



Care Quality Commission
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HM Assistant Coroner Hocking
Leicester City and South Leicestershire Coroner

14 January 2022

Dear HM Coroner Hocking

Regulation 28 Report following the inquest into the death of Jamie Francis O'Connor

We write further to the Regulation 28 report that you made following the inquest into the sad death of Jamie Francis O'Connor.

Prevention of Future Deaths Report

Under Section 5 of your report entitled you noted:

- 1. There is no central tracking system or central database to record what each person has been prescribed and dispensed and by whom. This is open to abuse as the person requesting the drugs has potential access to multiple online pharmacies who have no knowledge of what each other have been prescribing thus risking contra-indicated drugs being dispensed or over prescribing of drugs.*
- 2. There is no requirement to contact the GP of the person requesting drugs to let them know what has been prescribed. If the person requesting the drugs chose not to share with the GP there were no red flags which might indicate further enquiries should be made with that person as to why they did not want to share with the GP.*
- 3. There was no necessity for a face to face consultation with the person requesting the drugs and the prescriber before drugs were dispensed;*
- 4. There was a very limited questionnaire about the history of the person requesting the drugs. If the answer was 'no' to one question which meant that the drugs could not be prescribed it was very easy to go back and alter it to 'yes' (or vice versa) if that meant that the drugs could be dispensed;*
- 5. Persons requesting the drugs were able to ask specifically for which drug they wanted before contact with the prescriber;*
- 6. By virtue of where the company prescribing the drugs was registered there was limited regulation.*

CQC inspection of online provider services

As you are already aware the Care Quality Commission (CQC) is the independent regulator for health and social care in England. CQC's purpose is to make sure health and social care services provide people with safe, effective, compassionate, high-quality care and we encourage care services to improve. CQC's functions are to register health and adult social care service providers in England; to monitor, inspect and rate services; and to take action to protect people where appropriate using its powers under Health and Social Care Act 2008 and associated regulations.

CQC registers those providers who fall within the scope of regulation as defined by the Health and Social Care Act and associated Regulations. This means in order to be regulated by the CQC they must be providing defined activities in a manner which brings them in to regulation.

CQC regulates providers of online primary care services based in England where they are delivering a regulated activity by an online means to patients in England. This includes providers prescribing medicines in response to online forms, where those healthcare professionals employed to provide the service fall within the list of healthcare professionals defined in the scope of registration. In addition, all UK healthcare professionals are subject to their respective codes of professional conduct and these are enforced by, for example, the GPhC for pharmacists or the General Medical Council (GMC) for doctors.

For those providers who fall within the CQC's scope of regulation we inspect against the regulations using an inspection framework. All providers must comply with the regulations as set out in The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (RAR 2014). The regulations that would be most relevant to any reviews around online providers, would include, but not be limited to, the following:

- Regulation 9 (Person-Centred Care);
- Regulation 11 (Need for Consent);
- Regulation 12 (Safe Care and Treatment including the safe use of medicines);
- Regulation 13 (Safeguarding service users from abuse and improper treatment);
- And
- Regulation 17 (Good Governance)

As part of our inspection of online providers CQC routinely checks the management of medicines, prescriptions, consent and sharing information with a patient's other health care providers. CQC recognises that a provider's management of medicines and prescriptions in this way can be restricted where patients have not provided consent to share information and/or where a patient has used alternative identification.

CQC has published guidance for providers¹. The guidance describes the expectations of providers to ensure a patient's GP is informed of prescribed medications from their service. We also expect that should the patient decline to consent for the sharing

¹ How CQC monitors, inspects and regulates ONLINE PRIMARY CARE, April 2019
The State of Care in Independent Online Primary Care Services, May 2019

of such information to take place, the prescriber should consider whether it is still safe to continue and accept the full responsibility for their actions and act in line with GMC prescribing guidance.

A registered provider's compliance with the regulations will be assessed at inspection. As part of a CQC comprehensive inspection the online provider will be inspected against five key questions, whether a service is safe, effective, caring, responsive and well led. Each of the five key questions are broken down into a further set of questions, the key lines of enquiry (KLOEs). When CQC inspects, these are used to help CQC decide what the inspection needs to focus on. For example, the inspection team will look at the management of medicines and prescriptions, consent, identity checks and sharing information with a patients' other health care providers. As part of the consideration as to whether a service is safe, effective, caring, responsive or well led, CQC will consider how governance systems, processes and practices keep people safe, how these are monitored and improved and whether staff receive effective training in safety systems, processes and practices.

Where there are concerns a provider is operating carrying on a regulated activity falling within the scope of CQC registration without registration the CQC powers to investigate. Specifically, under section 10 of the Health and Social Care Act 2008 (section 10 HSCA 2008) it is an offence for persons to carry on regulated activities without being registered with the CQC to do so. Where it is brought to our attention that a provider may be offering a service that requires registration we do investigate and take such action as is necessary to bring them into regulation. CQC does investigate and has prosecuted the online provision of regulated activities without registration.

Coroner's concerns

We note and share HM Coroner's concerns as set out in your Regulation 28 report.

Through our regulation of independent online primary medical services, CQC has identified gaps in the regulatory framework for independent online providers. We continue to have concerns about safety gaps, which generally align to those you have identified. We do however recognise there are benefits in the provision of online services, and for consultations and prescribing without the need for a face to face consultation where there are appropriate safeguards in place. These include history taking, engagement with the registered GP, and monitoring, as well as a risk assessing those medicines that are prescribed by a service. Our specific concerns are in the following areas:

- over prescribing of opioids and other medicines online, including those with the potential for misuse;
- prescribing online without verified knowledge of a patient's history or access to patient records, and appropriate sharing of information with a patient's registered GP;
- the type and quantities of medicines that can be prescribed by independent providers online;
- the lack of measures and checks in place when medicines are dispensed in England, following a prescription from outside England or non-NHS prescriptions; and
- generally, there is limited jurisdictional ability for UK regulators to take action in response to harmful prescribing by providers or registered persons based outside the UK.

We are also aware that our regulatory partners, including MHRA and the GPhC, share our concerns about the lack of regulatory oversight in this area.

In the last few years, CQC has extensively engaged with members of a UK-wide cross-regulatory forum to improve oversight of online primary care providers. We have been working with our regulatory partners to ensure that the gaps in regulation are mitigated to the best of our abilities and within the limits of our, and their, regulatory powers.

We recognise the regulatory framework in this area needs to be updated to address emerging risks and to ensure independent online prescribers adhere to safe practice.


Since January 2021 CQC has been in formal discussion with, and submitted proposals for legislative changes to, the Department of Health and Social Care (DHSC) to improve CQC's ability to take action against independent providers of online primary care services that are putting people's wellbeing and lives at risk.

We are keen to look at how regulation can be best updated to address CQC's concerns as outlined above, as well as to address current and emerging threats to the health, safety and wellbeing of service users from online providers. This includes looking at what issues can be addressed through legislative change. CQC is continuing to work closely with our partners, other regulators (including MHRA and GPhC) and other government organisations to explore other opportunities for taking this work forward.

We do hope that this response addresses your concerns. Should you require any further information then please do not hesitate to contact us.

Yours sincerely

A handwritten signature in black ink, appearing to be a stylized 'D' followed by a flourish.


Head of Integrated Care and GP Inspection, Midlands
Care Quality Commission