

EXPLANATORY MEMORANDUM TO

THE AMENDMENTS RELATION TO THE PROVISION OF INTEGRATED CARE REGULATIONS 2019

2019 No. 248

1. Introduction

- 1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care (“the Department”) and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

- 2.1 The instrument makes changes to regulations which are considered necessary to support the introduction of proposed new contractual arrangements for the provision of integrated health and care services under an Integrated Care Provider (“ICP”) contract. This responds to the demand in some local areas for a single contract through which, general practice, wider NHS and, in some cases, some local authority services can be commissioned from a ‘lead’ provider organisation, responsible for integrating services. The Department has worked closely with the National Health Service Commissioning Board (which operates as NHS England (“NHSE”)) in the development of the ICP Contract, alongside commissioners of services, and health and care organisations across the country.
- 2.2 The Secretary of State has agreed to make these amendments following NHSE’s decision, following consultation, to make the contract available for use. The amendments made by these Regulations must be in force before an ICP contract can be entered into.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

- 3.1 None.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

- 3.2 As the instrument is subject to negative resolution procedure there are no matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business at this stage.

4. Extent and Territorial Application

- 4.1 The extent of the amendments being made in this instrument is England and Wales only.
- 4.2 The territorial application of the amendments being made in this instrument is England only because health is a devolved matter in Northern Ireland, Scotland and Wales.

5. European Convention on Human Rights

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

6. Legislative Context

- 6.1 This statutory instrument is an omnibus instrument which makes amendments to various sets of regulations made under the following Acts: the Medical Act 1983; the Health and Social Care (Community Health and Standards) Act 2003; the National Health Service Act 2006 (“the 2006 Act”); the Health and Social Care Act 2008; and the Health and Social Care Act 2012 (“the 2012 Act”).
- 6.2 The amendments made by this instrument ensure that the current regulatory framework which applies to contractual arrangements for the provision of health and care services continues to apply where services are provided under the new ICP contract, and to those organisations holding that contract. A substantive change is also made to the regulations underpinning the existing contractual arrangements for provision of NHS GP services. This will enable GPs who are currently providing services under existing arrangements to suspend rather than terminate those existing arrangements, in order to provide services under an ICP contract. The amendments made by this instrument are to the following regulations.

The National Health Service (Travel Expenses and Remission of Charges) Regulations 2003 (“the 2003 Regulations”)

- 6.3 Section 183 of the 2006 Act allows regulations to be made which make provision for people who are either in receipt of certain state benefits, or who are on a low income, to be reimbursed for travel expenses incurred in obtaining certain NHS services and for those same people to be exempt from the payment of certain NHS charges which would otherwise be payable.
- 6.4 The 2003 Regulations set out the details of the scheme which provides for payments and remission of payments to be made to eligible persons in respect of NHS travel expenses and NHS charges.
- 6.5 The amendments will ensure that all possible ICP contractors and subcontractors will be covered by the 2003 Regulations, to ensure that eligible people do not lose their entitlements under the new arrangements.

The Local Authority Social Services and National Health Service Complaints (England) Regulations 2009 (“the 2009 Regulations”)

- 6.6 The 2009 Regulations, as amended, align adult social care and health complaints processes into a single complaints system across health and social care.
- 6.7 For publicly-funded NHS care, a complaint at a local level may be made to either the provider of the service or the body that commissions that service. Each service provider must prepare an annual report on its complaints handling, which is to be sent to the body commissioning the care and made available to any person on request. The amendments bring all ICPs within the scope of the 2009 Regulations.

Medical Profession (Responsible Officers) Regulations 2010 (“the 2010 Regulations”)

- 6.8 Most doctors (with some exceptions) are licensed by General Medical Council (GMC) and are required to undergo periodic revalidation, to demonstrate that they meet

professional standards and are fit to practise. Revalidation is carried out by a responsible officer (or, suitable person) who will make a statement to the Registrar regarding the doctor's fitness to practise. Responsible officers evaluate doctors' performance through regular medical appraisal. A Responsible Officer is appointed or nominated by the designated body with whom the doctor has a prescribed connection. Prescribed connections are set out in the 2010 Regulations. Where a doctor carries out work for more than one designated body, the designated body will usually be the one for whom they do most work.

- 6.9 The amendments ensure that an ICP is the designated body with a prescribed connection to doctors who are employed by an ICP to provide primary medical services, and doctors who are engaged or contracted under an ICP contract to provide health services which are not primary medical services.
- 6.10 As a result of the amendments to the NHS (Performers Lists) (England) Regulations 2013 detailed below, where a medical practitioner is included on the medical performers list because they are engaged or contracted to provide primary medical services under an ICP Contract; the prescribed connection will be to NHSE as the designated body.

National Health Service (Clinical Commissioning Groups – Responsibilities and Standing Rules) Regulations 2012 (“the Standing Rules”)

- 6.11 Under section 6E(5) of the 2012 Act, the Standing Rules made by the Secretary of State must require NHSE to draft such terms and conditions as they consider appropriate for inclusion in commissioning contracts.
- 6.12 Regulation 17(1) of the Standing Rules gives effect to the requirement in section 6E(5). Regulation 2 defines commissioning contract for the purposes of the Standing Rules, that definition is narrower than the definition in section 6E(1), and excludes primary care contracts (also defined in that regulation).
- 6.13 The exclusion of primary care contracts means that NHSE cannot draft terms and conditions that make provision for primary care. The purpose of the ICP Contract is to allow primary and other NHS services to be commissioned in the same contract.
- 6.14 The amendments to the Standing Rules would expand the scope of the definition of ‘commissioning contract’ to include contracts used for integrated commissioning of primary care and other healthcare services. The primary care elements of the contract would still need to comply with Part 4 of the 2006 Act and any directions or regulations made under that Part that related to primary care commissioned a part of an ICP contract. The Standing Rules will apply to NHSE and CCGs, and not directly to individual ICP contract holders.

National Health Service (Performers Lists) (England) Regulations 2013 (“the Performers List Regulations”)

- 6.15 In order to perform NHS primary medical services, a medical practitioner must be a general medical practitioner (whose name is included in the GP Register held by the GMC), and must be included on the Medical Performers List. The performers list is held by NHSE and includes medical practitioners who are contractors or employees of contractors, providing services under a general medical service contract (“GMS”) contract or a personal medical service (“PMS”) agreement.
- 6.16 The amendments to the Performers List Regulations will additionally provide for applicants seeking inclusion on the performers list, to confirm whether they provide

primary medical services under, or pursuant to an Alternative Provider Medical Services (“APMS”) contract or an ICP contract. The amendments also provide for confirmation of whether the medical practitioner is a contractor under an APMS contract or an ICP contract, to be included in the contents of the medical performers list.

National Health Service (Licence Exemptions, etc) Regulations 2013 (“the Licence Exemptions Regulations”)

- 6.17 Section 81 of the 2012 Act requires any person who provides health care services for the purposes of the NHS to hold a Monitor licence. Section 83 of the 2012 Act provides that the Secretary of State may make regulations which provide for the grant of exemptions from the section 81 requirement. The Licence Exemptions Regulations make provision in relation to the grant of such exemptions.
- 6.18 Regulation 8 of Licence Exemptions Regulations provides that a person who provides health care services for the purposes of the NHS is exempt from the requirement to hold a licence if their applicable turnover for the relevant business year is less than, or is reasonably expected to be less than, £10.
- 6.19 The retrospective nature of the current exemption means that until a person has produced accounts for their last business year, that person (and Monitor) is unable to properly consider whether they should be licensed, or exempt. It also means that a provider whose in year applicable turnover exceeds £10m, can still rely on this exemption until their previous year’s accounts are available.
- 6.20 The amendments will ensure that, where joint ventures hold ICP contracts, they are subject to equivalent regulatory oversight for services of equivalent risk in more conventional provider models. The exemption for applicable turnover will change, so that it applies to a provider’s income from NHS services in the current business year, rather than the last. This will ensure that provider organisations known to meet the £10m threshold test will be subject to the licensing regime from the outset.

National Health Service (Charges for Drugs and Appliances) Regulations 2015 (“the Charges for Drugs and Appliances Regulations”)

- 6.21 Section 172 of the 2006 Act allows regulations to be made for the making and recovery of charges for the supply of drugs, medicines and appliances under the Act. The Charges for Drugs and Appliances Regulations set out a scheme for charges to be made and recovered for the supply as part of the NHS in England, of certain drugs, appliances, wigs and fabric supports, and the arrangements for exemption from those charges in certain circumstances. The amendments will ensure that the Charges for Drugs and Appliances Regulations will apply to contractors and subcontractors of ICPs in the same way.

National Health Service (General Medical Services Contracts) Regulations 2015 (“the GMS Regulations”)

- 6.22 The GMS Regulations are made under section 89(1) of the 2006 Act, and set out the conditions which must be met by those holding a GMS contract with NHSE for GP services, such as those relating to premises, opening hours and termination arrangements.
- 6.23 The amendments will allow holders of GMS contracts to suspend those contracts in order to participate in an ICP (for example, as employees), with provision to re-

activate the GMS contracts at fixed points throughout, or on expiry of the term of, that ICP contract.

National Health Service (Personal Medical Services Agreements) Regulations 2015 (“the PMS Regulations”)

- 6.24 The PMS Regulations are made under section 94(1) of the 2006 Act, and set out the conditions which must be met by those holding a PMS agreement with NHSE for GP services, such as those relating to premises, opening hours and termination arrangements.
- 6.25 The amendments will allow holders of PMS contracts to suspend those contracts in order to participate in an ICP (for example, as employees), with provision to re-activate the PMS contracts at fixed points throughout, or on expiry of the term of, that ICP contract.

7. Policy background

What is being done and why?

- 7.1 Promoting integrated care is a priority for the NHS. The NHS Long Term Plan, published in January 2019, set out the Government’s intention to create an NHS that is increasingly joined-up and coordinated in its care, breaking down traditional barriers between care institutions, teams and funding streams.
- 7.2 Since the publication of its Five Year Forward View in 2014, NHSE has been developing and testing new models of care to integrate different services.
- 7.3 NHSE tested these alternative models in a number of areas through its Vanguard programme, which ran from 2015 to 2018. The new models were found to have made a positive impact on emergency hospital admissions, with lower growth in admissions in Vanguard areas than in the wider NHS, despite receiving less than 0.1% of total NHS funding. NHSE now considers that this exercise has provided enough knowledge to commit to a wider series of community service redesigns.
- 7.4 The ICP Contract will be a contractual option for local areas wishing to integrate care. Some commissioners of care want the opportunity to use a contract designed specifically to promote an integrated service model including primary care, wider NHS and some local authority services. This is intended to ensure that contracting, funding and organisational structures all help rather than hinder staff to do the right thing and to define more clearly who has overall responsibility for integrating and coordinating care.
- 7.5 Between August and October 2018 NHSE consulted on the draft ICP contract, which is a variant of the generic NHS Standard Contract applicable for integrated care provision. This followed the publication of draft contracts in December 2016 (known as the ‘MCP Contract’) and August 2017 (known as the ‘ACO Contract’) respectively.¹ Each iteration has taken into account the feedback received on the previous version.

¹ It is worth noting that the nomenclature of ICPs has evolved since the publication of the draft MCP contract in December 2016. They have also been referred to as ‘accountable care organisations’. NHSE changed the terminology to ‘Integrated Care Provider’ in 2018 in recognition that, as reported by the House of Commons Health and Social Care Committee, use of the term ‘accountable care’ generated confusion about what was being proposed.

- 7.6 Following review and analysis of the consultation feedback, the NHS Long Term Plan announced that the ICP Contract will be made available for use from 2019. The Long Term Plan also restated the expectation that ICP Contracts would be held by public statutory providers. NHSE is finalising its full response to the consultation, which will be published shortly.
- 7.7 The Department has worked closely with NHSE in the development of the ICP Contract, alongside commissioners and Vanguard areas across the country. Through this process, a number of necessary changes to regulations have been identified. In some cases, the changes create additional flexibilities, for example for GPs who wish to enter into ICP arrangements without terminating their existing contracts. However, the vast majority of the changes are minor and are intended to ensure that current rules continue to apply to the provision of services under the ICP contract, and to those organisations using it.

What is an ICP?

- 7.8 Population health approaches are developing as a response to rising and changing demand in a number of high income health systems. (e.g. Spain, Netherlands, New Zealand, USA). The intention is to establish the right clinical, organisational and financial incentives for providers to collaborate in order to deliver preventative, proactive, and coordinated health and care to a given population. ICPs are based on the premise that, by bringing providers together into a single organisation, the historical partitions between primary, community, mental health and social care and acute services can be removed. By dissolving these boundaries, a single provider is intended to have the flexibility to utilise its resources to maximise the health of the population.
- 7.9 To achieve this, commissioners in an area will have a contract with a single organisation for the great majority of health and care services and for the population health in the area. The ICP contract allows commissioners (including CCGs and Local Authorities) to commission primary medical services alongside community and acute services in an integrated way.
- 7.10 There has been some public concern over the development of ICPs, with concern expressed that these represented a means of privatising NHS services, with reference to the ACO model that exists in the United States. The government does not accept this, and the House of Commons Health and Social Care Committee's report on integrated care (June 2018) found that the prospect of a private provider holding an ICP contract was unlikely.
- 7.11 Moreover, two legal challenges to this policy have been unsuccessful. The first judicial review, against the Department and NHSE, argued that the contract constituted unlawful delegation by CCGs² and the second, brought against NHSE, challenged the use of a whole population budget³. This latter ruling was reaffirmed by the Court of Appeal in December 2018⁴.

² R (oao Hutchinson & others) v SSHSC and NHS England [2018] EWHC 1698 (Admin)

³ R (oao Jennifer Shepherd) v NHS England [2018] EWHC 1067 (Admin)

⁴ R (oao Jennifer Shepherd) v NHS England [2018] EWCA Civ 2849

8. European Union (Withdrawal) Act/Withdrawal of the United Kingdom from the European Union

8.1 This instrument does not relate to withdrawal from the European Union.

9. Consolidation

9.1 No consolidation is required as a consequence of these amendments. However, consideration will be given to the consolidation of the respective instruments as and when further amendments are made to them.

10. Outcome of consultation on draft regulations

- 10.1 Between 11 September 2017 and 3 November 2017, the Department ran a public consultation on the proposed changes to regulations to support the ICP contract (known, at that time, as the ‘ACO contract’). This consultation ‘Accountable Care Organisations: Consultation on changes to regulations required to facilitate the operation of an NHS Standard Contract (Accountable Care Models)’, specifically asked consultees to consider whether the draft amendments to regulations which were consulted on delivered the policy objective of supporting the introduction of a model ACO contract.
- 10.2 However, the consultation became the subject of a ‘38 Degrees’ campaign and the Department received over 45,000 responses. These responses highlighted three main concerns: lack of Parliamentary scrutiny; inadequate public consultation; and opposition to privatisation of the NHS. Departmental analysis found that 44,621 of the responses can be attributed to the 38 degrees campaign. These responses took the format of one of 23 very similar templates. 811 responses did not follow these templates, but also expressed opposition to privatisation, gave examples from their personal experience and voiced general concerns over the future of the NHS.
- 10.3 Nine responses directly addressed the specific amendments to regulations and answered the consultation questions: British Dental Association, British Medical Association (BMA), Care Quality Commission, Healthwatch Committee, Hillingdon Healthwatch, National Community Hearing Association, NHSE, Optical Federation and the Royal College of Anaesthetists. These have resulted in a number of post-consultation revisions to the regulations.
- 10.4 Following comments from the BMA, changes have been made to the GMS, PMS, and Licence Exemptions Regulations:
- 10.5 For both the GMS contracts and PMS agreements, the period of notice has been amended to require notice to be given at least six months before the date on which the proposed reactivation of the contract is to take effect.
- 10.6 For both the GMS contracts and PMS agreements, the proposed amendments have been revised to allow reactivation where the parties to the contract have agreed, as appropriate, to the reactivation of the contract.
- 10.7 For the PMS agreement, the proposed amendments have been amended to allow a suspended PMS agreement to be reactivated as a GMS contract, subject to meeting the eligibility criteria.
- 10.8 For the Licence Exemptions Regulations, in recognition of the risk that providers might have to assess their turnover indefinitely, the revised regulations includes

wording to the effect that the requirement ceases with the contract (or set of contracts) that caused the provider's applicable turnover to cross the £10m threshold.

10.9 The Department published its [consultation response](#) in April 2018.

11. Guidance

11.1 The Department of Health and Social Care does not intend to produce guidance to accompany the Regulations.

12. Impact

12.1 There is no significant impact on business, charities or voluntary bodies. The voluntary sector should play a key role in delivering a population-based model of care, focused on the needs and wishes of individuals, which the ICP contract is designed to support. Voluntary sector organisations bring important and unique expertise, and can enhance the opportunities for patient choice and personalisation. We anticipate that commissioners will require bidders for any ICP contract to demonstrate how they will involve and work closely with local voluntary sector organisations to deliver choice and person-centred care.

12.2 There is no significant impact on the public sector.

12.3 An Impact Assessment has not been prepared for this instrument since it does not impose significant costs on the NHS and does not affect private business or other government departments. The legislation does not compel CCGs to change how they procure services, but gives them an option to do so.

13. Regulating small business

13.1 The legislation does not apply to activities that are undertaken by small businesses. GP practices are exempt from the Small Firm Impact Test as they are considered part of the public sector due to their provision of primary medical services for the NHS. Public sector organisations are exempt from this test.

14. Monitoring & review

14.1 The Department will need to monitor how these proposed regulatory changes work in practice for any ICP contract as and when it is in use, with a view to determining whether further amendments are necessary or existing amendments need revision.

14.2 In terms of the impact of the ICP contract itself, NHSE plan to study the effects of the first ICP contracts that come into being and share learning with others that may follow. Following its recent inquiry on integrated care, the House of Commons Health and Social Care Committee recommended that ICPs should be carefully evaluated before being implemented widely.

14.3 Dudley, the first area that plans to use the draft ICP contract, has a programme of evaluation underway. NHSE will work with the first systems using the draft ICP contract to ensure that:

14.4 in the near term lessons are learned around how to improve the local processes for designing and establishing an ICP under contract, including how amending national rules could aid this; and

- 14.5 in the longer term there is ongoing evaluation of any improvement in population health outcomes and other measures of performance in areas served by an ICP relative to others and how these were achieved.
- 14.6 NHSE would expect local areas that implement an ICP contract to evaluate outcomes and impact against local measures.

15. Contact

- 15.1 Nanda Ray and Nicola Golding at the Department of Health and Social Care (golding.ray@dhsc.gov.uk) can answer any queries regarding the instrument.
- 15.2 Philippa Baker at the Department of Health and Social Care (baker.green@dhsc.gov.uk) can confirm that this Explanatory Memorandum meets the required standard.
- 15.3 Stephen Hammond, Minister of State for Health at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.