



Department
of Health

Protecting and promoting patients' interests

Licence exemptions: guidance for providers

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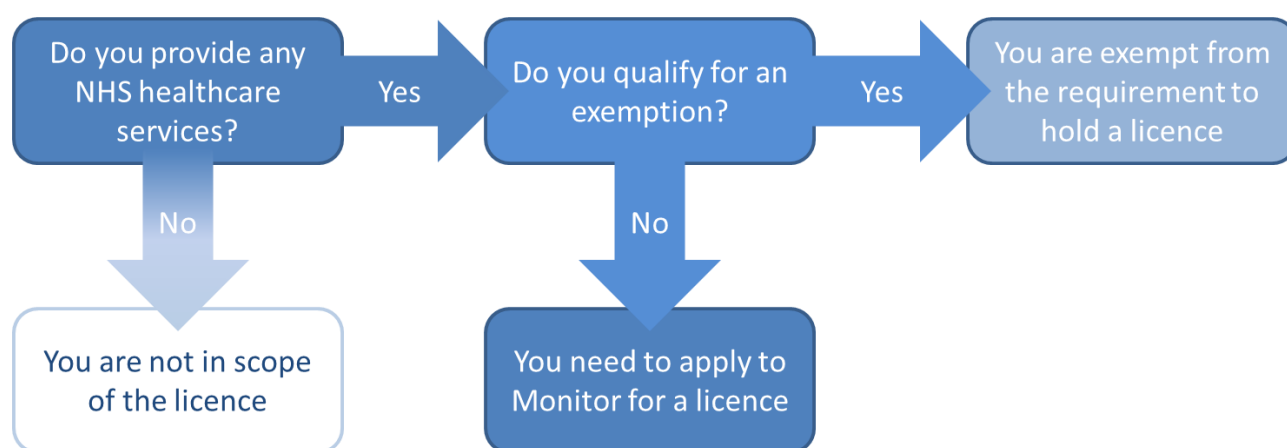
Executive summary

Under the Health and Social Care Act 2012, providers of NHS health care services in England are required to hold a licence issued by Monitor, unless they are exempt¹. On 1 April 2014, amendments to the regulations² which specify the licence exemptions came into force. It is the responsibility of providers to determine if they need to hold a licence. This guidance aims to help providers decide whether they are exempt or require a licence.

If a provider does require a licence they should apply to Monitor.

This document updates guidance published in December 2013 and 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. Providers should consider seeking independent legal advice if questions remain over the need for a licence.

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



A number of types of provider are exempt from the requirement to hold a licence from Monitor (subject to any overriding licence requirements, such as commissioner requested services). These providers are:

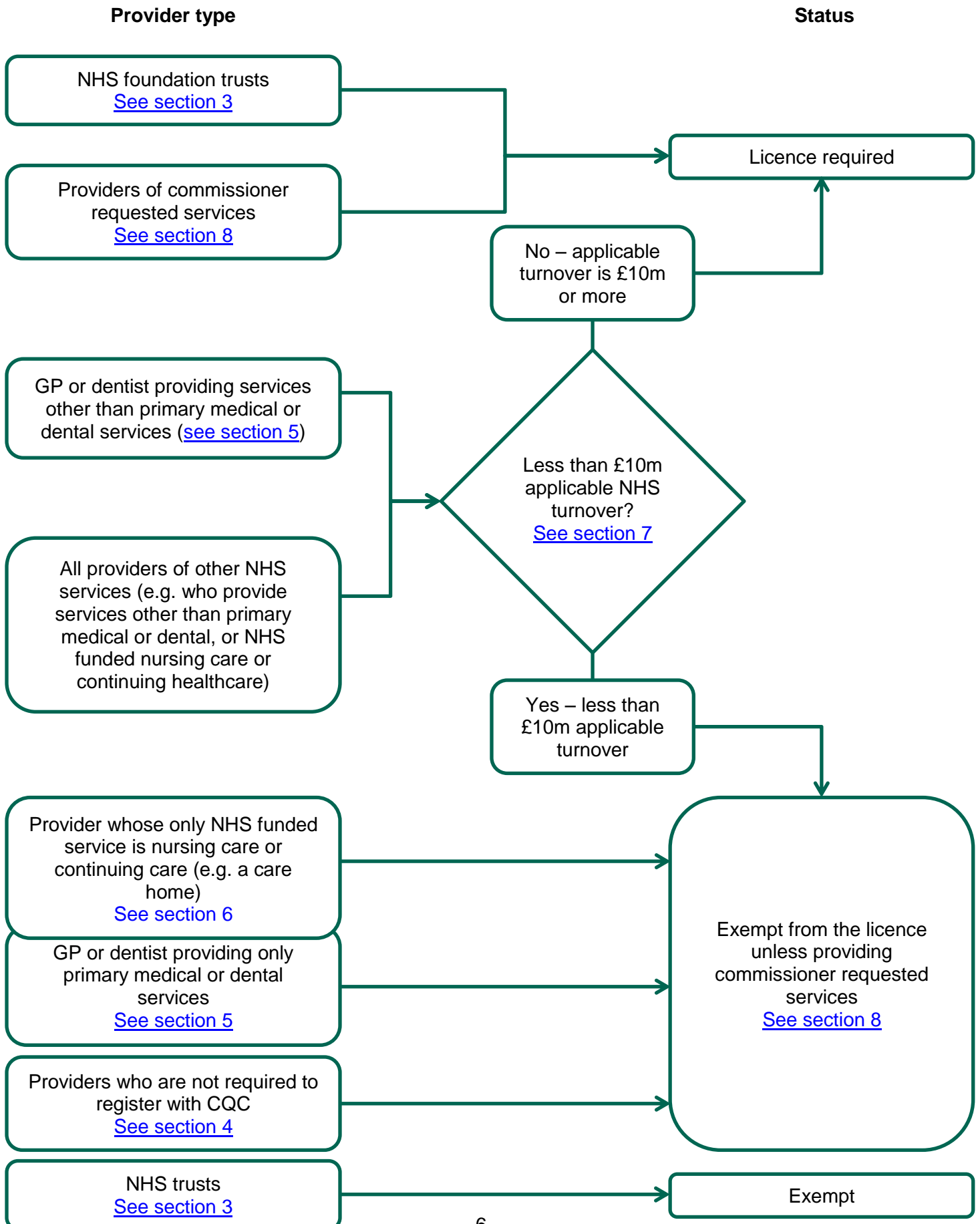
- NHS trusts
- Providers not required to register with the CQC
- Small and micro providers (those with less than £10m applicable NHS turnover)
- Providers of only primary medical and dental services commissioned by NHS England or under delegated authority from NHS England (e.g. GPs or dentists who do not provide any other NHS services)
- Providers of only NHS funded nursing care or continuing health care (e.g. care homes that provide no other NHS health care services). The diagram below is to

¹ Health and Social Care Act 2012, section 81-84

² *The National Health Service (Licence Exemptions, etc.) Regulations 2013*

<http://www.legislation.gov.uk/ukxi/2013/2677/contents/made>

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.

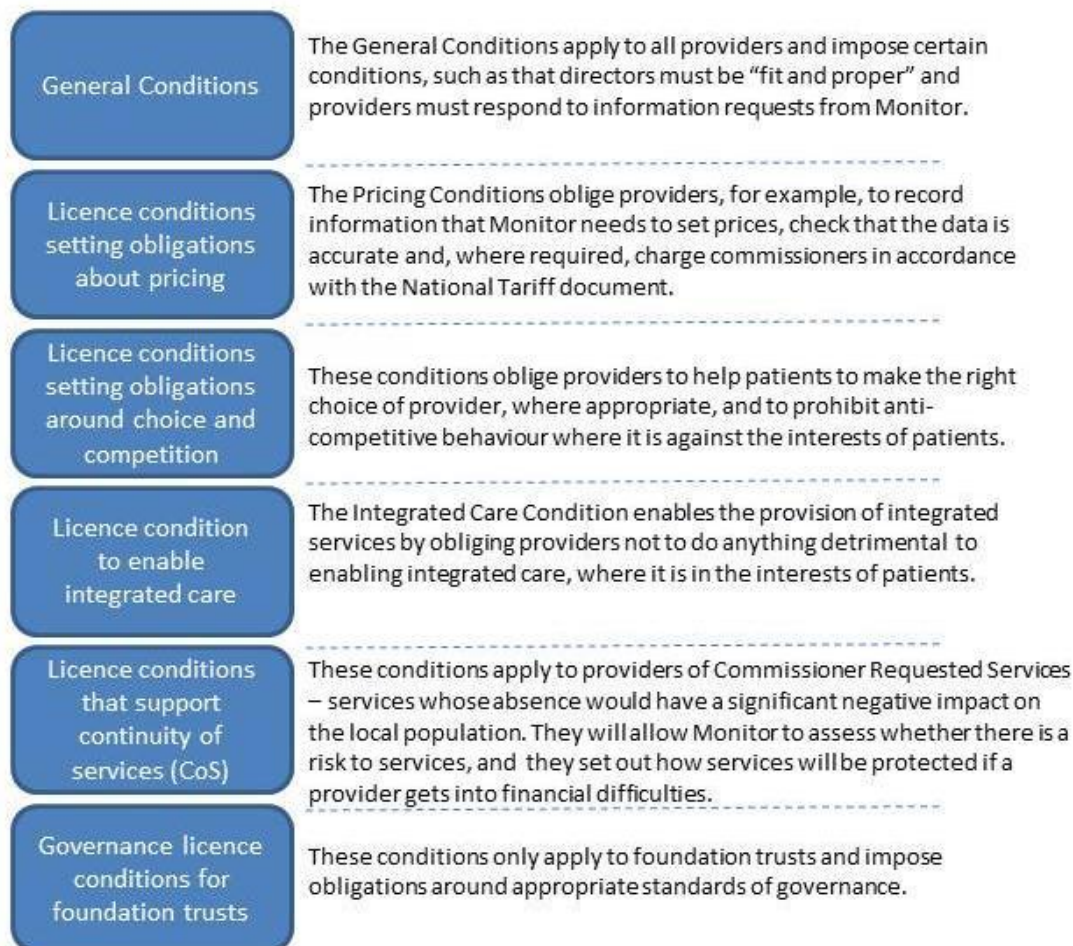


1. Introduction

- 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 has strengthened 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 NHS England. Each of the organisations have distinct responsibilities and will work in partnership to make sure people get the best possible care and service from the NHS.
- 1.3. The CQC continues to oversee and inspect the quality and safety of services. NHS England is responsible and accountable for the NHS commissioning system (including CCGs) delivering high quality and value for money services. NHS England does this by allocating funds to, guiding and supporting CCGs, 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 (prison) healthcare and some services for members of the armed forces.
- 1.4. NHS England is delegating some primary medical care functions to some 64 CCGs and will be exercising functions jointly with around 90 other CCGs from 1 April. The overarching principle is that NHS England remains liable for the commissioning of the services even when delegated. Other primary care services e.g. dentistry, community pharmacy aren't affected.
- 1.5. 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.
- 1.6. 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
- 1.7. Licensing providers of NHS health care services is one of the main tools Monitor uses to do this. The licence sets out the conditions that licence holders have to meet in order to provide NHS funded services. There are conditions which apply to all licence holders, or to particular types of licence holder. Monitor may also apply special conditions to an individual provider.

1.8. 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 website](#)³.

Figure 1



Why exemptions? Who needs a licence?

1.9. All providers of NHS health care services will require a licence from Monitor, unless they are exempt. In 2013, it was the intention of the Government that this licence exemption for providers of NHS Continuing Healthcare and NHS funded nursing care would be subject to a full review by the Department in 2016/17. [Section 11](#) of this guidance for further information.

1.10. Section 81 of 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 they are exempt by regulations made under section 83.

³ <https://www.gov.uk/independent-providers-of-nhs-funded-services-apply-for-an-nhs-provider-licence>

2. NHS health care services for the purpose of licensing

2.1. This section of the guidance has been designed to explain the definition of a provider of health care services.

2.2. The Health and Social Care Act 2012, Section 64 states that:

(3)“Health care” means all forms of health care provided for individuals, whether relating to physical or mental health, with a reference in this Part to health care services being read accordingly; and for the purposes of this Part it does not matter if a health care service is also an adult social care service.

(4)“The NHS” means the comprehensive health service continued under section 1(1) of the National Health Service Act 2006, except the part of it that is provided in pursuance of the public health functions (within the meaning of that Act) of the Secretary of State or local authorities.

2.3. The exemptions are contained in the National Health Service (Licence Exemptions, etc.) Regulations 2013⁴ (the Exemption Regulations). Health care services do not include services like catering and cleaning.

2.4. By health care services, we do not mean public health services. Therefore, anyone receiving payment for providing NHS health care services, whether directly or under a sub-contract, must consider whether they need to hold a licence, or whether 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 individual person directly involved in providing the health care 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?

2.5. Regulation 2 of the Exemption Regulations sets out 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.

2.6. For example, where 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 organisation A.

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

Types of providers of NHS health care services

2.8. There are many different types of legal entities that provide NHS services. The following are some examples. Importantly, where there is any doubt providers should obtain independent legal advice to ascertain whether or not they require a licence.

⁴ S.I. 2013/2677

Corporate groups

2.9. 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 health care services must apply for a licence, unless exempt.

Subcontracted services

2.10. 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 health care services. Subcontractors that provide NHS health care services will need a licence unless they are exempt.

2.11. However, there are examples of subcontracting arrangements where a provider of NHS health care 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.

2.12. 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

2.13. Franchise holders are usually separate legal entities to the parent company and must individually, consider if an exemption applies if they are providing NHS health care services.

Partnerships

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

Joint ventures

2.15. 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 would therefore require 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

2.16. 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 health care 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

2.17. Where a provider (A) is providing NHS health care services using another provider's (B) 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. Those NHS trusts authorised to take up FT status since April 2013 has automatically been granted a licence.

NHS foundation trusts need a licence

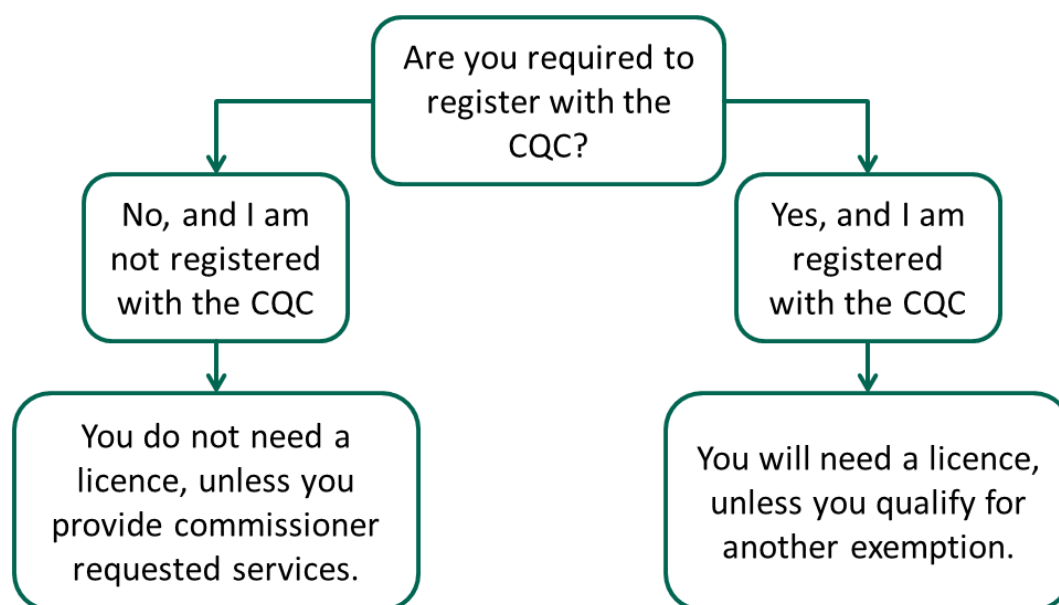
NHS trusts

- 3.2. Under regulation 4 of the Exemption Regulations, NHS trusts' are exempt from the requirement to hold a licence, including in relation to commissioner requested services described in [section 8](#).
- 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.

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](#)). In this scenario, before being able to obtain a licence, the provider would have to register with the CQC. The provider would then be subject to the conditions of the licence and the CQC regulatory regime. This would not apply to NHS Trusts as they are not subject to the CRS provisions. See Section 10 of this guidance for further information on the joint licensing and registration process.
- 4.2. The exemption for providers not required to register with CQC is set out in regulation 7 of the exemptions regulations, such as NHS Trusts.
- 4.3. 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](#)⁵ to view regulated activities and to find out if you require CQC registration.
- 4.4. If you are required to register with the Care Quality Commission, unless you qualify for another exemption you will need a licence.



⁵ <http://www.cqc.org.uk/organisations-we-regulate/registering-first-time/regulated-activities>

Are you required to register with the Care Quality Commission?

Providers which are not required to register with the Care Quality Commission do not need a licence, unless they provide commissioner requested services ([see section 8](#)).

- If you are required to register with the Care Quality Commission, you should consider the rest of the exemptions described in this document.
- You should also consider whether you provide commissioner requested services.

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 2006⁶.
- 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. Examples of services that might be commissioned by CCGs from GPs – outside of the GP contract – are minor injuries service and a phlebotomy service.
- 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 under another exemption.

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.

⁶ 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)

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 Healthcare and NHS-funded nursing care

- 6.1. The licence exemption in regulation 6 of the Exemption Regulations for providers solely of NHS Continuing Healthcare and NHS funded nursing care was due to expire on 1 April 2015. Following consultation in 2014 on whether or not to retain this exemption, it was agreed that the current licence exemption for NHS Continuing Healthcare and NHS funded nursing care would not expire⁷.
- 6.2. The National Health Service (Licence Exemptions, etc) Amendment Regulations 2015⁸ come into force on 1 April 2015, and amend the Exemption Regulations by removing the exemption expiry dates, so that providers of NHS Continuing Healthcare and/or NHS funded nursing care continue to remain exempt, unless designated as CRS. These regulations also provide for the continued exclusion of these services from calculation of annual turnover.
- 6.3. 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. If you provide other NHS services, you will need a licence unless you qualify for another exemption.
- 6.4. The terms NHS Continuing Healthcare and NHS-funded nursing care are defined in regulation 1 of the Exemption Regulations.

Definition of NHS Continuing Healthcare (CHC)

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.

Definition of NHS funded nursing care (FNC)

Nursing care provided by a registered nurse which is funded by the NHS to support the provision in a home providing such care.

Nursing care provided by a registered nurse is defined as any services provided by a registered nurse where such services involve—

(a) the provision of care, or

(b) the planning, supervision or delegation of the provision of care,

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.

⁷ <https://www.gov.uk/government/consultations/nursing-care-licence-exemption>

⁸ S.I. 2015/190.

- 6.5. Funding provided for NHS Continuing Healthcare (CHC) and NHS funded nursing care (FNC) should not be taken into account when calculating a provider's applicable turnover ([see section 7](#)).
- 6.6. In 2013, it was the intention of the Government that this licence exemption for providers of NHS Continuing Healthcare and NHS funded nursing care would be subject to a full review by the Department in 2016/17. See [Section 11](#) for further information.

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, 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 providing other NHS healthcare services, the provider would require a licence (unless they had income disregarded for the purposes of licensing, such as primary medical or dental 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 have been formally designated by your commissioner(s) to provide CRS. See Section 8 of this guidance for further detail on CRS.

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 CRS ([see section 8](#)). The details of this exemption are set out in regulation 8 of the exemption regulations.

Applicable turnover

7.2. A provider's **applicable turnover** is defined in regulation 1 of the Exemption Regulations as amounts from the provision of NHS healthcare services, minus any of the following - trade discounts, VAT and other taxes, amounts from the provision of primary medical services, dental services (services provided under Part 4 or Part 5 of the 2006 Act), NHS Continuing Healthcare and NHS funded nursing care.

Applicable turnover includes:

- Turnover from the provision of NHS healthcare services which do not require CQC registration.
- Turnover from NHS healthcare services which the provider has subcontracted to another provider.

Applicable turnover does not include turnover from:

- primary medical services (see section 5),
- primary dental services ([see section 5](#)),
- NHS Continuing Healthcare (see section 6),
- 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 regulation 1 of the Exemption Regulations as a period of more than 6 months in respect of which a provider prepares, or is required to prepare, accounts. In general this equates to 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:

The preceding business year **if signed accounts are available** (ie 2013/14)

If not, it is the last business year for which signed accounts are available (ie 2012/13)

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 2014/15, when it received £2m from local commissioners for provision of an NHS service and £9m in charitable donations. It does not provide CRS ([see section 8](#)). The provider will be exempt from the requirement to hold a licence. The provider will then need to consider what impact its accounts for 2015/16 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 CRS ([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 CRS.

8. Commissioner Requested Services (CRS)

8.1. With the exception of NHS Trusts, all providers of CRS 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 CRS

CRS 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 CRS will be subject to continuity of services licence conditions.

8.2. If NHS England or a CCG determines that you provide 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 that Monitor considers the CRS conditions of the licence should be applied. 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](#)⁹ published by Monitor to assist commissioners in determining whether local services should be CRS and the process to follow in making a designation.

Do you provide CRS?

- Providers of CRS always need a licence.
- If you do not provide CRS, you should consider whether the other exemptions explained in this document may apply.

⁹ *Guidance for commissioners on ensuring the continuity of health care services*
<https://www.gov.uk/nhs-commissioners-designate-commissioner-requested-services>

9. Removal of exemptions

Non-compliance with conditions of exemption

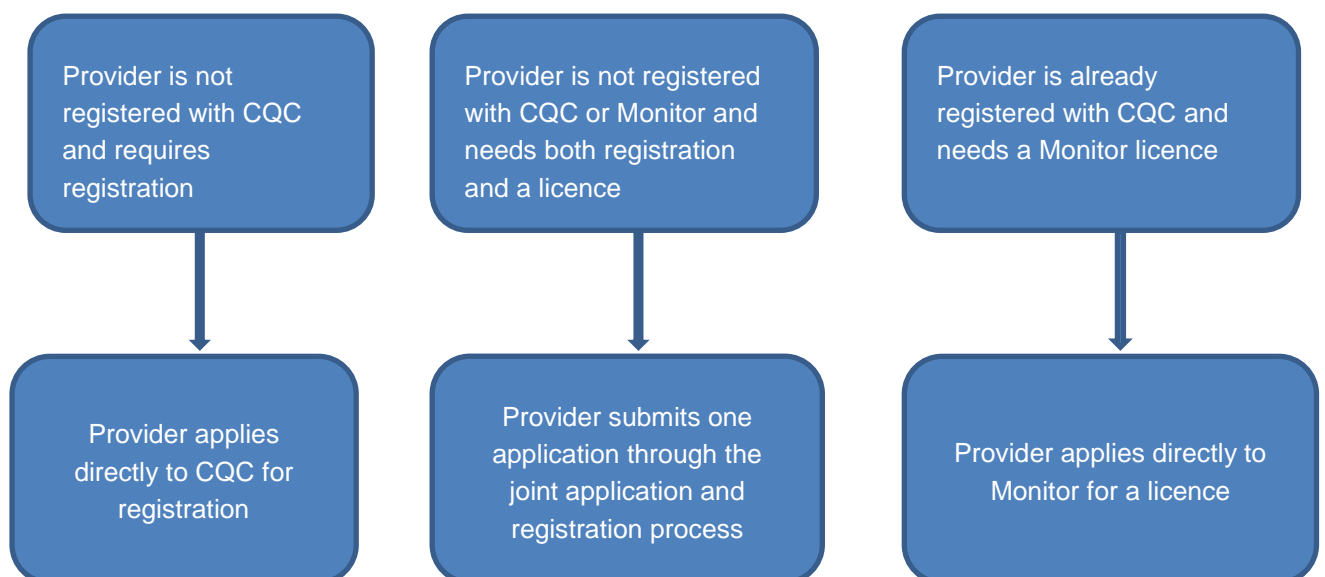
- 9.1. The 2012 Act¹⁰ enables the Secretary of State to place conditions on exemptions.
- 9.2. Regulation 9 of the [Exemption Regulations](#) enable the Secretary of State to withdraw exemptions from providers who benefit from an exemption under regulations 5 to 8 of those Regulations if they consistently 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.

¹⁰ Section 83(3)

10. Applying for a licence

10.1 If a provider is already registered with the Care Quality Commission and does not qualify for an exemption under the Exemption Regulations, it will need to apply for a Monitor licence. Monitor has published guidance to the application process, available on its website¹¹.

10.2 Providers that require both CQC registration and a Monitor licence are 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. The CQC guidance on the joint licensing and registration process is available here: <http://www.cqc.org.uk/service-providers/registering-first-time/how-apply/step-step-guide-applying-new-provider/joint-licen>



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https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/304838/Licensing_Application_Guidance_Updated_Final.pdf

11. Future of exemptions

- 11.1. In 2013, the Government intended for the Department to carry out a full review of licensing in 2016/17, when the exemptions will have been fully in place for two years. The objective of such a review would be to establish whether the licensing regime is achieving the intended objectives in the light of practical and operational experience. The review would include the exemptions regime. In particular, when looking at exemptions we would 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 would also consider existing sources of evidence such as complaints and whether and how information might be collected to inform any decision about exemptions.
- 11.2. 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