Londonwide LMCs
The professional voice of London general practice

Post-implementation review of regulations relating to the Care Quality Commission

The Consultation asks about the impact of CQC regulation on providers, including GP practices, and runs for 3 weeks – **closing 11.45am on 22 July.**

Consultation description:

We are conducting a post-implementation review of 3 sets of regulations made under the Health and Social Care Act 2008. These regulations are:

- Care Quality Commission (Registration) Regulations 2009
- Health and Social Care Act 2008 (Regulated Activities) Regulations 2014
- Care Quality Commission (Reviews and Performance Assessments) Regulations 2018

We are seeking feedback from all providers of a regulated activity that are registered with the Care Quality Commission (CQC) in England to determine:

- whether all 3 regulations meet their original objectives
- whether their scope is still appropriate and proportionate
- their impact on providers
- whether any changes are required to achieve those objectives with a system that imposes less regulation or to change what the regulations prescribe

Section 1: The Care Quality Commission (Registration) Regulations 2009

The Care Quality Commission (Registration) Regulations 2009 (the 2009 Regulations) requires all providers of regulated activities to register with the CQC. Regulated activities are defined in section 8 of the Health and Social Care Act 2008 and the list of regulated activities is specified in Schedule 1 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

The policy objective of the 2009 Regulations was to achieve the integration and alignment of health and adult social care regulation across all types of providers - whether public, private or third sector. This is to ensure, for example, that the NHS, private, and voluntary healthcare sectors are subject to common regulatory procedures and standards.

The 2009 Regulations:

- enable the CQC to set and maintain registration requirements
- enable the CQC to directly collect information from providers about the services they provide
- ensure providers of regulated activities meet these registration requirements to become and remain registered with the CQC
- set out provisions in relation to compliance with the regulations and offences
- contain provisions for providers to notify the CQC of certain incidents

Do you agree or disagree that the 2009 Regulations meet their original objectives?

- ○ **Strongly agree**
- ○ **Agree**
- ○ **Disagree**
- ○ **Strongly Disagree**

Please explain your answer:

Before we proceed with our responses, please note that this is a submission on behalf of Londonwide Local Medical Committees (LMCs) and not GP CTS Ltd, CQC provider ID:1-1373473088.

As completion of this consultation requires a CQC registration ID provider, Londonwide LMCs is using one of our providers' registration as a proxy, to enable us to submit our response.

Local Medical Committees (LMCs) are a stable part of the NHS landscape and have been in place, supporting GPs, for over a century. Recognised in statute under the NHS Act as the representative organisation for NHS general practice, LMCs remain the only independent, elected, representative body for local GPs, providing advice, guidance and support on a range of issues that affect general practice, including supporting practices in all dealings with regulatory bodies, including the CQC.

Londonwide Local Medical Committees (Londonwide LMCs) is the clinically led independent voice of general practice in the capital. We aim to secure the future of general practice in London through our work with all partners in the health and social care sector and beyond, and by supporting and representing over 7,000 GPs and 1,100 practices in London through the 27 locally elected committees that we serve. We ensure that London's GPs and their practices have access to the information and support they need to help them provide the best possible service to their patients.

Our responses to the consultation questions are provided from a primary care perspective and specifically on behalf of our constituent London GP practices.

Our response to the question on the 2009 (Registration) Regulations:

The 2009 (Registration) Regulations generally meet their original objectives, however their scope should be extended to cover emergency situations such as interim caretaking arrangements, which need to be put in place as a result of the suspension/cancellation of a GP practice's CQC registration. There needs to be a fast-track registration process for the caretaking provider to be able to add a location if they are already registered, which currently does not exist. There should be a flagging system that gives these type of registration changes priority.

Although the (Registration) Regulations cover the cancellation of a registration, there does not seem to be a section covering the suspension of a registration. This may not have been an original consideration but is something that is happening more frequently in general practice and requires further clarity.

We appreciate that the regulations are designed for the CQC to be able to regulate registered providers, however in the context of general practice this goes hand in hand with the NHS contract practices hold (GMS/PMS/APMS). The two regulatory frameworks should mirror each other, but currently they operate completely independently of each other despite practices having to comply with both. This needs to be acknowledged in the regulations so that commissioners can respond quickly to the suspension of a practice's registration with a contractual framework that reflects the CQC suspension requirements.

As CQC registration suspensions are operationally managed by local primary care commissioning teams, there needs to be clarity in the regulations regarding what a practice whose registration has been suspended can or should do or not do during suspension, and how best to work with their caretaking provider to enable the suspension to be lifted. We have seen many situations where these cases are managed with great variability between different commissioning areas and a set of high-level principles would make management of these cases much more efficient, effective, fair and consistent.

Do you agree or disagree that the 2009 Regulations are appropriate in carrying out their objectives?

- **Strongly agree**
- **Agree**
- **Disagree**
- **Strongly Disagree**

Please explain your answer:

It is not possible to know with certainty that the 2009 Regulations are meeting the original objective with regards to registrations and the aim of achieving *"integration and alignment of health and adult social care regulation across all types of providers".* For example, when reviewing the "Registered Manager Conditions" section, the definitions given are broad and open to interpretation. Therefore, it would be helpful if supplementary guidance were produced to help clarify the requirements in more detail as they apply in different sectors.

Do you agree or disagree that the 2009 Regulations are proportionate in carrying out their objectives?

- **Strongly agree**
- **Agree**
- **Disagree**
- **Strongly Disagree**

Please explain your answer:

Looking at the information contained in the 2009 (Registration) Regulations it would be fair to say that this is "proportionate" for the general practice sector. Most sections are short and give clear information therefore the implementation of the (Registration) Regulations 2009 should not be too onerous.

Section 2: The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

The Health and Social Care Act 2008 requires all providers who carry out 'regulated activities' in England to register with the CQC, and to comply with the requirements set out in regulations made under that Act.

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 ("the 2014 Regulations") are made in exercise of powers under the Health and Social Care Act 2008. The 2014 Regulations set out the regulated activities in Schedule 1 and the fundamental standards that all registered providers must comply with.

Overarching objectives

The 2014 Regulations prescribe the activities that providers should register with the CQC and set fundamental standards, below which care should not fall. We would like your feedback to understand whether the 2014 Regulations meet their objectives in ensuring that they require all health and/or adult social care providers that present a risk to the safety of patients or service users to be registered and help to maintain fundamental standards.

To the best of your knowledge, are the 2014 Regulations proportionate by regulating only activities, services and providers where there is a risk to the safety of patients and/or service users?

- ○ **Yes**
- ○ **No**
- ○ **Don't know**

If no, please explain your answer

The entire premise of the 2014 Regulations is that they are risk based. While this is appropriate, we have seen many examples of excessive criticisms in practice inspection reports and also poor ratings on the basis of perceived, but not necessarily proven risk. Assessment of risk to patient safety should be more consistent between different inspectors and proportionate to inspection findings. The Regulations should impose clear consistency requirements on CQC as the Regulator.

Are there activities not currently defined as 'regulated activities' in the 2014 Regulations where there is a possible risk to patient safety or service users?

- **Yes**
- **No**
- **Don't know**

Please explain your answer

We believe that the overall scope of services provided at GP practice level is adequately covered by the current list of regulated activities within the 2014 Regulations.

In your experience, are different providers (for example, NHS, adult social care, independent providers, and voluntary sector healthcare providers) treated fairly and equally by the CQC under the 2014 Regulations?

- **Yes**
- **No**
- **Cannot answer – no relevant experience**

Please explain your answer

The available answers here do not allow for nuances within possible responses to be captured. Instead of a blanket Yes or No, our preferred and more evidence-based response would be "Not always". As we have alluded to in previous responses, our experience of supporting practices faced with adverse ratings, enforcement action etc, has highlighted: a lack of consistency between inspectors; unrealistic expectations in terms of expected standards; the use of out of date/national data rather than practice-based performance data; lack of proper understanding of the realities of running a GP practice; and lack of understanding of cultural differences.

Any of these can and have resulted in unbalanced and disproportionately critical and damaging reports for practices.

The Regulations should be accompanied by supplementary operational guidance on their implementation, setting out specific standards for CQC inspections, inspectors, and internal governance and quality assurance processes within CQC.

The CQC should be as accountable for its processes as the providers it regulates, and the Regulations should incorporate this very important component within their scope, to avoid inconsistency and unfair treatment of registered providers.

In your experience, are providers treated fairly and equally by the CQC under the 2014 Regulations across settings (for example, acute hospital, community care, mental health and primary care)?

- ○ **Yes**
- ○ **No**
- ○ **Cannot answer – no relevant experience**

Please explain your answer

We work with GP providers therefore we are not in a position to comment on any other sectors other than primary care and general practice.

Have the 2014 Regulations encouraged improvement in quality and safety in the service you provide?

- ○ **Yes**
- ○ **No**
- ◉ **Don't know**

Please explain your answer

Generally they have, as they have introduced published standards and have encouraged registered providers to review their processes and procedures, reflect on their leadership structures, and understand their patients' wishes and expectations.

Having said that, and again the answer cannot be a binary Yes or No, our experience of working with practices on their CQC issues since 2014 shows that CQC does not always understand how practices are run on a day-to-day basis. Depending on the lead inspector involved, there may be standards expected that are not required in

the practice's contract or the regulations themselves. Practices are expected to continuously improve regardless of the challenges they are facing in terms of capacity, workforce and an ever-increasing workload. Good practice or "nice to dos" are often translated into "musts" and the bar keeps getting higher, which is simply not sustainable.

The Fundamental Standards

The 2014 Regulations set out the statutory minimum standards, below which care must never fall. We would like your feedback on the Fundamental Standards.

They cover person-centred care, dignity and respect, consent, safe care and treatment, safeguarding from abuse and improper treatment, meeting nutritional and hydration needs, premises and equipment, receiving and acting on complaints, good governance, staffing, fit and proper persons, duty of candour, and display of performance assessments.

Do you agree or disagree that the 2014 Regulations clearly set out the outcomes of the Fundamental Standards providers of regulated activities are expected to meet and/or avoid?

- ○ **Strongly agree**
- ○ **Agree**
- ○ **Disagree**
- ○ **Strongly Disagree**

Please explain your answer

Reiterating our previous responses, the standards are generally clear, but they are not always:

- Relevant and applicable to general practice.
- Proportionate *(e.g. a practice was criticised because the pull cords in their toilets were not clean and were advised to install plastic covers. The practice did as advised, but on re-inspection they were criticised again because despite the plastic covers, the pull cords were still not clean underneath.).*
- Applied consistently by inspectors.

Do you think anything is missing from the 2014 Regulations that could help providers of regulated activities improve quality and safety?

- ○ **Yes**

- **No**

If you answered yes to the above question, please provide some detail about the reason for your answer.

As stated previously, we wish to reiterate that the Regulations need to be accompanied by clear and specific guidance on implementation, with specific standards for CQC inspections and expectations of consistency between CQC inspectors.

Please explain your answer

Do you agree or disagree that the CQC's guidance for complying with the Fundamental Standards is clear and easy to follow?

- **Strongly agree**
- **Agree**
- **Disagree**
- **Strongly Disagree**

Please explain your answer

The CQC's guidance on complying with the 13 fundamental standards is helpfully linked to the respective Regulations, which makes it easy to follow.

Please refer to our concerns regarding the inconsistent implementation of the standards in previous responses.

Duty of Candour

We would like your feedback on a specific aspect of the Fundamental Standards, called the Duty of Candour (Regulation 20).

The Duty of Candour places a legal duty on all health and/or social care providers to be open and transparent with people using services in relation to their treatment and care. It also sets out some specific actions that providers must take when a notifiable safety incident occurs. These include:

- informing the relevant person affected about the incident
- providing reasonable support

- providing an account that is, to the best of their knowledge, true of all the facts known
- an apology
- a written record that is kept secure

Do you agree or disagree that it is straightforward to identify whether something qualifies as a notifiable safety incident?

- **Strongly agree**
- **Agree**
- **Disagree**
- **Strongly Disagree**

Please explain your answer

There is room for interpretation as to what constitutes a notifiable incident. Within a GP practice context, we would expect that a discussion takes place amongst the clinical team to decide if the Duty of Candour applies to a particular incident.

Do you agree or disagree that it is clear from the 2014 Regulations what we must do if a notifiable safety incident is identified?

- **Strongly agree**
- **Agree**
- **Disagree**
- **Strongly Disagree**

Please explain your answer

The GP provider would need to consider what "reasonable support" means and how the practice could offer this to the individual(s) affected.

Do you agree or disagree that the duty of candour requirement has helped us ensure people receiving care receive a proper apology (an expression of sorrow or regret) when things go wrong?

- **Strongly agree**

- Agree
- Disagree
- Strongly Disagree

Please explain your answer

We recognise that this is the intention of this Regulation, however in practical terms it does not "ensure" the affected individuals receive the apology they are looking for. One of the reasons is that reporting a Serious Incident or Near Miss can have significant consequences for a practice, both in terms of CQC and also their NHS Contract. While practices recognise the importance of being transparent and owning up to errors or incidents, they can be reluctant to highlight them for fear of punitive action from their regulators or commissioners.

For this to be a genuine provision that is complied with regularly by providers, the entire system needs to adopt a no-blame, learning culture that enables the provider in question to reflect, address any issues appropriately and engage with their affected patient(s) without fear of punishment.

Fit and Proper Person Requirement for Directors

We would like your feedback on the Fit and Proper Person Requirement for Directors.

This ensures that providers take the necessary steps to ensure that all directors are appropriate and fit for their role.

Do you agree or disagree that the fit and proper person requirement has helped your organisation take appropriate steps to ensure your directors are fit and proper for their role?

- Strongly agree
- Agree
- Disagree
- Strongly Disagree

Please explain your answer

The Fit and Proper Person requirements are clear but as with other CQC requirements, quite generic. Again, it is about the interpretation and implementation of this Regulation by the responsible CQC officers.

It is not always clear which new partners joining a practice will receive a Fit Person interview as part of their application to join the practice's CQC registration. Some will be interviewed, some will not.

The criteria are not specific. We had a prospective partner who applied to join a practice's registration and their application was returned as they had not explained an employment gap of two months in their CV. While we appreciate that Regulation 5 expects applicants to explain gaps in employment history, we considered that a two-month gap was not significant enough to warrant further explanation.

It would also be extremely helpful if there was supplementary guidance for new partners joining a practice to guide them through a Fit Person Interview and how they should prepare for it.

Section 3: The Care Quality Commission (Reviews and Performance Assessments) Regulations 2018

The CQC began ratings of providers in October 2014. However, it was limited to specific settings to allow time for the CQC to build capacity. Subsequently, we consulted on proposals to expand the scope of the CQC's duty to extend performance assessments and ratings to a variety of additional providers, including many of the independent sector providers, who carry out regulated activities.

Whilst considering changes to the ratings regime, DHSC and the CQC concluded that it would be beneficial to broaden the scope of the CQC's ratings regulations so that, with some exceptions, all providers of regulated activities are rated. The small number of providers who are excluded from ratings are, however, subject to the fundamental standards of care and to inspections. The reasons for exclusion are:

- the number of providers is so small that ratings would not contribute to consumer choice
- the service providers are already regulated by other agencies so a CQC rating could confuse the public; or
- the sector is relatively low risk and is inspected by the CQC too infrequently to make a rating meaningful

Providers that were excluded from ratings are primary dental care, minor cosmetic surgery services, national screening programmes, health and justice services, hyperbaric chambers, blood and transplant services, services licensed by the Human Fertilisation and Embryology

Authority and independent pathology laboratories, independent podiatry services and children's homes undertaking regulated activities.

Do you agree or disagree that the above mentioned providers should not be included in the CQC's ratings regime?

- ○ **Strongly agree**
- ◉ **Agree**
- ○ **Disagree**
- ○ **Strongly disagree**

Please explain your answer

As the above providers are already regulated and subjected to inspections, we believe that it would not add any value in including them in the CQC's rating regime.

Section 4: Resource needed to comply with The Care Quality Commission (Registration) Regulations 2009

Questions in this section will be used to help us understand what level of resources are required to comply with three aspects of the regulations:

- registration with the CQC
- completing Provider Information Returns
- facilitating inspections

The answers should only relate to the individual location registered with the CQC. Please do not include any information on your wider group or parent organisation – if you belong to one.

How many people does your organisation currently employ?
We are looking for the number of full-time equivalent (FTE) staff in the organisation covered by your CQC registration.

- ○ **Less than 10 people**
- ○ **Between 10 and 49 people**
- ○ **Between 50 and 249 people**
- ○ **250 people or more**

As explained at the beginning of our response, this submission is not made on behalf of GP CTS Ltd, CQC provider ID:1-1373473088, but on behalf of Londonwide LMCs. Therefore, the questions in the Registration and PIR paragraphs of Section 4 are not applicable.

Please proceed to the Inspections section.

Registration with the CQC

We would like to collect information on the average cost of completing a CQC registration to ensure the process is not too burdensome for providers.

Who worked on your organisation's original application to register with the CQC? Please include job titles, full time (gross) annual salary and estimated hours each individual spent on your initial application.

N/A

Has your organisation updated any aspect of its registration since it was first registered (for example, to register a new location that was opened)?

- **Yes**
- **No**
- **Don't know**

Please explain your answer

N/A

We would like to collect information on the average cost of updating a CQC registration.

Please provide information on who worked on your organisation's most recent registration update with the CQC
Please include job titles, full time (gross) annual salary and estimated hours each individual spent on most recent registration update.

N/A

Are the registration requirements for health and social care providers clear?

- **Yes**
- **No**

Please explain your answer

N/A

Is the regulatory burden placed on your organisation by the 2009 Regulations as low as possible?

- **Yes**
- **No**

Please explain your answer

N/A

Provider Information Returns

The CQC asks for information about the service(s) you provide each year, including any changes that have been made and how your organisation ensures the service is safe, effective, caring, responsive and well-led. This is known as a Provider Information Return (PIR).

Who worked on your organisation's most recent Provider Information Return? Please include job titles, full time (gross) annual salary and estimated hours each individual spent on this PIR/assessment.

N/A

Inspections

In response to the COVID-19 pandemic, the CQC carried out remote inspections to lessen the burden on providers and has subsequently changed the way it carries out inspections by taking a more intelligence-led and risk-based approach. As a result, we are aware that some providers may not have had an on-site inspection for at least two years.

Please note, the following questions relate to the pre-COVID-19 pandemic inspection regime based on routine programme of on-site inspections. Where these questions ask you to think about your most recent inspection, please answer with reference to your most recent on-site inspection.

Do you agree or disagree that DHSC understands that the work you do, when an inspection occurs, can be broken down into three phases: preparation for an inspection; facilitating the inspection; and the post-inspection follow up work?

- **Agree**
- **Disagree**

Please explain your answer

The binary nature of the available responses does not allow for a meaningful and nuanced response. In the absence of a Partially Agree option, we have selected Disagree.

As explained above, not all inspectors are fully aware of the realities of the everyday running of a practice and quite often have unrealistic expectations about what a practice should be doing or how it should be running its services.

There is a misguided concept shared by many inspectors that notice of a CQC inspection should not cause panic to a practice as they should already have the necessary systems and processes in place and therefore it should be "business as usual". This is not a realistic view of general practice, particularly in the current post-Covid climate.

CQC inspections are incredibly stressful for practices and CQC should acknowledge that.

Inspectors should be more flexible when key partners or managers of a practice are on leave or unavailable on the day that an inspection is scheduled and agree to reschedule inspection dates accordingly. At the moment it is very difficult to do that.

In terms of the three phases of an inspection, we can attest again to inconsistency of approach. There is significant variability in the information requested by a practice before the inspection, different points of focus during the inspection which quite often relate to the lead inspector's particular interests, and finally great variation in the information requested following the inspection.

As CQC is moving away from the traditional style of inspections and into more remote monitoring post-pandemic, we would like to request that law makers make the necessary changes to the Regulations to enable CQC to issue ratings without having to cross the practice's threshold. At the moment this is not allowed by the Regulations, however we receive regular feedback from practices that physical inspections can be not only disruptive and stressful, but most importantly, any improvements made by the practice will not be taken into account and will not affect their rating until there is another on-site inspection.

We believe this is limiting for CQC and demoralising for practices, particularly when they want to move away from a Requires Improvement rating or move out of Special

Measures (Inadequate rating) but cannot see their hard work being recognised sometimes for years, as the CQC is currently unable to update a practice's rating without crossing the threshold.

We trust that the established processes of the factual accuracy report and the ability to appeal against ratings will remain unchanged for ratings awarded as a result of non-physical inspections. In addition, practices should reserve the right to request an on-site inspection if they have reason to believe that the assessment and rating they received through a remote inspection was unfair or not sufficiently evidence-based.

Thinking about your most recent on-site inspection, who carried out any preparatory work required in your organisation?
Please include job titles, full time (gross) annual salary and estimated hours each individual spent on inspection preparation.

N/A

Thinking about your most recent on-site inspection, who was involved in facilitating the inspection in your organisation?
Please include job titles, full time (gross) annual salary and estimated hours each individual spent on facilitating inspection.

N/A

Thinking about your most recent on-site inspection, who was involved in any post-inspection follow up work in your organisation?
Please include job titles, full time (gross) annual salary and estimated hours each individual spent on post inspection follow up work.

N/A