



Care Quality Commission

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Dr Julian Morris,

Coroners Area: London Inner South

Reference: 2024-0628

**07 January 2025**

Dear Dr Morris,

Thank you for writing to CQC, highlighting matters of concern in relation to the tragic deaths of Aviva Otte, Oscar Barker and Yousef Al-Kharboush.

We have reviewed the collective concerns, and propose to address points 2 and 3 which are within our remit.

## **BACKGROUND**

CQC is the independent regulator of health and adult social care in England. We make sure health and social care services provide people with safe, effective, compassionate, high-quality care and we encourage care services to improve. We monitor, inspect and regulate services and publish what we find. Where we find poor care, we will use our powers to take action.

CQC employ a team of pharmacy professionals to assist in regulating the safe and effective use of medicines. We have an assessment framework to support us in assessing and monitoring services.

## **Our assessment framework**

Our assessment framework offers us the opportunity to ask all CQC registered service providers that handle, prescribe, supply and administer medicines how this is undertaken safely. This is derived from our Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. Medicines primarily sit within the remit of [Regulation 12, Safe Care and Treatment](#).

## **National Aseptics Review and CQC's role**

In 2020, [Transforming NHS pharmacy aseptic services in England](#) was published by the Department of Health and Social Care (DHSC). The national report was based on a review of the quality, safety and resilience of the hospital-pharmacy, aseptic service.

The report made two key recommendations for CQC:

*“The Care Quality Commission (CQC) should review its oversight of the governance and assurance arrangements for aseptic services as part of the assessment of the safe and effective use of medicines in NHS trusts.”*

*“The CQC should take into consideration the outputs from the EQA (External Quality Assurance) and accreditation schemes as part of their assessment of whether NHS services are safe, effective, caring, responsive to people's needs and well-led. This additional information will support a richer and broader understanding of the quality of service provided and enable commentary on leadership and governance in these areas.”*

CQC accepted these recommendations and has reviewed its oversight of the governance arrangements of aseptic services in NHS Trusts. Further details are provided below.

## **RESPONDING TO MATTERS OF CONCERN 2 AND 3**

### **Reporting requirements**

#### **Key matter of concern (2) is that:**

*The current reporting structures (for a section 10 entity) involve reporting to NHSE and the CQC but the threshold or necessity for such reporting appears unclear and, in essence, up to the Trust.*

Reporting requirements for Trusts are now more clearly defined than they were in 2014.

In 2023 NHS England published guidance on Assurance of Aseptic Preparation of Medicines. The guidance describes the oversight provided by the Care Quality Commission (CQC) and the inter-relationships between the regulatory bodies, such

as the CQC, Medicines and Healthcare products Regulatory Agency (MHRA) and General Pharmaceutical Council (GPhC). This is now much more comprehensive and organisations involved are better connected than in 2014.

Additionally, Under the CQC's Registration Regulations, CQC registered providers are [required to report a death in their service](#). This applies to providers in both the NHS and independent sector.

### **CQC access to audit data**

In line with the recommendations made by the review on aseptic services, CQC takes into account NHS England's commissioned audits on these services as part of our regulatory assessment of services (iQAAPS, interactive quality assurance of aseptic preparation services).

NHS England commissions the Specialist Pharmacy Services to undertake these. In 2024, CQC received access to a digital iQAAPS dashboard that enables us to review audits and risks in NHS services.

### **Our processes for monitoring services**

As part of how we monitor the quality of care offered by registered providers, we undertake annual engagement conversations with all NHS Trust Chief Pharmacists, as a minimum. If we need to, we can increase the frequency of these conversations. This enables us to discuss service specific risks with the Chief Pharmacist. If required, this would include risks relating to aseptic preparation of medicines and other sterile products such as Total Parenteral Nutrition (TPN).

### **Options for escalating concerns**

Where we identify concerns about aseptic preparation or incidents that fall within our remit, CQC have a range of options available in the context of our regulatory response, which include:

- Closer and more frequent monitoring
- Assessment
- Enforcement

Where we have identified concerns, we would also share these as early as possible with the relevant NHS England Regional Chief Pharmacist.

### **Sharing information of concern and learning**

#### **Key matter of concern (3) is that:**

*“There may be times when section 10 entities reach conclusions which would assist the wider industry and help to assist both other Trusts and commercial organisations in assessing their own risks and improving the provision of highly specific medication to a group of vulnerable patients.”*

## **Sharing learning**

Sharing of learning could be improved nationally. The [National Medication Safety Officer Network](#) functions well and could offer an opportunity to formalise and facilitate improvements in the sharing of information and learning in this area, including in the independent sector.

## **Sharing information of concern**

Whilst CQC expect providers to report service related deaths in line with our regulations, we now also have more formal information sharing agreements with other regulators.

In 2014, there was no Memorandum of Understanding (MOU) in place with other regulators, such as the Medicines and Healthcare Products Regulatory Agency (MHRA) and NHS England (formerly Monitor).

These MOUs came into effect in 2015, are still in place, and are updated when required. These are likely to be reviewed during 2025 and can be found on our [website](#).

## **Our actions**

Whilst most section 10 units are within NHS settings, there are some that sit with CQC registered services in the independent sector. These fall within CQC's remit. During 2025-26 CQC will review our oversight of providers who are not required to undertake the NHSE commissioned iQAAPS Audits.

Now CQC has full access to the electronic iQAAPS dashboard, we will undertake a systematic approach to discussing organisation specific risks with all NHS trusts during 2025-26.

Kind regards



Deputy Director for Medicines Optimisation and IR(ME)R, Care Quality Commission.

If you have any further questions about the contents of this response, please contact 