

The regulations covered by this guidance

This guidance covers two groups of regulations.

1. Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 (Part 3)

[\(See note 1\)](#)

These regulations introduced the new **fundamental standards**, which describe requirements that reflect the recommendations made by Sir Robert Francis following his inquiry into care at Mid Staffordshire NHS Foundation Trust. They will enable us to pinpoint more clearly the fundamental standards below which the provision of regulated activities and the care provided to people must not fall, and to take appropriate enforcement action where we find it does.

Part 3 of these regulations has two sections: Section 1 describes the **requirements relating to persons carrying on or managing a regulated activity**. Section 2 includes the **fundamental standards**, which came into force for all health and adult social care services on 1 April 2015.

The requirements in Section 1 (relating to persons carrying on or managing a regulated activity) include a regulation about fit and proper person requirements for directors (Regulation 5). This regulation was introduced to ensure that directors are fit to hold their position. Directors must meet certain criteria, including that they are "of good character"; have the qualifications, competence, skills and experience necessary for the relevant position; and are capable of undertaking the relevant position after any reasonable adjustments have been made. They must also not have been responsible for any serious misconduct or mismanagement in the course of carrying on a regulated activity.

The requirements in Section 2 (fundamental standards) include a statutory duty of candour (Regulation 20) and a requirement for providers to display their CQC rating (Regulation 20A). ([see note 2](#))

The aim of Regulation 20, statutory duty of candour, requires registered persons to be open and honest with the people who use their service when something goes wrong with their care or treatment. When a specified safety incident has occurred in respect of care provided, the regulation sets out a clear set of legal duties on registered providers about how and when to notify people using their service (or their relevant representatives) about those safety incidents. The regulation also describes when notifications about safety incidents need to be made to CQC.

The aim of Regulation 20A, the requirement to display performance assessments, is to require providers who have received a CQC rating to display it conspicuously at their premises and on their website.

2. Care Quality Commission (Registration) Regulations 2009 (Part 4)

([See note 3](#))

The Care Quality Commission (Registration) Regulations 2009 set out requirements that providers must have regard to in relation to their registration, including their financial position, fees, statement of purpose, the circumstances when the need to make notifications to CQC and requirements in relation to termination of pregnancies.

Notes

1. As amended by a) Health and Social Care Act 2008 (Registration and Regulated Activities (Amendment) Regulations 2015 and b) The Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2012.
2. The Health and Social care Act 2008 (and Regulated Activities) (Amendment) Regulations 2015.
3. As amended by a) The Care Quality Commission (Registration) and (Additional Functions) and Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2012 and b) The Care Quality Commission (Registration and Membership) (Amendment) Regulations 2012.