

Online doctors: an evolving sector and a developing regulatory landscape

Online doctor services have come under increased scrutiny from the media and regulators over the past 12 months, resulting in significant changes to the regulatory landscape. Raj Gathani and Brian Kelly of Covington & Burling LLP examine the developments taking place in this sector of the telehealth industry and in particular the standards that apply to online doctor providers in the UK.

'Online doctors' are web platforms providing remote consultations and issuing prescriptions to patients. Some offer live video consultations; the majority rely on patients completing web-based questionnaires that doctors review remotely. These services operate almost exclusively in the private sector, outside the infrastructure of the NHS. Many are run by or closely linked to online pharmacies, which dispense and deliver the prescribed medication to patients¹. Services of this kind have increased in popularity (and grown in number) markedly over recent years. Their proponents argue these platforms provide a convenient way for patients to access healthcare, particularly for low-risk, one-off medications (e.g., malaria prophylaxis when travelling) or sensitive conditions (e.g., erectile dysfunction). Critics have suggested that providers do not operate responsibly, putting patient safety at risk and facilitating the abuse of prescription-only medicines.

Heightened scrutiny

An October 2016 BBC investigation raised concerns about prescribing practices at certain online doctor services. Prompted by this, the Care Quality Commission ('CQC') - England's health and social care regulator² - conducted urgent inspections of the businesses the BBC named. CQC inspectors reported that at least two providers could have put patients at risk of harm by issuing prescriptions inappropriately. Both companies ceased providing medical services online. The CQC also conducted a review of the approximately 40 businesses registered as providers of online doctor services, including a series of inspections. During this process, inspectors identified serious shortcomings with a number of online doctor services.

The CQC took enforcement action against some; many others were ordered to take urgent remedial action. Only a handful passed the CQC's inspections with a clean bill of health.

On 3 March 2017, in response to the public controversy, CQC published a 'Clarification of Regulatory Methodology'³, which for the first time sets specific regulatory standards for providers of primary medical services online (henceforth, the 'Online Doctor Standards')⁴. In light of the new Standards, and as the CQC publishes inspection reports for online doctor businesses, a clearer picture is emerging of what regulators expect from providers operating in this area.

Regulatory background and changes

The CQC is obliged by statute to regulate providers of health and social care services in England (so called, 'regulated activities')⁵. Regulated activities include the 'treatment of disease, disorder or injury.' Therefore, the CQC's remit covers GP practices, private medical clinics and dental surgeries etc., irrespective of whether these providers deliver services face-to-face or remotely⁶. The individual healthcare professionals who actually perform treatment are regulated by their respective professional bodies (such as the General Medical Council ('GMC') for doctors). The CQC's role is to supervise the underlying business providing the service to patients (such as a GP partnership or an operator of a private clinic).

Providers of regulated activities must register with the CQC, be subject to its inspections, and comply with the law, professional guidance and the CQC's internal standards. The CQC has distilled

these compliance obligations into five key objectives, namely that services are safe, effective, caring, responsive and well-led. The CQC had historically issued sector-specific guidance on how it expected providers to meet the key objectives: one such document was addressed to GP practices and GP out-of-hours services⁷. The CQC is currently phasing out this guidance in favour of a universal document for all 'healthcare' providers⁸. The new guidance will apply to GPs and independent doctor services from November 2017⁹.

Both old and new guidance documents focus on traditional, face-to-face medical consultations and prescription-writing, without a particular focus on services provided online. The CQC has filled this gap by publishing the Online Doctor Standards, which apply to providers 'delivering GP consultations over the internet and [...] prescribing medications in response to online forms'¹⁰. This document sets out how online medical services providers can demonstrate compliance with the five key objectives and will be a key assessment tool for CQC inspections.

The Online Doctor Standards are currently provisional: we understand the CQC will finalise these in the near future. The CQC has positioned the Online Doctor Standards as supplementary guidance. Therefore, subject to further clarification, providers of online medical services must comply with the Online Doctor Standards as well as the CQC's other standards applicable to healthcare providers. Note, there are proposed legislative amendments to allow the CQC to issue ratings to a broader range of providers, including private online GP services. These proposals are currently out for consultation.



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Key themes from the Online Doctor Standards and the CQC inspections

Below, we outline some of the key themes emerging from the Online Doctor Standards and CQC inspection reports published for online doctor services. Note that the headings we have used are informal and do not correspond to headings in the documents.

- **Patient identity** - There is a clear focus on protocols to verify patient identity, age, capacity and location as well as preventing patients from using multiple identities. Providers meeting this condition have demonstrated that they run robust patient ID checks, often both before registering a patient and at each follow-up consultation. Acceptable checks have for example involved requesting photo ID; checking against the electoral roll or credit reference agencies; and/or consulting internal databases for duplicated or suspicious payment credentials, patient names and addresses.
- **Effective clinical assessment** - Since prescribers and patients are at a distance, the CQC requires providers to ensure that sufficient patient information is available to the prescriber (e.g., having an up-to-date, detailed medical history; a thorough explanation of the presenting complaint; and details of other factors relevant to the patient). Services that provide video consultations or other types of live patient interaction more straightforwardly meet the requisite standard, as the doctor can ask questions of the patient as required. The situation is more complex for questionnaire based services. For these, published inspection reports suggest there should be a robust and structured system that prompts patients to enter all relevant

information (including their medical history where relevant). Questionnaires with a one-size-fits-all approach or those that did not generate appropriate follow-up questions based on previous answers were heavily criticised. The CQC is clear that there should be a mechanism for prescribers to contact the patient where they require further details and that prescribers actually make use of that facility in practice. Inspectors have also highlighted the inappropriate use of decision support tools used in the clinical assessment. Providers using such software must ensure it is fit for purpose and that prescribers are aware they should use their clinical judgement to override such tools when required.

- **Safe and effective prescribing** - The CQC recognises the increased risk of prescribing inappropriate products online. The regulator expects providers to ensure prescribing is in line with the relevant guidelines (e.g., NICE clinical guidance and the GMC's guidance on remote prescribing). Providers should document clinical justifications when prescribers deviate from guidance. The CQC expects providers to establish protocols for the prescription of certain high-risk medicines and antibiotics. They should monitor, limit and audit the prescribing of drugs with the potential to be misused (e.g., opioid analgesics). Providers should ensure that patients are provided with clear information about medicines prescribed (e.g., instructions for use, risk of side effects, interactions etc.).
- **Responsibility for ongoing patient care** - Online doctor services should not operate in a vacuum. The CQC requires providers to have clear and effective processes to refer patients to other services. This might be because a patient requires emergency,

specialist, or follow-up treatment or a face-to-face GP consultation is more appropriate. Inspectors have looked favourably on sites that require patients to consent to the provider sharing information with a patient's regular GP. As a minimum, providers should advise patients of the risks in not sharing notes with GPs. In particular, the CQC has reprimanded providers who regularly issue prescriptions for long-term conditions (e.g., inhalers or monthly contraceptives) without interacting with the patient's wider medical network. Prescribing in this way risks creating a communication gap that could compromise the patient's overall treatment.

- **Good governance** - The CQC makes a number of governance requirements, including requiring providers to have a mechanism (e.g., a clinical board) to oversee and hold to account the remote prescribing of individual doctors. Providers should have appropriate contracts with individual prescribers and ensure the appropriate handling of confidential patient records.

It is worth noting that providers with positive inspection reports seem as far as possible to recreate online a face-to-face medical consultation (i.e., prescribers having full access to records and referral services; interacting with patients by video or telephone; and avoiding an over-reliance on questionnaires or decision support software). Providers facing the most severe criticism seem to have automated the relationship between doctor and patient too far, which has in some cases resulted in compromised safety.

Broader implications for the telehealth industry

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continued

industry that it expects providers of online doctor services in England to maintain a CQC registration and adhere to both the Online Doctor Standards and other applicable guidelines. The CQC's increased focus in this area is likely to lead to more forceful policing of online medical businesses. In future, one might expect robust enforcement action against non-compliant or unregulated service providers.

Recent inspections of online doctor providers have shown that - as a whole - this sector of the telehealth industry faces significant compliance issues. Faced with severe criticism, some providers have left the market altogether, while others will need to concentrate on improving their systems.

Market entry will likely require better planning and additional resource and expertise to ensure CQC compliance from the outset. For example, providers will need to consider (and possibly

invest in) a robust system for verifying patient ID. Patient online questionnaires and/or internal decision support tools will need to be precise and nuanced, requiring greater initial and ongoing oversight from expert clinicians. Therefore, it is possible that the high growth rate of online doctor services will face a slowdown in the short term.

The CQC intends for its recent interventions to improve prescribing practices and patient safety. It should also help to improve confidence that the public and policymakers have in the medical services provided online. Recent controversies have no doubt dented this confidence and may have hampered efforts to bring patient-facing eHealth into the mainstream.

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and dispensed in the UK are from NHS rather than private sources. According to its Five Year Forward View, the NHS is committed to harnessing technology and innovation to improve patient care. The NHS is taking steps to provide all patients with the right to access their medical records, book GP appointments and order repeat prescriptions online, in particular through certain accredited smartphone apps. Introducing remote GP services to the NHS is very much an aspiration for the telehealth industry. Opening up this route for treatment would help reduce the burden on doctors and patients of having to attend in-person consultations. Certain providers are currently in the midst of launching services with the potential to offer NHS patients online video consultations and NHS prescriptions. The CQC's interventions over recent months, in particular its publication of the Online Doctor Standards, are therefore timely and much needed in a rapidly changing environment.

1. The regulation of online pharmacies per se is a complex issue and beyond this article. The CQC does not regulate pharmacies unless they also provide medical treatment (e.g., issue as well as dispense treatment).
2. The CQC's remit does not extend to Scotland, Wales and Northern Ireland, which regions are subject to other regulatory bodies. We have only addressed the CQC's policies and procedures for the purposes of this article. However, we understand that similar rules to the CQC's would apply in the devolved nations.
3. See: http://www.cqc.org.uk/sites/default/files/20170303_pms-digital-healthcare_regulatory-guidance.pdf
4. So called, 'primary medical services' are patient-facing, and usually the first contact-points for patients to access care. Such services are usually generalist (e.g., a GP) rather than disease or treatment specific, 'secondary care' (e.g., a cardiologist). The new standards therefore do not apply to online platforms used in secondary care (e.g., patient monitoring apps used by a specialist hospital team).
5. Per the Health and Social Care Act 2008 and the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.
6. See the CQC's 'Scope of Registration' document, available at: http://www.cqc.org.uk/sites/default/files/20151230_100001_Scope_of_registration_guidance_updated_March_2015_01.pdf
7. See: http://www.cqc.org.uk/sites/default/files/20150327_GP_practices_provider_handbook_appendices_march_15_update.pdf
8. See: http://www.cqc.org.uk/sites/default/files/20170609_Healthcare-services-KLOEs-prompts-and-characteristics-FINAL.pdf
9. The universal guidance for all healthcare providers is beyond the scope of this article.
10. See page 2 of the Online Doctor Standards.