
EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 (“the Regulated Activities Regulations”) which prescribe the kinds of activities that are regulated activities for the purposes of registration in respect of the provision of health or social care. Regulation 3 allows service providers which are partnerships to meet the fitness requirements collectively rather than individually.

The definition of “medical device” is inserted into the Regulated Activities Regulations by regulation 4 to ensure the use of the terms “medical” and “dental” is consistent.

Regulation 5 ensures service providers have suitable arrangements in place where the service user lacks capacity to consent to care and treatment provided for them and Regulation 6 amends the defence of due diligence for an offence under the Regulated Activities Regulations.

Regulation 7 requires the Secretary of State to review the operation and effect of the Regulated Activities Regulations and publish a report.

Regulations 8 and 9 amend Schedules 1 and 2 to the Regulated Activities Regulations which respectively set out the activities that will be regulated activities for the purposes of the Health and Social Care Act 2008 and those which are exempt.

An impact assessment of the effect that this instrument will have on the costs and benefits to the service providers in question is available on the Department of Health’s web site at <http://www.dh.gov.uk/en/Publicationsandstatistics/Legislation/index.htm> and is published with the Explanatory Memorandum alongside the instrument at <http://www.legislation.gov.uk>.