

# HEALTH AND SOCIAL CARE ACT 2012

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## EXPLANATORY NOTES

### COMMENTARY ON SECTIONS

#### **Part 8 – The National Institute for Health and Care Excellence**

##### **Establishment and general duties**

##### *Section 232 – The National Institute for Health and Care Excellence*

1367. This section establishes the National Institute for Health and Care Excellence (NICE) as a body corporate. It also gives effect to Schedule 16.

##### *Schedule 16 – The National Institute for Health and Care Excellence*

1368. This schedule deals with the constitution of NICE; in many respects it makes similar provision to that made by Schedule 1 for the NHS Commissioning Board, Schedule 8 for Monitor, and Schedule 18 for the Health and Social Care Information Centre.

1369. [Paragraph 1](#) sets out the membership of NICE. Paragraphs 2, 3, 4 and 5 set out provisions relating to non-executive directors of NICE, including their tenure, ability to be suspended or removed from post by the Secretary of State, and their remuneration (which is to be determined by the Secretary of State).

1370. [Paragraph 6](#) relates to the appointment of NICE's employees. NICE requires the approval of the Secretary of State to its policies on the payment of remuneration, allowances, pensions and gratuities before it can make any such payment to an employee.

1371. [Paragraph 7](#) provides for NICE to establish committees and sub-committees. Paragraph 8 allows NICE to regulate its own procedures. Sub-paragraph (2) enables the Secretary of State to make provisions in regulations about particular procedures in order to deal with conflicts of interest. This provision is specific to NICE due to the nature of its duties. For example, this could be used to avoid the situation whereby the chair of one of NICE's technology appraisal committees had a commercial interest in a company doing research into that particular drug. Paragraph 9 allows NICE to arrange for its functions to be exercised by a non-executive member, an employee or a committee or sub-committee.

1372. [Paragraph 10](#) confers general powers and requires NICE to obtain the permission of the Secretary of State before undertaking certain commercial ventures. NICE may, for example, provide advice to overseas Governments under regulations made under section 240. Under the paragraph 10 powers NICE would, with the approval of the Secretary of State, be able to form, participate in the forming of, invest in or provide loans and guarantees to a company and thereby be able to determine the most appropriate business model for any such activities.

1373. **Paragraph 11** enables the Secretary of State to make payments to NICE out of money provided by Parliament with such conditions as the Secretary of State thinks appropriate. Paragraph 11 also allows Secretary of State to lend money to NICE.
1374. **Paragraph 12** sets out a requirement for NICE to publish an annual report. The Secretary of State may also ask NICE to prepare other reports or to provide information at other times, for example as required for in-year monitoring of NICE's performance and use of central funding.
1375. **Paragraphs 13, 14 and 15** relate to NICE's accounts, including duties of the Comptroller and Auditor General in relation to reporting on NICE's annual accounts, and laying copies of them in Parliament.
1376. **Paragraph 16** relates to NICE's seal. Paragraph 17 confirms NICE's status as a non-Crown body.

### ***Section 233 - General duties***

1377. This section describes the matters that NICE must have regard to in developing its products.

### **Functions: quality standards**

#### ***Section 234 - Quality standards***

1378. This section sets out the process for how the NHS Commissioning Board or the Secretary of State may commission NICE to develop quality standards for the provision of NHS, public health or social care services and the status accorded to the finished product.
1379. The Secretary of State and the NHS Commissioning Board are required to have regard to the quality standards in discharging their 'improvement duties' in relation to the health service (see new section 1A and new section 13E inserted in to the NHS Act by Part 1 of the Act). The Secretary of State or the NHS Commissioning Board is responsible for framing the remit of each quality standard, but cannot determine the content. A quality standard has statutory effect once it has been endorsed by the person who commissioned it (the Secretary of State or the Board). NICE has a duty to establish a process for the preparation of quality standards through consultation with interested parties. Responsibility for adult social care rests with the Department of Health and responsibility for children's social care rests with Department for Education. The Secretary of State in this context will be able to commission social care quality standards across all age groups.

#### ***Section 235 - Supply of quality standards to other persons***

1380. This section describes how, under regulations made by the Secretary of State, NICE would be able to supply quality standards to the devolved administrations (Scotland, Wales and Northern Ireland), and other bodies. NICE would be able to amend the quality standards to suit the needs of such customers (for example by translating a quality standard into Welsh) and could charge for this. The Department anticipates that work carried out by NICE on behalf of the devolved administrations would be on a cost-recovery basis only.

#### ***Section 236 Advice or guidance to the Secretary of State or the Board***

1381. This section enables the provision by NICE of any advice or guidance on quality matters to the Secretary of State or the NHS Commissioning Board should they require it. A quality matter is defined as a matter in respect of which NICE could be asked to prepare a quality standard.

**Functions: advice, guidance etc.**

***Section 237 – Advice, guidance, information and recommendations***

1382. This section describes how, as well as preparing quality standards, NICE may be able, under regulations, to give advice or guidance, or provide information or make recommendations on matters relating to the provision of NHS services, public health services or social care in England. The guidance provided for in regulations could include guidance on new and existing medicines, treatments and procedures and treating and caring for people with specific diseases and conditions or with particular social care needs. Regulations might also provide for NICE to be able to publish or disseminate advice, guidance, information or recommendations to the NHS, local authorities or other organisations in the public, private, voluntary or community sectors on how to improve people's health and prevent illness and disease.
1383. The section gives the Secretary of State a regulation-making power to enable him to confer additional functions on NICE. *Subsections (2) and (3)* enable provision to be made for functions conferred on NICE by regulations to be exercisable only on or subject to directions of the Secretary of State or the NHS Commissioning Board in relation to NHS services, or the Secretary of State in relation to public health services or social care. The direction-giving powers ensure that either the Secretary of State or the Board will have the flexibility to commission work from NICE. However, neither will be able to direct NICE as to the substance of its advice, guidance or information or recommendations (*subsection (4)*). *Subsection (5)* describes the additional provision that such regulations might make, such as for the persons or bodies that may commission work from NICE or matters relating to the publication or other dissemination of NICE products. *Subsections (5)(c) and (6)* enable such regulations to make provision for NICE to impose charges in connection with such giving of advice or guidance, provision of information or making of recommendations. *Subsection (7)* requires such regulations to make provision for NICE to set up, through consultation, processes for the development of such advice, guidance, information or recommendations.
1384. *Subsections (8) and (9)* allow regulations to require specified public bodies to have regard to NICE advice or guidance, or to comply with NICE's recommendations. The provision allows replication of the effect of an existing funding direction requiring commissioners to make funding available within three months for treatments recommended by NICE's technology appraisal guidance, so they are made normally available. *Subsection (10)* states that such regulations may only apply to local authorities in relation to their public health functions.

***Section 238 – NICE recommendations: appeals***

1385. This section allows the Secretary of State to include in regulations under section 237 arrangements for appeals against NICE recommendations.

***Section 239 - Training***

1386. This section allows the Secretary of State to make regulations setting out the arrangements under which NICE could provide or facilitate the provision of training, and when it could charge for these services. NICE currently delivers education, training and development on evidence-based therapeutics and medicines management to healthcare professionals, and regulations made under this section would enable this work to continue.

***Section 240 - Advisory services***

1387. This section allows the Secretary of State to make regulations setting out the arrangements under which NICE could provide advisory services to other persons, such as the devolved administrations and pharmaceutical companies. The Department

anticipates that any work carried out by NICE on behalf of the devolved administrations will be on a cost-recovery basis only.

### ***Section 241 - Commissioning guidance***

1388. This section provides for the NHS Commissioning Board to be able to direct NICE to prepare commissioning guidance on its behalf or carry out any other of the NHS Commissioning Board's functions in relation to preparation of commissioning guidance. Commissioning guidance will provide CCGs with practical advice on contracting for the provision of health services with a view to improving the quality of such services. If requested, NICE must provide the NHS Commissioning Board with advice or information on matters connected with the Board's functions as regards commissioning guidance. NICE may also be required by the Board to disseminate the commissioning guidance.

### **Functions: other**

#### ***Section 242 – NICE's charter***

1389. This section allows the Secretary of State to make regulations that require NICE to publish and review a NICE charter, which would set out publicly NICE's purposes and how it proposes to fulfil them.

#### ***Section 243 – Additional functions***

1390. This section enables NICE to carry out additional income generating functions connected with the provision of health care or social care provided that this work does not interfere with NICE's core functions. NICE may charge for its services pursuant to these provisions and may do so on what it considers to be the appropriate commercial basis.

#### ***Section 244 – Arrangements with other bodies***

1391. This section enables NICE to make arrangements with other bodies for their assistance in relation to its services, for example to support the development of its guidance products, and to make payments for this purpose as it sees fit.

#### ***Section 245 – Failure by NICE to discharge any of its functions***

1392. This section enables the Secretary of State, if he considers that NICE is failing to discharge its functions properly (which includes a failure to discharge a function consistently with what the Secretary of State considers to be the interests of the health service in England), and the failure is significant, to direct NICE to discharge the functions in the way that the Secretary of State specifies and within stated timescales. If NICE fails to comply with such a direction the Secretary of State may discharge the functions concerned himself or may make arrangements for another body to do so. The Secretary of State is required to publish his reasons for exercising the powers under this section.

#### ***Section 246 – Protection from personal liability***

1393. This section applies existing legislation so that the members and staff of NICE are protected from personal liability whilst carrying out work on behalf of NICE.

### **Supplementary**

#### ***Section 247 – Interpretation of this Part***

1394. This section defines terms used in this Part.

***Section 248 – Dissolution of predecessor body***

1395. This section provides for the abolition of the Special Health Authority known as the National Institute for Health and Clinical Excellence.

***Section 249 – Consequential and transitional provision***

1396. This section gives effect to Schedule 17 (part 8: consequential amendments) which makes consequential amendments to a range of statutory provisions to ensure that NICE is referenced appropriately. It includes, for example, changes to the Freedom of Information Act 2000, so that the Act would apply to NICE as re-established. It also includes a change to the Health Act 2009, so that NICE will have a duty to have regard to the NHS Constitution.
1397. This section also makes provision to ensure that any pre-existing “quality standard”, referred to in *subsection (2)* as a “statement of standards” prepared and published by the Special Health Authority, the National Institute for Health and Clinical Excellence, prior to commencement has the same status on and after commencement as a quality standard prepared by NICE as re-established.