
EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which are to come into force on 1st April 2010, are made under the Health and Social Care Act 2008 (“the Act”) and prescribe the kinds of activities that will be regulated activities for the purposes of Part 1 of the Act, and the requirements that will apply in relation to the way in which those activities are carried on. Part 1 of the Act establishes the Care Quality Commission and provides for the registration of persons carrying on a prescribed regulated activity. It also provides powers to make regulations imposing requirements in relation to the carrying on of those regulated activities.

Part 1 (regulations 1 and 2) are general provisions dealing with citation, commencement and interpretation.

In Part 2, regulation 3 deals with the activities that will be 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. Regulation 3(3) provides that, until 1st October 2010, an activity will only be a regulated activity if it is carried on by an English NHS body. Regulation 3(4) provides that where social care services are provided by an English NHS body which continues to be registered in respect of those services under the Care Standards Act 2000 then, in so far as those services are capable of being a regulated activity for the purposes of these Regulations, they will not be so until 1st October 2010. An activity is only a regulated activity if it is carried on in England (regulation 3(5)). In addition, regulation 3(7) provides that the activities listed in Schedule 2 (general exceptions) are not to be regulated activities for the purposes of the Regulations. Regulation 3(6) and (8) contain provisions relating to the time limiting of certain specified wording and provisions in Schedules 1 and 2.

In Part 3, regulations 4 to 7, and Schedule 3, contain requirements relating to the 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”) in respect of whom this information must be available (regulation 5(2)). Regulation 7 imposes general requirements as to the need for appropriate training in the case of a registered person.

Part 4 makes provision about the conduct of the regulated activity and, in particular, about the quality and safety of service provision including in relation to the care and welfare of service users (regulation 9), assessing and monitoring the quality of service provision (regulation 10), safeguarding vulnerable service users (regulation 11), cleanliness and infection control (regulation 12), the management of medicines (regulation 13), the meeting of nutritional needs (regulation 14), the safety and suitability of premises and equipment (regulations 15 and 16), respecting and involving service users (regulation 17) and the obtaining of consent to care and treatment (regulation 18). Provision is also made about complaints (regulation 19), record keeping (regulation 20), the fitness of workers, staffing and co-operation with other service providers (regulations 21 to 24).

Part 5 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 25). Regulation 26 states that, for the purposes of compliance with the Regulations, a registered person must take account of guidance issued by the 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 healthcare associated infections. Regulation 27 provides that a breach of regulations 9 to 24

is to be an offence, and also includes a due diligence defence relating to any proceedings under the Regulations. In addition, it provides that no prosecution may be brought unless the breach is one which the registered person has failed to remedy in response to a warning notice given under section 29 of the Act.

In Part 6, regulation 28 (and Schedule 4) 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 penalty notice 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.

In Part 7, regulation 29 revokes the Health and Social Care Act 2008 (Registration of Regulated Activities) Regulations 2009.

An impact assessment of the effect that this instrument will have on the costs and benefits to the service providers in question, together with an Equality Screening Assessment is available on the Department of Health website at <http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/index.htm> and is annexed to the Explanatory Memorandum which is available alongside the instrument on the OPSI website.