
EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations prescribe the kinds of activities that are regulated activities for the purposes of Part 1 of the Health and Social Care Act 2008 (“the Act”) and requirements that apply in relation to the way in which those activities are carried on.

Regulation 3 deals with the activities that are regulated activities for the purposes of section 8(1) of the Act. The activities are set out in Schedule 1 to the Regulations together with certain activity specific exemptions. An activity is only a regulated activity if it is carried on in England (regulation 3(3)). Regulation 3(4) provides that the activities listed in Schedule 2 (general exceptions) are not to be regulated activities for the purposes of section 8(1) of the Act and these Regulations.

In Part 3, regulations 4 to 7, and Schedules 3 and 4, contain requirements in relation to persons registered in respect of the carrying on or management of a regulated activity (“registered persons”), and require certain information to be available in relation to those persons. Where a regulated activity is carried on by a body other than a partnership, that body must nominate an individual (“the nominated individual”) who must meet certain requirements (regulation 6). Regulation 7 lays down requirements in relation to registered managers.

Regulation 5 lays down a new fit and proper person requirement that must be met by directors of an NHS trust, an NHS foundation trust or a Special Health Authority that carries on a regulated activity. The requirement lays down criteria to be met by such directors, including that they are of good character and that none of the grounds of unfitness specified in Part 1 of Schedule 4 apply. A person must not perform the relevant role if they fail the fit and proper person requirement. A health service body that fails to comply with this requirement could have a condition imposed on its registration with the Care Quality Commission, requiring it to comply with the requirement, under section 12(5)(b) of the Act.

Regulations 8 to 19 lay down fundamental standards to be met by registered persons. Regulation 20 lays down a further fundamental standard to be met by health service bodies. The fundamental standards provide that:

- (a) care and treatment must be appropriate and reflect service users needs and preferences (regulation 9);
- (b) service users must be treated with dignity and respect (regulation 10);
- (c) care and treatment must only be provided with consent (regulation 11)
- (d) care and treatment must be provided in a safe way (regulation 12);
- (e) service users must be protected from abuse and improper treatment (regulation 13);
- (f) service users’ nutritional and hydration needs must be met (regulation 14);
- (g) all premises and equipment used must be clean, secure, suitable and used properly (regulation 15);
- (h) complaints must be appropriately investigated and appropriate action taken in response (regulation 16);
- (i) systems and processes must be established to ensure compliance with the fundamental standards (regulation 17);

- (j) sufficient numbers of suitably qualified, competent, skilled and experienced staff must be deployed (regulation 18);
- (k) persons employed must be of good character, have the necessary qualifications, skills and experience, and be able to perform the work for which they are employed (regulation 19);
- (l) health service bodies must be open and transparent with service users about their care and treatment (regulation 20).

Regulation 8(2) deals with who is responsible for complying with the Regulations in circumstances where there is more than one registered person in respect of a regulated activity.

Regulation 21 states that, for the purposes of compliance with the Regulations, a registered person must take account of guidance issued by the Care Quality Commission under section 23 of the Act and the code of practice issued by the Secretary of State under section 21 of the Act in relation to the prevention or control of health care associated infections. The guidance issued by the Care Quality Commission is available from the Care Quality Commission, Citygate, Gallowgate, Newcastle upon Tyne, NE1 4PA (www.cqc.org.uk). The code of practice issued by the Secretary of State is available from the Department of Health, Richmond House, 79 Whitehall, London SW1A 2NS (www.gov.uk/government/organisations/department-of-health).

Regulation 22 creates offences in relation to breaches of requirements in regulation 11, 12, 13(1) to (4), 14, 16(3), 17(3) or 20(2)(a) and (3) and also includes a due diligence defence relating to any proceedings for such a breach. Regulation 23 imposes penalties for those who commit such offences.

Regulation 24 and Schedule 5 prescribe fixed penalty offences for the purposes of section 86 of the Act and the amount of the penalty, and make provision about the time by which a fixed penalty must be paid and the method by which the payment may be made, the period during which proceedings cannot be instituted for the offence to which the penalty notice relates, the content of the penalty notice and when a penalty notice can be withdrawn.

Regulation 25 revokes the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 (“the 2010 Regulations”), together with other enactments which amended those Regulations.

Regulation 26 makes transitional and transitory provision in consequence of these Regulations coming into force. It provides that where enforcement action has been taken in relation to a continuing breach of the 2010 Regulations, and the person or body concerned has been given a specified time by which it must secure compliance with the 2010 Regulations, no criminal proceedings may be taken under these Regulations in relation to the breach in so far as it occurred before that specified time.

Regulation 27 requires the Secretary of State to review the operation and effect of these Regulations and lay a report before Parliament within five years after 1st April 2015 and within every five years after that. Following a review it will fall to the Secretary of State to consider whether the Regulations should remain as they are, or be revoked or be amended. A further instrument would be needed to revoke the Regulations or to amend them.

A full impact assessment of the costs and benefits of this instrument is available from the Department of Health, Richmond House, 79 Whitehall, London SW1A 2NS (www.gov.uk/government/organisations/department-of-health) and is published alongside this instrument and its Explanatory Memorandum at www.legislation.gov.uk.