

Our enforcement policy

October 2010

About the Care Quality Commission

The Care Quality Commission is the independent regulator of health care and adult social care services in England. We also protect the interests of people whose rights are restricted under the Mental Health Act.

Whether services are provided by the NHS, local authorities or by private or voluntary organisations, we make sure that people get better care by:

- Driving improvement across health and adult social care.
- Putting people first and championing their rights.
- Acting swiftly to remedy bad practice.
- Gathering and using knowledge and expertise, and working with others.

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1. Introduction

This policy sets out the principles we will follow when using the enforcement powers in the Health and Social Care Act 2008 to improve health and social care services and protect the health, safety and welfare of people who use them.

We will continue to monitor the effectiveness of this policy and revise it when necessary.

Context

- 1. The Care Quality Commission (CQC) is the independent regulator of health and adult social care services in England. We register services if they meet essential standards of quality and safety required by the law and check that they continue to do so.
- 2. Where providers fail to meet the requirements of the law we have powers to intervene and if necessary take action against them. This includes services that are operating without being registered.
- 3. This enforcement policy describes how we will use our enforcement powers and the principles behind our approach. It was published on 1 October 2010 and replaces the policy we published on 1 April 2009.
- 4. This policy does not apply to the way we use our powers under the lonising Radiation (Medical Exposure) Regulations 2000.

Background

- 5. The Health and Social Care Act 2008 gives us a variety of powers to intervene and take action where the requirements of the Act are not being met.
- 6. These legal requirements and powers are set out in:
 - The Health and Social Care Act 2008 ('the Act')
 - The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010
 - ('the regulated activities regulations')
 - The Care Quality Commission (Registration) Regulations 2009 ('the registration regulations')
- 7. Providers and managers of regulated activities ('registered persons') have to comply with three different kinds of requirements under the Health and Social Care Act 2008:
 - They must apply for registration and show that they can comply with the requirements of the law.

After registration, they must comply with:

- Any conditions of registration.
- The relevant sections and regulations of the Act.
- 8. Our Guidance about compliance: Essential standards of quality and safety:
 - Sets out the outcomes people should be able to expect when they receive care. It is designed to help registered persons comply with the regulated activities and registration regulations. These are the regulations that most directly relate to the health, safety and well being of people who use services.
 - Where the Essential standards are not being met we can take compliance action, or enforcement action if this is due to failure to meet the requirements of the law.

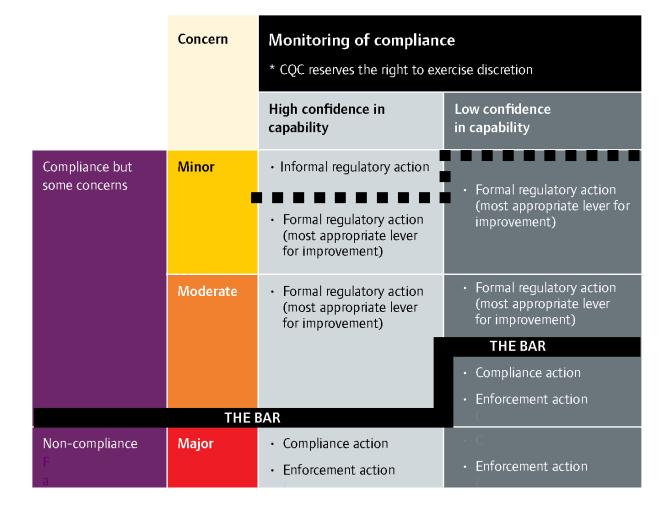
9. The Act and regulations:

- Provide direction to registered persons about what they must do.
- Provide CQC with powers to monitor and inspect regulated activities and to gather information about whether relevant requirements are being met.
- Provide CQC with powers to prosecute unregistered providers of regulated activities.
- Provide CQC with civil powers to promote compliance by limiting what a registered person is allowed to do, or by temporarily or permanently stopping them from carrying on regulated activities.
- Provide CQC with powers to prosecute, fine, warn and caution registered persons who break the law.

10. Our judgement framework:

- Sets out the processes we use to evaluate evidence about a service and assess the risk of failure to comply with the essential standards of quality and safety.
- Together with our 'setting the bar' guidance and this policy, sets out how we
 will make decisions about responding to registered persons who are not
 meeting the essential standards and the requirements of the law (see
 figure 1).
- 11. We will take into account the likely impact of enforcement action on people who use services, their carers and families and the wider community when planning what kind of action to take.

Figure 1: Setting the bar



Enforcement options

- 12. If we think a service is not meeting the Essential standards and the requirements of the law, or if it is operating outside of the law because it is unregistered, we will decide what kind of regulatory action to take. What we do will depend upon the circumstances we are dealing with.
- 13. Where problems can be resolved quickly and easily, and there is no immediate risk of unnecessary harm to people, we will discuss voluntary action with the provider to achieve improvements.
- 14. Where we have concerns that registered providers are not currently meeting the requirements of the law, or are not likely to meet the requirements of the law continuously over time, we can set improvement actions or compliance actions, and/or take enforcement action as appropriate.
- 15. Where enforcement is needed we can take 'civil enforcement' or 'criminal law' action.
- 16. Civil enforcement action is taken when we need to protect people who use services from unnecessary harm through improving care or preventing the provision of unsafe care.

- 17. Criminal law action is taken when we want to hold a registered person to account for causing unnecessary harm and/or failing to meet important requirements of the law.
- 18. Civil enforcement and criminal law can be used together if people who use services need protection from unnecessary harm and it is also appropriate that a registered person is held to account.
- 19. We can use the criminal law to prosecute unregistered providers of regulated activities.

Table 1: Enforcement options

Formal regulatory action					
Improvement actions					
Compliance actions					
Civil enforcement		Criminal law			
Warning notice		Warning notice Fixed penalty notice			
Variation / removal / imposition of condition(s) of registration					
Urgent variation / removal / imposition of condition(s) of registration					
Suspension of registration					
Extend a period of suspension of registration		Simple caution Prosecution			
Urgent suspension of registration / extension of suspension					
Cancellation of registration					
Urgent cancellation of registration					

20. We will at all times consider the likely outcomes of our enforcement work and where relevant and possible discuss our action with people who use services and their supporters, and keep them informed of developments.

2. Principles of enforcement

- 21. Our overarching concern and priority is to protect the safety of people who use the services we regulate, and improve the quality of care they receive.
- 22. We will be **proportionate** in how we work with providers and others to achieve compliance with the Act and regulations.
 - We will carefully assess any risks to people using, working in and visiting services, and where necessary take enforcement action that is in proportion to those risks.
 - We will encourage improvement without the need to take enforcement action wherever possible. This includes increasing monitoring activity and/or site visits where necessary, or ensuring that unregistered providers apply for registration. Where a service fails to meet the Essential standards in a way that breaks the law we may take enforcement action.
 - Where legal requirements are not being met we will choose the most proportionate way of achieving sustained compliance with the essential standards.
 - In making decisions about enforcement options we will take into account a provider's track record in:
 - Achieving and maintaining a service that meets people's needs and all relevant legal requirements.
 - Responding to any requirements made in reviews of compliance reports, improvement and compliance actions we have set, and formal enforcement action.
 - Our decisions about enforcement options will take into account how a provider has responded to actions that we and other regulators have made in the past, and how well their subsequent compliance was maintained over time.
- 23. We will be **accountable** for our decisions.
 - This policy clearly describes our approach to regulation, and it can be used by people when testing our actions and to hold us to account.
 - We positively welcome comments and feedback about our enforcement work and how we have used our powers. We have a complaints procedure that people can use to express concerns about our work and decisions.
 - The law provides means by which providers can make representations and appeals against our decisions. We will inform stakeholders about how they can use these, and we will engage with these processes positively and openly.
- 24. We will be **consistent** in applying our enforcement policy.
 - Consistency does not mean that we will use the same enforcement option every time a particular legal requirement is not met. It does mean that we will

use the same criteria and approach when deciding how to respond to non-compliance.

- These criteria include taking into account:
 - The impact on and outcomes for people, carers and families, and communities.
 - A provider's track record of compliance and responding to requirements.
 - The level of confidence we have in the capability of the provider to achieve and maintain change and compliance.
- In order for us to have high confidence in a provider's capability they must demonstrate that they:
 - Are willing to cooperate with us.
 - Understand the concern we have expressed and what they should do to resolve it.
 - Are a previously compliant provider (we cannot have high confidence in providers that are repeatedly non-compliant in the same areas or continue to drift between compliance and non-compliance).
 - Are aware of their shortfalls, include them in their Provider Compliance
 Assessments (a self-assessment tool for providers to use in monitoring
 their compliance with the essential standards), and have appropriate plans
 in place to manage them.
 - Have the resources needed to make improvements to meet essential standards of quality and safety.
- We will always try to avoid duplicating the work of other bodies with contractual relationships, service level agreements, performance management responsibilities or regulatory relationships with or for providers.
 - We will seek agreement on processes for identifying the most effective levers for achieving compliance, wherever they are held.
 - We will, however, use our powers whenever this is needed or appropriate.
- We will collect information about and monitor our enforcement activity to check that we are being fair and consistent, both nationally and across all kinds of provider.
- 25. We will be open and **transparent** about our approach to enforcement.
 - We will consult on any changes to this policy (as required by law) and produce guidance and information about it in plain English and in a variety of formats, so that it is accessible to all people who use services, their families and carers, providers, and the public.
 - We will publish information about our enforcement activity, both in national reports and also in reports about providers.
- 26. We will **target** our resources where they are most needed.
 - We will gather and review data and trends about our enforcement work, so that we can understand:
 - The scale of non-compliance with the essential standards and legal requirements.
 - How we are responding to it.

- How successful different options are in addressing different problems.
- The outcomes of our enforcement work for people, families and communities.
- Our activity and performance at a national, regional, area and individual levels.
- We will use this information to help us manage our resources in the most effective and efficient ways.
- We will report on our enforcement activity in our review of compliance reports on individual providers, on our website, and in our annual state of social and health care and other national reports.
- We will work with partner agencies and regulators to achieve agreement on ways of working that avoid duplication, in particular where:
 - The provider is an NHS body subject to regulatory, performance or contractual oversight.
 - The provider is a contractor to local social care and health commissioners.
 - The provider is regulated by another statutory body.
- We will take into account the equality and diversity dimension to enforcement. To help us, we will develop ways of gathering information about:
 - The enforcement options we choose in circumstances with a relevant diversity dimension, and how the diversity dimension is recognised.
 - Outcomes for people, carers, families and communities flowing from noncompliance with essential standards relating to inequality, direct or indirect discrimination, barriers associated with the diverse nature of our society, and breaches of people's human rights.
 - Whether this policy is being consistently applied regardless of the age, any disability, gender, gender identity, sexual orientation, race and ethnicity, religion or belief of providers and people who use their services.
- We will always take into account and gather information about the impact of our enforcement work on people who use a service, their families, community, and the local care economy.
- We will balance the consequences of taking enforcement action against the risks of taking no action.

27. We will always:

- Ensure that our work is led and undertaken by appropriately trained, skilled staff.
- Be consistent in applying our approach to enforcement to the NHS, adult social care, independent health care, private, voluntary and local authority providers.
- Follow up enforcement activity in a timely fashion.
- Monitor the operation of the enforcement policy, and take seriously any comments from providers and people who use services.
- Act in the best interests of people who use services and their families and carers.

3. Investigations

- 28. Section 48 of the Act gives us powers to carry out investigations into the provision of English NHS health care and adult social care, including related functions of local authorities. We must also carry out an investigation when asked to do so by the Secretary of State for Health.
- 29. We will use our investigation powers where we become aware of evidence of a significant problem affecting a whole local care system rather than a single provider. The principles that apply to our approach to enforcement also apply to how we manage investigations.
- 30. Investigations allow us to look into actual or potential serious systemic failings, for example where lack of coordination between sectors and / or services leads to unnecessary serious harm. We will publish the findings of any investigation we undertake, and ensure that improvements are made as a result. These improvements can be in the service under investigation or across a local care system.
- 31. We use investigations to understand the root causes of problems in a system. There can be overlaps between our investigation and enforcement powers. Investigations can uncover evidence that leads us to take enforcement action against individual registered persons.
- 32. Enforcement action following an investigation may include recommending special measures in relation to an English local authority and serving notices on relevant persons requiring action to deal with failures.
- 33. We have developed criteria to help us plan investigations. These are set out in appendix A. We are required by law to publish a report following an investigation and, as well as using our own powers, we can offer advice to the Secretary of State for Health on any of the issues raised for example, advice on policy issues or changes that we think are necessary to prevent similar problems arising elsewhere.

4. Our enforcement powers and how we will use them

- 34. Our enforcement powers under the Health and Social Care Act 2008 are explained in detail below. Additional detailed operational guidance has been prepared for individual processes and types of action.
- 35. Registered providers and managers both have a duty to make sure that the regulated activities they are responsible for are carried on and managed in a way that complies with the law. They should discuss any concerns about this that they cannot together resolve with the Commission, individually if necessary. Failure to do so will be taken into account when we take decisions about who we are going to take enforcement action against.
- 36. Where we have started taking action against a registered person and subsequently find failure to comply with a different regulation, we can begin additional, separate enforcement action against them for the new breach.
- 37. Where a provider makes 'low level' but continuous or frequent breaches of regulations, we will not hesitate to escalate our enforcement action so that problems are dealt with swiftly and firmly. We will always follow up enforcement action to ensure that improvements are made.

Advice and guidance about improvement

38. Where appropriate we will respond to minor concerns about a provider's compliance or risks to continuous compliance that do not impact on people's safety and welfare through discussion and guidance.

Improvement actions

- 39. Setting improvement actions is not civil or criminal enforcement activity, but is nonetheless an important and significant step.
- 40. Where a provider is complying with a regulation but we are concerned that they will not be able to **maintain** this compliance continuously, we will use our power under Regulation 10 (3) of the regulated activities regulations to require that they send us a report showing how they will maintain compliance and the action they will take to do so. Sending us these reports is required by the law and failure to do so can in itself lead to enforcement action.
- 41. When requiring a report under the improvement action process, we will show the relevant regulation, why we are concerned that compliance will not be maintained, and the outcomes that people should be experiencing. We will give a timescale for the return of a report.
- 42. Improvement actions are included in the review of compliance reports we publish on each location where regulated activity is carried on. They may also be set by letter or email where we have a very minor concern.

Compliance actions

- 43. Like improvement actions, setting compliance actions is not civil or criminal enforcement activity, but is also an important and significant step to take.
- 44. Where a provider is not complying with a regulation but people are not at immediate risk of unnecessary serious harm we will use our power under Regulation 10 (3) of the regulated activities regulations to require that they send us a report showing how they will achieve compliance and the action they will take to do so. Failure to send us a report can in itself lead to enforcement action.
- 45. We will say which regulation is not being met when setting improvement actions, and will give a timescale for the return of a report from the provider showing the action they will take to achieve compliance with the relevant regulation and essential standards outcome(s).
- 46. Compliance actions are also included in the review of compliance reports we publish on each location where regulated activity is carried on.

External processes

Working through partner agencies and their regulatory, performance management and commissioning processes

- 47. A number of partner agencies have powers, duties and/or responsibilities we can ask them to use to encourage providers to improve and/or achieve compliance.
 - Authorities and bodies with a regional or national performance management role relating to activities funded by the NHS.
 - Authorities and bodies with responsibilities for commissioning adult social care and NHS funded care.
 - Professional regulators and other statutory bodies such as Monitor, the General Social Care Council, the Independent Safeguarding Authority, the General Medical Council, the Nursing and Midwifery Council and local authority environmental health departments.
- 48. A number of regulators have powers and processes they can use to achieve compliance with requirements that are similar to our own. Before we use our criminal law and civil enforcement powers we will consider whether another body or bodies may be better placed to intervene in a way that achieves compliance with the law. If so we will arrange a meeting of relevant agencies that can lead to a collaborative review and/or action by the most appropriate agency or agencies.
- 49. Where people have been harmed or placed at risk of harm we will consider whether it is appropriate to refer a person to relevant outside agencies, such as to the Independent Safeguarding Authority.

Criminal law

Warning notices, penalty notices, simple cautions and prosecution

- 50. Criminal law procedures can be used in response to breaches of certain regulations and sections of the Act (see appendix C). They can be taken against any registered person, or, in the case of a service that is operating without registration, the person who appears to be carrying it on (warning notices cannot be used against unregistered providers).
- 51. We can use criminal law procedures:
 - Where a registered person has not taken compliance action we have set, and continues to fail to comply with the law.
 - When a registered person is not complying with the requirements of registration under their current conditions (see 'choosing enforcement options' below).
 - Where it is appropriate to serve a 'warning notice' (see below).
 - When a registered person has been dishonest or obstructive.
 - When people have or may suffer unnecessary harm because a registered person has failed to comply with a relevant regulation or requirement of the Act.
 - To formally warn, fine, caution and/or prosecute registered persons about failures to comply with certain regulations and requirements of the Act.
 - When it is appropriate to prosecute registered persons for a failure to comply with requirements.
 - When we are satisfied that an offence has taken place.

Warning notices

- 52. We serve warning notices where we believe compliance can be achieved without posing a risk to people who use services while the provider takes action to comply. This includes where:
 - There is clear evidence of failure to comply with the Act or a relevant regulation, and
 - We have judged that the provider is capable of achieving compliance.
- 53. Warning notices tell a provider formally that they are not complying with a requirement in the Act or a regulation. We can serve notices about individual breaches of the law or about continuing non-compliance. Where a notice is about continuing non-compliance it will include a timescale by when compliance must be achieved. If a provider is still not complying with the requirement when the timescale expires we can begin prosecution proceedings.
- 54. We can also serve warning notices about failures to comply with legal requirements under other Acts of Parliament that we consider are relevant, for example the Mental Capacity Act 2005. But we can only prosecute a registered person for continuing failure to comply with a Health and Social Care Act 2008 requirement.
- 55. Warning notices say which legal requirement is not being met, how it is not being met, and what must be done to achieve compliance. Where appropriate they will include a timescale.

- 56. When setting timescales in a warning notice we will take into account a provider's track record in complying with the law and responding to our concerns. Timescales will generally be the shortest period within which a provider can be reasonably expected to achieve compliance.
- 57. There are important rules relating to the evidence that warning notices are based on. We will take these rules carefully into account when deciding whether a warning notice is appropriate. If we serve a warning notice that is then complied with we cannot use the evidence supporting it in any subsequent legal proceedings. Because of this we might not serve a warning notice if that will stop us using the evidence in any future enforcement proceedings that may be needed to prevent or respond to further unnecessary harm. Where this is likely to be the case we can consider setting compliance actions as an alternative way of drawing the registered person's attention to failure to comply with the law.

Penalty notices

- 58. We can serve a penalty notice when:
 - A registered person has failed to comply with certain requirements of the Act or regulations.
 - Our evidence meets the standard for a criminal prosecution.
 - The code for crown prosecutors has been followed.

The registered person can take the opportunity to admit the offence, pay the fixed penalty, and avoid prosecution.

- 59. If a registered person decides not to pay the penalty we can consider using our other enforcement powers; this would normally be to prosecute the person.
- 60. We will consider using penalty notices when:
 - Our evidence meets the standard for a criminal prosecution and the code for crown prosecutors has been followed, and
 - We have judged that the provider has the capability to achieve compliance, and
 - Where relevant, the offence was continuing when the timescale in a warning notice has expired, and
 - We prefer to focus on improvement without beginning lengthy and costly alternative enforcement action.
- 61. The relevant legal requirements and associated fines are set out in appendix D:

Simple cautions

- 62. We can offer a 'simple caution' instead of prosecuting a registered person or a person who has carried on a regulated activity without being registered, where:
 - There is clear evidence of guilt, and
 - Our evidence meets the standard for a criminal prosecution, and
 - The code for crown prosecutors has been followed.

The offender must admit the offence and be prepared to accept a caution.

63. When deciding whether to caution a registered person we will consider guidance issued by the Home Office (currently HO Circular 016/2008).

64. Although we are not required by law to publish details of simple cautions, we have a general power to publish this type of information and will normally do so.

Prosecution

- 65. We have powers to prosecute for certain offences defined in the Act and the regulations made under it. Prosecution is a serious enforcement activity. It holds managers or providers to account for not complying with the law. It can sometimes be appropriate to prosecute at the same time as taking other enforcement action, for example to suspend a registration.
- We can only prosecute registered persons for certain breaches of the regulated activities regulations after a warning notice has first been served but compliance with the requirements it made has not been achieved, as set out in paragraphs 52 57 above. This means that we can only prosecute a registered person in relation to an offence which was continuing after the timescale in a warning notice had expired.
- 67. We would not begin prosecution proceedings unless we were satisfied that:
 - It was in the public interest
 - There was sufficient admissible and reliable evidence that an offence had been committed, and
 - There was a realistic prospect of conviction.
- 68. In reaching a decision to prosecute, we will take into account the principles in the code for crown prosecutors:

 www.cps.qov.uk/victims witnesses/code.html
- 69. Where another regulator has the power to prosecute we will coordinate activity with them to ensure the right action is taken, to avoid inconsistency, and to ensure that any proceedings taken are for the most appropriate offence.
- 70. Where we successfully prosecute a provider, the courts decide on the fine that is imposed and are able to issue a separate fine in relation to each conviction. The courts may decide to impose a prison sentence as well as, or instead of, a fine following conviction for failure to be registered.
- 71. The offences and maximum court fines are set out in appendix D:

Civil enforcement

Limiting providers through imposing, removing and varying conditions of registration, suspending registration, cancelling registration, and suspending or cancelling registration using the urgent procedures

- 72. Civil enforcement procedures follow processes laid down in the Health and Social Care Act 2008. They are used to impose temporary or permanent changes on a person's registered status.
- 73. We impose these changes:
 - When providers have failed to respond to improvement and compliance actions, relevant criminal procedures or intervention by our partner agencies, or when people are at risk of unnecessary serious harm

- To limit how an activity is provided, or
- To stop a provider from carrying on an activity, temporarily or permanently.
- 74. We use civil enforcement procedures:
 - When people have or may suffer unnecessary harm because a registered person has failed to comply with the essential standards.
 - Where a registered person is not capable of carrying on the regulated activity, either at all or under current registration conditions.
 - Where a registered person is capable of carrying on the regulated activity under current registration conditions but has a track record of not doing so.
- 75. We can use civil enforcement procedures where a provider has failed to achieve compliance after a warning notice has been served, with or without action under the criminal procedures.

Impose, vary or remove conditions of registration

- 76. Providers and managers who register with us always have certain routine conditions attached to their registration. These conditions are about things like the locations where regulated activity can be carried on or managed. For activities that include providing accommodation there will usually be limits on the number or age of the people who use the service. These registration conditions are usually agreed with providers and managers when they apply for registration.
- 77. Imposing, varying and removing conditions of registration is a flexible enforcement process that we can use in a variety of different ways to keep people safe and ensure that the requirements of the law are met. For example, we can use conditions in a proportionate and targeted way to ensure that the Essential standards are met without disrupting an entire service, for example by stopping an activity being carried on at an unsafe location while it continues at the provider's other locations. This can be temporary or permanent. We might also use conditions to stop new admissions to a service where we have issued a notice to cancel registration but an appeal is pending.
- 78. We begin formal proceedings in relation to conditions of registration by sending a notice proposing the change we think is needed together with our reasons and evidence. Registered persons have a right to make representations to us against our proposal before we make a final decision. If we decide to 'adopt' our proposal we send a notice to the registered person to tell them. Registered persons have a right of appeal to an independent tribunal against our notices of decision. We have written separate detailed guidance about the representations and appeals processes.
- 79. We also have powers to impose, vary or remove conditions using urgent procedures. These procedures do not require a notice of proposal and take immediate effect. We will only use the urgent procedures where people will or may be exposed to unnecessary and serious harm to their safety and welfare if we do not act immediately (see also paragraphs 87 and 88 below).

Suspension of registration

- 80. We can suspend the registration of a provider or manager entirely for a specified period of time, and extend a period of suspension. Suspension of registration is a serious step that can have major consequences for a provider. Suspension affects all of the locations where the relevant regulated activity is carried on or managed by the registered person. We will therefore give particular attention to the likely outcomes of taking this action. Suspension can, however, give a provider the chance to work towards achieving compliance and then resume carrying on or managing an activity. We follow the same notice of proposal and decision procedure described above for suspension of registration.
- 81. We can also suspend or extend a period of suspension using urgent procedures (see also paragraphs 87 and 88 below).
- 82. We will use our powers to suspend a registration when there is good evidence that that a provider or manager who is not able to meet relevant regulations will be willing and able to do so at a defined point in the future.

Cancellation of registration

- 83. Our most powerful sanction is to cancel a registration outright. As with suspension, this would affect all the locations where the registered person carried on or managed the relevant regulated activity. Cancellation normally follows considerable efforts to achieve or encourage compliance with the essential standards, but where necessary we can use the cancellation process without first having followed other processes.
- 84. Where people are at immediate risk of unnecessary serious harm to their life or well-being we can use urgent procedures to apply to a court for an Order to cancel a registration with immediate effect (see below). As in the other urgent procedures, there is no right to make representations, but there is a right of appeal with fast track procedures (see paragraphs 87 and 88 below). It would be an offence for a provider or manager to carry on or manage the activity after their registration had been cancelled.

Urgent procedures to cancel a registration

- 85. We would only consider using the urgent procedures to cancel a registration as a last resort and where the problem cannot be resolved in any other way. This is where people who use a service are put at unacceptable risk of serious unnecessary harm because care is so unsafe or of such poor quality that it would not be appropriate to allow time for representations and appeals to be considered.
- 86. When using our powers to apply to a justice of the peace for the cancellation of a registration using the urgent procedures we will wherever possible:
 - Tell the registered person in advance about our application to cancel their registration using the urgent procedures.
 - Only make an application without telling and involving the registered person in exceptional circumstances, such as when their whereabouts are not known.

Where we cannot give the registered person notice of our application to a justice of the peace we will make a full and frank disclosure of all relevant evidence and confirm that we have done so in our application.

Urgent procedures – general

- 87. Action under the urgent procedures takes immediate effect. Registered persons have the right of subsequent appeal to an independent tribunal. A memorandum of understanding recently agreed between CQC and the Tribunal service sets out how such appeals will be managed. CQC will comply with the memorandum.
- 88. When serving an Order or Notice on a registered person using the urgent procedures, it will always include information about:
 - Our memorandum of understanding with the tribunal about a 'fast track' option for appeals when we have used the urgent procedures.
 - How the registered person can appeal against the urgent cancellation order or notice.

Representations and appeals

Representations

- 89. Registered persons have the right to make representations to us about certain types of enforcement action. We have produced separate detailed guidance about this. Representations must be submitted within 28 days of the service of:
 - Relevant warning notices.
 - A notice of proposal to impose, vary or remove conditions of registration.
 - A notice of proposal to suspend a registration, or to extend the period of a suspension of registration.
 - A notice of proposal to cancel a registration.
- 90. Providers or bodies that are investigated under our Section 48 powers can also make representations to us about our subsequent report before it is published.
- 91. There is no right to make representations against Orders or Notices served under the urgent procedures, compliance and improvement actions, and criminal procedures. Registered persons can write to us with any concerns about these actions, and have access to our complaints procedure.

Appeals

- 92. Registered persons have the right to appeal to an independent tribunal against enforcement action using the civil enforcement procedures. We have produced separate detailed guidance about this. Appeals must be lodged within 28 days of the service of:
 - A notice of decision.
 - A notice of imposed, varied or removed conditions using the urgent procedures.
 - A court order to cancel a registration using the urgent procedures.
- 93. There is a fast track option for appeals against Orders and Notices served under the urgent procedures (see paragraphs 87 and 88).
- 94. There is no right of appeal to the Tribunal in relation to warning notices, penalty notices or conviction for offences.

Co-ordination with partner agencies

95. Action to cancel or suspend a registration, or to impose, vary or cancel conditions of registration using either normal or urgent procedures, will where necessary always be carefully coordinated with other relevant bodies, for example commissioning local authorities and health trusts or the independent regulator of NHS foundation trusts. We will always carefully consider the balance of risk between different options.

Enforcement pathway criteria

- 96. We will follow the criteria set out below when deciding whether to follow criminal or civil enforcement processes, or both.
- 97. We will follow only criminal enforcement procedures where an offence has been committed, and:
 - A provider is carrying on regulated activity without being registered, or
 - A registered person is capable of complying with the Essential standards of quality and safety but did not, and
 - We believe the registered person will comply in the future
 - We do not want to limit the registered person with conditions of registration or to stop them from carrying on or managing regulated activity
 - We decide that it is appropriate to hold the registered person to account.
- 98. We will follow only civil enforcement procedures where:
 - People have experienced or are at risk of significant unnecessary harm, and
 - The registered person is not capable of complying with the Essential standards.

Imposition, variation and removal of conditions

- We will follow procedures to impose, vary and/or remove conditions of registration where:
 - A registered person would be capable of meeting the Essential standards and relevant legal requirements if their activity was limited by appropriate conditions, and
 - We are reasonably confident that they will make any necessary improvements.

Suspension of registration

- We will follow procedures to suspend a registration where:
 - A registered person is not currently capable of meeting the Essential standards and relevant legal requirements, but
 - We are reasonably confident that they will be capable of making the necessary improvements by a specific date in the future.

Cancellation of registration

 We will follow procedures to cancel a registration where a registered person is not capable of meeting the Essential standards and relevant legal requirements, even if limited by appropriate conditions on their registration.

99. Urgent procedures

- We will use the urgent procedures to cancel a registration or impose, vary or remove conditions of registration where the relevant civil enforcement criteria are met and:
 - People are experiencing or are at risk of imminent serious unnecessary harm, and
 - There is no other way of ensuring their safety and welfare.
- We will use the urgent procedures to suspend a registration or extend a period of suspension of registration where the relevant civil enforcement criteria are met and:
 - People are experiencing or are at risk of imminent serious unnecessary harm, and
 - There is no other way of ensuring their safety and welfare, and
 - We are confident that they will be capable of making the necessary improvements by a specific date in the future.

100. Criminal and Civil enforcement procedures together

- We will use criminal and civil enforcement procedures where:
 - A registered person is capable of meeting the Essential standards and relevant legal requirements but did not do so, and
 - The registered person has failed to achieve continuing compliance after previous regulatory action we have taken, and/or
 - People experienced or are experiencing or are at risk of serious unnecessary harm as a result of their not meeting the Essential standards and the requirements of the law, and
 - We decide that the registered person should be held to account as well as prevented from or limited in carrying on or managing a regulated activity.
- 101. We will always use criminal procedures where a registered person is dishonest, obstructive and/or intimidating to people using services, their supporters, other witnesses and/or CQC staff.

5. Publication and notification of enforcement action

- 102. Regulations require and authorise us to publish certain information relating to enforcement action within three months from the end of proceedings, including about any representations and appeals.
- 103. Information about improvement actions, compliance actions and formal enforcement action in relation to individual locations is included in review of compliance reports. Our website will also publish summary information about improvement actions, compliance actions, and formal enforcement action taken against each provider.
- 104. The Act requires us to send copies of notices relating to enforcement action to various bodies, including primary care trusts (PCTs), local authorities, strategic health authorities (SHAs) and the independent regulator for NHS foundation trusts. Regulations specify which bodies should be given copies of notices relating to various aspects of enforcement action, and in which cases we do not need to provide notification of enforcement action.
- 105. We aim to publish an annual report on enforcement, in order to promote learning and review trends.

6. Working with other organisations

- 106. Where we and another enforcement body, for example the police or the Health and Safety Executive, have the power to take action about the same circumstances, we will work together to ensure that we coordinate our respective action and do not duplicate action against registered persons. This will avoid inconsistencies and ensure that action is taken by the most appropriate body.
- 107. Where there are allegations of or actual abuse involving people in services we regulate, we will inform the appropriate local authority using our adult safeguarding and child protection procedures. We will work with all other relevant agencies to ensure that people are appropriately protected using relevant local safeguarding procedures.
- 108. We will work with all appropriate organisations when using our enforcement powers, depending on the kind of provider. For example, we will work with:
 - The independent regulator of NHS foundation trusts.
 - Relevant national, regional and local NHS bodies in relation to NHS trusts and services provided or funded by NHS bodies locally.
 - Local authorities in relation to adult social care services.

This will help us to take into account what alternative services are available for the people affected by our action, consider alternative action where that is appropriate, and encourage joint working between relevant authorities.

- 109. Monitor's role (the independent regulator of NHS foundation trusts) is to ensure that NHS foundation trusts operate in an efficient, effective and economic manner. We will not duplicate this role. Failure by an NHS foundation trust to comply with our requirements may also be a breach of the independent regulator's terms of authorisation, and could lead to intervention by them.
- 110. Our role in relation to all providers, including NHS foundation trusts, is to ensure that they meet the essential standards of quality and safety. We will always liaise with the independent regulator of NHS foundation trusts before taking enforcement action against an NHS foundation trust. The only exception to this would be where we needed to take immediate action using the urgent procedures to protect the safety of people who use services.

Appendix A – Criteria for formal investigation

Our role and powers include undertaking investigations into the provision of:

- NHS provided or funded care.
- Adult social services.
- The functions of strategic health authorities and special health authorities in England.

We are required to publish a report following any such investigation.

We undertake investigations when we become aware of relevant and specific concerns. Investigations involve gathering evidence on, and developing an understanding of, the reasons for serious failing in the provision of care across a local system. We can make recommendations to prevent the failing happening again. When conducting an investigation we will take account of accepted standards or, in their absence, descriptions of good practice (for example from professional bodies).

Triggers that might alert us to the potential need for an investigation include:

- **Direct contact** from service users, the public, staff or the media.
- Issues brought to light during our other regulatory activities.
- Requests from the Secretary of State for Health, or from other regulatory bodies.

We have wide discretion about the circumstances which will lead to an investigation.

Generally, this will only be where we have credible information that suggests that there may be or may have been a serious failing in:

- The provision of care, or
- The exercise of functions.

by any of the above bodies that has or may affect:

- People's basic safety.
- The effectiveness of a service.
- The responsiveness of a service to people's needs.

Where a situation does not fulfil one or more of these criteria we can still consider whether an investigation should be started, taking into account its particular circumstances.

Factors which might trigger us to commence a formal investigation include:

- A higher number than anticipated of unexplained deaths.
- Serious injury or permanent unnecessary harm to people, whether physical, psychological or emotional.
- Events which put at risk public confidence in care provided, or in the NHS, independent sector or adult social services generally.
- A pattern of adverse outcomes for people or other evidence of high-risk activity.
- A pattern of failures on the part of a service or services; or team or teams, or concerns about them.
- Allegations of abuse, neglect or discrimination affecting people who use services, particularly those less able to speak for themselves or defend their rights.

When we are deciding whether to investigate, we will consider the extent to which local resolution, referral to another body, or other action might offer a more effective solution.

Generally, we will not investigate:

- Individual incidents that have not been pursued through the appropriate complaints procedure, unless it raises an immediate concern.
- Individual complaints about professional misconduct.
- Changes to how a service is organised (such as mergers).
- Employment or disciplinary matters.
- Matters being considered by a legal process.
- Specific matters already considered by a legal process.

This does not prevent us from investigating relevant circumstances associated with or flowing from these situations. A matter that has been dealt with by one of the processes above may have uncovered concerns about the safety of people using services, or suggest that an organisation is seriously flawed.

We will consider all allegations of serious failings, decide whether rapid or other action is required, and liaise with relevant bodies. Where appropriate we will refer the matter to another agency, such as the police.

Appendix B – Equality impact assessment

The Care Quality Commission (CQC) became the new independent regulator of health and adult social care services across England on 1 April 2009. It is responsible for registering, reviewing and inspecting these services. CQC aims to help services improve by ensuring that essential quality and safety standards are met and that bad practice is stamped out.

The CQC enforcement policy is a high-level document that sets out the principles behind our approach to enforcement and how we plan to use our related powers. The policy seeks to ensure that enforcement decisions made by CQC are consistent, fair and appropriate to the circumstances.

CQC, like any other public body, has a legal duty to promote equality and eliminate discrimination. The equality impact assessment considers the potential impact of the draft enforcement policy in relation to disability, ethnicity, gender, gender identity, age, sexual orientation, religion or belief, socio-economic disadvantage, carers and human rights.

This paper explains how we looked at the impact on equalities of the policy, and proposes things we can do to ensure that equality issues are addressed when subsequent measures are developed or revised, through regular monitoring and evaluation.

Objective of the policy

The objective of the policy is to set out how we intend to use our enforcement powers to protect and promote the health, safety and welfare of people who use health and social care services, and the principles we will follow in doing so.

The general principles we intend to follow in relation to enforcement are:

- Our overarching concern is to protect the safety of service users and improve the quality of care they receive.
- We will take a proportionate approach, based on our assessment of the risk of unnecessary harm, the quality of care and the evidence of non-compliance with the law.
- Our processes will be transparent and accountable.
- We will encourage improvement wherever possible, but if a service fails to fulfil its legal obligations, we may take enforcement action.
- We will put particular emphasis on equality, diversity and human rights, particularly where services are provided to those who are less able to speak for themselves.
- Our work will be led by appropriately trained, skilled staff.
- We will be consistent in the application of these principles across all sectors of care, while tailoring our approach to different types of provider.
- We will follow up all enforcement activity in a timely fashion.
- We will coordinate our work with other regulators.
- We will monitor the operation of the enforcement policy, and take seriously any comments from providers and people who use services.

Enforcement is a powerful tool that is used to change unacceptable behaviour and to redress unnecessary harm caused by illegal acts, including breaches of human rights and unlawful discrimination. It is important, therefore, to ensure that the enforcement policy

is not inherently discriminatory, and that our enforcement in practice will not discriminate against particular groups of the community and will promote equality and human rights. This is in line with our commitment to a rights-based approach to regulation.

Equality impact assessment

Equality and human rights for providers

The policy outlines the approach CQC will take in using its powers when dealing with any breaches of the law. Everyone, irrespective of disability, ethnicity and so on, has to comply with legislation and statutory notices. Enforcement action will be taken against those organisations and service providers that do not adhere to the law. It will not be aimed at specific groups directly.

Equality and human rights for people using services

The Human Rights Act 1998 covers the basic rights and freedoms we are all entitled to, including equality before the law. These core human rights (principles of dignity, equality, respect, fairness and autonomy) are fundamental to people using health and social care services. Therefore, it is crucial that we adopt a human rights approach to our work. The principles we have laid out in our draft revised policy seek to put people who use services first and respect people's rights and choices.

Our policy makes it clear to our staff and stakeholders that we will make sure that our actions will promote equality and protect all people's human rights and choices.

We will ensure that providers meet their statutory obligations and, where necessary, take enforcement action to improve the safety and quality of health and social care services. By ensuring the processes that underpin our policy promote human rights and choices, we will ensure that human rights are also protected. We can take a range of enforcement actions in order to improve poor or dangerous care practices when we find them. Our powers include urgent cancellation of registration in the most serious cases. We work with others to protect the interests of people who are at risk and cannot protect themselves.

Evidence of impact on equality and human rights

There is no evidence to suggest that this enforcement policy would have an adverse impact in relation to age, disability, race, religion and belief, gender identity or sexual orientation or infringe individuals' human rights. The changes introduced by the 2008 Act to create CQC did not, in themselves, introduce any new services. Rather they support plans for the diversification of services available to the users of health care (including privately funded care) and adult social care.

However, the assessment has highlighted one particular area of high importance: more factual data is needed in respect of enforcement activity. CQC will undertake annual analyses of all enforcement action that will include a particular focus on any evidence of bias towards or against particular groups and the need for any changes to the policy. This will help CQC to show that it can regulate health and adult social care services effectively and tackle any issues of equality.

The sources of evidence

- We conducted a literature review and accessed a number of databases to find published evidence.
- We carried out a web search to identify relevant literature, in particular websites of key public sector regulators with enforcement policies in line with their statutory roles – for example the Health and Safety Executive, Local Authority Trading Standards and the Environment Agency as well as the Healthcare Commission and the Commission for Social Care Inspection.
- We also spoke directly to some regulators to ask about their enforcement policies and their experience of conducting equality impact assessments.
- We had a detailed discussion with the Equality and Human Rights Group of the Department of Health, which helped us to find examples of good practice and to get advice about this assessment.

Quantitative evidence

Due to limited powers and a wide variation in the remit of the existing regulators, there was insufficient data on which to base robust conclusions about the extent to which enforcement may have had an adverse impact on any group, or to which it has promoted equality or protected human rights.

However, a review of the equality impact assessments of the regulatory enforcement policies (such as building control, environmental health, health safety and licensing, planning, private housing and trading standards) of a number of local authorities (for example, Brent Council) provided good evidence that their policies have no direct adverse impact on any particular group of people.

Qualitative evidence

Within a wider policy context, the Department of Health has already carried out an equality impact assessment of the Health and Social Care Act 2008. This relates to CQC's full scope of regulatory activity, and some specific concerns were raised:

- Firstly, about the ability of a new integrated regulator to adequately monitor and safeguard services for older people (particularly in social care settings) and those with disabilities (particularly learning disabilities).
- Secondly, the role of protecting the rights of users of mental health services who are subject to compulsion could be diminished within an organisation with a wide range of functions that will compete for limited resources. This is particularly important in light of the new function of monitoring the application of the deprivation of liberty safeguards, as provided for in the Mental Capacity Act 2005.

In relation to the first concern:

- CQC is able to direct resources and attention where they are most needed. CQC's regulatory regime is building upon the targeted, risk-based and proportionate regulation pioneered by its predecessor commissions.
- This allows CQC to ensure that poorly performing providers receive the level of monitoring and intervention necessary to maintain the safety and quality of their services.
- CQC has been given a wider range of sanctions than was available to the bodies it replaced. These sanctions include new powers to take into account compliance with other relevant enactments, issue penalty notices, and suspend registration. This

greater range of enforcement powers will allow CQC more effectively to safeguard the quality of services and tackle any equality issues that become apparent in the provision of those services.

In relation to the second issue:

- We recognise that the Mental Health Act Commission (MHAC) had a somewhat different focus to the other two commissions whose functions transferred to CQC.
- CQC worked with the Department of Health and MHAC to ensure that MHAC's unique functions and expertise would be properly maintained in the new organisation. This has been successful.
- There are significant benefits in MHAC's functions being within the remit of CQC. It
 enables closer links between monitoring the operation of mental health legislation
 and the wider regulation of mental health service providers. There is now greater
 flexibility and more effective monitoring of the operation of mental health
 legislation, as CQC is able to draw upon a wide range of analytical skills, information
 and corporate resources.
- Regulations under the Mental Capacity Act 2005 give CQC a monitoring function in relation to the operation of the deprivation of liberty safeguards. CQC checks that safeguards are working properly, highlights where they are not and, where necessary, makes sure that remedial action is taken. CQC is able to visit hospitals and care homes and, where necessary, interview any patients who are deprived of their liberty and ask to see relevant records. CQC reports once a year to the Secretary of State summarising its activities and findings in relation to these safeguards.

CQC has statutory duties in relation to the promotion of race equality. The Race Equality Duty, which came into force in 2002, requires public authorities to promote equality of opportunity and eliminate discrimination. In addition, CQC has specific duties to help it ensure that, in the discharge of its functions under the Mental Health and Mental Capacity Acts, it is able effectively to monitor and tackle any instances of unlawful discrimination and adverse impact on the basis of race, gender identity and disability.

CQC is building on the work of its predecessor regulators in relation to the Disability Equality Duty, the Race Equality Duty and the Gender Equality Duty (which came into force in 2007). CQC is committed to promoting human rights and diversity, not only in terms of how we operate as an organisation (including how we deal with our own staff), regulate service providers and carry out enforcement, but also in how we improve the public's experiences of health and adult social care services.

Future action points

1. Public consultation

During consultations we considered whether there was any potential for the policy to disproportionately affect different groups of people. No such risk was identified, but if our monitoring of the outcomes of our enforcement work suggests that such a risk exists, we will consider what action we need to take and whether any additional monitoring is needed.

When reporting our enforcement findings in reviews of compliance and other reports we will write our reports in plain English, and will provide the reports in different formats.

2. Indirect consequences

Based on our literature search and discussions with other regulators, we found no evidence to suggest that our enforcement policy would adversely impact or infringe human rights. However, while the policy itself is not prone to promote or produce inequality, the procedures we use to monitor compliance with the essential standards of quality and safety that can lead to enforcement activity will be monitored and reviewed for evidence of adverse direct and indirect impact on equality.

Similarly a review of how past enforcement has addressed equality and human rights issues raised through investigations will inform future policy development and practice. Therefore, COC:

- Makes sure that its methodologies respond to and promote diversity by consulting with people from diverse groups. CQC involves a wide range of users of services, regulated providers, commissioners and other interested parties. This approach helps us to ensure that we have appropriate tools built in to our methodologies to tackle any areas where there may be equality issues. We are using the experience of the Commission for Social Care Inspection and the Healthcare Commission in assessing the impact of their methodologies and tools on equality and diversity.
- Train its staff to understand what they need to do to ensure their ways of working
 fully integrate equality, diversity and human rights. For example, staff should be
 aware of and respect different cultural requirements and be familiar with legislation
 on human rights. When necessary, they can use translation services and encourage
 the use of third parties to translate and mediate with users of services.
- We will develop an equality and human rights checklist for use in our investigation and enforcement work.
- We will share information with the Equality and Human Rights Commission (EHRC)
 to enable both to undertake their regulatory and enforcement roles. For example,
 we will share information with the EHRC if we think that they are better placed than
 us to take enforcement action on equality issues using their powers.

3. Annual enforcement reports

This impact assessment has highlighted that monitoring and analysis is needed to identify and address any equality and human right issues in relation to enforcement action undertaken by CQC. The equality impact assessment in our first policy recommended that enforcement activity be monitored and reported on in annual reports. These reports will include:

- The differences in feedback and complaints between minority groups, age groups, genders, and between people who are and who are not disabled, and the general population.
- Data on the diversity of who owns and runs different types of health and social care businesses (for example nursing homes and private clinics) that are regulated by CQC. These reports will provide baseline data against which meaningful comparisons can be made. There are challenges in collecting such data. CQC needs to ensure that its methodologies do not inadvertently discriminate against registered managers and providers on the basis of race, gender identity, sexual orientation and so on.
- A breakdown of population profiles to highlight high black and minority ethnic and aged population areas could also help CQC.

To achieve the above, CQC needs to ensure that its staff contribute to the reports. The information, which should include analysis by ethnic group, gender identity and other equality strands and human rights, should be evaluated to establish whether

discriminatory practices or adverse impact have occurred and to identify areas where equality and human rights can be better promoted.

4. Regular surveys

In carrying out its functions, CQC will need to show effective involvement of users of services and others affected by its activities. Based on the experience of other regulators, it would be valuable to seek regularly the views of users, carers and public about the services and businesses that CQC regulates, on issues such as:

- The speed with which reported breaches of the law are resolved (recognising that enforcement needs to follow due legal process).
- Whether our enforcement action is sufficient to address specific problems and bring about improvements, including where enforcement action is designed to impact on breaches of people's human rights, discrimination or unequal outcomes for people with protected equality characteristics.
- The representative views should cover age, gender, disability, race, religion and belief, gender identity and sexual orientation.

5. Collaboration with other regulators

CQC will take account of best practice among other regulators who are performing similar enforcement functions. An opportunity to do this is provided through the voluntary Concordat already signed by a number of regulators, to share their data for regulatory purposes. The analysis of the shared data of enforcement action might provide some insight of institutional inequalities and help to develop new enforcement approaches.

Appendix C – Offences and fines

Fixed penalties

Offence	Fine
Failure to comply with regulations about quality and safety (See	Provider £4,000
regulation 27 of the activities regulations)	Manager £2,000
Carrying on a regulated activity without being registered	£4,000
Failure to comply with conditions of registration	Provider £4,000
	Manager £2,000
Carrying on a regulated activity while registration is suspended	£4,000
Managing a regulated activity while registration is cancelled or suspended	£2,000
Obstructing entry and inspection	£300
Failure to provide documents or information	£300
Failure to provide an explanation of any relevant matter	£300

Offences and fines: Prosecution

Offence	Fine
Failure to comply with regulations about quality and safety (See regulation 27 of the activities regulations)	£50,000 ¹
Carrying on an activity without being registered	£50,000
Failure to comply with conditions of registration	£50,000
Offences relating to suspension or cancellation	£50,000
False descriptions of concerns	£5,000
False statements in applications	£2,500
Obstructing entry and inspection	£2,500
Failure to provide documents or information	£2,500
Failure to provide an explanation of any related matter	£2,500

1: Some lesser requirements have a maximum court fine of £2,500

Appendix D – Glossary of significant enforcement terms

Harm

'Harm' includes where there has been *impairment* of the structure of the body or how the body functions, together with any negative effects that this has had. These effects include *disease*, *injury*, *suffering*, *disability* and death, and can be physical, social or psychological

Impairment is a long term characteristic of an individual that affects their functioning and/or appearance

Disease is abnormal functioning in a body's structures (for example lungs or muscles), systems (for example blood circulation and the nervous system) or psychological health.

Injury is damage to any part of the body caused by an agent (for example a poison), incident or event.

Suffering is the experience of anything subjectively unpleasant. Suffering includes pain, feeling unwell, nausea, depression, agitation, alarm, fear and grief.

Disability is the disadvantages experienced by an individual as a result of barriers (attitudinal, physical etc) that impact on people with impairments/ill health.

For regulatory purposes harm also includes abuse as defined in 'No Secrets' (Department of Health) and 'Working Together' (Department for Children Families and Schools) and its effects and outcomes, for example discriminatory abuse and financial or material abuse.

Some kinds of harm are useful, for example where a person has surgery that they need. Inappropriate harm is usually therefore described as 'unnecessary harm' in this policy.

Order

An order means an Order of the Court. An order is a written record of the court's decision about an application it has considered.

Notice

A notice is a formal notice in writing given by the commission to a registered person under one of the sections of the Health and Social Care Act. For example, a proposal or decision in relation to registration, a warning notice, or a fixed penalty.

Serving or service of an Order or Notice

These terms refer to the way that documents are formally sent or given to a person. Serving is the way we will carry out that process, while service normally refers to the completed act. We can serve documents by post, in person or sometimes, by e-mail. Where the Act requires us to give a notice to a registered person we must make sure this is done as described in sections 93 and 94.



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