



General
Medical
Council

General
Pharmaceutical
Council



Nursing &
Midwifery
Council

24 August 2017

Dear provider,

Regulation of providers of online primary care

As regulators with responsibilities across the UK healthcare landscape, including professional, pharmacy, medicines and four-nation quality regulators, we are writing to draw your attention to developments in the regulation of online providers of primary care services.

We recognise the importance of encouraging innovation, improvement and sustainability in care while ensuring that fundamental standards of quality and safety are met. The Care Quality Commission (CQC) has outlined its approach to innovation, and its desire to learn alongside providers who offer new care models in the strategy document *Shaping the Future*. Healthcare provision in the online environment challenges the existing regulatory landscape by transforming how care is delivered and blurring the geographic borders that are frequently clearly defined in physical practice.

In order to develop a shared view of quality and to provide consistent expectations of those we regulate, we have undertaken to coordinate our approaches to regulation of online primary care services, and to share intelligence where providers cross our areas of regulatory oversight. Where providers deliver services to any of the four nations (England, Wales, Scotland, Northern Ireland), they should ensure that they are compliant with the requirements of that nation's regulatory framework.

CQC has now completed its first round of inspections of registered online primary care providers in England, and has coordinated inspection activity with the General Pharmaceutical Council where services have fallen under their regulatory responsibilities.

In line with our commitment to work closely together with healthcare providers and with the support of the other regulators, we are keen to outline a number of themes where concerns have been identified on some inspections. We have provided additional detail on how these will apply to CQC inspections in Annex A. We have also included more detailed guidance from the professional regulators on a number of these themes.

- **Identity** – this plays an important role in ensuring that patients are who they say they are for the purposes of safe care and treatment. Offering no confirmation of identity, or reliance on credit card checks in isolation where no visual contact with the patient is made is insufficient, as cards may be shared, misused or stolen. Prescribing for potentially unknown patients makes the identification or escalation of safeguarding concerns unreliable – as well as creating issues around correct or appropriate prescribing, accurate communication with other healthcare professionals and safe transfer of clinical information.

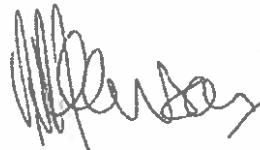
- **Capacity** – we have been told that the ability of a patient to complete an online ordering process provides sufficient evidence of mental capacity. This is not sufficient. Whilst there is a presumption of mental capacity in adults, it is time and decision specific, and where there are concerns about a potential lack of capacity, an assessment should be made in line with established good practice. Providers must be able to outline both how they can identify where there may be concerns about capacity, and how staff are able to carry out an assessment if required.
- **Consent** – 'one size fits all' consent processes do not align with current legal expectations or current regulatory standards and guidance published by the professional regulators. For example, in the guidance on consent published by the GMC, the GMC states that it expects that consent is obtained via a two-way dialogue, with the amount of information shared guided by the patient's individual circumstances. The 2015 judgment in *Montgomery* (see Annex A for more) also expects that information is tailored to the patient. Discussion to obtain consent must include the options available to the patient, including the option not to receive treatment. Providers should review their processes and ensure these align with the expectations of law and any relevant regulatory standards and guidance.
- **Communication with a registered GP** – patients increasingly receive care from a variety of providers – both in the NHS and independent sector. As more providers share the care of a patient, joined up communication is critical, including for example, where the actions of one provider may impact on the management of long-term conditions by another, or where medicines have the potential for misuse. We expect that providers support their clinicians to practise in line with the GMC guidance on remote prescribing, and open a dialogue with patients to explore when consent to share information with registered GPs is declined.
- **Safeguarding** – CQC has seen several examples of ineffective or insufficient safeguarding policies and procedures. In the accompanying guidance we have outlined our expectations, and the legal and guidance framework that providers should use to inform their policies, procedures and training. It is essential to ensure that policies and procedures account for when care is delivered outside of the geographic area local to the provider (be that nationally or internationally) for these to be fit for purpose.

In the autumn, CQC will be establishing a provider forum to enable us to draw on the views of providers and industry bodies in this sector and we will be inviting registered providers to join us.

Yours sincerely,



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Identity

Ensuring patients are who they say they are plays an important role in delivering effective care. It facilitates accurate handover when communicating with other healthcare providers; including in emergency circumstances; that medicines are suitable for the person (e.g. doses appropriate for children vs adults); supports the safeguarding of adults at risk and vulnerable children; and ensures the correct patient information is shared and that letters can be filed into the correct notes.

Providers should consider how they can assure themselves of the identity of a patient, and the relationship (including parental responsibility) between a child and any accompanying adult where appropriate. Where there is no visual contact with patients, there are significant limitations to a credit card check in isolation as cards may be lost, stolen or borrowed.

When considering S1 of the draft Key lines of enquiry and the following prompts:

- *What protocols are there to identify and verify the patient at the start of the first and subsequent consultations?*
- *How does the provider protect against patients using multiple identities?*

CQC will look, in line with S1 in the published draft prompts, at: what systems and processes a provider has in place to manage identity and multiple accounts, how the provider assures themselves that the patient is who they say they are for the purposes of safe and effective care and treatment, and how the provider manages any perceived risks, including safeguarding of vulnerable children and adults at risk of abuse and neglect. Where concerns are found we will raise them through our reports, or enforcement action.

When a national standard for confirmation of online identity for health services is consulted upon and published, CQC will write to all providers to advise them to implement systems which align with that standard.

Capacity

The identification of potential lack of mental capacity, and the ability of staff working for an online provider to identify and, where appropriate, assess mental capacity to make a decision is as important in online practice as physical practice. CQC will expect providers to act in line with the Mental Capacity Act (including its application to children aged 16 and 17 years) and relevant Children's Acts when considering mental capacity.

There is always a presumption of mental capacity in adults; however, we would expect that a provider and their staff are able to outline how they are able to identify where there may be evidence of a lack of mental capacity. In these cases, we would expect the provider and staff to outline a process, within their model of consultation, which facilitates an assessment of capacity in line with legal expectations.

With respect to capacity, providers must also be able to consider how they can take steps to maximise a patient's capacity, and to handle lasting powers of attorney, proxy decision-making, and appropriate (and reasonable) handling of accompanying individuals.

Consent

Consent is a core component of good clinical practice. When obtaining consent, this discussion must include the options available to the patient, including the option not to treat.

Legal and guidance requirements for a valid consent process require tailoring of information to each patient. A one-size-fits-all consent process, which provides the same information to all patients without discussion, is unlikely to meet the standard set out in *Montgomery*, or the GMC guidance on consent. (*Montgomery (Appellant) v Lanarkshire Health Board (Respondent) (Scotland) 2015*)

“following Montgomery it was [sic] important to bear in mind that patients should be told about material risks and the test was twofold: whether a reasonable person in the patient’s circumstances would attach significance to it or whether the doctor was or should have been aware that the particular patient would be likely to attach significance to it. In the light of the second part of that test there cannot be a one size fits all approach, as has been clear in GMC guidance for many years.” [Clinical Reference Group member].

The GMC’s guidance on consent outlines an expectation of two-way communication of tailored information between the patient and clinician:

“(7) How much information you share with patients will vary, depending on their [the patient’s] individual circumstances. You should tailor your approach to discussions”.
(General Medical Council 2008)

Consultations which only rely on transmission of standardised, generic information to the patient for the purpose of consent would not represent a discussion between clinician and patient, nor provide tailored information. This would therefore not meet the standard expected in guidance for consent and shared decision-making.

CQC expect that providers facilitate their clinicians to act in line with best practice, and to abide by the standards expected by their professional regulator. Providers should review their processes and ensure these align with the expectations of law, and relevant regulatory standards and guidance.

Communication with patient's registered GP

Providers operating outside of the NHS system may prescribe treatments or advice to patients which impacts on the care delivered by other clinicians involved in a patient's care. For example, a registered GP's ongoing management of a patient's Asthma may be impacted by other prescriptions of inhalers in the wider system. Where patients increasingly receive care from multiple venues in the health and care landscape, coordination and communication is even more essential to delivering quality outcomes for patients.

CQC expects providers to provide care, and to facilitate their clinicians to practise, in line with the professional expectations laid out in GMC Good Medical Practice (2013) and Prescribing and managing medicines and devices (2013). We expect that providers prompt patients on registration to provide informed consent to share information with their registered GP. Where a patient does not have a GP or declines consent to contact their GP, this should be explored with the patient.

Where the clinician does not have consent to contact the registered GP or there is no registered GP, they have explored this with the patient, and lack sufficient and reliable enough information to provide a safe prescription, they should decline to prescribe and signpost the patient to suitable alternative services.

The clinician must act in line with paragraph 32 of the GMC prescribing guidance following an episode of care. The safety of the patient must come first. When the decision is made that it is safe to prescribe without informing the registered GP following the episode of care, or for patients without a registered GP, this should be clearly documented in the patient's notes, together with any advice, monitoring arrangements or follow-up required.

Safeguarding

CQC's roles and responsibilities concerning the safeguarding of children and adults are set out in our Safeguarding Statement (2015). CQC will assess safeguarding in line with the prompts in our healthcare services Key Lines of Enquiry and prompts, supplemented by our digital-specific prompts.

Providers frequently deliver care throughout the UK and potentially beyond and should ensure that their policies and procedures take into account the legislative and guidance expectations of the countries where their patients are located, as well as UK requirements.

Identification of trends in safeguarding is often locality specific, and so providers should endeavour to link to local authority updates from areas in which they operate to be aware of trends in safeguarding concerns.

For patients in England, CQC will expect that policies and procedures are in line with Working together to safeguard children (2015, updated 2017) and the statutory guidance accompanying the Care Act (updated 2017)

Providers must ensure that all staff have completed training relevant to the online environment, to appropriate levels in line with national guidance as outlined in the Intercollegiate Document (2014). A similar document for adults is in development, and providers should have regard to relevant updates or new publications in this area.

Providers should take a 'Think Family' approach to safeguarding children and adults and have separate policies for children and adults, ensuring they have developed protections within their systems to effectively identify children or adults who are at risk of exploitation. Staff must be aware of their responsibilities, and procedures should outline the actions they need to take and who to contact in the event of a safeguarding concern.

Links to relevant professional guidance

GMC guidance

NMC guidance

GPhC guidance

