriate responses to all to coronial correspondence in line with our commitment to good and timely engagement and cooperation with coronial investigations and Regulation 28 reports. Accordingly, the CQC is making internal enquiries to establish how and why it was that HM Coroner's letter dated 28 July 2023 was not forwarded to the responsible CQC operational team and/or responded to in a timely and appropriate way. Upon completion of that review the CQC will identify, implement, and appropriately communicate improvements to internal policy, process, and guidance products to seek to ensure that such delays are avoided in future.

- A key feature of those internal processes and products designed to support systematic and robust handling of coronial correspondence is the dedicated email inbox set up to receive, record and distribute all coronial correspondence. In response to your regulation 28 report the CQC asked of the Chief Coroner's Office that messaging was sent to all coroners to request that:

    - In relation to notifications of inquests:

        - CQC is notified as soon as is reasonably practicable of any inquest where concerns exist about the care or treatment received by the deceased using the designated inbox. This includes deaths in secure settings and detained patient deaths.

        - Notifications are made to CQCInquestsandCoroners1@cqc.org.uk. This notification should, whenever practicable, please include the deceased's name, date of birth, the registered provider's name and address, brief details of the immediate circumstances and any other relevant information as determined by the coroner.

    - In relation to Regulation 28 Preventing Future Deaths Reports and so that they can be considered properly to inform CQC's monitoring function and/or formal response as appropriate:

        - CQC are provided with copies of any Regulation 28 report and response where concerns about care or treatment provided by a registered provider have been identified during or at the conclusion of the inquest. This includes Regulation 28 Reports following deaths in secure settings and deaths or detained patients.

        - These reports and the responses thereto are sent to CQC as soon as reasonably practicable to the following email address: CQCInquestsandCoroners1@cqc.org.uk

    - Where the Coroner requires CQC to respond to a Prevention of Future Death report pursuant to paragraph 7 Schedule 5 of the Coroners and Justice Act 2009 these reports are sent to: CQCInquestsandCoroners1@cqc.org.uk.

The Chief Coroner's Office kindly acceded to the CQC's request and messaging was disseminated to all Coroners to that effect in December 2023.

Please do not hesitate to contact me if you require any further information.

Yours sincerely

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Deputy Director of Operations
Midlands Network