Protecting and promoting patients’ interests

Licence exemptions: guidance for providers
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Licence exemptions: guidance for providers
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Executive summary

Under the Health and Social Care Act 2012, providers of health care services in England are required to hold a licence issued by Monitor, unless they are exempt\(^1\). From April 2014 new regulations\(^2\) come into force that set out the exemptions. It is the responsibility of providers to determine if an exemption applies to them. This guidance aims to help providers decide whether they need a licence or are exempt according to the new regulations.

If a provider does require a licence they should apply to Monitor, which providers will be able to do from January 2014.

This document fulfils the Secretary of State’s obligation to publish the exemptions to the requirement to hold a licence. It is intended to provide guidance for providers and is not an authoritative statement of the law.

The following diagram is to help work out if a provider needs a licence

A number of providers are automatically exempt from the requirement to hold a licence from Monitor. These providers are:

- NHS trusts
- Providers not required to register with the CQC
- Small and micro providers (those with less than £10m applicable NHS turnover)
- Providers of primary medical and dental services (eg GPs or dentists who do not provide any other NHS services)
- Providers of only NHS funded nursing care or continuing health care (eg care homes who provide no other NHS health care services).

\(^1\) Health and Social Care Act 2012, section 81-84

Protecting and promoting patients’ interests

The diagram below is to help providers work through the exemptions and consider whether they are exempt or will need to apply for a licence from Monitor. It should be read alongside the rest of this document.

Provider type

NHS foundation trusts

Providers of commissioner requested services

GP or dentist providing services other than primary medical or dental services (see section 5)

All providers of other NHS services (e.g., who provide services other than primary medical or dental, or NHS nursing care or continuing care)

Provider whose only NHS funded service is nursing care or continuing care (e.g., a care home)

GP or dentist providing only primary medical or dental services

Providers who are not required to register with CQC

NHS trusts

Status

Licence required

No – applicable turnover is £10m or more

Less than £10m applicable NHS turnover? (see section 7)

Yes – less than £10m applicable turnover

Exempt from the licence unless providing commissioner requested services (see section 8)

Exempt
1. Introduction

1.1. The Government wants NHS services to be more responsive to the needs of patients, carers and the wider public. A key way of achieving this is greater freedom for those who plan, commission and provide services. To ensure they use these freedoms in ways that safeguard the interests of patients and the wider public, the Government is strengthening the existing system for regulating NHS health care services. The Health and Social Care Act (the 2012 Act) established a comprehensive, proportionate and robust legal framework for sector regulation.

1.2. The framework built on Monitor’s previous role as the regulator of foundation trusts, and was designed to complement the roles of the Care Quality Commission (CQC), clinical commissioning groups (CCGs), and the NHS Commissioning Board (known and referred to in this document as NHS England). Each of the organisations have distinct responsibilities and will work in partnership together to make sure people get the best possible care and service from the NHS.

1.3. The CQC will continue to oversee and inspect the quality and safety of services. NHS England is responsible and accountable for the NHS commissioning system (including CCGs) to deliver high quality and value for money services. NHS England does this by allocating funds to, guiding and supporting CCGs, and holding them to account. It is also responsible for directly commissioning primary care (including GP services), specialised services (such as those for rare diseases), offender (prisoner) health care and some services for members of the armed forces.

1.4. Monitor is the sector regulator for health services in England and its main duty is to protect and promote the interests of patients by ensuring that the whole sector works for their benefit. Monitor’s powers include setting and enforcing a framework of rules for providers and commissioners, implemented in part through licensing NHS-funded providers.

1.5. Monitor’s key functions are to:
   - make sure foundation trusts are run well
   - set prices for NHS-funded services
   - tackle anti-competitive practices that are against the interests of patients
   - help commissioners ensure essential local services continue if providers get into serious difficulty, and
   - enable better integration of care so services are less fragmented and easier to access

1.6. Licensing providers of NHS services will be one of the main tools Monitor will use to do this. The licence will set out the conditions that licence holders will have to meet in order to provide NHS funded services. There will be standard conditions which will apply to all licence holders, or to particular types of licence holder, and special conditions that will apply to an individual provider.

1.7. Figure 1 sets out Monitor’s standard licence conditions. These are grouped into seven sections. Some sections apply to all licence holders and some sections only apply to
certain types of licence holder, for example, NHS foundation trusts. Further detail of the Monitor licence can be found on Monitor’s website³.

Figure 1

1.8. All providers of NHS services will require a licence from Monitor, unless they are exempt. We want 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. During the next Parliament, the Government intends to review how licensing is operating, including the exemptions. Section 11 of this guidance sets out more about how we will do this.

2. NHS health care services for the purpose of licensing

2.1. This section has been designed to add further clarity to the definition of a provider of health care services.

2.2. The Health and Social Care Act 2012 (the 2012 Act) stipulates that providers of health care services for the purposes of the NHS in England must hold a licence issued by Monitor, unless exempt under regulations. Health care services do not include services like catering and cleaning as these are not health care services.

2.3. By health care services, we do not mean services provided for the purposes of the public health service. Therefore, anyone receiving payment for providing NHS services must consider whether or not an exemption applies to them. It is the legal entity who provides the NHS services that must be licensed, not a location, and not necessarily the person involved in providing the services. This will normally be the entity which has registered with the Care Quality Commission.

Who needs a licence when there are two or more providers?

2.4. Regulation 2 of the National Health Service (Licence Exemptions, etc.) Regulations 2013 (the exemptions regulations) sets out how who is considered to be a provider where two or more persons are involved in providing an NHS health care service, and will therefore require a licence.

2.5. For example where an organisation A employs staff to provide an NHS health care service, that organisation will be considered to be the provider and will require a licence, rather than all staff involved in providing the service. Where staff employed through an agency are involved in providing the service, the requirement to hold a licence will not apply to the staff or to the agency, but to the organisation A.

2.6. If you are providing an NHS service you should then consider the exemptions set out in sections 4 to 8.

Types of providers of NHS services

2.7. There are many different types of legal entities that provide NHS services. The following are some examples.

Corporate groups

2.8. Where a provider is a subsidiary of a bigger company, it will need to be licensed in its own right if it is the legal entity responsible for the health care service, rather than the parent company. For example, if a number of provider companies all trade under the same brand, each company that provides NHS services must apply for a licence, unless exempt.

Subcontracted services

2.9. For the purposes of licensing, there is no distinction between a main contractor and a subcontractor in terms of who is considered to be a provider of NHS services. Subcontractors that provide NHS services will need a licence unless they are exempt.

2.10. However, there are examples of subcontracting arrangements where a provider of NHS services subcontracts services which are not NHS health care services. For example,
subcontractors providing catering and cleaning services will not need to be licensed as these are not health care services.

2.11. For the purposes of the exemption for small and micro providers described in section 7, services that a provider has subcontracted out to another provider must still be counted towards the prime contractor’s applicable turnover.

**Franchises**

2.12. Franchise holders are usually separate legal entities to the parent company and, as such, must consider if an exemption applies if they are providing NHS services.

**Partnerships**

2.13. Partnerships are separate legal entities and each partnership which provides NHS services must consider whether exemptions apply.

**Joint ventures**

2.14. Where an activity is provided as a joint venture between two providers, the venture will often be a corporate entity in its own right and therefore needs a licence, unless exempt. Where the joint nature of the venture is reflected in contracts or agreements rather than in organisational form, each party, depending on the individual case, may need to be licensed.

**Section 75 (National Health Service Act 2006) agreements**

2.15. Section 75 agreements enable NHS bodies and local authorities to establish joint funding, delegate functions, and integrate resources and management structures, such as integrated community mental health care. These do not usually constitute a new, separate legal partnership and each body that provides NHS services and does not qualify for an exemption must be licensed separately. However, only income from NHS health care services should be taken into account when considering the exemption for small and micro providers (see section 7).

**Hosting and renting arrangements**

2.16. Where a provider (A) is providing NHS services using another provider’s (B’s) facilities, A is still providing an NHS service and must consider whether or not an exemption applies. If B also provides NHS health care services, B will require a licence unless an exemption applies.
3. NHS trusts and NHS foundation trusts

NHS foundation trusts

3.1. All NHS foundation trusts (FTs) are required to hold a licence with Monitor. Exemptions do not apply to FTs. All FTs were automatically issued with a licence on 1 April 2013. Any NHS trust authorised to take up FT status after April 2013 will automatically be granted a licence.

NHS foundation trusts need a licence

NHS trusts

3.2. NHS trusts are exempt from the requirement to hold a licence.

3.3. All NHS trusts are moving towards becoming FTs, either through the normal authorisation process or via mergers with or acquisitions by existing FTs. Until NHS trusts become FTs, they are overseen and supported by the NHS Trust Development Authority (NHSTDA). The NHSTDA oversees all aspects of governance and performance in relation to NHS trusts. Directions from the Secretary of State require the NHSTDA to ensure that NHS trusts comply with equivalent conditions of the NHS provider licence as it deems appropriate, which includes giving directions to an NHS trust where necessary. The Directions also require the NHSTDA to seek and consider advice from Monitor about how to ensure compliance with such conditions. When new FTs are authorised, they will be granted a licence.

3.4. The exception for providers of commissioner requested services described in section 8, does not apply to NHS trusts.

NHS trusts do not need a licence
4. CQC registration

4.1. Any provider not required to register with the Care Quality Commission (CQC) is exempt from the requirement to hold a licence from Monitor. The only exception is if they provide a designated commissioner requested service (see section 8). The exemption for providers not required to register with CQC is set out in regulation 7 of the exemptions regulations.

4.2. 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 health care services as a whole. This is in line with other regulatory protection on individuals delivering health care services – i.e. professional regulation. If a provider provides any regulated activity, they must register with CQC. See the CQC website[^4] to view regulated activities and to find out if you require CQC registration.

4.3. Where a provider is not required to register with CQC for the provision of any NHS services, the provider is exempt from the requirement to hold a licence from Monitor.

4.4. If you are required to register with the Care Quality Commission, unless you qualify for another exemption you will need a licence.

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5. Primary medical care and primary dental care services

5.1. Providers of only primary medical and primary dental services are exempt from the requirement to hold a licence. Regulation 5 of the exemptions regulations defines primary medical and dental services as those provided under Part 4 and Part 5 of the National Health Service Act 2006\(^5\).

5.2. All providers of NHS-funded primary medical and dental services commissioned by NHS England, or commissioned under delegated authority from NHS England, in accordance with Parts 4 and 5 of the National Health Service Act 2006, will be exempt from holding a licence in respect of those services.

5.3. This includes enhanced services that are commissioned by NHS England or that NHS England has directed clinical commissioning groups (CCGs) to commission on its behalf.

5.4. Where providers of primary medical or dental services also provide other NHS funded services, they will be in scope of the licensing regime in respect of those other services. However, they will not need a licence if they qualify for another exemption. For example they may be eligible for the exemption for small and micro providers set out in section 7 where their applicable turnover (which excludes turnover from primary medical and dental services) is less than £10m per year.

5.5. Where CCGs, under their own commissioning powers, commission services from GP practices these services would not fall within the exemption in regulation 5. These services may be analogous to local enhanced services previously commissioned by primary care trusts and those NHS England delegated to CCGs to manage in 2013/14 under transitional arrangements.

5.6. If you solely provide primary medical or dental services under parts 4 or 5 of the National Health Service Act 2006, you will be exempt from the requirement to hold a licence. However, if you provide other NHS services, you will need a licence unless you qualify for another exemption.

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\(^5\) These are often referred to as General Medical Services (GMS), Personal Medical Services (PMS), Alternative Provider Medical Services (APMS), and General Dental Services (GDS) or Personal Dental Services (PDS)
Example

The local CCG has commissioned an ultrasound service under its own commissioning powers. The service includes GP practice providers but does not fall under the primary medical services exemption, and turnover from that service would count towards the provider’s applicable turnover. However, the turnover from that service is significantly less than £10m and qualifies for the exemption described in section 7 of this guidance. Therefore this provider does not need a licence.

Do you provide only primary medical and primary dental services?

Providers whose only NHS health care services are provided under Part 4 or 5 of the National Health Service Act 2006 do not need a licence, unless they provide commissioner requested services (see section 8).

- If you provide services other than under Part 4 or 5 of the National Health Service Act 2006, you should consider the rest of the exemptions set out in this document.
- You should also consider whether you provide commissioner requested services.
6. NHS continuing health care and NHS-funded nursing care

6.1. Providers of adult social care services (e.g., care homes) are not regulated by Monitor and do not require a licence to provide social care services. Providers of NHS continuing health care and NHS-funded nursing care services are exempt from the requirement to hold a licence, until at least 1 April 2015. This is set out in regulation 6 of the exemptions regulations. However, if you provide other NHS services, you will need a licence unless you qualify for another exemption.

6.2. The definitions of NHS continuing health care and NHS-funded nursing care are set out in regulation 1 of the exemptions regulations.

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<tr>
<th>Definition of NHS continuing health care (CHC)</th>
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<tr>
<td>A package of care arranged and funded solely through the NHS for an individual aged 18 or over who has been assessed as having a primary health need, where such care is provided to meet physical or mental health needs which have arisen as a result of disability, accident or illness.</td>
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<th>Definition of NHS funded nursing care (FNC)</th>
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<tr>
<td>Nursing care provided by a registered nurse which is funded by the NHS to support the provision in a home providing such care.</td>
</tr>
<tr>
<td>Nursing care provided by a registered nurse is defined as any services provided by a registered nurse where such services involve—</td>
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<tr>
<td>(a) the provision of care, or</td>
</tr>
<tr>
<td>(b) the planning, supervision or delegation of the provision of care,</td>
</tr>
<tr>
<td>other than any services which, having regard to their nature and the circumstances in which they are provided, do not need to be provided by a registered nurse.</td>
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6.3. Funding provided for NHS continuing health care (CHC) and NHS funded nursing care (FNC) should not be taken into account when calculating a provider’s applicable turnover (see section 7).

6.4. A significant and increasing number of adult social care providers 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.

6.5. This exemption expires on 1 April 2015 and will be subject to a full review by the Department in advance of this date, taking into account the proposals set out in the Care Bill for adult social care oversight arrangements. Section 11 sets out more information about how we will review exemptions.
Example

A provider who 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 threshold described in this guidance. If, however, only £1.5 million comes from CHC and FNC payments, and the remaining £10.5 million is from other 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).

**Do you provide only NHS funded nursing care or continuing health care, and no other NHS services?**

Providers whose only NHS services are nursing care or continuing health care do not need a licence, unless they provide commissioner requested services (see section 8).

- If you provide NHS health care services other than NHS funded nursing care or continuing health care, you should consider the rest of the exemptions set out in this document.
- You should also consider whether you provide commissioner requested services.
7. Small and micro providers

7.1. The Government is committed not to impose unnecessary regulatory burdens on small and micro businesses. Therefore, 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 (see section 8). The details of this exemption are set out in regulation 8 of the exemptions regulations.

Applicable turnover

7.2. A provider’s applicable turnover is defined in regulation 1 of the exemptions regulations as turnover from the provision of NHS services, excluding turnover from the provision of primary medical or dental services (services provided under Part 4 or Part 5 of the 2006 Act), and, until 31 March 2015, excluding turnover from the provision of NHS continuing health care or NHS funded nursing care.

Applicable turnover includes:
- Turnover from the provision of activities which do not require CQC registration
- Turnover from services which the provider has subcontracted to another provider

Applicable turnover does not include turnover from:
- primary medical services,
- primary dental services (see section 5),
- NHS continuing health care,
- NHS funded nursing care (see section 6)

7.3. Applicable turnover is to be calculated using generally accepted accounting practice and is turnover from the provision of health care services for the purposes of the NHS.

Relevant business year

7.4. A relevant business year as defined in the regulations is the last business year for which a provider’s signed accounts are available. If figures from the preceding business year are not available, turnover is to be calculated from the previous business year’s accounts.

For example, in 2014/15 a provider’s relevant business year will be:

<table>
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<tr>
<th>The preceding business year if signed accounts are available (ie 2013/14)</th>
<th>If not, it is the last business year for which signed accounts are available (ie 2012/13)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The preceding business year if signed accounts are available (ie 2013/14)</td>
<td>If not, it is the last business year for which signed accounts are available (ie 2012/13)</td>
</tr>
</tbody>
</table>

7.5. Where the provider’s relevant business year is less than 12 months (for example where a new business has just been set up), turnover is to be calculated by taking the applicable turnover from that year, divided by the number of months that have passed that year and multiplied by 12.
Examples

A provider’s most recent signed accounts are for 2012/13, when it received £2m from local commissioners for provision of a service and £9m in charitable donations. It does not provide commissioner requested services (see section 8). At 1 April 2014, the provider will be exempt from the requirement to hold a licence. The provider will then need to consider what impact its accounts for 2013/14 will have on its exempt status.

A provider’s NHS turnover is £15m for its relevant business year. If £3m of this was from the provision of primary medical care, the provider would require a licence. However if £7m of this was from primary medical care, the provider would be exempt.

Is your applicable turnover less than £10million?
Providers whose applicable NHS turnover is less than £10million do not need a licence, unless they provide commissioner requested services (see section 8).

- If your applicable NHS turnover is £10million or more, you should consider the rest of the exemptions set out in this document.
- You should also consider whether you provide commissioner requested services.
8. Commissioner requested services

8.1. With the exception of NHS trusts, all providers of Commissioner Requested Services must be licensed, even if the provider qualifies for other exemptions. CRS are services which NHS England or CCGs may determine as requiring additional regulatory protection, in order to protect the interests of patients who use those services should the provider get into financial difficulty.

Meaning of commissioner requested services

Commissioner requested services 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 will be subject to continuity of services licence conditions.

8.2. If NHS England or a CCG determines that you provide a CRS, you no longer qualify for any exemptions and you must make an application to Monitor for a licence. Eligibility for any exemption will be withdrawn within 60 days of being notified by commissioners of a CRS designation, so providers will need to ensure they apply for and receive a licence within that period.

8.3. NHS England and CCGs will have regard to guidance\(^6\) published by Monitor to determine whether local services should be CRS.

Do you provide commissioner requested services?

With the exception of NHS trusts, providers of commissioner requested services always need a licence.

- If you do not provide commissioner requested services, you should consider whether the other exemptions explained in this document may apply.
- If you have not been notified that you are providing a commissioner requested service, you should consider the exemptions explained in this document and apply for a licence if you do not qualify for an exemption. If you are notified after submitting your application or after receiving your licence, you will need to notify Monitor that you now provide commissioner requested services.

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\(^6\) Guidance for commissioners on ensuring the continuity of health care services
9. Removal of exemptions

Non-compliance with conditions of exemption

9.1. The 2012 Act\(^7\) enables the Secretary of State to place conditions on exemptions.

9.2. The National Health Service (Licence Exemptions, etc.) Regulations 2013 enable the Secretary of State to withdraw exemptions from providers who benefit from an exemption under regulations 5 to 8 of those Regulations if they fail to provide necessary documents and information to Monitor. Those exemptions are described in sections 5 to 8 of this document.

9.3. Those exemptions are conditional on the exempt providers complying with requests from Monitor under section 104 of the 2012 Act for any information which Monitor considers necessary or expedient to have in order to perform its regulatory functions. For example, in order to inform its work on the national tariff, Monitor may need to request costing information from providers. Monitor must ensure its requests for information are necessary and proportionate – in line with obligations under the 2012 Act.

9.4. Monitor may use its enforcement powers if providers do not comply with reasonable requests for information. If exempt providers consistently fail to comply with the requests, Monitor will be able to advise the Secretary of State and recommend the withdrawal of the provider’s exemption.

\(^7\) Section 83(3)
10. Applying for a licence

Before April 2014

10.1. If a provider is already registered with the Care Quality Commission, and does not qualify for an exemption under the regulations, it will need to apply to Monitor for a licence. Monitor has published guidance to the application process, available on its website.

10.2. A provider which requires both registration and a licence will need to apply to CQC and Monitor separately.

After 1 April 2014

10.3. A provider requiring both registration and a licence will be able to apply through a joint licensing and registration process operated by Monitor and CQC. For example, where a new entrant to the market needs to apply for both registration and a licence, it will be able to submit one set of information and, if successful, receive one document confirming both their registration and licence.

10.4. Providers will be able to find more information about applying for a licence on Monitor’s website.
11. Future of exemptions

Review

11.1. The exemption under regulation 6 in respect of NHS continuing health care and NHS funded nursing care (described in section 6) expires on 31 March 2015. The Department will review the exemption in 2014. This review will look at whether it is appropriate for the exemption to continue. As part of the review, the Department will also publish revised guidance.

Longer term

11.2. 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 the intended objectives in the light of practical and operational experience. The review will include the exemptions regime. In particular, when looking at exemptions we will take into account whether there have been any changes to the scope of CQC registration, or to the nature of the provision of NHS services. We will also consider existing sources of evidence such as complaints and whether and how information should be collected to inform any decision about exemptions.

11.3. We plan to conduct this longer review during 2016/17, when the licensing regime and the exemptions will have been fully in place for two years.

11.4. While the Department is not able to provide legal advice on whether a provider is exempt, we would welcome views on the impact of these exemptions to inform our work on licensing going forward. Comments can be sent to licence.exemptions@dh.gsi.gov.uk