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Our References: MRR1-4162633255 and MRR1-4225051596
Your reference: ALB/SLR/9713

Dear HM Senior Coroner

Prevention of future death report following inquest into the death of Sheila Margaret Gaskin

Thank you for sending CQC a copy of the prevention of future death report issued following the death of Sheila Margaret Gaskin.

We can confirm that we did not receive any statutory notification regarding Ms Gaskin's death but we would not have expected to do so. This is because Ms Gaskin was being provided with care from Affinity Homecare Newtown, a service which is not regulated by CQC, rather falling under the jurisdiction of the Care and Social Services Inspectorate Wales (CSSIW). There would, therefore, have been no requirement placed on the service provider Affinity Homecare Newtown to inform CQC in this instance.

Currently registered with CQC are two limited companies, Affinity Homecare (Cheshire) Limited and Affinity Homecare Shrewsbury Limited. Originally these two companies had the same directors but in September 2016 they separated and Affinity Homecare Shrewsbury Limited is no longer affiliated in any way to the Affinity Homecare group. Therefore the current group consists of Affinity Homecare Wales, with offices in Aberystwyth and Newtown,` and Affinity Homecare (Cheshire) Limited with an office in Wilmslow. The nominated individual for all these offices is [redacted]. Affinity Homecare Shrewsbury Limited has an office at Oxon Business Park in Shrewsbury and the nominated individual is [redacted]

In response to your matters of concern:

1. *The evidence revealed that there was an identified risk in Ms Gaskin's care plan of her smoking in bed. The fire service had been involved in risk assessing the situation and had provided flame retardant bedding and linen. Despite this obvious risk having been identified and implemented into the care plan, there was nothing prohibiting carers assisting Ms Gaskin to smoke in bed which, the evidence revealed, was a regular occurrence.*

The registered person (the service provider and/or registered manager) is responsible for ensuring that care and treatment is provided in a safe way for service users (Regulation 12 (1) of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014). As part of this regulation the registered person is required to assess the risks to the health and safety of service users receiving care or treatment and do all that is reasonably practicable to mitigate any such risks.

Another key requirement relating to persons carrying on an activity regulated by CQC is that care and treatment of service users must only be provided with the consent of service user (or other person as relevant) (Regulation 11 of the 2014 Regulations).This regulation places a responsibility upon the service provider to consider consent where people lack capacity, in accordance with the Mental Capacity Act 2005.

As part of CQC's inspection methodology, inspectors assess risk and look at key lines of enquiry to determine if a provider is compliant with these regulations. When planning the inspection the inspector takes account of any information that has been received from the provider and from other stakeholders, for example members of the public and the local authority. This information might include notifications (that the registered provider has a statutory duty to submit) in respect of specific events occurring at the service, for example incidents where the police have been involved, deaths that have occurred whilst staff have been delivering the regulated activity of personal care or changes to the registration of the service. Information we might receive from other stakeholders can include complaints, or issues of concern, or indeed positive feedback about how the service is meeting people's needs. Inspectors will also contact commissioners of the service to ascertain their views prior to the inspection. CQC would also accept as a matter of course any information from the Fire Service and would assess this information against other information we hold. This might lead to CQC inspecting a service to assess whether persons using the service are being kept safe.

In instances where care is being provided to service users in their own homes, one of the methods CQC inspectors use to determine whether the provider is complying with the regulations is 'pathway tracking'. This involves the inspector taking a random sample of people, with different care needs, who each receive

the regulated activity of "personal care". This generally takes place during the CQC inspectors' visit to the office from where the care is delivered and managed.

Pathway tracking is a process by which inspectors review how individuals' care and support needs have been assessed, planned for, delivered and reviewed. This involves inspection of people's care records and corroboration of the care they receive by means of conversations with the people receiving the service, family members and the staff.

In line with Inspection methodology how many people the inspector or inspection team need to make contact with is dependent on the size of the service. Inspectors are not able to pathway track all the people using the service. (As with all public bodies) we have limited resources. We seek to maximise these in terms of our ability to obtain service user feedback, by sending questionnaires to service users prior to the inspection and speaking with a number of service users or their relatives by phone. We are also able to visit a number of people using the service but given that they are living in their own homes and not all together in one place, as is the case when we inspect care homes, we do not have the resources to visit everybody. In addition the inspector may only pathway track certain key elements of a person's care, although this would generally involve the people with more complex needs. Where concerns are observed by inspectors, or where information is available to inspectors to indicate that care plans are not being adhered to then CQC can take enforcement action against the service provider.

As a starting point therefore, CQC relies upon the service provider to ensure that risks are identified and mitigated as far as is reasonably practicable in line with the regulatory requirements placed on them. Inspectors will assess the systems that providers have in place, to oversee the risk management process which should take into account the varied and more complex/high risks involved in providing care, such as how people with a high degree of immobility can be moved safely, or how medicines can be managed safely where people require them to be administered at very specific times. We would expect that the issue of a service user smoking in bed would be considered as a high risk activity and we would expect the service provider to mitigate the obvious risks and to record the action taken. Our inspectors will consider whether the registered person has balanced the requirement to mitigate risk with the requirement to enable people with capacity to make decisions.

Where a person is assessed as lacking capacity this in many ways is more straight forward as it may be determined after following the best interest process and having mind to the Mental Capacity Act that no smoking products should be kept at a service user's house and they may only be supported to smoke under the supervision of staff when they are present.

However, where someone is assessed as having capacity we would seek to satisfy ourselves that a thorough risk assessment has taken place, and that if the service user is choosing to make what may be considered an unwise decision staff have clear guidance on what they can and cannot do. We would be unable to issue blanket guidance around this because each situation would have to be determined on a case by case basis. For example, the provider may need to balance the risks of facilitating the service user to smoke in bed, with the risk that should staff not do that, the service user may attempt to get out of bed without support and suffer a fall.

2. *Management of the care provided accepted that there was no effective oversight by them on a day to day basis and they were unaware that carers were assisting the deceased in this way. They agreed that what was required was a blanket prohibition on care workers assisting the service user in smoking which would have given a greater degree of clarity.*

Under Regulation 17 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 the registered person has a legal duty to ensure that systems and processes are established and operated effectively to ensure compliance with these requirements.

In complying with this regulation it is incumbent on the registered person to develop systems or processes that enable them to assess, monitor and improve the safety of services provided to people. Furthermore they are required to develop a system to assess, monitor and mitigate the risks relating to the health, safety and welfare of service users and others who may be at risk.

Part of our current methodology includes inspectors making an assessment of the provider's governance systems and how these are used to ensure that risks are managed and mitigated and the quality of assessment is under appropriate scrutiny by the registered person. Governance systems should include "spot checks" by the registered manager or delegated person to ensure that staff in the field are working in accordance with individuals' care plans. This also enables the registered person to assess specific risks and offer guidance and support to their staff.

As part of the inspection process we check that these systems are in place and that staff receive supervision, an opportunity for them to discuss issues and concerns relating to practice. Inspectors will also review records of any accidents and incidents, to form a view regarding how learning from these is cascaded across an organisation. All these area form part of the day to day work and oversight of the registered person and we would expect that if operated effectively these would be sufficient to enable the registered person to identify key risks to people and work with staff to mitigate them appropriately.

With regard to the suggestion of a blanket prohibition on care workers assisting service users smoking, we are concerned that this approach is not consistent with the person-centred approach to care planning that we would expect to see. A blanket ban on this activity could inadvertently lead to a person's care and support needs not being met in a way that promotes their needs and preferences; we would prefer that prohibition is risk assessed as appropriate on a case-by-case basis.

However, that does not remove the requirement placed on providers and registered managers to ensure that they are delivering care in a safe way and doing all that is practicable to mitigate any risks. CQC will continue to review through its inspection processes the systems and processes being operated by those services it regulates and will challenge and if appropriate take enforcement action against the registered person where it finds that care is being provided in an unsafe way and is being provided contrary to the care plan.

Yours sincerely

[redacted]
Head of Inspection