EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (CLINICAL COMMISSIONING GROUPS – DISAPPLICATION OF RESPONSIBILITY) REGULATIONS 2012

2012 No. [DRAFT]

THE NATIONAL HEALTH SERVICE COMMISSIONING BOARD AND CLINICAL COMMISSIONING GROUPS (RESPONSIBILITIES AND STANDING RULES) REGULATIONS 2012

2012 No. 2996

1 This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

2 Purpose of the instrument

Affirmative instrument

2.1 The affirmative instrument provides that a clinical commissioning group ("CCG") does not have the duty to commission services for certain groups of people or in specified circumstances, even if they would otherwise fall within the responsibility of a CCG under section 3(1A) of the NHS Act 2006 ('the 2006 Act').

Negative instrument

2.2 The negative instrument sets out:

- additional categories of people for whom a CCG will have responsibility for commissioning health services for the purposes of both a CCG's duty to commission services under section 3 of the 2006 Act and its power to do so under section 3A of the 2006 Act, including emergency care for every person present in their geographical area;
- certain health services which the NHS Commissioning Board ('the Board') will commission;
- requirements relating to the commissioning of mental health after-care services;
- 'standing rules' for the Board and CCGs;
- matters relating to administration which may apply to controls on revenue resource use by the Board and CCGs.

3 Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None

4 Legislative Context

Affirmative instrument

4.1 The affirmative instrument and the negative instrument together replace in part the National Health Service (Functions of Strategic Health Authorities and Primary Care Trusts and Administration arrangements) (England) Regulations 2002 and make provision about the scope of CCG and Board responsibilities under the new commissioning arrangements for health services introduced by the National Health Service Act 2006, as amended by the Health and Social Care Act 2012.

4.2 Section 3(1) and (1A) of the 2006 Act give each CCG the duty to commission health services necessary to meet the reasonable requirements of all people who are provided with primary medical services by a member of a CCG , and persons who usually reside in the CCG's area, but who are not registered with a GP.

4.3 Section 3(1D) of the Act allows regulations to specify that a CCG does not have responsibility for people in these categories, if they are of a prescribed description, or in prescribed circumstances, as specified in the affirmative instrument. At the recommendation of the Delegated Powers and Regulatory Reform Committee, this instrument is subject to the affirmative resolution procedure.

Negative instrument

CCG commissioning responsibility

4.4 Section 3(1B) of the 2006 Act allows regulations to specify that a CCG also has responsibility (either generally, or in relation to a specific service) for persons who are provided with primary medical services by a GP practice which is, or was, a member of the CCG (section 1(1B)(a)), or who have a prescribed connection with the CCG's area (section 3(1B)(b). The negative instrument specifies these additional categories in relation to both the duty of a CCG to commission services under section 3 of the 2006 Act and their power to do so under section 3A.

4.5 Section 3(1C) of the 2006 Act sets out that the power in section 3(1B) must be exercised to ensure that a CCG commissions emergency care for every person present in their area.

Services to be commissioned by the NHS Commissioning Board

4.6 Section 3B of the 2006 Act enables regulations to be made by the Secretary of State requiring the Board (rather than CCGs) to arrange for the provision of certain services. These are services in addition to those that the Board will be responsible for commissioning under section 4 and Part 6 of the 2006 Act. The regulations may require the Board to arrange for the provision of certain dental services, health services for members of the armed forces and their families, health services for people detained in prisons or other accommodation of a prescribed description. Under subsection (2), regulations may also prescribe certain other services or facilities, which the Board is to be required to arrange the provision of if it is appropriate to do so having regard to certain specified factors. The negative instrument specifies those services the Board should commission.

Mental health after-care services

4.7 The instrument makes regulations under section 117(2E) of the Mental Health Act 1983 (as amended by the Health and Social Care Act 2012) governing which CCG is to be responsible, in a given case, for arranging mental health after-care services under that section. The purpose of the regulations is to ensure that wherever possible, the CCG responsible for commissioning after-care services is the same as that for meeting the patient's other needs for health services. The regulations also cover a situation in which a patient requires, as part of section 117 after-care, a service which would (if provided under the NHS Act 2006) be commissioned by the Board. They allot the

responsibility for arranging that service to the Board (in place of any clinical commissioning group which would otherwise have a duty to arrange that service under section 117).

Standing rules

4.8 The Health and Social Care Act 2012 removes the Secretary of State's wide direction-making powers, as set out in sections 7 and 8 of the 2006 Act, and replaces them with specific powers that enable him to oversee health service bodies and hold them to account. For example, the Secretary of State will use the mandate to set strategic direction and objectives for the health service, and to hold the Board to account.

4.9 Section 6E of the 2006 Act gives the Secretary of State the power to make 'standing rules' regulations. The standing rules will set core, ongoing requirements for the health service. The instrument makes regulations under this power, imposing requirements on the Board and CCGs as to the exercise of their functions, largely replicating existing policy in the new system.

Financial duties of the Board and CCGs: controls on revenue resource use

4.10 Under section 223D(3) of the 2006 Act the Board must ensure that the use of revenue resources in a financial year by the Board and CCGs taken together does not exceed the amount specified by the Secretary of State. Section 223E(3) provides that the Secretary of State may direct the Board to ensure that total revenue resource use, and the Board's revenue resource use, in a financial year attributable to such prescribed matters relating to administration as are specified in the directions do not exceed the amounts specified. Section 223J(3) then provides the Board with a power to direct a CCG in relation to its revenue resource use in the same way.

4.11 Regulations in the negative instrument prescribe the matters relating to administration that may apply for the purposes of the directions, which may be given by the Secretary of State to the Board, and by the Board to a CCG.

5 Territorial Extent and Application

5.1 This instrument applies to England.

6 European Convention on Human Rights

The Secretary of State for Health has made the following statement regarding Human Rights:

'In my view the provisions of the National Health Service (Clinical Commissioning Groups – Disapplication of Responsibility) Regulations 2012 are compatible with the Convention rights.'

As the National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012 are subject to negative resolution procedure and do not amend primary legislation, no statement is required.

7 Policy background

- What is being done and why

7.1 *Equity and Excellence: Liberating the NHS* set out the Government's intention to change how NHS care is commissioned, and the structural changes to the NHS to make this possible.

7.2 The Secretary of State will continue to be under a duty to promote a comprehensive health service, and will be held accountable for the system through the duties set out in the Act and a duty to keep under review the effective exercise of functions by national bodies, including the Board, and a duty to report annually on the performance of the health service.

7.3 However, the Secretary of State no longer has extensive general powers to intervene in the NHS; these are replaced with specific and limited powers. For example, Secretary of State will set strategic direction and objectives for the health service through the mandate.

7.4 CCGs will be responsible for commissioning most NHS services, supported by, and accountable to, a new non-departmental public body, the NHS Commissioning Board, which in turn will be accountable to the Secretary of State. This approach builds on the key role that GP practices play in coordinating patient care and acting as patient advocates.

7.5 CCGs will be responsible for commissioning most NHS services, but where conditions are high cost or clinical expertise needs to be concentrated, certain services are better commissioned and organised separately. In these cases, the Board will have responsibility for commissioning them. Where the Board is required to commission a service, CCGs will not be able to commission those services (unless the Board enters into joint commissioning arrangements with a CCG or CCGs).

CCG commissioning responsibility

7.6 As with PCTs, each CCG will cover a geographical area (defined in their constitution), and the whole of England will be covered by CCGs with no overlap. The membership of each CCG will comprise of all GP practices in the geographical area it covers and it will have continuity of commissioning responsibility for all patients registered with those practices, together with anyone who is usually resident in the area who is not registered with a member of any CCG (the same principle as applied to PCTs).

7.7 Some patients in these categories however will necessarily be the responsibility of another commissioner, whether an NHS commissioner or, in the case of people in police custody suites, for example, the police. The affirmative regulations set out these groups. In brief, they are:

- people registered with a GP in England, but usually resident in Scotland (for whom the Scottish Health Board would have responsibility;
- people registered with a GP in England, but usually resident in Wales (for whom the Local Health Board would have responsibility);

- people who access GP services as a temporary patient outside of the CCG where they are registered or usually resident (if not registered with a GP practice anywhere). They would temporarily become the responsibility of the CCG where they accessed GP services. This is to ensure that they are able to access any subsequent care needed, and ensure that CCGs covering areas which attract large numbers of temporary patients (e.g. holiday resorts), are appropriately commissioning services to meet the needs of these patients;
- people provided with primary medical services which are not those received either as a registered patient, temporary patient, or when usually resident in the CCG area (e.g. from a GP-led walk-in centre or out-of-hours service). This ensures that the basis for primary medical services is registration with a GP practice or usual residence;
- people detained in an immigration removal centre, secure training centre, youth offender institution or in police custody;
- people who have been placed in a CCG area by another CCG or local authority (for example, for the purposes of NHS Continuing Healthcare, or in accommodation for special educational needs). The regulations continue the current policy under PCTs, so that the responsibility for the patient remains with the placing CCG, even if the patient registers with a GP practice in the area of the new CCG.

7.8 The negative instrument similarly ensures CCGs retain responsibility for patients who have been moved out of the CCG area, for the above reasons. Together, this ensures continuity in commissioning, and ensures a commissioner cannot dispose of a commissioning obligation by moving the patient out of area. The negative instrument also includes provision for continuity of responsibility where a PCT has made arrangements and is then succeeded by a CCG.

7.9 To give CCGs maximum flexibility in commissioning services, their discretionary power to commission is not limited to particular groups of patients, and a CCG may commission a service for a patient who is the responsibility of another commissioner, with the exception (as specified by section 3A(2) of the Act) of services which the Board has a duty to commission.

7.10 Both the affirmative and negative instruments include provision for determining the usual residence of a patient.

Services to be commissioned by the Board

7.11 The negative instrument requires the Board to commission, to such extent as it considers necessary to meet all reasonable requirements:

- all specified hospital dental services and community dental services

- except for emergency services (the responsibility of CCGs), all secondary care and community services for serving members of the armed forces and their families, where they are registered with Defence Medical Services (DMS). This includes certain IVF/assisted fertility treatments for veterans.
- all community and care, secondary services, except for emergency services, and services for rare and very rare conditions for prisoners and other detainees in prescribed accommodation including most young offender institutions and, as specified in Schedules to the regulations, some secure children's homes, secure training centres, and immigration removal centres.
- services for rare and very rare conditions
- clinical services provided by certain Independent Sector Treatment Centres under contracts currently held by the Secretary of State
- services for the specialist mental health assessment and management of people with mental health problems who may present a risk to prominent people or locations

Mental health after-care

7.12 Section 117 of the Mental Health Act 1983, as amended by the Health and Social Care Act 2012, places a duty on local social service authorities and clinical commissioning groups to provide or arrange for the provision of after–care services for certain groups of people who have been detained in hospital for treatment for their mental disorder, after their discharge from hospital.

7.13 Mental health after-care services are not defined in legislation. In practice, they are services provided to a patient who has been discharged from hospital after treatment for a mental disorder. They may consist of health or social care services or both.

7.14 The regulations make clear that the responsibility for commissioning after-care services should, wherever possible, sit with the organisation commissioning services to meet that patient's other healthcare needs.

Standing rules

Standard commissioning contractual terms and conditions

7.15 Requirements relating to the development of standard commissioning contractual terms and conditions, for example the standing rules:

- authorise the NHSCB to draft a standard contract;
- require the NHSCB to draft the terms and conditions that will be included in the contract;
- authorise the NHSCB to require CCGs to use the standard contract when commissioning services; and
- require the Board to include a standard contractual term relating to the duty of candour.

7.16 Prior to making changes to the standard contract, the standing rules require the NHSCB to consult:

- the Secretary of State,
- CCGs (the requirement to consult CCGs means that the NHSCB has to consult in such a way that any individual CCG is engaged by the consultation and could respond if they wanted to),
- Monitor,
- the Care Quality Commission,
- HealthWatch England; and
- any other such person the NHSCB considers it appropriate to consult.

NHS Continuing Healthcare

7.17 The standing rules will give statutory effect to the National Framework for NHS Continuing Healthcare. The National Framework sets out the eligibility criteria and decision-making process for accessing NHS continuing healthcare.

NHS Constitution rights

7.18 The NHS Constitution sets out what patients, public and staff can expect from the NHS and what the NHS expects from them in return. Rights in the Constitution are legal entitlements, protected by law. These include rights conferred explicitly in legislation and rights derived from legal obligations imposed on NHS bodies and other healthcare providers.

7.19 The standing rules provide the legal basis for three patient rights set out in the NHS Constitution. These are:

- The right to expect local decisions on the funding of other drugs and treatments to be made rationally following proper consideration of the evidence and information on the content of local decisions made readily available to the public[1];
- The right to make certain choices about NHS care and the information to support these choices, specifically the rights to choice at referral to secondary elective care services, the choice of a named consultant-led team and the choice of a named professional-led team at referral to elective secondary mental health care; and
- The right to access services within maximum waiting times, or for the NHS to take all reasonable steps to offer a range of alternative providers if this is not possible.

[1] The legal basis for the NHS Constitution right which sets out the right to drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor says they are clinically appropriate is set out in regulations made under section 237 of the Health and Social Care Act 2012.

Multiple Sclerosis Risk Sharing Scheme

7.20 Arrangements to ensure the continuation of certain Multiple Sclerosis therapies, through the Multiple Sclerosis Risk Sharing Scheme ("the scheme"). The scheme, set up in 2002 following agreement with a group of pharmaceutical manufacturers, provides suitable patients with access to four disease-modifying therapies at an agreed, cost effective price, underpinned by a 10-year monitoring programme to assess whether the drugs have achieved the outcome targets set at the Scheme's inception.

Financial duties of the Board and CCGs: controls on revenue resource use

7.21 In the mandate to the Board, the Secretary of State must set out the limits that will apply to total capital and revenue resource use (that is, use by the Board and CCGs taken together) for that financial year.

7.22 The Secretary of State will also have the power to set a limit on the use of revenue resources by the Board itself, and by the Board and CCGs taken together, in relation to certain administrative matters. The Board has the power to set similar limits for individual CCGs where the Secretary of State has set a limit on the total revenue resource use in relation to those matters. The administrative matters that may apply for the purposes of these limits are set out in regulations in the negative instrument.

8 Consultation outcome

8.1 The provisions of the 2012 Act are based on policies tested through a series of consultations; the White Paper, *Equity and Excellence: Liberating the NHS*, and the listening exercise led by the NHS Future Forum particularly informed the development of commissioning policy, aspects of which this SI supports.

8.2 The principle of establishing GP-led commissioning organisations (then known as GP consortia) was first set out in the Government's white paper *Equity and Excellence: Liberating the NHS. Liberating the NHS: commissioning for patients* consulted the public over 12 weeks on proposals for commissioning. Apart from the change from SHAs and PCTs to the NHS Commissioning Board and CCGs and the transfer of responsibility for commissioning some NHS services to the NHS Commissioning Board, no changes were proposed to the basic principles of area-based commissioning responsibility.

8.3 Following the Listening Exercise, and the report of the NHS Future Forum, the Government changed the name of local commissioning organisations to 'clinical commissioning groups', to indicate wider clinical involvement in these organisations.

Services to be commissioned by the Board

8.4 Under section 15 of the Act, the Secretary of State must seek advice appropriate for enabling him to determine which services should be commissioned by the Board, including from people or bodies with appropriate expertise and from the Board itself. The Secretary of State has sought such advice in relation to the various categories set out in these regulations; for example, a Clinical Advisory Group for Prescribed Services, established to advise the Government on which specialised services should be commissioned nationally, examined the current list of specialised services against the factors listed at section

3B(1)(d) and provided advice in a report published in September 2012 at: http://www.dh.gov.uk/health/2012/09/cagreport/.

8.5 Before deciding whether to make regulations, the Secretary of State has also consulted the Board and has taken into account its comments.

Standing rules

8.6 For the most part the standing rules reflect existing policy. However there are two areas which new policy has been consulted on.

Greater choice and control consultation

8.7 The White Paper, *Equity and Excellence: Liberating the NHS,* committed to introduce choice of named consultant-led team where clinically appropriate. The Department of Health consulted on this proposal as part of the consultation *Greater Choice and Control* in October 2010. The majority of respondents who answered this question supported the Department of Health's proposed approach as set out in the consultation document. The Department of Health issued guidance to the NHS in October 2011, with choice of named consultant-led team coming into effect in April 2012.

8.8 In addition to this the consultation document, *No decision about me, without me,* proposed enabling service users to choose any named consultant-led team within their secondary mental health service provider, and further to extend this choice to any team led by a clinically appropriate professional. The majority of responses were supportive of this proposal and the standing rules will set out the legal basis for this right.

Duty of candour consultation

8.9 A consultation on the Government's proposed contractual duty of candour was held in late 2011 and early 2012. The results of this consultation were mixed, although a slight majority of respondents agreed with the principle of a contractual duty of candour.

8.10 Further details from the consultation relates to the specific contractual requirement, the support that would be useful for staff and patients, and equalities aspects. As the detail of the contractual duty will be for the NHS Commissioning Board to set out, these aspects are not discussed here.

9 Guidance

CCG commissioning responsibility

9.1 The Board will have powers (and in some cases will be required) to issue guidance to CCGs. In particular, the Board will issue a document, under the power in section 14Z7 of the 2006 Act specifying circumstances in which a CCG is liable to make a payment in respect of services provided as a result of services made by another CCG.[2]

Services to be commissioned by the Board

9.2 The Board will be able to issue information on its commissioning of those services, such as specialised services, that it will commission for patients that are the responsibility of CCGs.

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[2] For current guidance, see *Who pays? Establishing the responsible commissioner* at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_078466

Standing rules

9.3 The standing rules section of the regulations requires the Board and CCGs to have regard to guidance in certain areas. These are:

- NHS Continuing Healthcare – the National Framework: http://www.dh.gov.uk/health/2012/11/continuing-healthcare-revisions/
- Referral to treatment – 18 week waits – http://transparency.dh.gov.uk/2012/06/29/rtt-waiting-times-guidance/
- Choice Framework – http://www.dh.gov.uk/health/tag/patient-choice/

Financial duties of the Board and CCGs: controls on resource use

9.4 The Secretary of State will provide Accounts Directions to ensure the Board and CCGs satisfy the requirements of the Government Financial Reporting Manual issued by HM Treasury.

10 Impact

10.1 The impact on business, charities or voluntary bodies is negligible.

10.2 For the most part the impact on the public sector is negligible; further details of the impact on the public sector of the duty of candour requirements are set out below.

10.3 An Impact Assessment has not been prepared for this instrument: the costs and cost-savings of transferring the commissioning responsibilities from Strategic Health Authorities and Primary Care Trusts to the Board and CCGs have been set out in Commissioning for Patients Impact Assessment (see pages 3 – 29, Annex A)[3] that accompanies the Health and Social Care Act 2012. These costs and cost-savings are not easily attributable to any one particular piece of secondary legislation.

10.4 Since the publication of the Impact Assessment for the Health and Social Care Act 2012, officials have been tracking closely the actual costs and benefits of the changes. The costs were revised and the current estimate is in the range of £1.5 to £1.5 billion. These costs remain within the wider possible range specified in the coordinating document. Full details were set out by Secretary of State in a written statement to Parliament on 18 October 2012.[4]

10.5 At the time the policies now reflected in the standing rules were developed, impact assessments were undertaken where required. Where there are no changes to policy, the original Impact Assessments, taken with the Impact Assessment produced for the 2012 Act, set out

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[3] to be found at http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_129917.pdf

[4] **18 Oct 2012 : Column 36WS:** http://www.publications.parliament.uk/pa/cm201213/cmhansrd/cm121018/wmstext/121018m0001.htm#12101829000017

the costs and benefits of each policy area. There are two exceptions, set out below.

Standing rules

Duty of candour

10.6 An Impact Assessment has been prepared relating to the introduction of a contractual duty of candour: http://www.dh.gov.uk/health/2012/12/duty-candour

10.7 The Impact Assessment indicates that the policy will have a net benefit of around £20m in the first year. However, it should be noted that, while the total benefits calculated (around £50m) are to the population as a whole, based on improvements in Quality Adjusted Life Years (QALYs) that are derived from reduced anxiety and distress linked to non-disclosure, the costs of the policy are borne directly by the NHS in implementing the policy. These are around £29m in the first year.

10.8 There are likely to be indirect, unquantifiable benefits for the NHS due to the duty leading to a more open and transparent NHS culture, thereby improving reporting and learning from incidents, which in turn will reduce the future number of patient safety incidents and their associated costs. We do not have enough firm data on which to base any robust estimates of this benefit, however.

Choice

10.9 An Impact Assessment has been prepared relating to the introduction of the proposals for greater patient involvement and patient choice, as set out in the consultation, *No decision about me, without me.*

10.10 The Impact Assessment indicates that the proposals will result in patients having more say in their care and treatment. This may impact referral patterns and, in the medium term, commissioning decisions to ensure that services best reflect patient preferences, given their ability to choose services that best suit their needs and preferences. The lack of evidence available does not permit an extrapolation of reliable monetised values for benefits to be made; the Impact Assessment discusses the benefits expected, and their likely magnitude. The delivery mechanisms for the proposals are largely in place, so the marginal cost of the proposals is expected to be low.

11 Regulating small business

11.1 The legislation does not apply to small business.

12 Monitoring & review

12.1 The Secretary of State will keep the Board's performance under review in line with his duty under the NHS Act 2006, as amended by the Health and Social Care Act 2012. In turn and as part of its responsibilities, the NHS Commissioning Board will monitor the exercise by CCGs of their statutory functions as part of its annual performance assessment of CCGs.

12.2 The standing rules will be reviewed annually and updated as required.

13 Contact

Helen Dixon at the Department of Health (Tel: 0207 210 5719 or email: helen.dixon@dh.gsi.gov.uk) can answer any queries regarding the affirmative instrument.

Stephanie Croker at the Department of Health (Tel: 020 7210 3822 or email: Stephanie.croker@dh.gsi.gov.uk) can answer any queries regarding the negative instrument.