

EXPLANATORY MEMORANDUM TO
THE NATIONAL HEALTH SERVICE (LICENCE EXEMPTIONS, ETC)
AMENDMENT REGULATIONS 2015

2015 No. 190

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 These Regulations amend the National Health Service (Licence Exemption, etc.) Regulations 2013 (the 2013 Regulations) so that the exemption of providers of only NHS Continuing Healthcare or NHS funded nursing care from the requirement to hold an NHS provider licence, and the exclusion of NHS Continuing Healthcare and NHS funded nursing care¹ from the turnover calculation, remain after 31st March 2015.

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

3.1 None.

4. Legislative Context

4.1 The Health and Social Care Act 2012 (the 2012 Act) provides for Monitor to regulate NHS services, with an overarching duty to protect and promote the interests of patients by promoting NHS provision which is economic, efficient and effective. Part 3, Chapter 3 of the 2012 Act gives Monitor the power to operate a licensing regime for providers of NHS services.

4.2 The 2013 Regulations make provision in relation to the grant of exemptions from the requirement under section 83(1) of the 2012 Act for providers of health care services for the purposes of the NHS to hold a licence to provide such services. The exemption that applies to a person providing NHS Continuing Healthcare or NHS funded nursing care (those terms are defined in regulation 1(2) of the 2013 Regulations) ceases to have effect after 31st March 2015.

4.3 These Regulations amend the 2013 Regulations so that providers of only NHS Continuing Healthcare or NHS funded nursing care remain exempt from the requirement to hold a licence (regulation 2(3)), amends the definition of “applicable turnover” to ensure that all deductions are cumulative and so that the turnover from

¹ NHS Continuing Healthcare means a package of care arranged and funded solely through by the NHS where the individual has been assessed as having a “primary health need”. Such care is provided to an individual aged 18 or over, to meet physical or mental health needs which have arisen as a result of disability, accident or illness.

NHS-funded nursing care is the funding provided by the NHS to homes providing nursing to support the provision of nursing care by a registered nurse. Nursing care by a registered nurse has the same meaning as in section 49(2) of the Health and Social Care Act 2001.

providing NHS Continuing Healthcare or NHS funded nursing care remains excluded from the calculation of applicable turnover (regulation 2(2)).

5. Territorial Extent and Application

5.1 This instrument applies to England only.

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 2012 Act established a comprehensive legal framework for healthcare regulation. This included a new role for Monitor, building on its previous one as the regulator of NHS Foundation Trusts and designed to complement the role of the Care Quality Commission, which continues to set and monitor quality standards for NHS treatment and care.

7.2 As well as continuing to act as the regulator of Foundation Trusts, Monitor has three key functions:

- working with NHS England to provide independent regulation of pricing for NHS services;
- protecting patient choice and using its specialist knowledge and healthcare expertise to address anti-competitive behaviour which acts against patients' interests; and
- working with commissioners to secure continuity of services, where necessary.

7.3 Licensing is the primary mechanism for Monitor to exercise its new regulatory functions on pricing, choice and competition, integration and supporting NHS commissioners in protecting continuity of services. Section 81 of the 2012 Act requires any person who provides an NHS healthcare service to hold a Monitor licence, unless exempt under regulations made under section 83 of the 2012 Act.

7.4 Some NHS providers are exempt from the requirement to hold a Monitor licence as a result of the 2013 Regulations, because licensing these bodies would mean they would be subject to disproportionate or duplicate regulatory oversight elsewhere in the system, for instance by the NHS Trust Development Authority. The licence is a regulatory tool, not a kitemark of quality, and nor is it a badge of financial stability or a guarantee of NHS contracts.

7.5 The licensing regime became fully operational on 1 April 2014. The licence sets out conditions that licence holders have to meet in order to provide NHS services – there are standard conditions which apply to all licence holders or to particular type of licence holder, and special conditions which apply to an individual provider.

7.6 The 2013 Regulations set out which providers are exempt from the requirement to hold a Monitor licence. The regulations exempt:

- Any provider who is not required to register with the Care Quality Commission
- NHS trusts, which will be expected to meet similar requirements to those in the standard licence conditions, with the NHS Trust Development Authority taking action to address failings;
- Small providers, i.e. those providers with a turnover from supplying NHS services of less than £10 million in a relevant business year; and also provides for income from exempt services (primary medical and dental care and NHS Continuing Healthcare or NHS funded nursing care) to be excluded from a provider's turnover for the purposes of the £10m threshold;
- Primary medical or dental services provided under Parts 4 and 5 of the National Health Service Act 2006; and
- Providers that only provide NHS Continuing Healthcare or NHS-funded nursing care as defined in the regulations as an integral part of social care packages.

7.7 Providers of adult social care services are currently not regulated by Monitor and do not require a licence to provide social care services. Under Regulation 6 of the 2013 Regulations, providers who only provide NHS Continuing Healthcare or NHS funded nursing care are exempt from the requirement to hold a licence until 31 March 2015 unless the services are designated as Commissioner Requested Services. Commissioner Requested Service are those services which commissioners consider would need to continue if a provider became financially unsustainable because removal of the services would cause harm to patients, and there are no alternative providers. Providers of Commissioner Requested Services are subject to Monitor's licence conditions that secure continuity of services.

7.8 The exemption under regulation 6 will not apply where a care provider provides additional NHS services, consequently a licence will be required unless another exemption applies.

7.9 Currently, a provider's turnover from NHS Continuing Healthcare or NHS funded nursing care is not taken into account in determining a provider's applicable turnover. Applicable turnover is defined in regulation 1(2) of the 2013 regulations. Providers with an applicable turnover below £10 million are exempt from the requirement to hold an NHS provider licence unless any of its services are designated a Commissioner Requested Service by an NHS commissioner.

7.10 The current calculation of applicable turnover excludes the vast majority of social care providers from Monitor's licensing regime, although some larger providers are required to hold a licence.

8 Consultation outcome

8.1 The Department consulted between 6 June to 15 August 2015 on two options as part of the Care Act 2014 consultation:

- to allow the current nursing care licence exemption to expire. This would require providers of NHS Continuing Healthcare and NHS funded nursing care and whose

total NHS turnover exceeds the de minimis threshold to hold a Monitor licence from 1 April 2015; and

- to continue with licence exemption for provider organisations that provide NHS Continuing Healthcare and NHS funded nursing care services. Most care and support providers that provide these services will continue to be exempt. These services will also be exempt from being designated as a Commissioner Requested Service under Monitor's regime. This option would allow the Care Quality Commission to have sole and focussed financial oversight over these providers, liaising with Monitor where necessary.

8.2 The Department raised awareness of the consultation, holding a series of stakeholder events across the country. A stakeholder event was held on market oversight, which included the current licence exemption on NHS Continuing Healthcare and NHS funded nursing care.

8.3 Following the stakeholder event, the Department also wrote to 30 care providers who were invited to attend the market oversight event, reminding them of the consultation, drawing their attention to the licence exemption and the consultation, seeking their views.

8.4 Consultation responses were collated and analysed. Over 60% of respondents were in favour of continuing the current exemption for nursing care providers from holding a Monitor licence after 31 March 2015.

8.5 Monitor and the Care Quality Commission accepted the proposals to maintain NHS Continuing Healthcare and NHS funded nursing care outside the calculation of applicable turnover and to retain the exemption of providers of only NHS Continuing Healthcare and NHS funded nursing care from the requirement to hold an NHS provider licence. This is in line with the Department of Health's view.

8.6 The reason respondents opted for maintaining the exemption was that the current arrangement with oversight by the Care Quality Commission, in consultation with Monitor when appropriate, was adequate. They felt that it was clearer to have one organisation, the Care Quality Commission, responsible for quality and standards. They did not see the need to introduce an additional regulatory system overseen by Monitor, which would duplicate work with the Care Quality Commission. Respondents considered this would be a burden for providers that may not have the resources to deal with requests from both organisations. Respondents were also of the view that small providers may need additional support and resources.

8.7 39% of respondents, including Monitor and the Care Quality Commission, were not in favour of removing the ability of NHS commissioners to designate NHS Continuing Healthcare and NHS funded nursing care as Commissioner Requested Services. Monitor and the Care Quality Commission argued that removing this ability would remove the ability of commissioners to protect the continuity of certain services. They noted that the

proposed removal would only apply to persons that were not already licensed and only relate to providers of only NHS Continuing Healthcare and NHS funded nursing care services and as such a person providing any other healthcare services could still be designated by commissioners for those other services. They also noted that the test for entry to the Care Quality Commission's Market Oversight regime² were unrelated to those for Monitor's Commissioner Requested Services Regime, such that exclusion from one did not ensure inclusion in the other. They also explained that the Commissioner Requested Service regime and Market Oversight regime have different objectives so the removal of a provider from either regime would undermine both regimes.

8.8 While there would be an overlap between Monitor and the Care Quality Commission in their respective Commissioner Requested Services and Market Oversight regimes, the impact would be minimal, affecting few providers. In light of this overlap, Monitor and the Care Quality Commission have agreed to enter into and publish a Memorandum of Understanding which will set out how both organisations will exercise their respective functions.

8.9 However, 33% of respondents were in favour of removing that ability to designate NHS Continuing Healthcare and NHS funded nursing care services as Commissioner Requested Services because it would be excessive, bureaucratic and costly. Respondents told us that there was no need to designate as a Commissioner Requested Services because Care Quality Commission already regulated providers. Being designated Commissioner Requested Services would provide no guarantee of protection from provider failure, and if a provider failed then it is important that Clinical Commissioning Groups and local authorities took the appropriate action regardless of whether they were Commissioner Requested Services designated. 28% of respondents did not give a definitive response.

8.10 Taking into account responses and Monitor's and Care Quality Commission's position on Commissioner Requested Services, the Department of Health's view is that the exemption should remain, and that the current position with respect to Commissioner Requested Services should not change, i.e. that commissioners should continue to be able to designate as Commissioner Requested Services persons whose only provision of health care services is that of NHS Continuing Healthcare and NHS funded nursing care. Where a social care provider within the Market Oversight regime is also designated as providing a Commissioner Requested Service, Monitor and the Care Quality Commission will work with the affected provider.

² The Care Act 2014 establishes a market oversight regime, whereby the Care Quality Commission (CQC) will assess the financial sustainability of those 50-60 care providers who because of their size, geographic concentration, spread or specialism local authorities would find 'difficult to replace' were their business to fail from April 2015. Where a provider in their regime is experiencing financial difficulties, the CQC will ensure the provider is taking necessary steps to return to a position of financial health. Where this is not possible and it is likely that a care provider will no longer be able to carry on because of business failure, the CQC will warn the local authorities affected to ensure service users do not suffer a gap in care services.

8.11 The Department notified NHS England, Care Quality Commission, Monitor and Healthwatch England of the intent to amend regulations.

9 Guidance

9.1 Updated revised guidance on licence exemptions will be published in March 2015 to reflect the change in regulations. Social Care provider organisations will also be informed of the change in legislation.

10 Impact

10.1 A full regulatory impact assessment has not been carried out as the effect on business is not significant. A regulatory triage impact was done instead as the impact to affected providers across the sector would be minimal (£4,506 in the first year, £2,304 per on-going year).

11 Regulating small business

11.1 The Government is committed to not imposing unnecessary regulatory burdens on small and micro businesses. Providers, whose applicable NHS turnover is less than £10 million a year, are exempt from the requirement to hold a licence, unless they provide Commissioner Requested Services.

12 Monitoring and review

12.1 The Government is committed to carrying out a full review of licensing. The objective of the review will be to establish whether the licensing regime is achieving its intended objectives in light of practical and operational experience. The review will include the licence exemptions regime and will consider whether there have been any changes to the scope of registration by the Care Quality Commission, or to the nature of the provision of NHS services. The Department will also consider existing sources of evidence such as complaints and whether and how information should be collected to inform any decision about exemptions. This review will be conducted during 2016/17, when the licensing regime and the exemptions will have been fully in place for a minimum of two years.

12.2. The Department also holds quarterly accountability meetings with Monitor, where Monitor's performance is kept under review, which also takes into account any problems of its licensing regime.

13 Contact

13.1 Marsha David at the Department of Health Tel: 020 7210 5242 or email: Marsha.David@dh.gsi.gov.uk can answer any queries regarding the instrument.