

Guidance on accessing medical and care records using powers under the Health and Social Care Act 2008

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Summary

The purpose of this document is to provide guidance to CQC staff on the use of our powers under the *Health and Social Care Act 2008* to access medical and other care records for the purpose of exercising our regulatory functions – which include registration, inspection and enforcement.

It is important that we use our powers in an appropriate and proportionate way so as to comply with the law, to protect the privacy and dignity of people who use services, and to maintain the trust and confidence of care providers and the public.

1. What are CQC's powers to access medical and care records?

Under section 63(2)(b) of the *Health and Social Care Act 2008*, a person authorised to carry out an Inspection on behalf of CQC may access, inspect and take copies of any documents or records held by the service that they are inspecting, where they consider it 'necessary or expedient' to do so for the exercise of CQC's 'regulatory functions'.

CQC's regulatory functions include registration, inspection and enforcement.

Section 63(2)(e) also allows us to seize and remove these records, if we consider it necessary or expedient to do so.

Section 63(8) explicitly specifies that these powers include access to 'personal and medical records'.

Section 64(1) allows CQC to require certain persons to provide us with any information, documents or records ('including personal and medical records') that we consider it necessary or expedient to have for the purposes of our regulatory functions. This power allows us to require those persons to send this information to us, without us having to visit the service or conduct an inspection.

The persons from whom we can require records under this power are:

- A person who carries on or manages a regulated activity,
 - A person providing adult social services commissioned by an English Local Authority,
 - An English Local Authority,
 - An English NHS body
 - A person providing health care commissioned by a CCG.
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You should use CQC's powers whenever you access medical or care records, as use of the powers protects the provider from subsequent action for breach of confidentiality under common law.

CQC has separate powers that apply to our functions under the *Mental Health Act 1983* and the *IR(ME)R* regulations. This guidance does not apply to those powers, although the same principles of confidentiality and privacy apply.

2. Who can exercise these powers on behalf of CQC?

Our section 63 powers (to access, obtain, copy or seize records during an inspection) may only be exercised by a person who holds a duly authenticated document showing that they have been granted these powers by CQC.

This document may only be provided by a person authorised to do so under CQC's Scheme of Delegation.

This 'document' may be the authorisation printed on the rear of Inspectors' CQC identity badges, or may be a separate letter or document from CQC.

Anyone attending, observing or taking part in a CQC Inspection who does not hold such a document cannot and must not attempt to exercise CQC's powers to access medical and care records. However, they may be shown relevant medical and care records where there is a legitimate reason for doing so (see question 16 for further guidance)

3. What other legal requirements apply to the use of CQC's powers to access medical or care records?

Evidence gathered during a criminal investigation or a visit which may lead to criminal enforcement action should be logged, recorded and retained in line with the guidance contained in the *Enforcement Handbook*.

Any access to, or obtaining or seizing of, medical or care records is 'processing' of 'sensitive personal data' and must be compliant with the requirements of the General Data Protection Regulation (GDPR) and the Data Protection Act 2018 (DPA). In particular, this requires that this processing must be 'fair and lawful' – this requires that the access is reasonable, not deceitful, for a defined and legitimate purpose, and that people whose information is accessed are informed of this, where it is possible to do so.

Access to the records must also meet a 'lawful basis'

under Articles 6 *and* 9 of GDPR. Access to medical or care records that is necessary for the exercise of CQC's regulatory functions will meet those conditions because it is:

- Necessary for the exercise of official authority vested in CQC – Article 6(1)(e);
- Necessary for the management of health and social care systems in accordance with the Health and Social Care Act 2008 – Article 9(2)(h); and
- Necessary for reasons of public interest in the area of public health (ensuring high standards of quality and safety of health and social care) in accordance with the Health and Social Care Act 2008 and subject to the restrictions on disclosure under that Act – Article 9(2)(i).

Accessing any person's medical or care records also impacts upon their privacy. As such, we may only do this in a way which is compliant with Article 8 of the *Human Rights Act 1998* - this Article relates to the right to 'respect for private and family life'.

Article 8, allows that the right to privacy may be interfered with to the extent that doing so is necessary for the purpose of 'protecting the health [...] or for the protection of the rights and freedoms of others'. Use of our powers in a *proportionate* way, to the extent that is necessary for the purpose of exercising our statutory functions, will therefore be compliant with Article 8.

Where CQC's powers are properly and proportionately used to access medical and care records, the *Common Law Duty of Confidentiality* is not a barrier, as there is an exception to the common law position where there is a statutory power of access.

4. How do I decide whether to access medical and care records?

Any decision to access medical and care records should be taken in accordance with the 'necessity test' in CQC's *Code of Practice on Confidential Personal Information*.

This is a 2 step test, requiring the person seeking to access the records to decide:

1. **Whether accessing the records is necessary to achieve the purpose CQC is pursuing.** This 'purpose' should be directly related to the exercise of CQC's regulatory functions (e.g. to assess compliance with a regulation). Where this purpose could effectively, reasonably and practicably be met by other means (e.g.

by use of anonymised data such as audit reports) then medical or care records should not be accessed.

- 2. Whether accessing the medical or care records is a proportionate act.** This requires consideration as to whether the public interest (to be served by the purpose CQC is pursuing) justifies the likely impact upon personal privacy. The more records are being accessed, or the more sensitive those records are likely to be, the greater the potential impact upon privacy and therefore the greater the required justification for this intrusion. Any objections that have been raised to accessing the records should also be carefully considered.

Only if both parts of the test are met should you proceed to access the records. In most cases, this judgement will be very clear and can be made quickly.

The test is not intended to unduly impede the exercise of CQC's powers and it *does not* require that there is existing evidence or reason for concern about a breach of regulations before records can be accessed.

Sector specific guidance may also be provided to assist in making this decision.

However, you *must* remember that you are exercising your own professional judgment to access people's most personal and intimate records – as such, there must be a conscious decision-making process and you must be ready to explain and justify your decision, if challenged.

If you are unsure whether both parts of the necessity test are met, seek further advice from your manager, or the Information Rights Manager, before accessing medical and care records.

5. What parts of medical or care records should I access?

You should only ask for, and access, the parts of the medical or care records that are necessary for your regulatory purpose.

Whilst you may need to search through records to find the information that you require, casually 'browsing' through someone's records – i.e. looking at parts of those records without a clear and justifiable purpose – would be a gross and unlawful infringement of their privacy.

6. Should I ask for

If you do not need to access the records of specific individuals –

medical or care records to be anonymised before I look at them?

for example, if you simply wish to look at a sample of care plans to assess their general quality – then it *may* be appropriate to ask the service to select and provide evidence to show that they meet the required standards, and to ‘anonymise’ any of those records before providing them to you.

This could be done by simply covering over or removing the names and other identifying information of the people to whom the records relate.

However - consideration should be given as to the practicality and resource requirements of doing this. If it would place a disproportionate burden on the provider or cause excessive delay, then it may not be appropriate to ask for this.

In making this judgment of proportionality, you should take into account the likely sensitivity of the care records. For example, if the records relate to sexual health, there is likely to be a greater sensitivity, and greater than usual efforts to anonymise the records may be appropriate.

Clearly, where specific records are required (e.g. for the purposes of case tracking) anonymisation may not be possible.

7. Do I need consent to look at medical and care records?

No. CQC’s powers allow you to access medical and care records *without* the consent of the people to whom those records relate – and even, if necessary, against their express wishes.

We do not seek consent to access people’s records because their agreement or refusal to such a request would not normally be the *deciding factor* in whether or not we do so.

If consent was to be requested and refused, we would risk being in the position where we would need to either; respect that person’s decision with the result of being unable to effectively carry out our regulatory functions, or to access their records anyway.

Accessing someone’s records, after you have asked them for consent and this has been refused, is ‘unfair’, and therefore is likely to be a breach of data protection law.

8. Do I need to inform or consult

If it is reasonably practicable and possible to do so, you must inform people about access to their records. Where ever

with people before looking at their medical or care records?

possible, this should be done before you access the records so as to give them an opportunity to raise any objections to you doing so.

This is *not* the same as seeking consent. The final decision on whether to access the records is *yours to make*, and you must not state or imply otherwise.

Deciding whether it is practicable and possible to inform and consult with someone is a matter of professional judgment and may involve a number of factors including (but not limited to):

- Whether the person is on the premises, or otherwise easily available, at that time,
- The sensitivity of the records (the greater the privacy implications, the more effort we should apply to informing people),
- The number of records you plan to access (and therefore the number of people you'd need to inform and consult),
- Whether the person has the mental capacity to understand what you intend to do and to raise any objections,
- The time and resources available to CQC to conduct the exercise.

Examples:

If you are speaking to a person who uses a service, and you consider it likely that you will subsequently access their records – for example, because they have raised issues about their care which you want to investigate further – then there is no practical impediment to informing them of this and giving them an opportunity to raise any objection, so you must do so.

If you have received concerns about an individual's care and intend to use our section 64 powers to obtain their records from the provider, you should consider whether it is possible to phone or write to the person to inform them of this. You should do this, unless there is a good reason not to.

On the other hand, if you are reviewing a sample of records in the course of an inspection, you may consider that the process of identifying, locating and informing/consulting all of the individuals would be difficult, time consuming and disproportionate. In that case, it may be your judgment that you will not do so.

It is important to remember that accessing medical and care records impacts upon the privacy and dignity of the people to whom those records relate. Therefore it is a matter of decency and respect, as well as a legal requirement, that we should inform them where ever possible and listen to, and give consideration to, their views.

If the person lacks capacity to understand your intentions, you should consider whether it is possible to consult with their relative or carer.

Whenever you have a conversation with someone who uses the service you are inspecting, it is good practice to explain what CQC does and how – including telling them that we have powers to access medical and care records, and how and why we use that power.

CQC also generally informs people about our role and powers, including our powers to access records, through our public communications, our website and the media.

9. What should I do if someone has concerns or objects to me looking at their medical or care records?

It is understandable that some people may have concerns about CQC accessing their records.

Where someone raises these concerns or objections you should try to provide reassurance. You can do this by explaining CQC's purpose (i.e. to assess the quality and safety of care, rather than to make judgments about that person), and by explaining how we will use and protect their records. You should consider whether you could take other steps to alleviate their concerns (for example, maybe the person could be with you whilst you look at their records).

Where objections and concerns remain, you should consider whether you could achieve your purpose by accessing the records of someone who does not have objections instead,

Where this is not possible, the person's concerns should be taken into account when considering part 2 of the necessity test - deciding whether accessing the records is proportionate by considering whether the public interest justifies the likely impact upon the individual.

In some cases, you may decide to access a person's medical or care records in spite of the concerns and objections of that person. Where this is the case, you should inform the person of

this (if possible) and explain the reason for your decision. You should keep a record of this conversation within your inspection notes.

10. What should I do if a provider tells me that someone has asked that their records not be used for 'secondary purposes' (i.e. any purpose other than their direct care)?

Wherever possible, these wishes should be respected. If you can achieve your regulatory purpose without looking at these records – for example, by choosing the records of people who have not raised similar objections – then you should do so.

However, there may be circumstances where this is not possible. For example, you may need to access specific records in order to investigate a particular issue.

Where this is the case, the person's objections should be taken into account when considering part 2 of the necessity test - deciding whether accessing the records is proportionate by considering whether the public interest justifies the likely impact upon the individual.

In some cases, you may decide to access a person's medical or care records in spite of their wishes otherwise. Where this is the case, you should inform the provider of this and explain the reason for your decision so that they can inform the person. You should keep a record of this conversation in your inspection notes.

11. What if a provider refuses to let me have access to medical and care records?

It is a criminal offence for any person to interfere with CQC's powers under section 63 or 64 of the Health and Social Care Act 2008 'without reasonable excuse'.

You should explain CQC's powers and the serious implications of obstructing those powers, and give the provider an opportunity to explain why they are refusing access to the records. Where possible, you should try to resolve any issues and alleviate any concerns.

If the provider continues to refuse access to records, you should consult with your manager and seek legal advice to consider how to proceed.

12. Should I sign a confidentiality agreement if a

No.

Whilst any such confidentiality agreement is unlikely to be

provider asks me to?

(Note: this relates only to confidentiality agreements with providers in relation to the regulation of their service. We may enter into confidentiality agreements in other circumstances, e.g. as members of a safeguarding board).

legally binding, entering into such an agreement may give the appearance that CQC is accepting limitations upon our legal powers.

When you use CQC's powers to access medical and care records, you are subject to CQC's policies and procedures – including our *Code of Practice on Confidential Personal Information*. Unlawful disclosure of confidential personal information obtained by CQC is a criminal offence. Therefore there should be no need for you to sign up to additional confidentiality agreements.

If the provider refuses access to records because you refuse to sign a confidentiality agreement, you should follow the advice above.

13. Should I look at medical and care records during a site visit, or ask for them to be sent to me?

Wherever possible, it is preferable to access medical or care records on site, in the course of an inspection, rather than requiring them to be sent to CQC.

Inspecting records on site avoids the inherent risks to information security that arise whenever sensitive information is sent by post, fax or electronically. This approach also removes the requirement for CQC to process, store and protect these sensitive personal records and so limits the risk and impact upon privacy.

14. When should I take copies or seize medical or care records?

Copying or seizing medical or care records impacts upon privacy and introduces information security risk, and should therefore only be done when you consider it both necessary and proportionate to do so. This should happen as the exception, not as the rule.

Usually when you copy or seize medical or care records it will be as part of, or in anticipation of, enforcement action and/or prosecution. Where criminal prosecution or enforcement action is anticipated, you must follow the guidance set out in the *enforcement handbook*.

Original records must only be seized where you have assessed that CQC's purposes cannot be adequately met by taking a copy of the original record.

If you seize records, you must consider whether this will impact

upon the quality and safety of that person's care – if so, you must allow the care provider to make a copy of those records, or provide them with a copy of them as soon as practicable, so as to ensure that safe and continuous care can be provided.

15. Who can I share copies of medical or care records (or information from those records) with?

CQC will not normally share medical or care records with other agencies, but may do so in exceptional circumstances – for example, where we consider disclosure to be necessary to protect any person from serious harm, or to assist in the investigation of serious crime.

Decisions on sharing information should be made in accordance with relevant policies and procedures (e.g. CQC's safeguarding policy), memoranda of understanding / information sharing agreements (where these are in place with the organisation we propose to share the records with) and our *Sharing Information* guidance.

It is your responsibility to ensure that you only share medical and care records (and other confidential personal information) where it is lawful to do so. Unlawfully sharing confidential personal information that has been obtained by CQC is a criminal offence. You can obtain advice from the Information Access Team if necessary.

Where you do share medical or care records, you should keep a record of this, setting out; what has been shared, who it has been shared with, and the purpose/reason for sharing the records. This record should be kept in an appropriate place, depending upon the circumstances – for example, alongside a safeguarding record on CRM.

Where ever possible, we must inform a person if we are sharing their medical or care records. The potential impact upon privacy is likely to be high, therefore we should make significant efforts to inform the person unless there is a very good reason not to.

We cannot and must not use our powers to obtain records on behalf of any other organisation or person. They can only be used to access records we consider it necessary to have for our own regulatory functions.

16. Can I show medical or care records to other people whose

If you reasonably believe that it is necessary to show medical or care records to another person for the purpose of obtaining advice or assistance in exercising CQC's regulatory functions, then you have the legal power to do so.

assistance or advice I require, such as medical advisors or experts by experience?

If the person to whom the records relate is identifiable, then such persons who we give access to must have been engaged to provide this assistance under CQC's policies and procedures (e.g. experts by experience), or be subject to an appropriate agreement of confidentiality (e.g. subject to a memorandum of understanding with CQC, or confidentiality requirements as part of a safeguarding board or risk panel), or be a person with a duty of confidentiality equivalent to that of a registered medical professional.

It may also be necessary to share records with external legal advisers for the purpose of obtaining legal advice. This should be done in accordance with the relevant CQC processes, and with the agreement of CQC's Legal Services team.

Where you do share medical or care records - other than with members of the Inspection team - you should keep a record of this, setting out; what has been shared, who it has been shared with, and the purpose/reason for sharing the records.

These parties should only be given access to the parts of the record that are necessary for them to provide the required advice and assistance.

Medical or care records must not be shown to, or accessed or viewed by, people who are simply 'shadowing' or observing a CQC inspection.

17. What records should I be keeping of my access to medical or care records?

This is a matter of judgment, and largely depends upon the circumstances and the likelihood of challenge. You are a professional applying your judgment to exercise CQC's powers, and you should consider how likely you are to be challenged on that judgment, and what you will be required to do to explain and justify your decisions and actions.

You should always keep a general record of the medical and care records you have accessed and why (e.g. that you looked at 10 people's care records to check whether they were accurate and up to date) within your inspection notes.

In some cases, you may consider it appropriate to keep a record which identifies *whose* medical and care records you have accessed. In particular, this is likely to be appropriate where:

- You have reason to believe that your access to the records, or the information you find within them, is likely

- to be the subject of dispute, complaint or challenge,
- You are accessing the records against the express wishes of the person to whom they relate,
 - You find information in a record that is likely to result in further investigation or follow-up action which will require you to be able to identify the person to whom the record relates at a later date,
 - You are tracking an individual's care,
 - The record contains evidence of a serious breach of regulation, or
 - The content of the record raises serious safeguarding concerns.

When making a record, you should take care to limit the potential privacy impact and information security risk as far as possible. Where possible, you should not record the person's name but should instead use their NHS Number, or another unique identifier. Recording initials and/or age or date of birth is preferable to full name, but provides very limited privacy protection (because it is often relatively easy to re-identify the person).

Medical or care records being accessed for the purposes of a potential criminal prosecution should be recorded in accordance with CQC's guidance on the Code B of the Police and Criminal Evidence Act 1984.

18. Where can I get advice and assistance?

Advice is available from:

- Your line manager
 - The Information Rights manager
 - The Information Access Team (information.access@cqc.org.uk)
 - CQC legal advisors
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Tools for the job

Links to:

- [*Code of Practice on Confidential Personal Information*](#)
 - [*Sharing Information guidance*](#)
 - [*Information Governance policies*](#)
 - [*Enforcement Handbook*](#)
 - [*Our regulation – *guidance* for inspectors*](#)
-