EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (DIRECTIONS BY STRATEGIC HEALTH AUTHORITIES TO PRIMARY CARE TRUSTS REGARDING ARRANGEMENTS FOR INVOLVEMENT) (No.2) REGULATIONS 2008

2008 No. 2677

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

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Description

2.1 This instrument revokes and supersedes the National Health Service (Directions by Strategic Health Authorities to Primary Care Trusts Regarding Arrangements for Involvement) Regulations 2008 (SI 2008/2496) ("the defective instrument"). For the reasons explained in this explanatory memorandum, the defective instrument was partially invalid. This instrument revokes and replaces the defective instrument.

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

3.1 This instrument revokes and replaces the defective instrument. In so far as the provisions of the defective instrument purported to be made under section 242B of the National Health Service Act 2006 ("the 2006 Act"), the instrument was invalid. Section 242B of the 2006 Act was brought into force on 26th September for the purpose of making regulations under that section (see the Local Government and Public Involvement in Health Act 2007 (Commencement No.7) Order 2008 (S.I. 2008/2434). The defective instrument contained provisions purportedly made in exercise of the power in section 242B of the 2006 Act but due an oversight the instrument was made on 14th September, 10 days before the relevant power was in force.

3.2 Regulation 6 of the defective instrument was made under provisions of the National Health Service Act 2006 other than section 242B. The Department's view is that in so far as the provisions of the defective instrument are made under those sections, it is valid. In the circumstances, however, the Department considers it appropriate to revoke the whole of the defective instrument, not just the provisions that are invalid. The Department has also taken the opportunity to make changes to the drafting of regulation 6. This instrument therefore revokes and replaces the defective instrument in its entirety. In accordance with paragraphs 3.4.11 to 14 of Statutory Instrument Practice, this instrument is being made available free of charge to all known recipients of the defective instrument.

3.3 This instrument was laid less than 21 days before regulation 7 comes into force. Regulation 7 revokes the defective instrument. The Department identified the oversight which led to the defect only after the instrument had been made and laid. The 21 day rule was breached in order to ensure that the defective instrument was revoked as soon as possible after the error was discovered.

3.4 The Committee are asked to note that the provisions of this instrument other than regulation 7 come into force at least 21 days after the instrument was laid.

4. Legislative Background

4.1 Section 242(1B) of the NHS Act places a duty on certain NHS bodies, including SHAs and PCTs, to make arrangements to secure that users of health services for which those bodies are responsible are involved in the planning of the provision of those services and in the development and consideration of proposals for change or decisions made where those proposals or decisions have an impact on the way in which services are provided or the range of services provided.

4.2 Section 242B of the NHS Act 2006 gives the Secretary of State the power to make regulations enabling an SHA, in certain circumstances, to direct a PCT about arrangements for involvement.

4.4 Sections 242(1B) and 242B of the NHS Act 2006 are inserted by section 233 of the Local Government and Public Involvement in Health Act 2007.

5. Territorial Extent and Application

5.1 This instrument applies to England

6. European Convention on Human Rights

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

7.1 The Department of Health's view is that although over the past few years the NHS has improved at involving users in the development, planning and delivery of health services, involvement is not yet a mainstream activity alongside other policy and performance requirements and that NHS organisations view it as a marginal activity, largely centred on process and dependent on the commitment of individual managers.

7.2 World class commissioning, the Operating framework for 2008 - 09 and Lord Darzi's review reflect the shift of involvement to the forefront of the policy agenda and establish it as one of the key developmental challenges for NHS organisations. High performing organisations are increasingly mainstreaming and embedding involvement activity in all aspects of their work.

7.3 One of the policy objectives of Part 14 of the Local Government and Public Involvement in Health Act (patient and public involvement in health and social care) is to secure improved involvement of service users in the provision of health services by amending the duty placed on certain NHS organisations about involving users. The responsibility for making arrangements for involvement is with the NHS organisation responsible for providing those services and in the Department's view that is best placed to secure the efficient and effective involvement of users in certain circumstances. It has been recognised that in some circumstances SHAs were well placed to lead or coordinate the planning and delivery of involvement arrangements that secure effective and efficient involvement of users. Where involvement and consultation activity might span a number of PCTs there are benefits to be derived from the SHA making the arrangements for involvement activity rather than the individual PCTs but there existed no legal framework for this to happen without the PCT being at risk of failing to discharge the duty to involve under section 242(1B) of the NHS Act.

7.4 Section 242B allows the Secretary of State to make regulations that enable an SHA to give a direction to a PCT in certain circumstances. These regulations set out the circumstances when the SHA can issue such a direction.

A SHA can issue a direction to a PCT concerning involvement if:
a) a Primary Care Trust has made or is to make arrangements under section 242(1B) to involve users in a particular matter; and

b) those users will be involved under arrangements made by the Strategic Health Authority.

Directions can only be given where:
a) in the opinion of the SHA, it would be more appropriate for the SHA to secure the involvement of users; and
b) the arrangements made by the SHA would satisfy the duty placed on the PCT by section 242(1B).

7.5 The direction must be made in writing and specify the matter to which it relates. A direction can also be given where the PCT has already made its involvement arrangements; in these circumstances the direction from the SHA must specify which part(s) of the involvement arrangements the PCT is to conclude and how the involvement arrangements are brought to a close and communicated to stakeholders. An SHA may direct a PCT, in accordance with the regulations, to act jointly with the SHA to carry out the involvement activity.

7.6 Where a direction has been given by an SHA, the SHA and PCT must make available information that each other may require in order to make arrangements for involvement.

7.7 If an SHA directs a PCT not to involve users or to stop an existing involvement exercise, the PCT would not be in breach of its obligations to involve users under section 242(1B) of the NHS Act provided that it complies with the direction.

Consultation

7.8 A draft of the regulations was put out for consultation with key stakeholders from SHAs, PCTs and key external stakeholders such as Centre for Public Scrutiny and Health Link. Drafting amendments were made for the final instrument but there were no substantive policy changes. Responses received were supportive but reinforced the need for supporting guidance.

Guidance

7.9 The Department will be publishing statutory guidance for NHS organisations on section 242(1B) and 242B of the NHS Act 2006. This will provide help and support for NHS organisations in understanding the provisions and impact of the regulations.

8. Impact

8.1 A Regulatory Impact Assessment has not been prepared for this instrument as it has no impact on business, charities or voluntary bodies.

8.2 The impact on the public sector is estimated at £600,000 per annum. Costs arise in two areas from the administrative arrangements required to operate these regulations – costs for PCTs and SHAs in producing information required by these regulations and staff costs in the SHA in carrying out its duties under these regulations. It is expected there would be economies of scale in coordinating involvement work at SHA level. The identified costs would be met from within existing allocations to NHS organisations.

9. Contact

Vince Roose at the Department of Health Tel: 02079725002 or email: vince.roose@dh.gsi.gov.uk can answer any queries regarding the instrument.