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1 June 2021

Care Quality Commission
[redacted]

Dear HM Assistant Coroner Abigail Combes

Prevention of future death report following inquest into the death of Anthony Wilkinson

Thank you for sending CQC a copy of the prevention of future death report issued following the death of Anthony Wilkinson. CQC has contacted the provider Stars Social Support Limited ("Stars Social Support") to request written confirmation and evidence of the action they have taken to date following this death and any additional action they intend to take in response to the prevention of future death report.

CQC has reviewed all the concerns contained in the Regulation 28 report, as well as the subsequent suggested actions contained in Section 6. We will respond to each point addressed to CQC in order, as set out in the Regulation 28 report.

Section 5, Point 13 - CQC did not take steps to access records held by the Police or the provider in a timely fashion following Tony's death. This potentially created risk to other service users as the Regulator had not inspected the service promptly following a significant event.

CQC has reviewed a chronology of steps taken by the local inspection team to access records held by the Police or the provider to consider the timeliness of the actions taken. The team requested Anthony Wilkinson's care records from the provider less than a week after being notified of his death on 5 April 2018. At this time the police were carrying out a criminal investigation following the incident and held primacy of the investigation. In line with The Work Related Deaths Protocol CQC made contact with the Police on 3 May 2018. The Police had seized original records from Stars Social Support as part of their investigation. CQC progressed

their parallel investigation as much as they reasonably could, however access to records was limited in the beginning of our initial enquiries due to the police seizing these, however CQC were in regular contact with the Police to ensure we adopted a cooperative and coordinated approach. CQC received copies of all records held by the Police on 29 November 2018 at the conclusion of their investigation.

CQC has reviewed whether, as a result of Anthony Wilkinson's death, Stars Social Support should have been inspected sooner than the comprehensive inspection which was completed on 29 and 30 May 2018. This inspection did not lead to a rating or a report being published as at that time, the Police had seized Stars Social Support's computer servers as part of their investigation, which in turn, impacted on the availability of key records necessary to make a fair and complete assessment about the service against all of CQC's key line of enquiries (KLOE's). We have concluded from our review that the inspection of 29 and 30 May was completed promptly, based on the information and risks we were aware of at that time. The local inspection team followed internal guidance responding to specific incidents, assessed the level of risk of harm this incident posed to others at the service, in conjunction with known CQC intelligence, the service's regulatory history, as well as taking into account any relevant stakeholder feedback or actions to mitigate potential wider risk at the service. CQC were aware Barnsley Local Authority's safeguarding team had visited Stars Social Support in April 2018 shortly after Anthony Wilkinson's death and implemented a voluntary embargo on admissions. Following receipt of the specific incident the local inspection team assessed the level of risk at the service did not necessitate urgent regulatory action or an inspection. CQC's inspection findings on 29 and 30 May 2018, and again on 12 and 13 February 2019, confirmed that our assessment of risk was accurate as at that time no serious/urgent concerns were identified. Although the inspection on 29 and 30 May 2018 did not lead to a rating or report, the information gathered from our visit to Stars Social Support's office and a selection of service user's homes, assured CQC that people were receiving a safe service at that time. Therefore, the overall risk level of the service could be de-escalated.

Section 5, Point 14 – CQC too readily accepted the lack of an action plan from the provider and did not use this lack of engagement from the provider to increase the risk profile for this provider. Had they done so an earlier re-inspection may have been triggered for further regulatory action. This failure may have exposed other service users to unnecessary risk of harm as a result of inaccurate picture being provided by the CQC.

We understand point 14 refers to the re-inspection of Stars Social Support following the February 2019 inspection, where the local team identified two breaches of regulations. Civil enforcement action was taken; a Warning Notice was served against the breach of regulation 17; and a Requirement Notice was serviced against the breach of regulation 19. As a Warning Notice was served, we did not request an action plan in line with CQC Enforcement Policy. We did, however, request an action plan be submitted to CQC by 29 May 2019 for the

breach of regulation 19. This breach concerned a failure to complete all staff recruitment checks in line with regulatory requirements and was assessed as posing no serious risk to people who used the service.

CQC acknowledged at the Prevention of Future Deaths hearing that the re-inspection of Stars Social Support (completed on 27 August 2020 to 3 September 2020) fell outside of our usual timeframe of re-inspecting a service, rated requires improvement, 12 months from the last inspection publication date. However at that time, the decision not to inspect the service sooner we feel was justified and proportionate. COVID-19 resulted in CQC adapting its inspection priorities during the pandemic to ensure risk and people's safety were the highest priority. A decision was taken by the CQC that during the pandemic, CQC would take on a more supportive role, as well as not adding to the overall risk and pressures COVID-19 presented to the rest of the health and social care sector. As at May 2020, there needed to be an "extreme" level of risk for CQC to cross the threshold for inspection. This ensured during the pandemic, that CQC continued to carry out their regulatory function when there was extreme risk at a service. This was determined on a case by case basis. CQC's inspection priorities remained under continuous review in line with national priorities, but our monitoring of Stars Social Support as well as their failure to provide a completed action plan in relation to the breach of regulation 19, was not assessed as an 'extreme' risk in all of the circumstances. CQC monitored all ASC care providers throughout the pandemic and has implemented several systems to support remote monitoring of services. A decision was taken not to inspect the service at this time and the team considered the providers failure to submit an action plan when reaching this determination.

Section 5, Point 15 – CQC did not take into consideration relevant factors when risk assessing this care provider at the start of the pandemic leading to an inappropriate risk profile being established and an exaggerated level of confidence being placed in the provider to provide safe services to residents without appropriate monitoring and oversight from the Regulator.

Following receipt of the Regulation 28 report, CQC has reviewed assessments and monitoring decisions made about the service. At the beginning of the pandemic CQC monitoring consisted of reviews to intelligence we held about a service, reviewing received statutory notifications or provider requested information in surveys. We also reviewed information or concerns received from stakeholders or the general public. As mentioned in our response under Point 14, our monitoring of Stars Social Support did not suggest urgent or emergent risk, which would necessitate a different regulatory approach, such as inspecting sooner, or enhanced monitoring.

CQC's approach to monitoring services at the beginning of the pandemic in lieu of changes to routine inspections was reviewed in December 2020 and CQC implemented a monitoring system to improve the approach that had been taken up until that date. This system analyses intelligence we hold about services and

generates a prioritisation score to support operational colleagues to prioritise services most at risk. This system is used in conjunction with more 'traditional' monitoring activities described in the first paragraph of Point 15. This system continues to inform our regulatory approach to Stars Social Support.

In relation to observations that CQC had an exaggerated level of confidence in the provider to provide safe services to residents without appropriate monitoring or oversight. CQC did monitor the service during the pandemic. After the 12 and 13 February 2019 inspection, a management review meeting took place to assess the seriousness of the breaches identified, risks to people, as well as the provider's capabilities to improve the service. This management review meeting concluded that it was appropriate and proportionate to give the Stars Social Support the opportunity to address concerns identified at inspection. The assessment was evidence based, robust and balanced. Assessing a care provider's capability to improve or operate a service safely is a key factor in all CQC's decision-making where a breach of regulation is identified. Where appropriate, if the provider can improve the service on their own and the risks to people who use services are not immediate, we will generally work with them to improve standards rather than taking enforcement action. We will intervene if there is evidence that people may be exposed to the risk of harm, there is serious risk to a person's life, health or wellbeing, or providers are repeatedly or seriously failing to comply with their legal obligations.

Section 5, Point 16 – The report from the August 2020 inspection was inaccurate and misleading and may have caused service users to be added to his service where that ought not to be the case. The report published in October 2020 refers to their being no evidence of harm however there is a woeful lack of detail about the context of this within the report. CQC should review this particular report for this provider and also reconsider the way in which reports are written to ensure that they are no misleading and therefore dangerous. This includes either omitting from the report any comment about harm where there is clearly a context and evidence of harm to service users previously, which is open and live, but which does not form part of the inspection or very clear confirmation in the report that there has been evidence of harm which not form part of the specific inspection report.

Stars Social Support has been under voluntary admissions embargo since April 2018 and remains under embargo. Therefore, there is no risk this report may have caused service users to be placed at the service.

We have reviewed all Stars Social Support inspection reports since April 2018 to present and found the information contained in CQC reports is accurate and adheres to CQC guidance available at the time the reports were written. In January 2019 after a period of consultation, the style of CQC reports were reviewed to become shorter, clearer and easier to understand. The comment in the report that there was no evidence of harm refers to the period of time since we last inspected

the service (in February 2019) to the inspection date (referenced in the August 2020 report), and in that period we found no evidence of harm. It is recognised that it doesn't detail the service's entire history and does not detail that a service user had died. However, as the criminal investigation was ongoing at that time, this inspection did not examine the circumstances of this incident. Had the report examined the circumstances of the incident it may have prejudiced future proceedings or caused unfair reputational harm towards the care provider. The February 2019 inspection report referenced the specific incident and stated in the summary section, 'The inspection was prompted in part by notification of an incident following which a person using the service died. This incident is subject to a criminal investigation and as a result this inspection did not examine the circumstances of the incident.' At that time CQC guidance in relation to report writing, did not require CQC inspection reports to reference the specific incident in future reports, only in the report where the incident prompted the inspection. This remains CQC's guidance on reporting on specific incidents. This regulation 28 report will be referred to the CQC policy team to consider whether the guidance needs to be reviewed.

Section 5, Point 17 – Where CQC are required to decide whether evidence ought to be used for the basis of an inspection or regulatory action, they ought to ensure there is a consistent approach to this including consideration of policies and standard operating procedures. This should be approached on the basis of safeguarding the majority of remaining service users from harm being the priority even where that means prosecutions for breaches of regulations may be compromised.

CQC's main objective in performing its functions is to protect and promote the health, safety and welfare of people who use health and social care services. When CQC are made aware of concerns at a service, the priority will be to ensure that current service users are safe, and then consideration will be given to whether a prosecutable offence has occurred. The inspection report details the current findings at a service, specifically whether a provider is meeting the regulatory requirements required to be a registered provider. Civil enforcement, (for example removing a location or cancelling a provider's registration) will be taken if there is evidence that people may be exposed to the risk of harm or there is serious risk to a person's life, health or wellbeing. Criminal enforcement action will be considered in relation to the specific incident, namely whether there was a registered person failure to provide safe care and treatment which resulted in avoidable harm to a service user or a service user being exposed to a significant risk of such harm occurring. In the matter of Anthony Wilkinson and Stars Social Support, there was no observed difficulties deciding whether evidence ought to be used for the basis of an inspection or regulatory action. CQC methodology is clear that these processes should be conducted separately. There had been no observed delays inspecting Stars Social Support after the specific incident, to ensure people who used the service were safeguarded from unsafe care through CQC's regulatory model. Whilst evidence from the specific incident was not directly used to inform

inspection judgements, it was still used to help us plan inspections in a manner that focussed on known risks or potential areas of concern, to robustly assure ourselves that similar incidents, would not be repeated.

Section 6, Point 8 – Care Quality Commission should urgently review the report related to this provider from October 2020 and correct any errors or misleading statements within it.

CQC has reviewed the report (publication date 29 October 2020) in respect of the inspection completed on 27 August 2020 and 3 September 2020. The report was accurate at the time of publication and followed the house reporting style. Although it did not detail the specific incident in relation to Anthony Wilkinson, it had been referenced in the previous inspection report. It would not be appropriate to make changes to the October 2020 report retrospectively because it remains CQC's guidance to not report on specific incidents, unless the specific incident prompted the inspection, which in this inspection it did not.

This regulation 28 report has been referred to CQC's policy team to consider the guidance in relation to report writing.

Section 6, Point 9 – Care Quality Commission should review its processes where their regulatory functions collide with criminal investigations to ensure that timely regulatory oversight and action is taken notwithstanding, HSE or indeed CQC prosecution activity.

When CQC are made aware of incident such as the circumstances of the death of Anthony Wilkinson, the CQC applies Specific Incidents Guidance. The initial assessment is framed around two questions and will generate two separate workstreams, and those workstreams can run concurrently.

The first question (Q1) in Specific Incidents Guidance for inspectors generally serves the first purpose of CQC Enforcement Policy to protect service users from harm and the risk of harm, and to ensure they receive health and social care services of an appropriate standard. The actions generated will be the priority. The workstream could be to carry out an inspection where appropriate to consider ongoing risk in answer to Question 1. In the matter of Stars Social Support, the assessment of Q1 precipitated an action to inspect the service in May 2018, shortly after Anthony Wilkinson's death. Provider assurances and Stakeholder actions taken or planned at that time fed into CQC's assessment of Q1.

The second question (Q2) in Specific Incidents Guidance for inspectors determines whether to progress to formal criminal investigation of the historic specific incident of avoidable harm under Reg 22(2), Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. The second active work stream may, in answering Question 2, be to carry out a formal criminal investigation to investigate historical non-compliance relevant to that historic specific incident. In

the matter of Anthony Wilkinson, a criminal investigation was completed, and the outcome was no further action.

Section 6, Point 10 – Care Quality Commission should review the presentation of its report to ensure that where statements such as 'we found no evidence of harm to service users' are placed in the context of the inspection. For example, statements should be read as 'This service has 90 service users. We inspected 9 records as part of our inspection, and we validated these records against the care provided to those service users. We checked the records held by the Head Office and did not confirm that these were replicated in the service users home address. Of those records we did not find any evidence which would support breaches of Regulations relating to the delivery of safe care'. The organisational context of an inspection is as important as the individual outcomes found on the day of inspection; indeed, it is the context which sets the inspection intervals.

We have addressed some of your comments in our earlier response (Section 5, Point 16). As stated in our earlier response we have reviewed the report in question, and we are satisfied that the content is accurate and complies with CQC's house style.

Historically CQC did have lengthier reports, which similarly conveyed the level of detail as explained in your example. However, following a lengthy review/ consultation period with commissioners/providers/and the general public, about what information we should include in CQC reports, it highlighted a need to change our house style. The results of this review showed some reports were inconsistent in content from service to service, were difficult to understand, and did not effectively support people or commissioners to make an informed choice about care services. Another common theme was that many people who accessed our reports on our website did not read the inspection reports beyond the first page. The shorter report guidance was implemented in January 2019 to address comments from our main audience, commissioners and the general public. In the guidance it directs inspectors to write 'judgment statements' instead of providing detail about context to support this statement, which is not always necessary or appropriate. The shorter report format includes important contextual information about the service in the summary and background sections. For example, it includes details like when we last inspected, records we looked at, the number of people we spoke to, previous ratings and (publishable) enforcement actions.

This Regulation 28 report has been referred to CQC's policy team to review this further.

Section 6, Point 11 – Care Quality Commission should review the way in which it treats evidence which relates to inspection standards and breaches

of Regulations (including criminal offences) where that evidence relates to the same actions.

Evidence gathered during the course of an inspection will feed into inspection reports and where relevant civil enforcement action. The information may lead CQC to carry out a criminal investigation, but the evidence gathered during a criminal investigation will not be detailed in an inspection report. A report must provide an accurate reflection of what is happening at a service, but that does not require the report to detail the criminal investigation.

As your comment concerns CQC policy around how we treat evidence, the relevant team in the Commission will review this further.

Thank you for your assistance bringing certain concerns and actions to CQC's attention. CQC will continue to monitor, inspect and regulate Stars Social Support in a manner which places service user safety at the forefront of what we do.

Yours sincerely

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Head of Inspection