



Clarification of regulatory methodology: PMS digital healthcare providers

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Introduction

This document clarifies our existing primary care guidance by setting out how we propose to regulate digital healthcare providers in primary care. By 'digital healthcare providers' we mean

“Healthcare services that provide a regulated activity by an online means. This involves transmitting information by text, sound, images or other digital forms for the prevention, diagnosis, or treatment of disease and to follow up patients’ treatment.”

We welcome comments on our proposals, particularly from providers who are working within this arena.

Context

The use of technology to deliver regulated activities remotely is increasing significantly. Digital health (encompassing telehealth, telecare, tele-monitoring, e-medicine, eHealth, mobile health) is a rapidly developing sector, which aims to improve people’s access to healthcare advice, diagnosis and treatment. CQC has seen an increase in the number of providers seeking registration for digital healthcare services in primary care. We are also aware that some individuals and organisations are providing regulated activities without registering as they are required to do.

There is professional and public concern that some of these services may not be clinically safe and may put patients at risk. Our findings from early inspections have also highlighted concerns about safe care. Our proposed methodology will encourage improvement in the quality of care provided through:

- the application of standard key lines of enquiry
- clear sector-specific prompts and guidance.

Scope

CQC regulates primary care providers of digital healthcare services in England where they provide the [regulated activities](#) of: ‘treatment of disease, disorder or injury’ and ‘transport services, triage and medical advice provided remotely’ or ‘diagnosis and screening’. This proposed methodology covers the regulation of such providers within primary care. Examples include providers delivering GP consultations over the internet and providers prescribing medications in response to online forms.

Our regulatory approach

In *Shaping the Future: CQC's Strategy for 2016-2021*, we said that we would “focus on areas where there may be emerging risks...for example,...digital health providers” and that we would “learn alongside providers who offer new care models **or use new technologies**, to encourage innovation by flexibly and effectively registering and inspecting such new models.”

Our proposed approach has been developed in consultation with a range of stakeholders. We have established an external advisory group with representation across the healthcare landscape and have a clinical reference group of stakeholders to define good digital clinical practice. We now want to get feedback from a wider range of people with an interest in this area of healthcare.

Our proposed approach to regulating digital healthcare providers in primary care is based on our [operating model](#) that is underpinned by regulations in the Health and Social Care Act 2008 and Registration Regulations made under it.

At the heart of our operating model is the interest of the people who use services. We ask five key questions about quality. Are services:

- Safe?
- Effective?
- Caring?
- Responsive to people's needs?
- Well-led?

Unlike some sectors that CQC regulates, we do not currently have the legal powers to rate digital healthcare providers although we expect to be granted these powers in the future. We will, however, carry out an assessment of the quality of care provided, leading to a judgement about whether the care is safe, caring, responsive and well-led, based on whether the relevant regulations are being met.

Registration

Before digital healthcare providers can begin to provide services, they must apply to CQC and secure registration for the regulated activities they intend to deliver. Providers must satisfy CQC that the care and treatment to be provided will meet the requirements of the Health and Social Care Act 2008 and its associated regulations.

The registration team will review the initial information from the provider and identify any areas of risk for consideration at the registration site visit. A registration inspector, supported by specialist advisors, for example with expertise in digital healthcare or pharmacy, as appropriate, will then carry out a site visit using a set of prompts based on the key lines of enquiry in our [assessment framework for the health sector](#) and the additional prompts set out in the [appendix](#) to this document. Following the site visit the registration team will decide whether there is sufficient evidence to be assured that the provider has the capability, capacity, resources and leadership skills to meet relevant legal requirements, and whether they will be able to provide people with high quality care that is safe, effective, caring, responsive and well-led.

Intelligent use of data, evidence and information to monitor services

We are committed to delivering an intelligence-driven approach to regulation – we will use information from the public and providers to target our resources where the risk to the quality of care provided is greatest. To do this, we must make sure that we have the right information to help us to focus on what matters most to people. This will influence what we look at, who we will talk to and how we configure our inspection team. We will collect and analyse data about digital healthcare providers in primary care from a range of sources including the provider itself, people who use services, other regulators and oversight bodies and other stakeholders and service providers. The information we gather is also used as evidence when we make our judgements against the legal requirements providers have to meet.

One important way to gather data and information is to request it directly from the provider. Before an announced inspection we will ask providers to complete a provider information request, which will help us to understand more about the service provided. Providers will have 10 working days to respond to our request. Over time, we plan to make this an annual information collection.

The information we request is likely to include:

- details about the services provided
- results from patient feedback and information about how the provider has used these findings to improve its services
- a summary of any complaints received in the last 12 months, any action taken and how learning was implemented
- a summary of any serious adverse events in the last 12 months, any action taken and how learning was implemented

- evidence of monitoring the quality of the services provided and examples of quality improvement activity
- information about volumes of prescriptions and numbers of consultations in the last 12 months
- lists of medications dispensed
- copies of templates used in making assessments
- a request for the provider to use their existing electronic communication channels (email, text, social media) to tell their patients that they are due to be inspected and to encourage feedback direct to CQC through our Share Your Experience webform or by phone.

This list is not exhaustive.

People's experiences of care are vital to our work; they help to inform when, where and what we inspect. We want people to tell us about their care at any time through our website, helpline and social media. We are committed to engaging with the public to encourage people to share their views and experiences with us. In addition to requesting providers to use their existing electronic communication channels to encourage feedback direct to CQC, we will develop other ways in which to capture information about people's experience of digital healthcare.

Inspect

Our inspections are at the heart of our regulatory model and are focused on the things that matter to people. There are two types of inspection:

Comprehensive

Comprehensive inspections address all of the key questions and relevant legal requirements.

Comprehensive inspections will usually be announced with three to four weeks' notice given to providers. We feel that this is the most appropriate way to make sure that the care provided to patients is not disrupted and that we are able to obtain and review the pre-inspection information from the provider and from patients. However, we may also carry out unannounced or short-notice inspections if, for example, we have concerns about a service.

On unannounced or short-notice inspections where we do not use a provider information request, we will ask the provider at the start of the inspection to use their existing electronic communication channels to tell their patients that they are being inspected and encourage feedback direct to CQC.

Focused

There will be circumstances when we will carry out a focused inspection rather than a comprehensive inspection. We will undertake a focused inspection when we are following up on:

- concerns that were originally identified in a previous inspection
- concerns that have been raised with us through other sources, such as information from monitoring, members of the public, staff or stakeholders.

Focused inspections do not address all key questions or regulations; they focus on the areas indicated by the concerns that trigger the focused inspection.

Although they are smaller in scope, focused inspections broadly follow the same process as a comprehensive inspection. The reason for the inspection determines many aspects, such as the scale of the inspection, when to visit, what evidence needs to be gathered, the size of the team and which specialist advisors to involve.

These inspections may be announced or unannounced, depending on the focus of the inspection. When a focused inspection identifies further significant concerns it may trigger a comprehensive inspection.

Assessment framework

To direct the focus of their inspection, our inspection teams use a set of key lines of enquiry (KLOEs) that directly relate to the five key questions – are services safe, effective, caring, responsive and well-led? For digital healthcare inspections, we will use the standard KLOEs developed for health services. CQC has recently consulted on a revised single assessment framework with new and updated KLOEs for all healthcare providers. Once the revised assessment framework has been rolled out, we propose to use this set of KLOEs for digital healthcare providers.

Each KLOE is accompanied by a number of questions that inspection teams will consider as part of the assessment. We call these prompts. In addition to the prompts that accompany the standard KLOEs, we have also developed a set of prompts specifically tailored for digital healthcare providers in primary care. These prompts are set out in the [appendix](#).

Our inspection teams will consider the information and data gathered in preparing for the inspection to decide which of the prompts they will use to help them make a judgment on the KLOEs.

Site visits

As part of the inspection, the inspection team will visit the provider's main office location. At this visit the inspection team may meet with the provider or their nominated representative, talk with staff and examine systems, documents and records.

Inspection teams will be led by an inspector. This lead inspector is the main point of contact during the inspection. For announced inspections, the lead inspector will contact the provider in advance of the site visit to make any necessary logistical arrangements and to ensure that the provider is prepared for the visit. The onsite part of the inspection will usually be completed in one day. However, we may need longer for more complex services or if significant issues arise on the day.

The team may also include other inspectors and specialist advisors with specific relevant expertise, for example pharmacists or people with knowledge and experience of digital healthcare. Teams will vary in size and composition depending on the complexity of the services being inspected.

At the start of the site visit, the inspection team will meet with the registered manager if there is one and/or with the provider or their nominated representative. This introductory session will be short and will explain:

- who the inspection team are
- the scope and purpose of the inspection
- how we will escalate any concerns identified during the inspection
- how we will communicate our findings.

The provider will be given an opportunity to:

- tell the inspection team about the service, including the context in which they operate
- share any notable practice that they think goes beyond the requirements of the regulations, and
- tell the inspection team about any concerns they have identified themselves about their ability to meet the regulations and what they are doing about it.

This should take no longer than 30 minutes.

Feedback on the visit

At the end of the inspection visit, the inspector will provide summary feedback to the provider. This would usually include:

- explaining findings to date
- any issues that were escalated during the visit
- any plans for follow-up or additional visits (unless they are to be unannounced)
- explaining how we will make our assessment against the regulations
- explaining the next steps
- answering any questions about the process.

Making judgements

When making our judgements we consider the weight of each piece of relevant evidence. In most cases we seek to verify our evidence with other sources to support our findings. When we have conflicting evidence we will consider its source, how robust it is and which is the strongest. We may conclude that we need to seek additional evidence or specialist advice to make a judgement.

Reporting

After each inspection we produce a draft report on what we found. Our reports focus on what our findings about each of the key questions mean for the people who use the service. The report clearly states whether, for each key question, the provider was providing care in accordance with the relevant regulations.

We describe any good practice we find as well as any concerns we have. In our reports we clearly set out any evidence about breaches of the regulations.

We include in our report any concerns, required improvements or enforcement action taken. We expect providers to respond to areas of concern that we have identified and to make the necessary improvements.

Factual accuracy

Following internal quality checks we send the draft report to the provider to comment on its factual accuracy before the report is published. Providers have 10 working days to review draft reports and draw attention to any issues in relation to the accuracy and completeness of the evidence.

Publication

The report will be published on our website following any necessary changes.

Encouraging improvement

Our approach is to carry out an assessment of the quality of primary care digital healthcare services, leading to a judgement about whether they provide people with care that is safe, effective, caring, responsive and well-led and whether the regulations are being met. This is part of our role in encouraging services to improve.

During inspections we will also look at what providers do over and above the requirements of the Act and the regulations made under it to assure themselves that patients receive good outcomes. We will ask the provider at the start of an inspection to tell us about this. We may also wish to identify and share 'notable practice.'

Enforcement

Where we have identified concerns, we will decide what action is appropriate to take. The action we take is proportionate to the impact or risk of impact that the concern has on the people who use the service and how serious it is. Where the concern is linked to a breach of any legal requirement or standard we have a wide range of enforcement powers, for example, requiring improvement to protect people from harm or the risk of harm, imposing or varying conditions of registration and suspending or cancelling registration. Our enforcement policy describes our powers in detail and our general approach to using them.

We follow up any concerns or enforcement action that we take. If the necessary changes and improvements are not made we can escalate our response, gathering further information through a focused inspection.

In addition to our statutory powers, we also work with other regulatory and oversight organisations to ensure that they take action on any concerns that we may have identified where that is more proportionate or likely to be more effective than CQC acting on its own.

Appendix: Additional prompts for digital healthcare providers in PMS

Key question	Additional prompt
Safe	
S1	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?
	How does the provider determine the patient's location at the start of consultations?
	How are 'caller withheld' numbers dealt with?
S2	What protocols are there for what to do when it becomes clear that a patient is severely unwell and needs urgent treatment? How does the provider ensure that the patient gets access to that treatment and what are the arrangements for follow-up?
	What are the connections to emergency or urgent care services (beyond 999)?
S3	How does the provider ensure compliance with appropriate guidance on remote prescribing?
	Is the prescribing of medicines evidence-based, or are the clinical reasons for deviating from evidence-based medicine clearly documented? Are patients appropriately informed when unlicensed or off-label medicines are used?
	If medicines are prescribed by non-medical prescribers, how does the provider ensure they have the relevant knowledge, skills and experience in the conditions being treated?
	How does the provider monitor and limit prescribing of drugs that have the potential to be misused? How does the provider audit prescribing?
	What protocols are in place for prescribing high-risk medicines and for antibiotics?
	Are paper prescriptions despatched the same day to ensure that the pharmacy receives them within 72 hours?
	How are e-signatures controlled for electronic prescriptions?
	How are emergency prescriptions managed?

	Are patients given clear information about medicines, which includes when to take the medicine, the purpose of the medicine, what side effects may occur and the action to take if they do? How is this recorded and where?
	Can patients select a pharmacy of their choice for a prescription to be dispensed?
S4	What medical records and personal data are held? How and where?
	Can previous contacts/history be viewed? By whom?
	What systems are in place to safely manage and review test results and letters?
	Does the provider allow proxy access? How is this agreed and monitored?
Effective	
E1	Is there evidence that patients' individual needs and preferences have been established? This includes: <ul style="list-style-type: none"> • an up-to-date medical history • explanation of the presenting complaint or purpose of the appointment • a clinical assessment including diagnosis, referral and ongoing management • treatment already received • medication that is being taken (prescribed or over the counter).
	What tool is used to gather information for the above assessment? Is it an externally provided tool or one developed by the service? What procedures and policies are in place to ensure currency and accuracy of clinical content (e.g. editorial policy, editorial board, evidence base, clinical review, how often updated, how are changes in evidence identified and reflected)?
	How detailed is the patient's medical history before the initial consultation? When is it made available to the clinician?
	Do clinicians use a clinical decision support tool? Which tool (in-house or external)? What procedures and policies are in place to ensure currency and accuracy of clinical content?
E3	What is the nature of the employment contract for clinicians?
	Does the provider check, when appropriate, that GPs are on the GMC register and have a licence to practise?
	Does the provider check that other clinicians are appropriately registered?
	How does the provider ensure that clinicians have adequate indemnity arrangements? Are there appropriate indemnity arrangements to cover potential liabilities that may arise, including liabilities of any staff who do not carry their own indemnity?
E4	Are there clear and effective processes to make referrals to other services and, where necessary, for following up people referred to other services? What are the referral rates? How are patients informed of the referrals made?
	If a patient needs a face-to-face consultation are they referred to their own GP/another professional without delay? How does this work?

	When people are referred to another professional/service is all information that is needed to deliver their ongoing care appropriately shared in a timely way? Are patients given a copy of that information?
	Does the provider share notes with a patient's NHS GP (where there is one)? Are they technically able to do so?
	Does the provider advise the patient of the risks of not informing their GP if they decide to opt out? Is this documented on the patient record? Are there situations when the provider would still contact the GP?
Caring	
C2	Is the patient able to see referral letters and receive all test results? Are they able to have test results interpreted? What happens if the clinician with whom a patient had the interaction is not available to review the results?
	What information is given to patients about the clinician they consult with? How can a patient find out about the staff who work for the provider?
C3	Are patients informed and is consent obtained if interactions are recorded?
	How does the provider ensure patients are fully aware of how their records are stored and managed, who has access to them and whether any of their personal information is shared? Is it made clear what personal data is captured about a patient?
	Has a privacy impact assessment been carried out?
	Does the provider ask the patient if they want any sections of the medical record removed when sharing with other health professionals? Are there some sections that will always be shared?
	How are patients made aware of the sharing protocol before the service is delivered?
	How is confidentiality assured for a remote consultation?
	Are patients and staff aware of preferences and settings to maximise privacy (e.g. privacy settings on video and voice call services?)
	How does the provider ensure that consultations take place in appropriate environments to ensure confidentiality?
	Does the provider advise patients on how to protect their online information?
Responsive	
R1	How does the provider make clear to patients what the limitations of the service are?
	How is a 'not treated' condition managed if it emerges during a consultation?
	What systems are in place to manage termination or interruption of connection during a consultation?
	How does the provider engage with both the wider NHS and the local NHS to ensure its actions are in line with both national and local priorities? Is there a system in place to notify Public Health England of suspected notifiable infectious diseases?
	Are consultations time-limited? What is the average time-slot for a consultation? Is the length of time appropriate to the type of interaction?

R2	Does the provider use an appropriate translation service or are patients able to select a clinician who speaks a particular language?
	How accessible is the service to patients with disabilities?
	How accessible is the service to people who are less able to use IT services and are alternatives available?
R5	How does the provider obtain/assess informed consent?
	Can a child consult a doctor without parental knowledge? If so, what are the criteria?
	How does the provider determine the age of a patient (to ensure that a child is not posing as an adult)?
	If children are treated, what protocols are in place for verifying 'accompanying' adults?
	Is full, clear, detailed information provided about costs of initial/further consultations, all treatment and responding to queries or concerns?
Well-led	
W1	Is digital expertise represented in the provider's leadership?
W3	How does the provider ensure the clinical oversight of remote staff?
W5	How is the health and safety of remote employees maintained? Has the provider given employees advice about the correct use of display screen equipment? Have work areas been assessed?
W6	Are medical records held in line with guidance and requirements? Is the level of security in line with the principles of the N3 spine or similar?
	If patient records are held on a portable or mobile device are they appropriately backed up in real time?
	Is all data encrypted, in transit and at rest? Are portable or mobile devices encrypted when they hold patient information?
	Is the provider registered as a data controller with the Information Commissioner's Office and is this in the same name as the CQC registration? Is the registration current with all provider details up to date?
	Who has access to the patient record? Do any third parties have access? What measures are in place to monitor and control this access? Can a patient see who has accessed their record?
	How is any unusual access identified and followed up?
	What will happen to data and records if the provider ceases to trade? Are there contracts in place?
W7	Is there a clear, well publicised mechanism for patient feedback? Does the provider always respond to feedback?
	Is patient feedback published in an open and transparent way? Is patient feedback edited or censored before publication?
	How does the provider ensure that their service is person-centred?