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Changes to the way the CQC regulates – guidance notes for Apolline Members

The CQC changed the way it regulates and inspects on 1st April 2015 when they moved from inspecting against the 'essential standards of quality and safety' to inspecting against their new 'fundamental standards' regulations.

A number of other things have also changed. These guidance notes from Apolline summarise the main things you need to know about all the recent CQC changes. The list is not intended to be exhaustive, therefore practice teams are also encouraged to familiarise themselves with all the latest information published on the CQC website.

The main changes and things you need to know – a summary for busy readers

Inspections and standards

- CQC's 'essential standards of quality and safety' ceased to exist on 1st April and have been replaced by 12 new 'fundamental standards' – all inspections will now be against these.
- Two types of inspection will happen in 2015/16 – 'comprehensive' and 'focused'.
- **Comprehensive** inspections seek to establish whether the practice provides care that is safe, effective, caring, responsive and well-led; **focused** inspections focus only on areas indicated by the particular information that triggered the inspection.
- 10% of dental practices will have comprehensive inspections in 2015/16 - these will be selected either randomly or on a risk-based basis.
- Focused inspections will be in addition to this and in response to concerns. If the inspection identifies significant concerns, it may trigger a comprehensive inspection.
- Key Lines Of Enquiry (KLOEs) will be used for consistency from inspectors.
- The new Dental Providers Handbook – Appendix A, focuses on the KLOEs and provides examples of questions inspectors will ask and evidence they will expect to see.
- Comprehensive inspections will usually be announced (two weeks' notice); focused inspections can be announced or unannounced depending on why the inspection is being undertaken.
- Comprehensive inspections will take one day and will be undertaken by a CQC inspector with support from a Specialist Adviser (often a dentist) who will either attend the inspection or provide remote advice.
- Inspectors will speak to dental nurses, dentists, practice managers and receptionists.
- They will review policies and protocols and will expect these to be tailored to the individual practice.

New things and things practices need to know

- Each practice will have a member of CQC's inspection staff as their 'relationship manager'.
- Practices will be asked for information before their inspection and have 5 days to respond.
- Information shared with and feedback encouraged/requested from NHS Area Teams, the GDC and local Healthwatch organisations.
- Strong focus on gathering feedback, including asking for results of the FFT.
- Strong focus on complaints and compliments.
- Strong focus on consent and an understanding of the Mental Capacity Act.
- Patient records will be scrutinised.
- At their inspection, practices will be asked to share any concerns they have identified themselves in their ability to meet the requirements of the regulations (including the new fundamental standards) and, what they are doing about it.
- CQC has a new role in and focus on highlighting good practice (to be referred to as 'notable' practice in reports) and sharing this.
- Inspectors want providers to be aware of and provide examples of where they provide notable practice that goes beyond the regulations.
- When an inspection team is inspecting, the lead inspector will review emerging findings enabling the team to refocus the inspection if necessary.
- Feedback will be provided to the practice at the end of the inspection ahead of the draft report.
- Following an inspection, all providers will be rated as 'Outstanding', 'Good', 'Requires improvement' or 'Inadequate' – won't apply to dental practices in 2015/16 but they reserve the right to introduce this in future.

The main changes and things you need to know – the detail

CQC's Fundamental Standards

These are new standards below which the standard of care must not fall. There are 12 fundamental standards that apply to dental practices and each standard relates to a specific regulation.

- Person-centred care (Regulation 9)
- Dignity and respect (Regulation 10)
- Need for consent* (Regulation 11)
- Safe care and treatment* (Regulation 12)
- Safeguarding service users from abuse and improper treatment* (Regulation 13)
- Cleanliness, safety and suitability of premises and equipment (Regulation 15)
- Receiving and acting on complaints+ (Regulation 16)
- Good governance+ (Regulation 17)
- Staffing (Regulation 18)
- Fit and proper persons employed (Regulation 19)
- Fit and proper person requirement for directors (Regulation 5)
- Duty of candour* (Regulation 20)

* These regulations have prosecutable clauses relating specifically to harm or the risk of harm.

+These have clauses requiring information to be provided to CQC on request. Not providing the information could prevent CQC from identifying and responding to harm/risk of harm in a timely and appropriate manner. Breaching these clauses is therefore prosecutable.

Fit and proper persons (5) and duty of candour regulations (20)

Two new regulations, Regulation 5: Fit and proper persons: directors and Regulation 20: Duty of candour, apply to all providers from 1st April 2015.

The intention of Regulation 5 is to ensure that people who have director level responsibility for the quality and safety of care, and for meeting the fundamental standards, are fit and proper to carry out this important role. It applies to all providers that are not individuals or partnerships. Organisations retain full responsibility for appointing directors and board members (or their equivalents). CQC may intervene where it has evidence that a provider has not met the requirement to appoint and have in place fit and proper directors, using the full range of enforcement powers.

The intention of Regulation 20 is to ensure that providers are open and transparent with people who use services and other 'relevant persons' (people acting lawfully on their behalf) in general in relation to care and treatment. It also sets out some specific requirements that providers must follow when things go wrong with care and treatment, including informing people about the incident, providing reasonable support, providing truthful information and an apology. This statutory duty on organisations supplements the existing professional duty of candour on individuals.

Further guidance on these regulations is published on the CQC website.

KLOEs (Key lines of enquiry)

In March 2015 the CQC published a new handbook for dental providers. Appendix A focuses on the KLOEs and provides examples of questions inspectors will ask and evidence they will expect to see. KLOEs will be used to try to ensure consistency from inspectors. Apolline members can download this from the Apolline website. Members are advised to refer to this document for further guidance.

Appendix A also outlines what they mean by safe, effective, caring, responsive and well-led and gives guidance on which regulation fits into which domain. Please note, some regulations are applicable to more than one domain.

Safe

By safe, they mean that people are protected from abuse and avoidable harm.

The following regulations are applicable to 'safe':

- Safe care and treatment
- Safeguarding patients from abuse and improper treatment
- Fit and proper persons employed

- Staffing
- Premises and equipment – including cleanliness
- Duty of candour
- Good governance
- Person-centred care
- Consent.

Effective
By effective, they mean that care and treatment achieves good outcomes, promotes a good quality of life and is based on the best available evidence.

The following regulations are applicable to 'effective':

- Person-centred care
- Duty of candour
- Consent
- Staffing
- Safe care and treatment
- Fit and proper persons employed

Caring
By caring, they mean that staff involve patients in their care and treatment and treat them with compassion, kindness, dignity and respect.

The following regulations are applicable to 'caring':

- Consent
- Dignity and respect
- Person-centred care.

Responsive
By responsive, they mean that the services the practice provides are organised to meet patients' needs.

The following regulations are applicable to 'responsive':

- Complaints
- Person-centred care
- Duty of candour
- Dignity and respect
- Good governance.

Well-led

By well-led, they mean that the leadership, management and governance of the practice assures the delivery of high quality, person-centred care, supports innovation and learning and promotes an open and fair culture.

The following regulations are applicable to 'well-led':

- Complaints
- Good governance
- Duty of candour
- Staffing
- Fit and proper persons (directors)
- Fit and proper persons employed
- Safeguarding patients from abuse and improper treatment.

Areas the CQC will focus on

The fundamental standards are much clearer about important areas they will focus on.
In particular, practices should ensure that they have a demonstrable governance system that enables them to monitor the quality of care delivered. This means that practices must:

- Undertake compliance audits and risk assessments and be able to demonstrate these have been acted upon, e.g. infection control audits every six months
- Understand areas of non-compliance and have an action plan for becoming compliant
- Get feedback from patients and staff and be able to demonstrate this has been acted upon
- Record and analyse complaints and be able to demonstrate that learnings from complaints have improved service provision
- Keep comprehensive, accurate patient records that clearly demonstrate that patients have been fully involved in the treatment planning process and that valid consent has been obtained before treatment starts, and understand how the Mental Capacity Act applies
- Undertake regular patient record audits and be able to demonstrate improvements made to record keeping as a result
- Record all significant events and be able to demonstrate that learnings from these have improved safety and service
- Train and involve the whole team in compliance because inspectors will talk to all team members.

Inspections

There have been significant changes to CQC inspections in terms of format and focus. In addition, there have been significant changes to pre-inspection information gathering.

Inspection types

Two types of inspection will happen in 2015/16 – 'comprehensive' and 'focused'.
Comprehensive inspections seek to establish whether the practice provides care that is safe, effective, caring, responsive and well-led; **focused** inspections focus only on areas indicated by the particular information that triggered the inspection.

10% of dental practices will have comprehensive inspections in 2015/16 - practices will be selected either randomly or on a risk-based basis. Practices classed as being a greater risk include:

- Practices that have been registered for more that 18 months and have not been inspected
- Any concern or risk identified from a previous inspection or from information gathered from other sources
- Any concern or complaint received by CQC, e.g. from a whistleblower or a patient complaint.

Comprehensive inspections will usually be announced with two weeks' notice being given.

Comprehensive inspections will take one day and will be undertaken by a CQC inspector with support from a Specialist Adviser (often a dentist) who will either attend the inspection or provide remote advice. The inspection will be thorough and will result in a judgement on whether the practice provides care that is safe, effective, caring, responsive and well-led.

Inspectors will use KLOEs (as described in Appendix A of the Dental Providers Handbook) to try to ensure a consistent approach.

Focused inspections will be in addition to the 10% of comprehensive inspection and will be triggered in response to concerns. Focused inspections can be announced or unannounced depending on why the inspection is being undertaken. The team undertaking the inspection will depend on the nature of the concern.

Focused inspections will not address the five key questions (safe, effective, caring, responsive, well-led) and instead will focus on the issue or issues that triggered the inspection. If a focused inspection identifies significant concerns, it may trigger a comprehensive inspection.

The purpose of all CQC inspections will be to establish whether the practice complies with the new fundamental standards regulations or not.

Before the inspection

CQC will spend much time gathering information ahead of a planned comprehensive inspection.
In the 4-8 weeks before an inspection, they will contact the NHS Area Team and the local Healthwatch requesting information either of them holds on the practice. They will ask for information relating to:

- Complaints received

- Assessments undertaken
- Risks or issues received
- Investigations undertaken
- The quality of care provided
- Evidence of good practice.

Two weeks before the inspection, the CQC inspector will call the practice and outline the agenda for the visit. The practice will receive a letter requesting information that includes:

- Quality monitoring information, e.g. compliments and complaints, results of patient surveys
- Information about staff employed
- An up-to-date statement of purpose
- Membership of any accreditation/good practice scheme.

Practices must respond and send the information requested within five working days.

They will also send comment cards for patients to complete and posters that they will expect the practice to display. Posters will advertise the inspection and provide information for patients on how to contact the CQC.

At the inspection

Before the inspection starts, the inspector will meet the registered manager or provider to explain the agenda for the day.

Practices will be asked to share any concerns they have identified themselves in their ability to meet the requirements of the regulations (including the new fundamental standards) and, what they are doing about it.

Inspectors will ask the practice to share examples of where they provide notable practice that goes beyond the regulations.

Please note, this is a significant change in the inspection format and means that practices must know what areas they are deficient in and what they are doing about it. The Apolline Compliance Audit and action plan provides this information.

It also means that practices need to know what the standards require in some detail in order to be able to say whether there are areas in which they exceed the standards and provide notable practice. The Apolline Compliance Audit and action plan also provides this information.

During the inspection

Inspectors will speak to dental nurses, dentists, practice managers and receptionists. They will review policies and protocols and will expect these to be tailored to the individual practice.

They will review some or all of the following:

- Equipment maintenance and certification documents
- Radiation protection file
- Audits and action plans, e.g. infection control, patient records, risk assessments, compliance
- Infection control – policies, procedures and records (they will expect these to be tailored)
- Staff recruitment – policies, procedures and staff files
- Staff training records
- Patient satisfaction surveys.

Please note, this list is not exhaustive. If the inspector has confidence the practice is on top of their compliance, they are less likely to dig deeper. If the inspector does not have confidence or staff give inconsistent answers to questions, they are likely to keep digging.

When an inspection team is inspecting, the lead inspector will review emerging findings enabling the team to refocus the inspection if necessary.

Feedback will be provided to the practice at the end of the inspection ahead of the draft report.

Following the inspection

The inspector will send the practice a draft report focusing on their findings against the five key questions (safe, effective, caring, responsive, well-led). The report may include information on any improvement they think could be made, even if the practice meets the standards and information about notable practice. It will also identify any breaches in the fundamental standards.

CQC will send the draft report to the provider to comment on the factual accuracy. The report is then published on the CQC website following any necessary changes. CQC encourages practices to publish their report on their own website, including any action plans.

Following an inspection, all providers other than dental providers will be rated as 'Outstanding', 'Good', 'Requires improvement' or 'Inadequate'. This new rating system will not apply to dental practices in 2015/16 but they reserve the right to introduce this in future.

Opinion from Apolline

The changes introduced on 1st April 2015 are significant. Despite the CQC saying the dental sector is lower risk than other sectors they regulate (which is undoubtedly true) the latest reports on the CQC website tell a different story.

The latest reports published on the CQC website from inspections of dental practices point to a significant amount of non-compliance, with anywhere between 50% and 90% requiring improvements and around 10-15% receiving a compliance action plan for a breach of the regulations.

There is no doubt there will be fewer inspections in 2015/16 but those that do get inspected should be prepared for a considerably more challenging experience than previously.

Preparation will be key to this, as will ensuring the whole team understands what they need to do and is fully involved in the practice's compliance.

10 hints and tips to help Apolline Members

1. Involve your whole team.
2. Ensure your policies and protocols are all customised to your practice, dated, up to date and understood and 'lived' by the whole team.
3. Get feedback from your patients and act on it. ***Apolline Surveys provide this.***
4. Measure your compliance against the fundamental standards to understand your strengths and weaknesses. ***The Apolline Compliance Audit and action plan provides this information.***
5. Have plans for addressing your weaknesses. ***An Apolline action plan provides this.***
6. Undertake infection control audits every six months and have evidence to demonstrate you have acted on the findings.
7. Record all significant incidents (both positive and negative) and have evidence to demonstrate you have acted on the findings.
8. Undertake regular patient record audits and have evidence to demonstrate you have acted on the findings. ***The Apolline Patient Record Audit provides a template for this.***
9. Have a method for ensuring actions from action plans do not get forgotten or overlooked. ***The Apolline Task Management Application provides this.***
10. Track your complaints and be able to show what actions you have taken.

Help and support from Apolline

Apolline provides help with all matters relating to regulatory compliance, whether that be audits, action plans, surveys, policies and protocols, templates for recording significant incidents and complaints or in-practice training. We also provide a simple means of ensuring tasks are not forgotten or overlooked. Please do not hesitate to contact us with any queries or if you need help.

Apolline provides the following help and support to dental practices.

The Apolline Compliance Audit

The Audit is mapped to the CQC's regulatory requirements in England or to the Regulatory and Quality Improvement Authority's (RQIA) standards in Northern Ireland. It also encompasses GDC requirements and includes a comprehensive patient record audit. Practices receive an action plan with items rated as red, amber or green to indicate their relative importance. The audit is undertaken by an experienced Practice Advisor and actions arising from the audit are fed into the Apolline Compliance and Task Management Application as described below. Following an audit, practices will know what areas they are compliant in and what areas they need to work on.

The Apolline Compliance and Task Management Application (the App)

This innovative application comes pre-loaded with 150+ routine tasks that help to maintain compliance and thus reduce risk. It has an intuitive user-friendly interface and practices have the ability to create their own tasks and customise the application to the particular needs of the practice. It also allows for delegation of tasks to multiple users, meaning that the whole team becomes involved in achieving and maintaining compliance.

In addition to pre-loaded routine tasks, the actions arising from the audit automatically flow into the application and are demarcated from routine tasks by a red border to indicate they have come from the audit and need attention. Actions from the audit feed are date specific and agreed at the audit, and practices receive an email prompt to help ensure tasks are not forgotten or overlooked. Practices can also upload and store evidence of their compliance on their App, meaning that evidence of compliance is readily available at all times, including for an inspection.

Apolline Questionnaires Application

Apolline's innovative patient and staff satisfaction surveys are mapped to the CQC's regulations and provide real-time feedback results with benchmarking. The questionnaires application is designed for use on a tablet device but can also be completed on a desk top, laptop and mobile phone or at home via an email link. Questionnaires can also be provided in hard copy and analysed.

Results from the surveys feed into the Apolline Compliance and Task Management Application with an electronic dashboard and PDF reporting.

The questionnaires application also provides free access to the Friends and Family Test (FFT) as required by all practices with any NHS patients.

For further information on all the services Apolline provides and how these can help you with all matters relating to regulatory compliance, please call 0800 193 1033 or email *enquiry@apolline.uk.com*