
EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision in relation to the National Institute for Health and Care Excellence (“NICE”) (established under Part 8 of the Health and Social Care Act 2012 (c. 7) (“the Act”)) and the Health and Social Care Information Centre (“the Information Centre”) (established under Chapter 2 of Part 9 of the Act).

Part 2 makes provision in relation to NICE, which is established by section 232 of the Act.

Regulation 3 provides for procedures for conflicts of interests of members of NICE.

Section 234 of the Act (quality standards) enables the Secretary of State or the National Health Service Commissioning Board (“the Board”) to direct NICE to prepare a quality standard. Regulation 4 confers powers on NICE for the supply of a quality standard to a devolved authority or other person and to make adjustments to, and impose a charge in connection with, such supply.

Regulation 5 confers functions on NICE in relation to the giving of advice or guidance, provision of information or making of recommendations about any matter concerning or connected with the provision of NHS services (exercisable only on the direction of the Secretary of State or the Board), or public health services or social care in England (exercisable only on the direction of the Secretary of State). The Secretary of State or the Board may give directions about the exercise of a function (regulation 5(2)(b) and, in the case of the Secretary of State, (3)(b)), but must not give a direction about the substance of advice, guidance, or a recommendation (regulation 5(8) and (9)).

Regulation 6 provides powers for NICE to be able to impose a charge for or in connection with the functions conferred by regulation 5, other than on the Secretary of State or a person identified in a direction of the Secretary of State.

Regulation 7 makes provision for NICE to make a technology appraisal recommendation, in relation to a health technology identified in a direction of the Secretary of State, that recommends that the Board, a clinical commissioning group or a local authority arranging for the provision of services for the purposes of the health service, provide funding to ensure that the health technology can be made available for the purposes of treatment of patients. The NICE technology appraisal recommendation must be complied with normally within 3 months of publication of the recommendation (regulation 7(3)).

Regulation 8 makes provision for NICE to make a highly specialised technology recommendation in relation to a highly specialised health technology identified in a direction of the Secretary of State, that recommends that the Board provide funding to ensure that the highly specialised technology can be made available for the purposes of treatment of patients, normally within 3 months of publication of the highly specialised technology recommendation.

Regulations 9 to 11 make provision for appeals against a technology appraisal recommendation or a highly specialised technology recommendation.

Regulation 12 confers functions on NICE in relation to the provision of training in connection with the provision of NHS services, public health services or social care in England.

Regulation 13 provides for NICE to be able to give advice to persons (whether or not in the United Kingdom) on any matter concerning or connected with the provision of health care or social care or the protection or improvement of public health, and to impose a charge for or in connection with the giving of the advice.

Regulation 14 makes provision in relation to NICE’s charter.

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

Regulations 15 to 23 make transitional provision for the continuation of work in progress, or procedures being undertaken, by NICE's predecessor, the Special Health Authority, the National Institute for Health and Clinical Excellence, immediately before 1st April 2013.

Part 3 provides for functions of the Information Centre, established by section 252 of the Act.

Regulations 25 to 30 provide for the establishment of a database of quality indicators in relation to the provision of health services and adult social care in England. A quality indicator is defined in section 268(3) of the Act to mean a factor by reference to which performance in the provision of services or care can be measured. The database is to consist of a repository of applications for a quality indicator and related information (regulation 25(2)(a)) and a library of assured quality indicators (regulation 25(2)(b)).

Regulation 31 provides for the Information Centre to have functions in relation to the assignment of a prescribing number to a general medical practitioner.

Regulation 32 confers systems delivery functions on the Information Centre that are exercisable on the direction of the Secretary of State or the Board. The giving of a direction does not prevent the Secretary of State or the Board from exercising the function in respect of which the direction is given (regulation 32(3)).

Regulation 33 makes transitional provision for the continuation of procedures being undertaken in relation to a quality indicator or prescribing number by the predecessor Special Health Authority, the Health and Social Care Information Centre, immediately before 1st April 2013.

A full impact assessment has been produced in relation to the provisions of the Act, and a copy is available at www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_123583. Pages 126 and 127 of Annex E to the assessment contains information relevant to the establishment of NICE and pages 136 and 137 contain information relevant to the establishment of the Information Centre. No separate impact assessment has been produced in relation to Parts 2 or 3 of these Regulations as the Parts have no impact on the private sector or civil society organisations.