

**EXPLANATORY MEMORANDUM TO
THE NATIONAL HEALTH SERVICE (LICENCE EXEMPTIONS, ETC)
REGULATIONS 2013**

2013 No. XXXX

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:

- provides exemptions to the requirement for a provider of NHS services to hold a licence with Monitor; and
- defines, for the purposes of licensing, the person who provides health care services.

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) provided 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.

4.2 Part 3, Chapter 3 of the 2012 Act gives Monitor the power to operate a licensing regime for providers of NHS services and work with the National Health Service Commissioning Board (known as and referred to below as “NHS England”) to provide independent regulation of pricing for NHS services.

4.3 This instrument is the first made under sections 81(2) and 83 of the 2012 Act.

5. Territorial Extent and Application

5.1 This instrument applies to England.

6. European Convention on Human Rights

The Parliamentary Under Secretary of State for Quality has made the following statement regarding Human Rights:

In my view, the provisions of the National Health Service (Licence Exemptions, etc) Regulations 2013 are compatible with the Convention rights.

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 (CQC), which will continue to set and monitor quality standards for NHS treatment and care.

7.2 Monitor will have 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 providers of NHS services will be one of the main tools Monitor will use when exercising its functions in order to meet its main statutory duty to protect and promote the interests of people who use the health service.

7.4 The licence sets out the conditions that licence holders will have to meet in order to provide NHS-funded services. Licence conditions can take the form of standard conditions, which apply to all licence holders, or to particular types of licence holder; and special conditions which will apply to an individual provider.

Persons to be regarded as the person who provides a health care service

7.5 Regulation 2 makes provision for determining, in relation to a health care service provided by two or more persons acting in different capacities, which of those persons is to be regarded as providing a health care service for the purposes of licensing requirements. The regulations ensure that the organisation providing NHS services require a licence, rather than employees of the organisation or clinicians working in the organisation under practicing privileges. They also ensure that persons providing NHS services under sub-contracting arrangements are also required to hold a licence.

Exemptions to the requirement to hold a licence

7.6 All providers of NHS services will require a licence from Monitor, unless they are covered by an exemption. These Regulations set out the exemptions that will apply. The Department wants to avoid imposing unnecessary or disproportionate regulation on providers. We also want to make sure that Monitor concentrates on protecting the interests of patients where there is the most risk to those interests.

7.7 The NHS Trust Development Authority (NHSTDA) and the NHS Commissioning Board (NHS England) will also impose requirements on providers. NHSTDA has a bespoke oversight and escalation regime in the

case of NHS trusts, and NHS England impose requirements through contractual requirements. This creates the risk of duplication of, and potentially contradictory, regulation and oversight. Therefore, the instrument includes provision that, where Monitor can work with other bodies to secure equivalent standards, particular types of provider will be exempt from the requirement to hold a licence. During the next Parliament, the Government intends to carry out a full review of how licensing is working.

7.8 Regulations 4 to 9 provide the exemptions to the requirement to hold a licence.

Foundation Trusts

7.9 The effect of section 88 of the 2012 Act is that all Foundation Trusts (FTs) are treated as having made an application for a licence and have met the criteria for holding a licence. Regulation 3 confirms that exemptions do not apply to FTs.

NHS Trusts

7.10 As noted above, the Department is seeking to minimise potential regulatory overlaps and ensure that licensing is focused where there is most potential risk to patients' interests. The Policy is for all NHS trusts, to acquire Foundation Trust status, and that acquisition will be overseen and supported by the NHS TDA. The NHS TDA will operate a bespoke performance management regime, on behalf of the Secretary of State and supported by the Unsustainable Provider Regime for NHS trusts. The NHS TDA will also oversee all other aspects of governance and performance in relation to NHS trusts.

7.11 The National Health Service Trust Development Authority Directions 2013¹ require the NHSTDA to ensure that NHS trusts comply with such conditions which are the equivalent of the NHS providers' licence issued by Monitor as it deems appropriate, including giving directions to an English NHS trust where necessary (direction 4(c)). Direction 4(e) also provides that, in doing this, the NHSTDA must seek and consider advice from Monitor. These Directions will be underpinned by a Memorandum of Understanding between Monitor and the NHSTDA.

Commissioner Requested Services

7.12 Under Monitor's licensing regime, NHS England or clinical commissioning groups may determine that certain services require additional regulation in order to protect the interests of patients who use those services in the event that the provider gets into financial difficulty. Using guidance² from Monitor, commissioners may designate such services as 'commissioner requested services'.

¹ <https://www.gov.uk/government/publications/nhs-trust-development-authority-directions-2013>

² <https://www.monitor-nhsft.gov.uk/home/news-events-publications/our-publications/browse-category/guidance-health-care-providers-and-co-19>

7.13 Where a provider is providing a service that has been specified as a commissioner requested service, the Government's view is that the importance of Monitor being able to exercise its functions to secure continuity of that service should override any eligibility for exemption that might otherwise apply. Thus, regulation 9(1) ensures a provider of a commissioner requested service would always be required to hold a licence, even if it would otherwise meet the criteria for one of the exemptions.

Registration with the Care Quality Commission

7.14 In determining our exemptions policy the Department's starting point for prioritising providers for licensing, and considering the case for exemptions, is to follow the same approach taken for providers who are required to register with CQC. The decision about whether an activity should be regulated by CQC is based on the underlying risk of harm to people using those services and takes account of the need to ensure the quality and safety of healthcare services as a whole. If a provider provides any regulated activity, they must register with CQC.

7.15 The Department's view is that protecting patient safety is the paramount consideration when determining the scope of healthcare regulation, and is consistent with section 82 of the 2012 Act, which requires providers to maintain registration with CQC as a pre-requisite for holding a licence. Therefore regulation 7 exempts any provider that is not required to register with the CQC from the requirement to hold a licence from Monitor (unless the provider supplies commissioner requested services). This exemption would cover, for example, providers of ophthalmic services. Additional protections for patients from licensing providers not requiring CQC registration seem small and unlikely to justify the additional regulatory burden.

Primary medical and dental care services

7.16 NHS England is responsible for commissioning primary medical services and primary dental services provided under Parts 4 and 5 of the NHS Act 2006 and some specialist services under section 3B of that Act. NHS England will enter into contractual arrangements with providers of primary medical services and primary dental services in accordance with terms and conditions made under Parts 4 and 5 of the NHS Act 2006. NHS England is therefore well placed to enforce standards in relation to primary medical and dental services equivalent to those included in Monitor's standard licence conditions. Further, NHS England itself will be under obligations to protect patient choice, avoid anti-competitive conduct and enable integration (sections 13C to 13P of the NHS Act 2006). It will need to ensure that contracts with providers of the services include provisions allowing it to meet those obligations.

7.17 Regulation 5 therefore exempts persons providing primary medical and primary dental services commissioned by NHS England or commissioned under delegated authority from NHS England in accordance with Parts 4 and 5 of the NHS Act 2006 from the requirement to hold a licence. This includes enhanced primary medical services that are commissioned by

NHS England or that NHS England has directed clinical commissioning groups (CCGs) to commission on its behalf. Such primary medical and dental services would be excluded in the calculation of NHS turnover for the purposes of determining whether a person is exempt under regulation 8, subject to the review during the next Parliament, with the intention that NHS England will make similar requirements to some of those in the licence through its contracts with these providers. An agreement between Monitor and NHS England will underpin these arrangements.

7.18 For 2013/14, NHS England has delegated commissioning of certain local enhanced services to CCGs (as set out in guidance³ from NHS England). Such arrangements if extended into 2014/15 would mean these services would be exempt. However where CCGs, under their own commissioning powers in section 3A of the 2006 Act, commission services from GP practices (which may be analogous to local enhanced services previously commissioned by primary care trusts), these services would not fall within the exemption provided for in regulation 5. A person providing services as a consequence of a CCG commissioning in accordance with section 3A of the NHS Act 2006 may, depending on applicable turnover, qualify for the exemption in regulation 8.

Adult Social Care

7.19 Providers of adult social care are not regulated by Monitor and cannot be licensed, although there is provision in section 65 of the 2012 Act to allow the Secretary of State, subject to approval by Parliament, to extend certain Monitor functions to providers of such services. A significant and increasing number of providers of adult social care also attract NHS funding for the provision of nursing care, for example nursing homes and residential care homes. Some also provide other types of NHS-funded services that are not connected to social care, for example diagnostic services or independent acute hospital services. Section 81 of the 2012 Act requires all such providers to hold a licence, unless they are exempt.

7.20 Adopting a de minimis licensing exemption approach from April 2014 would risk pre-empting the implementation, subject to parliamentary approval of the Care Bill, of CQC's financial oversight regime for providers of adult social care. This could lead to duplication and unnecessary additional burdens being placed on providers of both healthcare and adult social care, without clear benefits and protections for people receiving nursing care. Regulation 6 therefore exempts providers to the extent that they provide NHS continuing healthcare (CHC) or NHS-funded nursing care (FNC) and provides that the exemption will expire on 1 April 2015. The Department will consider the future of the exemption in the context of the decision on adult social care market oversight and the exemption will be subject to a full review before it expires.

7.21 Regulation 8 also exempts from the calculation of a provider's NHS income, for the purposes of Regulation 6, any funding received in respect of the provision of CHC or FNC as an integral part of a social care package.

³ <http://www.england.nhs.uk/wp-content/uploads/2013/04/pri-med-care-ccg.pdf>

7.22 Providers of both NHS funded healthcare and adult social care will be licensed in respect of their NHS funded services (excluding CHC and FNC), but also eligible for the de minimis exemption in relation to turnover from those services. So, for example, a provider which has a total of £12 million NHS income per year, of which £2.5 million comes from CHC and FNC payments will be exempt from the requirement to hold a licence until at least April 2015, because disregarding the CHC and FNC payments will take the provider's NHS income from other sources below the £10 million de minimis threshold. If, however, only £1.5 million comes from CHC and FNC payments, and the remaining £10.5 million is from other NHS sources, the provider would require a licence from April 2014 (unless the other NHS services provided attract an exemption in their own right, eg primary medical services).

7.23 In the context of this role for CQC, the benefits of licensing such providers are currently unclear. Regulation 6 provides that the exemption for providers of CHC and FNC is time limited and will expire on 1 April 2015. The Department will consider the future of the exemption in the context of the decision on adult social care market oversight and the exemption will be subject to a full review before it expires.

Small providers

7.24 Regulation 8 exempts from the requirement to hold a licence providers whose turnover from supplying NHS services is less than £10 million in a relevant business year as defined in the regulations. This proposal reflects the Government's commitment to impose additional regulatory burdens on small and micro businesses only where necessary.

7.25 Regulation 8 also provides for income from exempt services under regulations 5 and 6 – primary medical and dental care, NHS continuing care and NHS funded nursing care – to be excluded from a provider's turnover for the purposes of the £10 million threshold.

8. Consultation Outcome

Protecting and promoting patients' interests – licensing providers of NHS services – Consultation on proposals

8.1 From 15 August to 22 October 2012, the Department of Health consulted on proposals for exemptions to the requirement to hold a licence. The Department received 70 responses from various organisations. The responses to the consultation and the Government's response can be found on the Department's website.⁴

8.2 On exemptions, respondents were broadly supportive of both the general principles and the specific proposals for exemptions of particular provider types. In particular, respondents welcomed an approach that minimised

⁴ <https://www.gov.uk/government/publications/new-licensing-regime-for-providers-of-nhs-services-response-to-consultation--2>

duplication and bureaucratic burdens. The Government's commitment to a full review during 2016/17 of how the exemptions regime is working in practice was also widely welcomed.

Small providers

8.3 The consultation acknowledged issues and potential difficulties around how any threshold to exclude small providers should be defined; and suggested alternatives. Respondents were in favour of a threshold based only on annual NHS turnover of £10 million or less. Evidence from engagement activities carried out during the consultation suggested that the option proposed in the consultation of using staff numbers over 50 for the threshold (either alone or with NHS turnover) would risk not exempting some small providers, because:

- staffing ratios are higher in healthcare than in most sectors, so there would be many cases where staffing numbers would exceed 50, but turnover be significantly below the £10 million threshold; and
- it would be extremely difficult to differentiate between staff delivering 'healthcare' or 'social care' in a normal working environment.

8.4 Regulation 8 therefore provides that providers whose applicable NHS turnover is less than £10 million are exempt from the requirement to hold a licence.

Adult social care providers

8.5 The consultation considered whether there should be an exemption for providers of adult social care who also provide NHS services. It noted that the Department expected that applying a threshold to exclude small providers from the requirement to hold a licence would exclude many adult social care providers who also provide NHS services and that the Department was shortly to consult separately on options for the changes to arrangements for oversight of the social care market. The consultation sought views on a number of options in relation to whether and if so, in what circumstances, adult social care providers should be excluded from the requirement to hold a Monitor licence.

8.6 A number of respondents to the consultation argued strongly that no decisions on licensing should be made before the outcome of the consultation on market oversight in social care was known. Some respondents also argued that all providers of adult social care should be licensed. Regulation 6(2) ensures the exemption is time limited to April 2015 in order to allow it to be reviewed in light of the decision on adult social care market oversight. The Department recently announced that CQC will take on this responsibility⁵ and we intend to review the exemption during 2014/15 in order to determine whether it should be retained, amended, or allowed to expire.

8.7 Responses to the consultation also highlighted that funding for the provision of nursing care in the context of adult social care is materially

⁵ <https://www.gov.uk/government/consultations/new-protection-if-care-providers-fail>

different from other NHS-funded services and it would be unfair to include funding from these sources in assessments of NHS income.

9. Guidance

9.1 The Department of Health intends to publish guidance on how licensing exemptions apply to providers of NHS services later this calendar year.

10. Impact

10.1 An impact assessment is attached to this memorandum and will be published alongside the Explanatory Memorandum on www.legislation.gov.uk.

11. Regulating small business

11.1 Exemptions to the requirement to hold a licence include an exemption for small providers. A small business exempt under the £10 million threshold set out in regulation 8 could be licensed if they provide a commissioner requested service. However it is unlikely a small business would provide a commissioner requested service.

12. Monitoring and review

12.1 The Department of Health will keep Monitor's performance as sector regulator under review through quarterly accountability meetings. These reviews will cover performance of its pricing, licensing and competition functions. In addition, during 2016/17, the Government intends to carry out a full review of how the licensing regime is operating.

13. Contact

13.1 Catherine Fiegehen at the Department of Health (Tel: 020 7210 5569 or email: catherine.fiegehen@dh.gsi.gov.uk) can answer any queries regarding the instrument.