

EXPLANATORY MEMORANDUM TO
THE NATIONAL HEALTH SERVICE (PRIMARY MEDICAL SERVICES)
(MISCELLANEOUS AMENDMENTS AND TRANSITIONAL PROVISIONS)
REGULATIONS 2013

2013 No. 363

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**
 - 2.1 This Instrument amends the following sets of Regulations relating to primary medical services:-
 - i. The National Health Service (General Medical Services Contracts) Regulations 2004 (SI 2004/291) (GMS Contracts Regulations) which set out the framework for General Medical Services (GMS) contracts.
 - ii. The National Health Service (Personal Medical Services Agreements) Regulations 2004 (SI 2004/627) (PMS Agreements Regulations) which set out the framework for Personal Medical Services (PMS) agreements.
 - iii. The Primary Medical Services (Sale of Goodwill and Restrictions on Sub-contracting) Regulations 2004 (SI 2004/906) which prohibit the sale of goodwill in a medical practice.
 - iv. The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc) Regulations 2004 (SI 2004/629) which list drugs, medicines and other substances which may not be ordered under a General Medical Services contract, and those which may be ordered only in certain circumstances and sets out those circumstances.
 - 2.2 The amendments are required as a consequence of the abolition of Primary Care Trusts and Strategic Health Authorities by the Health and Social Care Act 2012 (“the 2012 Act”) and the transfer of primary medical services contracts and agreements held by Primary Care Trusts to the National Health Service Commissioning Board under property transfer schemes made under section 300 of that Act. The instrument also makes some minor and updating amendments.
3. **Matters of special interest to the Joint Committee on Statutory Instruments**
 - 3.1 None

4. Legislative Context

- 4.1 Part 4 of the National Health Service Act 2006 (“the 2006 Act”) currently requires primary care trusts (PCTs) to provide, or secure the provision of, primary medical services in their area. It makes provision for regulations to be made to govern primary medical services contracts and agreements.
- 4.2 This instrument amends the GMS Contracts Regulations and the PMS Agreements Regulations that control the way in which NHS primary medical services are delivered. These Regulations contain the mandatory contractual terms that must be contained in primary medical services contracts and agreements made between PCTs and primary medical services contractors.
- 4.3 The 2012 Act abolishes PCTs and Strategic Health Authorities (SHAs) with effect from 31st March 2013. The 2012 Act also amended the NHS Act 2006 to place responsibility for securing the provision of primary medical services across England on the NHS Commissioning Board “the Board” from 1st April 2013.
- 4.4 This Instrument amends the GMS Contracts Regulations and the PMS Agreements Regulations to ensure that the mandatory contractual terms and conditions that are required are amended to reflect that the Board will hold primary care contracts and agreements from 1st April 2013. The Instrument makes provision in respect of existing primary medical services contracts and agreements that are to be transferred to the Board on 1st April 2013 as a consequence of property scheme transfers made under section 300 of the 2012 Act and also make provisions in respect of new contracts and agreements which will be entered into between contractors and the Board on or after 1st April 2013. Transitional provisions enable contracts and agreements to continue as if the necessary contractual amendments required by the amending Regulations had been made. There are also minor updating and policy changes reflected in the amendments to the GMS Contracts Regulations and PMS Agreements Regulations.
- 4.5 This Instrument makes consequential amendments relating to the abolition of PCTs and SHAs and the establishment of the Board and updating amendments to;
- The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc) Regulations 2004 (SI 2004/629).
 - The Primary Medical Services (Sale of Goodwill and Restrictions on Sub-contracting) Regulations 2004 (SI 2004/906).

5. Territorial Extent and Application

- 5.1 This instrument applies to England.

6. European Convention on Human Rights

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

7. Policy background

- What is being done and why
- 7.1 This Instrument amends the Regulations, as detailed above, as a consequence of the provisions of the 2012 Act and in particular in relation to the abolition of PCTs and SHAs, the establishment of the Board and the transfer of GMS contracts and PMS agreements from PCTs to the Board. The Regulations make transitional provision in respect of the abolition of, and the transfer of contracts and agreements to, these bodies.
- 7.2 This Instrument also make some updating and minor policy changes in respect of the way in which primary medical services are delivered pursuant to Part 4 of the 2006 Act which are set out in paragraph 7.3.
- 7.3 There are also policy initiatives which require amendments to be made to the GMS Contracts Regulations and the PMS Agreements Regulations. These are:
- The requirement on primary medical services contractors to be a member of a Clinical Commissioning Group (CCG) and to nominate a health care professional to act on their behalf.
 - The requirement on primary medical services contractors to be registered with the Care Quality Commission (CQC).
 - A new Patient Choice Extension Scheme which is a partial replacement of the Patient Choice Scheme established in 2012.
 - The introduction of new categories of independent prescribers.
- 7.4 The Primary Medical Services (Prescription of Drugs) Regulations 2004 prevent primary medical services contractors from prescribing certain drugs, and allow them to prescribe certain listed drugs only in prescribed circumstances (the “black” and “grey” lists). The amendments in this Instrument revise the grey list to reflect recent clinical advice and in addition make consequential amendments arising from the abolition of PCTs and the establishment of the Board.
- 7.5 The PMS (Sale of Goodwill and restrictions on sub-contracting) Regulations 2004 contain the prohibition of the sale of goodwill in a medical practice. These Regulations effectively prevent a GP practice being sold treating its registered patients as a commodity. This Instrument also contains amendments to these Regulations as a consequence of the 2012 Act (the abolition of PCTs and the establishment of the Board).

Patient Choice Extension Scheme

- 7.6 The Patient Choice Scheme was introduced on 30th April 2012 as a temporary scheme to run until 31st March 2013. The Scheme allows primary medical services contractors, who participate in the Scheme, (i) to accept patients who do not reside in their practice area onto their list of registered patients and thus provide primary medical services to them; or (ii) allows contractors to provide treatment to patients who

live outside of the practice area without the requirement on the patient to register with that contractor.

- 7.7 Under the existing scheme, which will run until 31st March 2013, PCTs and contractors are required to vary contracts to relieve the contractor from providing services to patients registered under the scheme out of hours or when they are outside of the practice area. Under the Patient Choice Scheme Directions 2012 made by the Secretary of State, PCTs are required to ensure registered patients are notified of where they may obtain primary medical services when they are outside of the practice area or out of hours.
- 7.8 The Patient Choice Extension Scheme Directions 2013 (a copy is attached) introduces a new scheme which is effectively a partial extension of the existing Scheme, which is outlined in paragraph 7.6 and 7.7 above. The new Patient Choice Extension Scheme 2013 will allow only those patients registered under the current temporary scheme to remain registered - pending the outcome of the evaluation of the temporary scheme and the extension scheme will run until 31st March 2014. It does not, however, allow contractors to provide services to patients not registered with them. A document which summarises the New Patient Choice Extension Scheme is available on the Department of Health's website (www.dh.gov.uk). Under the new Patient Choice Extension Scheme, contractors are still required to vary contracts to relieve the contractor from providing services to patients registered under the scheme out of hours or when they are outside of the practice area. This instrument contains amendments to enable the contracts of those who are participating in the Scheme to continued to be varied.

Requirement to be a member of a CCG

- 7.9 This Instrument also includes a requirement for primary medical services contractors to become a member of a Clinical Commissioning Group (CCG) and to appoint an individual to act on the contractor's behalf in dealings with the CCG. CCGs are established under section 11 of the 2006 (amended by section 10 of the 2012 Act). This is to ensure contractors are engaging with the work on CCGs from 1st April 2013.

Introduction of new category of Independent Prescriber

- 7.10 This Instrument also introduces a further category of independent prescribers. These allow certain chiropractors/podiatrists and physiotherapists to prescribe independently where they are included in the register maintained under the Health and Social Work Professions Order 2001 and that register includes an annotation that they are qualified to order drugs, medicines and appliances as an independent prescriber.

Requirement to be registered with the Care Quality Commission (CQC)

- 7.11 The Health and Social Care Act 2008 established the Care Quality Commission as the regulator of all health and adult social care

services. All providers of regulated activity are required to be registered with CQC.

- 7.12 Specified out of hours providers of primary medical services were required to register with CQC from 1st April 2012. However, due to the scale of the exercise, regulations were made deferring the requirement for primary medical services contractors to be registered until 1st April 2013. This Instrument provides an amendment to the GMS Regulations. A GMS contractor is required to provide essential services. The amendment provides that where a contractor is suspended by CQC under section 18 of the Health and Social Care Act 2008 and may be unable to provide essential services as a consequence of that suspension, that contractor will not be in breach of his primary medical services contract.

The Primary Medical Services (Sale of Goodwill and Restrictions on Sub-contracting) Regulations 2004

- 7.13 This Instrument also makes amendments to the Primary Medical Services (Sale of Goodwill and Restrictions on Sub-contracting) Regulations 2004 as a consequence of the Health and Social Care Act 2012.
- 7.14 Section 259, and Schedule 21, of the 2006 Act prohibit the sale of goodwill of a medical practice by those who provide, or who have provided, primary medical services except where the person no longer provides those services and has never provided the services in a relevant area. Relevant area is defined as, for these purposes, the area in which the person provides services under arrangements with a PCT.
- 7.15 Section 259 of the 2006 Act was amended by the 2012 Act to define services provided under arrangements with the NHS Commissioning Board in a “prescribed area”.
- 7.16 The amendment in this Instrument defines relevant area, for the purposes of the Sale of Goodwill as area teams of the NHS Commissioning Board and also makes consequential amendments arising from the abolition of PCTs and the establishment of the Board. This will allow continuation of the provisions post 1st April 2013.

The National Health Service (General Medical Services Contracts)(Prescription of Drugs etc) Regulations 2004

- 7.17 Amendments are required to the provisions relating to the prescribing of Cyanocobalamin in the Schedule 2 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004 (“the 2004 Regulations”). Under the 2004 Regulations, Cyanocobalamin is restricted on NHS prescription, except for patients who are vegans or have a proven vitamin B12 deficiency of dietary origin. General medical practitioners would be in breach of their contractual terms of services if the drug were ordered for patients who do not meet these criteria.
- 7.18 Clinical evidence has emerged that diabetic patients who are being treated with Metformin can become vitamin B12 deficient. Schedule 2

to the 2004 Regulations restricts the prescribing of Cyanocobalamin and only enables it to be prescribed in specified circumstances. The amendments remove the restrictions on prescribing Cyanocobalamin and will therefore allow Cyanocobalamin to be prescribed to all patients including those who are being treated with Metformin.

7.19 The changes outlined in Regulations 2(3) and 2(4) relate to the capability to distribute antivirals in a future UK pandemic to symptomatic individuals. These changes reflect the need for this distribution capability to be maintained despite the changes in health structures in England on 1st April 2013. It enables the named organisations to provide these distribution services which were previously delivered by PCTs.

- Consolidation

7.20 In introducing the current set of amending Regulations, the Department of Health considered the possibility of consolidation, the resources required and other sources of information for those who might use these Regulations.

7.21 Each time the GMS Contracts and PMS Agreements Regulations have been amended previously the Department has issued electronically:

- A consolidated GMS contract template
- A standard variation notice for use by PCTs (in future, the Board) when amending existing GMS contracts.

The Department intends to publish a consolidated GMS contract template which reflects the amendment made by this Instrument.

7.22 Through necessity, resources have had to concentrate on the implementation of the 2012 Act and on the annual negotiations on changes to the NHS (General Medical Services Contracts) Regulations.

7.23 The Department proposes to consolidate the GMS Contracts Regulations and the PMS Agreements Regulations before 2015 which will allow the Board to assume responsibility for the provision of primary medical services and to determine what, if any, further amendments are required to allow them to carry out their functions.

7.24 Payments to GMS contractors are set out in the Statement of Financial Entitlements (SFE) which are directions made by the Secretary of State. New directions are being made and will effectively be a consolidation to take account of the 2012 Act. These directions will be consolidated with effect from 1 April 2013.

8. Consultation outcome

8.1 The Department of Health has consulted the British Medical Association (BMA), the Royal College of Nurses, the National Association of Primary Care, NHS Alliance, the Family Doctors' Association and the NHS Commissioning Board.

- 8.2 It is usual practice to consult the BMA on any proposed changes to the GMS contracts regulations. However, due to the scope of the changes in these regulations, we have widened the group of bodies consulted to those who may represent personal medical service contractors or who represent those involved in the commissioning or provision of primary medical services.
- 8.3 The BMA have had a number of comments on the drafts, particularly in relation to membership of a CCG, provision of information and the patient choice extension scheme. We have responded to the comments received and made appropriate changes to the Regulations – although none of the comments received were particularly contentious.

9. Guidance

- 9.1 As these amendments are, in the main, consequential on the 2012 Act, the Department of Health does not propose to issue guidance on the impact of these regulations.

10. Impact

- 10.1 An Impact Assessment has not been prepared for this instrument. The majority of amendments are being made as a consequence of the Health and Social Care Act 2012 for which a full impact assessment was undertaken and is available at www.dh.gov.uk. Consideration has been given to whether any future impact assessment was required but this was not considered to be necessary.
- 10.2 In respect of regulation 20 and 45 which cross refer to the Patient Choice Extension Scheme devised by Secretary of State, no impact assessment has been prepared as Better Regulation have previously confirmed that this policy is part of HMT approved negotiated deal on changes to the GP contractual arrangements and does not require an impact assessment.
- 10.3 In respect of regulation 20 and 45 which cross refer to the Patient Choice Extension Scheme devised by Secretary of State, no impact assessment has been prepared as Better Regulation have previously confirmed that this policy is part of HMT approved negotiated deal on changes to the GP contractual arrangements and does not require an impact assessment.
- 10.4 In respect of regulation 54(2)(a) which relates to the omission of the entry for Cyanocobalamin Tablets from the list of drugs which cannot be prescribed, there is minimal impact on business and no impact on charities or voluntary bodies is foreseen. There is no impact on the public sector. Therefore it does not require an impact assessment.

11. Regulating small business

- 11.1 GP practices are exempt from the Small Firm Impact Test as they are considered as part of the public sector due to their provision of primary medical services for the NHS. Public sector organisations are exempt from this test.

12. Monitoring & review

12.1 Monitoring of GMS and PMS contracts will become the role of the NHS Commissioning Board however the Secretary of State will retain responsibility for the terms of contracts contained in regulations and for the consolidation of those regulations.

13. Contact

Jenny Smith at the Department of Health Tel: 0113 254 5020 or email: jenny.smith@dh.gsi.gov.uk can answer any queries regarding the instrument.

Sarah Burrow at the Department of Health Tel: 0113 254 6323 or email: sarah.burrow@dh.gsi.gov.uk can answer any queries regarding the instrument.