Public Domain

NCHA Position Statement on the Reporting to CQC of the Death of a Homecare Patient

Last Updated: 3 Dec 2021

Background and Scope

In principle, NCHA fully supports patient safety reporting initiatives and recognises the need for reporting and follow-up of all patient deaths associated with activities regulated by CQC. This position statement has been issued following NCHA initial engagement with CQC about the inspection of homecare services. It was noted that there have been significant differences in the approach and advice given to homecare providers by individual CQC Regional Engagement Relationship Owners.

NCHA asks CQC to note the Royal Pharmaceutical Society (RPS) Further Guidance on Managing Complaints and Incidents in Homecare Services and the work being done with NHS National Homecare Medicines Committee (NHMC) and Medicines & Healthcare Products Regulatory Agency (MHRA). This work aims to reduce the inappropriate over-reporting to MHRA of Adverse Drug Events (no causality) as Adverse Drug Reactions (assumed causality). Inconsistent interpretation of pharmacovigilance regulations by some MHRA inspectors leading to adverse findings to pharmaceutical companies who fund homecare services has fuelled over-reporting. This over-reporting is creating "noise" in the national pharmacovigilance reporting systems that have the potential to mask real adverse reaction signals. This includes inappropriate reporting of deaths without reasonable suspicion of a causal link to the homecare medicines.

NCHA is also engaged with the PSIMS team to ensure patient safety incidents relating to homecare are reported into the NHS Learn from patient safety events (LFPSE) service. When LFPSE system is fully operational, it may be appropriate to extend the exemption from CQC reporting of deaths to those already reported to the LFPSE to avoid multiple reporting of the death of a homecare patient.

NCHA believes the consistent approach, outlined in this Position Statement, to the reporting of deaths of homecare patients across multi-organisation homecare services will support regulation of clinical and medicines homecare services, ensure patient safety and minimise duplication of reporting. Furthermore, this consistent approach will prevent over-reporting and the "noise" that creates which can detract from patient safety by masking signals in the national patient safety reporting systems.

This NCHA Position Statement is applicable to all NCHA member homecare providers registered with CQC and undertaking regulated clinical services.

For further information please contact info@clinicalhomecare.co.uk

NCHA Limited Registered Office: Ground Floor, 4 Victoria Square, St Albans, Hertfordshire, AL1 3TF.
A Private Limited Company registered in England and Wales No: 6642621

Disclaimer

NCHA Position on the Reporting to CQC of the Death of a Homecare Patient

The Care Quality Commission (Registration) Regulations 2009 require healthcare organisations registered with CQC to report the death of a service user. In this Position Statement we provide the rationale for appropriate reporting of deaths of homecare patients to CQC "when a regulated activity is being provided" as required by the regulations.

NCHA believes that reporting the death of a homecare patient by the homecare provider to CQC should be restricted to circumstances where the patient died as a direct result of and/or at the time of the regulated activity is provided by the homecare provider. It is clear that any act(s) or omission(s) of any healthcare professional employed by the homecare provider undertaking a regulated activity that caused or substantially contributed to the patient's death would be reportable to CQC by the homecare provider without delay. In addition, a homecare provider would report a previously unreported death to CQC if any subsequent investigation were to show that the death of a homecare patient might have been caused by any acts or omissions of the homecare provider.

At all other times, the hospital clinical team / referrer retains primary responsibility for the homecare patient and therefore will be the primary investigator and reporter of the patient death to CQC. Where the investigation determines that the regulated activity of the homecare provider is implicated in the circumstances of the patient death, the homecare provider will be involved in the investigation and will also report the death to CQC, as a secondary investigator/reporter, providing the incident reference of the primary investigator/reporter, so CQC are able to identify where several reports relate to the same patient death.

The only exception would be in rare cases for non-NHS homecare patients where the homecare service referral includes transfer of primary clinical responsibility for the ongoing patient treatment to the homecare provider.

Further detailed guidance on managing complaints and incidents in homecare services is provided by the Royal Pharmaceutical Society in the Handbook for Homecare Services Appendix 19[1]. This guidance covers the investigation and reporting of incidents involving services provided by multiple organisations ensuring that the most appropriate single organisation retains primary responsibility for investigating and reporting any complaint or incident with the support of the other organisations as required.

Rationale for NCHA Position of the Reporting to CQC of the Death of a Homecare Patient.

Homecare services for NHS patients are a shared care service between the hospital clinical team and the homecare provider who delivers specified elements of the patient's treatment pathway. At all times during the homecare service, the hospital clinical team retain overall clinical responsibility for the patient. When a homecare service is "stopped" for any patient registered for the homecare service, a reason is normally provided. This means that homecare providers are routinely informed by the hospital clinical team of the death of patients registered for the homecare services. Where the homecare provider is informed of a homecare patient's death by the patient's carer, this will be reported immediately to the hospital clinical team who will be responsible for following up and, if appropriate, making

[1] https://www.rpharms.com/resources/professional-standards/professional-standards-for-homecare-services/appendix-19

further investigations into the circumstances of the patient death. Where the death is directly related to the provision of the homecare service, the homecare provider will be involved in the investigation and reporting of the death. In other cases, the homecare providers will not have any other information about the circumstances of the patient's death, nor is it appropriate for the homecare provider to launch any independent investigation of that death.

When providing a homecare service, the homecare provider is responsible for ensuring the contract for homecare services clearly states, and ensuring that the referrer/prescriber understand that they retain primary clinical responsibility for the patient treatment unless other clinical responsibilities are documented and approved by both parties. In rare cases, for non-NHS homecare patients, where the homecare service referral included, and the homecare provider accepted, primary clinical responsibility for the ongoing patient treatment, the homecare provider will be responsible for all CQC reporting of death of that patient.

Regulations and Guidance

The Care Quality Commission (Registration) Regulations 2009 place a requirement on regulated healthcare providers to report the death of a service user.

16.—(1) Except where paragraph (2) applies, the registered person must notify the Commission without delay of the death of a service user—
(a) whilst services were being provided in the carrying on of a regulated activity; or
(b) as a consequence of the carrying on of a regulated activity.
(2) Subject to paragraph (4), where the service provider is a health service body, the registered person must notify the Commission of the death of a service user where the death—
(a) occurred—
(i) whilst services were being provided in the carrying on of a regulated activity, or
(ii) as a consequence of the carrying on of a regulated activity; and
(b) cannot, in the reasonable opinion of the registered person, be attributed to the course which that service user's illness or medical condition would naturally have taken if that service user was receiving appropriate care or treatment.
(3) Notification of the death of a service user must include a description of the circumstances of the death.
(4) Paragraph (2) does not apply if, and to the extent that, the registered person has reported the death to the National Patient Safety Agency (11).

CQC guidance[2],states that a notification of death should be made if:

- the person died while a regulated activity was being provided
- their death may have been a result of the regulated activity or how it was provided

History

Version Status	Date	Reason for change	Author(s)
v1.0	3 Dec 2021	New	C McCall

[2] https://www.cqc.org.uk/guidance-providers/notifications/death-person-using-service-notification-form