Classification: Official



Licensing application guidance

For NHS-controlled providers

December 2020

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1. Introduction

- 1.1. In this document, references to NHS Improvement are references to Monitor.
- 1.2. The NHS provider licence is NHS Improvement's main tool for regulating providers of NHS services. The licence sets out conditions that healthcare providers must meet to ensure that the sector works for the benefit of patients.
- 1.3. This guidance is for NHS-controlled providers. It explains:
 - how to work out whether you need to apply for a licence
 - the criteria that must be met for a licence to be granted
 - how to apply for a licence and how long it generally takes us to review your application
 - what happens after you submit your licence application
 - how we review your application
 - the process for making representations and appeals in the event of an unsuccessful licence application.
- 1.4. For information on NHS-controlled providers, see Guidance on our oversight of NHS-controlled providers and the full NHS-controlled providers licence conditions.

Who should apply for an NHS provider licence?

1.5. All providers of NHS healthcare services must hold a licence unless they are exempt. The Department of Health and Social Care (DHSC) has published guidance on what it means to be a provider of NHS healthcare services and the licence exemptions (the exemptions guidance).

When is an NHS provider licence not required?

- 1.6. Providers of NHS healthcare services are exempt from the licensing requirement if they are:
 - NHS trusts
 - providers who are not required to register with the Care Quality Commission (CQC)
 - providers of primary medical or primary dental services only
 - small providers of NHS healthcare services with annual applicable turnover from the provision of NHS services of less than £10 million
 - providers of NHS continuing healthcare or NHS-funded nursing care only.
- 1.7. These exemptions do not apply if the provider's services have been designated by a commissioner as commissioner requested services (CRS). CRS providers need to apply for and obtain an NHS provider licence even if they would otherwise have been exempt. This paragraph does not apply to NHS trusts, as NHS trusts cannot be CRS designated.
- 1.8. If you are currently exempt from the requirement to hold an NHS provider licence and your services are not CRS designated, you do not need to apply for a licence. However, if your circumstances change, you must apply for a licence as soon as you become aware that you are no longer exempt from licensing (see paragraph 2.48).
- 1.9. You should seek independent legal advice if you are in any doubt as to whether your organisation is required to hold an NHS provider licence. You are advised to refer to the detailed explanation of the exemptions provided from paragraph 2.32 of this document as well as the exemptions guidance.
- 1.10 If you have any queries about this document, please contact NHS Improvement's licensing team at: NHSI.Licensing@nhs.net.

What criteria must be met for a licence to be granted?

- 1.11. To be granted a licence, two licence criteria must be met:
 - criterion 1: the provider must be registered with CQC, the independent regulator of health and adult social care in England
 - criterion 2: relates to the 'fitness' of the provider. This is a test applied to the persons involved in overseeing your organisation (see paragraphs 2.66 to 2.71).
- 1.12. The main rules giving NHS Improvement the powers to design and operate the licensing regime are set out in the Health and Social Care Act 2012 (the 2012 Act). DHSC has issued regulations regarding the licensing regime made under the 2012 Act, namely the National Health Service (Licence Exemptions, etc) Regulations 2013, the National Health Service (Approval of Licensing Criteria) Order 2013 and the National Health Service (Licence Exemptions, etc) Amendment Regulations 2015. Links to these and other relevant documents, including those describing the legal basis of our licensing regime, are given in Section 6 of this guidance.

How can you apply for a licence?

1.13. You should complete the application form. There is no fee for applying for or obtaining a licence.

What is the licence application process?

Single licence application process

1.14. Providers that become required to hold an NHS provider licence and are already registered with CQC should apply to us for a licence through the application process detailed in Figure 1 below. Independent providers should apply for a provider licence online. NHS-controlled providers should complete the application form.

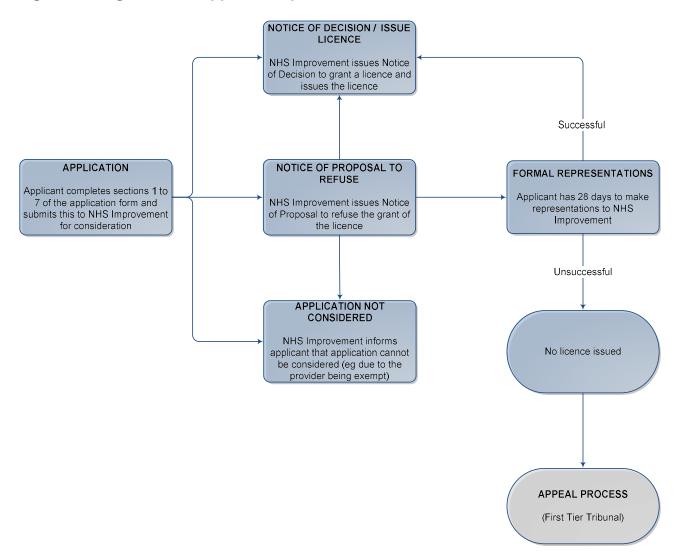


Figure 1: Single licence application process

How long does it take us to process your application?

1.15. We aim to process your application and issue you with a formal decision within 20 working days of receiving a complete application. Applications that raise queries or concerns may take longer.

What information is needed to complete the application?

- 1.16. During the application process you will be asked for:
 - information about the applicant: name, registered address, contact details, company/charity registration number and legal status.

- your CQC provider ID number
- key contact correspondence details
- the completed appendix to your application if we ask you to provide one with your application. You are likely to be asked to do so if you provide services that have been designated as CRS (see paragraph 2.53 for more details)
- details of your financial year end for the last business year
- information regarding any services you provide that have been designated as CRS
- details of your directors and governors or those with similar or equivalent functions and their dates of birth
- details of your ultimate controller, if any
- details of CQC conditions and enforcement actions
- details of any past applications you have made to NHS Improvement for a licence.
- 1.17. The sections of the application form are summarised in Figure 2 below.
- 1.18. NHS-controlled providers should complete all sections of the application form before submitting it to: NHSI.Licensing@nhs.net.

Who should complete the licence application?

- 1.19. Where the provider is an organisation rather than an individual, you will be asked to designate a key contact who is responsible for making the application. The application is completed and submitted by the provider's key contact. The key contact must have the authority to complete the application on the provider's behalf and act as our main contact during the application process.
- 1.20. We may contact the key contact if we have questions about your application or need additional information to support your application. Once licensed, providers can designate a new key contact or change contact details.

Figure 2: Summary of sections of the application form

Section 1: Licence Questions relating to the identity of the applicant and the key applicant details contact completing the application form. Section 2: Provision of • Questions to establish whether the applicant provides healthcare healthcare service(s) for services for the NHS and whether this is under a direct contract or the purpose of the NHS through an arrangement with other providers. Section 3: Licence • Questions to understand whether the applicant is exempt from the exemptions requirement to hold a licence. Section 4: Licensing grant Questions to determine whether the applicant meets the licensing criteria. Section 5: Care Quality • Questions to understand whether the applicant has any conditions Commission registration on its CQC registration. conditions Questions to gather additional information required for NHS Section 6: Additional Improvement's functions, including information required to start information request licensee monitoring in the event that the provider is licensed. Section 7: Licence • General declaration to be signed by a person authorised to submit application declaration this application on behalf of the applicant.

Who should be contacted for more information?

- 1.21. For any general or administrative enquiries regarding the licence application process or for technical queries on the completion of the form, please contact NHS Improvement's licensing team at: NHSI.Licensing@nhs.net.
- 1.22. Please note that it is your responsibility to ensure your compliance with all applicable legal requirements, taking independent professional advice if needed.

2. Application questions

Section 1: Licence applicant details

- 2.1. In this section of the application form you should confirm that you have read and understood the guidance. The key guidance documents you need to complete your application are:
 - this document
 - the exemptions guidance issued by DHSC.
- 2.2. If we ask you to fill in and return an appendix to your application, you need to confirm that you have done so on the application form. This applies in particular to providers of CRS (see paragraphs 2.53 and 2.54 for more details).
- 2.3. The key contact should enter the applicant's CQC provider ID, confirm the provider name and registered address, and enter the key contact's name, job title, correspondence address and email.

Section 1 questions

1.1 CQC provider ID number

1.2 Provider information

Your (provider) name, name(s) you trade under (if different), company registration number (if applicable), charity registration number (if applicable), address of registered office, website address, telephone number, legal status (options include: PLC, limited company, charity, partnership, joint venture and 'other').

1.2.1 NHS-controlled providers

Does this application relate to an NHS-controlled provider? (Y/N)

- (a) List the names of each organisation (or individual) that has a direct or indirect ownership stake in, or acts as guarantor to, the NHS-controlled provider.
- (b) Specify their percentage ownership stake (this should add up to 100%).
- (c) List the names of all organisations (or individuals) that exert 'control' over the NHS-controlled provider (as defined by the IFRS10 criteria).
- (d) Briefly explain how control is exerted by the NHS provider(s) listed under
- (c) (based on the IFRS10 criteria).

1.3 Key contact information

Job title, first name, last name, address for correspondence (this could be an address held by CQC which relates to the provider's ID number or other address, eg the address registered with Companies House), email address and business telephone number.

CQC provider ID

2.4. The CQC provider ID is a unique registration number given to a provider by CQC on granting a CQC registration. You cannot use a CQC provider ID that is being used on another NHS provider licence application, or one that has previously been used to generate a licence that is still in place.

Provider

2.5. The licence requirement applies to the provider of healthcare services for the purposes of the NHS. 'Healthcare' means all forms of healthcare, whether relating to physical or mental health.1

¹ See the 2012 Act, s64(3).

2.6. The provider is the person (natural or legal) – that is, the legal entity – who provides healthcare services. The exemptions guidance provides guidance on the definition of a provider.

Name and registered address

2.7. Question 1.2 requires you to give the provider name and registered company address, and any other location address held by CQC. The key contact needs to confirm that the provider name and registered address are correct.

Trading name

If your company trades under a name which is different from its registered 2.8. name, that name must be included.

Company/charity registration number

2.9. A registration number is a unique number (company number or LLP number) allocated by Companies House. The Charity Commission issues unique registration numbers for charities.

Legal status

2.10. We ask you what the legal status of the applicant is: limited company; a public limited company; a partnership; a charity; a joint venture; or other.

Charity

- 2.11. If you are either a charitable trust or a charitable incorporated organisation, you can indicate this by entering the word 'charity' in this field.
- 2.12. If you are a limited company with a charitable purpose, you should enter either 'limited company' or 'public limited company' based on the legal status of your company, as set out in paragraph 2.10.

Other

2.13. If your organisation's legal status is not listed above, you should provide us with further detail.

NHS-controlled providers

- 2.14. In question 1.2.1 we ask you to confirm that you are applying on behalf of an NHS-controlled provider. From 1 April 2018, a new licence was introduced for NHS-controlled providers that is distinct from the licence issued to independent providers. NHS-controlled providers are providers that are:
 - 1. not themselves an NHS trust or foundation trust
 - 2. required to hold a provider licence
 - 3. ultimately controlled by one or more NHS trusts and/or foundation trusts, where 'control' is defined on the basis of IFRS10.
- 2.15. If you are applying on behalf of an NHS-controlled provider, we ask you to give the names of every organisation that has an ownership stake (NHS or otherwise) in that NHS-controlled provider. You should provide the details of any organisation that has either a direct or indirect ownership stake in the NHS-controlled provider. This includes any parent organisation(s) with ultimate ownership of the NHS-controlled provider that is not itself a subsidiary.
- 2.16 We also ask you to explain how your organisation is 'controlled' based on the IFRS10 criteria. Broadly speaking, directing the investee's financial and operating policies (either directly or by appointing the majority of the board of directors, or equivalent) indicates control.
- 2.17. Majority ownership (by one or more investors) normally indicates control. Where there is no majority investor(s), a significant minority investor may exercise control where its power/rights are sufficient for it to unilaterally direct relevant activities. Relevant activities can include:
 - selling and purchasing goods or services
 - managing financial assets
 - selecting, acquiring or disposing of assets
 - researching and developing new products or processes
 - determining a funding structure or obtaining funding.
- 2.18. Where two or more investors have rights to direct different relevant activities, the investor currently able to direct the activities that most significantly affect

- the returns has power of control. For more detail on how IFRS10 works, please consult the published guidance.2
- 2.19. If your organisation is an NHS-controlled provider, please ensure that you complete the paper-based version of the application form.

Key contact information

- 2.20. You are asked for the name and job title of the key contact, as well as a correspondence address. You should provide us with either the CQCregistered address or one of the other location addresses held by CQC, or an alternative correspondence address if you wish.
- 2.21. An address that is not held by CQC must be accompanied by either a URL to a publicly-listed address on the provider website or the name, job title and contact details of a director at the provider organisation who we can contact to confirm that the address is valid. If we cannot validate this address, we will notify you by email using the address you have provided, and to proceed you will need to provide a further correspondence address that can be validated.
- 2.22. The key contact also needs to provide their own contact details, including an email address. When you submit your application, we ask you to confirm that this email address can be used for administrative correspondence as well as formal notices, including of our decisions (as explained in paragraph 2.96). The email address will then be used throughout the process as our main way to correspond with you, including to update you on the progress of your application.

Section 2: Requirement for licence – provision of healthcare service(s) for the purposes of the NHS

- 2.23. We ask you to provide information about the type of healthcare services you provide. This information is relevant to the question about whether you provide healthcare services for the purposes of the NHS.
- 2.24. The 2012 Act requires every provider of healthcare services for the purposes of the NHS to hold a licence unless they are exempt. You can be a provider

² For instance Under control? A practical guide to IFRS10 consolidated financial statements.

³ See the 2012 Act, ss81-83.

of healthcare services for the purposes of the NHS if you provide services as a contractor commissioned directly by a clinical commissioning group(s) (CCG) or NHS England. This also applies if you provide services as a subcontractor.

2.25. For guidance on what it means to be a provider of NHS healthcare services, please see the exemptions guidance.

Section 2 questions

- Q2.1 Do you provide healthcare service(s) for the purposes of the NHS? (Y/N)
- Q2.1.1 Do you provide healthcare service(s) for the purposes of the NHS through a contract directly with a clinical commissioning group(s) and/or NHS England? (Y/N)
- Q2.1.1.1 Do you provide any healthcare service(s) for the purposes of the NHS through a multi-party contract with clinical commissioning group(s) and/or NHS England and other provider(s)? (Y/N)
- 2.26. These questions ask you whether you provide healthcare services for the purposes of the NHS directly through arrangements with a CCG and/or NHS England when one or more other providers are a party to that contract.

Section 2 Question

- Q2.1.2 Do you provide healthcare service(s) for the purposes of the NHS through an arrangement with another provider? (Y/N)
- 2.27. These questions ask whether you provide healthcare services for the purposes of the NHS as a subcontractor.
- 2.28. NHS healthcare services can be provided through an arrangement with another provider. If you provide healthcare services through an arrangement

- with another provider, such as subcontracted services, you need to consider if you are required to hold a licence independently.4
- 2.29. For the definition of a provider for the purposes of working out if you are required to hold a licence, please refer to the exemptions guidance.

Section 3: Requirement for licence – licence exemptions

- 2.30. Section 3 of the application form asks for information that allows us to assess whether or not you might be exempt. If based on the information you submit in your application, we consider you are exempt from the requirement to hold a licence, we will not consider your application further and we will not issue a licence.
- 2.31. It remains the provider's responsibility to ensure compliance with all the legal rules of the licensing regime, including compliance with the requirement to hold a licence if applicable. If you fail to obtain a licence when you are required to do so, you will be acting in breach of legal rules and could be subject to enforcement action including, potentially, being fined. For more information see paragraph 5.2.

Assessing whether an exemption applies

- 2.32. The exemptions to the requirement to hold a licence are set out in the regulations.⁵ It is the responsibility of providers, taking independent advice if necessary, to check if a licence is required in their particular circumstances. NHS Improvement can take enforcement action as described above against providers that do not hold a licence when required to do so.
- 2.33. The following are not required to hold a licence:
 - NHS trusts
 - providers that are not required to register with CQC
 - providers of primary medical or primary dental services only

⁴ The National Health Service (Licence Exemptions etc) Regulations 2013. Reg 2(5)

⁵ The National Health Service (Licence Exemptions etc) Regulations 2013.

- small providers of NHS healthcare services that is, those with an annual applicable turnover from the provision of NHS services of less than £10 million
- providers of NHS continuing healthcare or NHS-funded nursing care only.
- 2.34. However, all providers of CRS are required to hold a licence, even if they are otherwise exempt.
- 2.35. The definitions of primary medical and primary dental services, annual applicable turnover, NHS continuing healthcare and NHS-funded nursing care are set by DHSC in the National Health Service (Licence Exemptions, etc) Amendment Regulations 2015 and are described in more detail in the exemption regulations. More details on CRS can be found in paragraph 2.51 onwards.
- 2.36. If you cease to qualify for an exemption, you must obtain a licence. For example, if you are exempt on the basis of the provision of non-regulated activities, but then start providing regulated activities (as defined in paragraphs 2.40 and 2.41) and are required to register with CQC, you will need a licence unless you qualify for another exemption. 6 For guidance on the timeframe that applies when an exemption ceases to be available, see the exemptions guidance.
- 2.37. The exemptions to the requirement to hold a licence are set out in paragraph 2.33. For guidance on assessing whether you are exempt or need to apply for a licence, please see the exemptions guidance.

⁶ The National Health Service (Licence Exemptions etc) Regulations 2013, reg 7.

Section 3 questions

Q3.1 Are one or more of the healthcare services you provide for the purposes of the NHS regulated activities for the purpose of registration with the Care Quality Commission under Chapter 2 of Part 1 of the Health and Social Care Act 2008? [Y/N]

Q3.1.1 Are you registered with the Care Quality Commission in accordance with Chapter 2 of Part 1 of the Health and Social Care Act 2008 in respect of the carrying out of all regulated activities? [Y/N]

CQC registration

- 2.38. The CQC is the independent regulator of health and social care in England. It requires those that undertake regulated activities to register with it.
- 2.39. Providers that are not required to register with the CQC are not required to hold a provider licence unless they provide CRS (see paragraph 2.51 onwards).

What are the 'regulated activities' referred to in Q3.1 and Q3.1.1 of the application?

- 2.40. Question 3.1 asks whether you provide regulated activities. Regulated activities are those listed in Schedule 1 of the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.⁷ They are:
 - personal care
 - accommodation for persons who require nursing or personal care
 - accommodation for persons who require treatment for substance misuse
 - treatment of disease, disorder or injury
 - assessment or medical treatment for people detained under the Mental Health Act 1983
 - surgical procedures

⁷ As amended by the Health and Social Care Act 2008 (Regulated Activities) (Amendment) Regulations 2015

- diagnostic and screening procedures
- management of supply of blood and blood-derived products, tissues and tissue-derived products, donor organs, stem cells, bone marrow, etc
- transport services, triage and medical advice provided remotely
- maternity and midwifery services
- termination of pregnancies
- services in slimming clinics
- nursing care
- family planning services.
- 2.43. See the CQC website for more information on what constitutes a regulated activity and to find out if you need to register with CQC.
- 2.42. Question 3.1.1 asks whether you are registered in respect of all the regulated activities you carry out. Question 4.1 asks you which regulated activities you are registered with CQC to provide.

Primary medical and dental care services, NHS continuing healthcare and NHS-funded nursing care

Section 3 questions

Q3.2 Do all the healthcare services you provide for the purposes of the NHS fall into one or more of the categories below:

- primary medical services
- primary dental services
- NHS continuing healthcare
- NHS-funded nursing care?

Q3.2.1 Please indicate which of the following healthcare services you provide for the purposes of the NHS: (options include: primary medical services; primary dental services; NHS continuing healthcare; NHS-funded nursing care). [Y/N]

- 2.43. Providers that only deliver primary medical services or primary dental services are exempt from the requirement to hold a licence. Primary medical and primary dental services are those provided under Parts 4 and 5 of the NHS Act 2006, known as general medical services (GMS), personal medical services (PMS), alternative provider medical services (APMS) and general dental services (GDS). Similarly, providers that only deliver nursing care, defined as providing NHS continuing healthcare and/or NHS-funded nursing care, are not required to hold a licence.
- 2.44. For guidance that will help you understand whether you are a provider of NHS primary medical or dental services, NHS continuing healthcare or NHSfunded nursing care, please see the exemptions guidance.

Applicable turnover

Section 3 question

Q3.3 Is your applicable turnover for the next 12 months expected to be £10 million or more?

- 2.45. Providers are exempt if their annual applicable turnover from the provision of NHS services is less than £10 million. To qualify for this exemption, providers are required to undertake a forward-looking estimate of their applicable turnover for the 12-month period beginning on the date they started providing NHS services, and at the end of every month thereafter, for determining whether their applicable turnover is reasonably expected to be less than the £10 million exemption threshold. The 12-month period begins on the same date of each month, ie the date on which the provider first started providing the services.
- 2.46. Applicable turnover is defined in regulation 2(2) of the National Health Service (Licence Exemptions, etc) Amendment Regulations 2015 as the turnover from the provision of NHS healthcare services, minus any turnover from the provision of primary medical or primary dental services, or from the provision of NHS continuing healthcare and NHS-funded nursing care.

- 2.47. The exemption will apply on the basis of knowledge or reasonable expectation of the applicable turnover. For further guidance and examples, please see the exemptions guidance.
- 2.48. You must notify us as soon as you realise that this exemption no longer applies. The exemption will be withdrawn 60 days from the date on which the provider becomes aware that the exemption no longer applies. You will need to apply and obtain a licence from us within this 60-day period.

Multiple services

2.49. Where a company provides a number of different NHS services, more than one exemption may apply. Therefore, you should consider whether or not an exemption applies by referring to each NHS service provided. For example, a provider of primary care services, sexual health and community services is not required to hold a licence in respect of the primary care services provided under Parts 4 and 5 of the 2006 Act. That provider may be required to hold a licence for the other services it provides. However, if the income (calculated in terms of applicable turnover) is less than £10 million annually, then the provider does not require a licence.

Information provision

2.50. All exemptions (except for NHS trusts) are conditional on providers complying with requests from NHS Improvement for any information we consider necessary or expedient to have to perform our regulatory functions.9.

⁸ The National Health Service (Licence Exemptions etc) Regulations 2013, reg 8(5).

⁹ See The National Health Service (Licence Exemptions etc) Regulations 2013, reg 9(4).

Commissioner requested services

Section 3 questions

- Q3.4 Do you provide healthcare services for the purposes of the NHS that are designated as commissioner requested services?
- Q3.4.1 Please provide a list of all commissioners you provide commissioner requested services for with the specified details.
- 2.51. CRS are services that NHS England or commissioners may determine as requiring additional regulation to protect the interests of patients who use those services in the event that the provider gets into financial difficulty. Services are designated as CRS based on guidance from NHS Improvement.
- 2.52. Under the exemption regulations, if a provider would otherwise be exempt from the requirement to hold a licence, the designating commissioners should make a request to NHS Improvement that the provider be licensed.

How are services designated as commissioner requested services?

- 2.53. To designate your service as a CRS, your commissioner must first inform you in writing that they are proposing to designate your service as a CRS. Your commissioner should give you 28 days to object to the designation in writing with your reasons.
- 2.54. Your commissioner must also submit a formal request to NHS Improvement for you to be licensed under the exemption regulations. Your commissioner should use the form developed by NHS Improvement to complete their CRS request.
- 2.55. NHS Improvement may grant or refuse the request. 10 If we decide to grant a request for licensing, then you are required to obtain a licence even if you

¹⁰ See The National Health Service (Licence Exemptions etc) Regulations 2013, reg 9(4).

- are otherwise exempt from that requirement. We will formally notify you and your commissioner of our decision to accept the request for licensing.
- 2.56. If you are applying for a licence because your commissioner(s) has designated your service as a CRS, you should forward the notification you received from us or your commissioner(s) as an appendix to your application. This should be sent to nhsi.crs@nhs.net. Should we require any additional information to consider your application under the above circumstances, we will contact you as soon as possible to discuss our requirement.

When should CRS designated providers apply for a licence?

- 2.57. If you are exempt from the requirement to hold a licence and NHS Improvement subsequently grants a commissioner's request for licensing, it is your responsibility to apply for a licence. When we grant a request for licensing, commissioners have a duty to send a formal notification to the provider. Once you receive this notification from your commissioner, you have a maximum of 60 days to obtain a licence. Should you fail to do so, we can take any necessary action against you. However, you do not need to wait to be notified by your commissioner; you can apply as soon as we grant the request. Where we receive an application under these circumstances, we first confirm with the relevant commissioner(s) that such a designation exists.
- 2.58. We aim to review your application within a reasonable timeframe to ensure that you will have a licence in place within 60 days. However, we may take longer to make our final decision if we need to request additional information.
- 2.59. If we notify you that we have granted a commissioner's request for licensing after you submit your application to us but before we issue a licence or Notice of Refusal, you will need to amend your application. For further information on amending your application, see paragraph 2.102.

Information about commissioner requested services contracts

2.60. Question 3.4.1 requests information about the contracting arrangements under which you provide CRS. We need this information to reconcile a provider with the commissioner that has designated the services as CRS.

- 2.61. In response to question 3.4.1, please provide:
 - name of the commissioner(s) you provide CRS for (eg NHS Barnet CCG)
 - your contract reference (this can be a reference number or the name that appears on the contract documentation)
 - a short description of the services and value of the contract
 - contract start date
 - contract end date
 - name of the parties to the contract.

Section 4: Licence – licensing grant criteria

2.62. Section 4 of the application form asks for the information that allows us to assess if you meet criteria 1 and 2 and therefore whether we can grant you a licence.

Criterion 1: CQC registration

- 2.63. If in providing a healthcare service for the purposes of the NHS, an applicant carries out a regulated activity, they must be registered with CQC in respect of that regulated activity. Therefore, we must consider whether or not an applicant that is required to be registered with CQC – because it is carrying out a regulated activity – is in fact registered.
- 2.64. A provider that is not required to register with CQC may still be required to hold a licence. Where the provider does not provide an activity that is regulated by CQC, but provides services that have been designated as CRS, that provider is still required to hold a licence. A provider that is not required to register with CQC still has to satisfy criterion 2.

Section 4 question

Q4.1. If you answered yes to question 3.1.1 above to confirm that you are registered for all regulated activities you carry out, please select either Y or N below to confirm all your registered activities:

- personal care [Y/N]
- accommodation for persons who require nursing or personal care [Y/N]
- accommodation for persons who require treatment for substance misuse [Y/N]
- treatment of disease, disorder or injury [Y/N]
- assessment or medical treatment for persons detained under the Mental Health Act 1983 [Y/N]
- surgical procedures [Y/N]
- diagnostic and screening procedures [Y/N]
- management of supply of blood and blood-derived products, tissues and tissue-derived products, donor organs, stem cells, bone marrow etc [Y/N]
- transport services, triage and medical advice provided remotely[Y/N]
- maternity and midwifery services [Y/N]
- termination of pregnancies [Y/N]
- services in slimming clinics [Y/N]
- nursing care [Y/N]
- family planning services [Y/N].
- 2.65. Question 4.1 requires you to indicate the regulated activities you engage in for the purposes of CQC registration. Please see paragraphs 2.40 and 2.41 for more information about regulated activities.

Criterion 2: Provider fitness

Section 4 questions

Q4.2. Please provide below the required details for all directors, governors and those performing equivalent or similar functions of: your organisation (which is applying for a licence); your corporate director(s) (if applicable); and the parent body (bodies) of all your corporate director(s) (if applicable).

If you are an individual provider, please provide your own name, surname and date of birth. For 'Function' please select 'Equivalent/similar to director or governor' and for 'Organisation' please select 'Applicant organisation'.

Q4.2.1 to 4.2.2.3: Detailed questions on provider fitness.

2.66. The second criterion we must consider is whether or not the provider of healthcare services for the purposes of the NHS is fit to hold a licence. 11 The criterion sets out two definitions of unfit persons, one for individuals and one for corporate bodies, and how these are applied to assess the fitness of applicants who are individuals and of applicants that are not individuals. The definitions of unfit persons are set out below.

Applications from individuals (natural persons)

2.67. Where the provider is an individual, NHS Improvement must consider that person's fitness only, by reference to the definition of individual unfit persons.

Applications from others/those that are not individuals, including companies and other entities (legal persons)

- 2.68. Where the provider is not an individual, such as a company or other entity, we must consider that provider's fitness by reference to:
 - all its directors (if any) and all its governors (if any), none of whom must fall within the definition of individual unfit persons
 - all its corporate directors (if any) in the following ways:

¹¹The National Health Service (Approval of Licensing Criteria) Order 2013, Schedule 1, paragraph 2.

- the corporate directors, none of whom must fall within the definition of corporate unfit persons (note that this definition includes reference to parent bodies of such corporate directors if any)
- the individual directors or governors of that corporate director, and of any parent body of that corporate director, none of whom must fall within the definition of individual unfit persons
- all those performing equivalent or similar functions to directors or governors (if any) as described below.

Directors and governors

- 2.69. The regulations define 'director' as including 'any individual who performs the functions of ... a director of an NHS foundation trust ... or of a company registered under the Companies Act 2006.'12 Therefore, those who have been formally appointed as directors of registered companies are directors for the purpose of this criterion.
- 2.70. The regulations define 'governor' as including any 'individual who performs any of the functions of ... a governor of an NHS foundation trust, as conferred by any enactment'. 13 Therefore, those who have been formally appointed or elected as governors of NHS foundation trusts are governors for the purpose of this criterion.
- 2.71. The regulations define 'governor' as including any 'individual who performs any of the functions of ... a governor of an NHS foundation trust, as conferred by any enactment'. 14 Therefore those who have been formally appointed or elected as governors of NHS foundation trusts are governors for the purpose of this criterion.
- 2.71. The regulations provide that references to any individual who performs any of the functions of, equivalent or similar to, a 'director' or 'governor', include a partner in a partnership. 15

¹² The National Health Service (Approval of Licensing Criteria) Order 2013, Schedule, paragraph 2.

¹³ The National Health Service (Approval of Licensing Criteria) Order 2013, Schedule, paragraph 2.

¹⁴ The National Health Service (Approval of Licensing Criteria) Order 2013, Schedule, paragraph 2.

¹⁵ See the Explanatory Memorandum to The National Health Service (Approval of Licensing Criteria) Order 2013

Those performing equivalent or similar functions to directors or governors

- 2.72. In responding to question 4.2, it is the responsibility of providers to consider whether they have within their organisations any people who are performing equivalent or similar functions to directors or governors. We will accept the responses of providers unless alerted to information indicating that these responses need to be queried further or challenged.
- 2.73. In considering this point, providers should have in mind, as described in the explanation of the regulations, 16 that the aim of this part of the regulations is to include within the fitness test those other than the actual directors or governors who are involved in overseeing the provider and thus influencing the provision of healthcare services by that provider in a comparable way to directors and governors.
- 2.74. Providers should consider this point by taking into account all the relevant facts and circumstances. In each case, the role performed by the relevant person must be considered in the context of the governance of your organisation given its size, operations and financial status. The focus of any assessment must be the substance of the role performed by the relevant person and not their job title alone. Set out below is a non-exhaustive list of considerations for this assessment by reference to the roles of actual directors and governors.
- 2.75. If a person holds themselves out as a director and carries out the role of director even if not formally appointed as such, that person is to be regarded as performing functions of, or similar or equivalent to, a director. This position is consistent with that taken under the Companies Act 2006, which states 'director' as including 'any person occupying the position of director by whatever name called'.17
- 2.76. We consider that the following can indicate that a person may be regarded as performing a function equivalent or similar to a director:
 - the person presumes to act as if they were a director

¹⁶ See the Explanatory Memorandum to The National Health Service (Approval of Licensing Criteria) Order 2013.

¹⁷ Section 250.

- the person is either solely directing the affairs of the company, or they have a predominant influence and force with respect to those affairs
- the degree of their involvement with the management of the company is at least equivalent to that of the named directors
- the functions performed are ones that would generally be undertaken by a director, rather than a manager or other employee below board level
- the person is not accountable to others in their organisation, other than at board level, for their decisions.
- 2.77. A person in accordance with whose directions or instructions the directors of a company are accustomed to act, referred to as a 'shadow director', is also considered to be a person performing functions of, or similar or equivalent to, a director.
- 2.78. To assess whether someone is performing equivalent or similar functions to an NHS foundation trust governor, providers should have regard to governors' statutory functions and consider whether any person other than an actual director or governor performs such functions.
- 2.79. NHS foundation trust governors perform a range of functions, prescribed by statute. 18 These include:
 - appoint and, if appropriate, remove the chair of the board of directors
 - decide the remuneration and allowances and other terms and conditions of office of the chair and the other non-executive directors
 - approve (or not) any new appointment of a chief executive
 - approve an application by the trust to enter into a merger, acquisition, separation or dissolution.
- 2.80. Given the relatively unique combination of functions of foundation trust governors, when considering if someone performs equivalent or similar functions to the statutory functions of a governor, providers should consider the role that such functions enable governors to play in the governance of their organisations, including in relation to strategic, operational, regulatory or financial matters.

¹⁸ NHS Act 2006, as amended by the 2012 Act, Section 56(A); Schedule 7, paragraphs 17 and 18.

CQC registration conditions and additional information requests

2.81. Sections 5 and 6 of the application form asks for the additional information with which to monitor licence holders. This information is not used in making the decision whether or not to grant you a licence. We also ask licensed providers to provide further information within a month of being licensed (see Section 3 of this guidance) and we let you know in advance about this.

Section 5: CQC registration conditions

Section 5 question

Q5.1 Is your registration with CQC subject to any conditions? [Y/N]. If yes, please provide details below.

- 2.82. We need to know if your registration with CQC is subject to conditions. We do not need to know about the routine 'restrictive conditions' which are made during the initial registration process, such as the location where a regulated activity can be provided and the need to have a regulated manager. However, we do require you to provide information regarding:
 - any restrictive conditions imposed by CQC at the time of registration because it had concerns about compliance
 - any restrictive conditions imposed after initial registration because CQC had concerns about compliance.
- 2.83. The information provided should be:
 - the text of all conditions as they currently stand (that is, after variation if relevant)
 - the dates on which all conditions were imposed.
- 2.84. As part of our ongoing monitoring, we may discuss these conditions, including their basis, with CQC.

2.85. You do not need to tell us about those conditions which have now been removed.

Section 6: Additional information requests

Information related to provision of CRS

Section 6 question

Q6.1 Do you have an ultimate controller(s)? If yes, provide: name of ultimate controller(s); company registration number(s) (if applicable); website address(es); key contact(s) at ultimate controller(s), job title, first name, last name, address for correspondence, email address, business telephone number.

- 2.86. An ultimate controller is any body that could instruct the licensee to carry out particular actions so long as that body cannot be required to act in accordance with the instructions of another. In practice, the ultimate controller is usually the parent company of a subsidiary company, where it is the subsidiary company that has been licensed by NHS Improvement. If nobody can instruct the licensee in this way, then the licensee does not have an ultimate controller.
- 2.87. Where a licence holder has an ultimate controller, it is required to put in place a legally enforceable agreement with its ultimate controller, called an ultimate controller undertaking. This is a regulatory instrument designed to prevent parent companies from taking actions that would cause a licensee to breach its licence. The agreement between the licensee and the ultimate controller requires the ultimate controller to refrain from taking any action that would cause the licence holder to breach its licence obligations.
- 2.88. It may be unusual for a provider to have more than one ultimate controller. However, if you consider that you have two or more ultimate controllers, please provide the specified details for all of them.

CQC enforcement action

Section 6 question

Q6.2 Are you currently subject to enforcement action by CQC? [Y/N] If yes, please provide details below (including date of issue).

2.89. CQC has the power to regulate services and take enforcement action against those that fail to comply with the relevant legislation (eg the Health and Social Care Act 2008 and the regulations made under it). We ask here whether the applicant is currently subject to enforcement action by CQC.¹⁹

Financial records

Section 6 questions

- **Q6.3** What is the date of your last financial year end?
- **Q6.4** What is the date of your establishment/date of incorporation?
- Q6.5 If your last financial year was not 12 months, please indicate the period it covered.
- **Q6.6** What is the date of your next financial year end?
- 2.90. We require certain information about the way you maintain your financial records. This is to assist us, if you are licensed, with our monitoring of licence holders.

¹⁹ The CQC Enforcement policy outlines the enforcement action that may be taken by the CQC: www.cqc.org.uk/sites/default/files/20150209 enforcement policy v1-1.pdf

Licence previously held/applied for

Section 6 questions

- Q6.7 Have you previously held an NHS provider licence? [Y/N] If yes, please provide details (provider name, licence number and date granted).
- Q6.8 Have you ever applied for an NHS provider licence and been refused? [Y/N] If yes, please provide details (including provider name(s), date(s) and reason(s) for refusal of the licence).
- Q6.9 Have you ever withdrawn an application for an NHS provider licence before NHS Improvement made its decision to grant or refuse this? [Y/N] If yes, please provide details (including provider name(s), date(s) and reasons for withdrawal of the application).
- 2.91. You need to tell us if you have previously held, or applied for, a licence. If you have, please provide the name of the licence holder, the licence number and the date the licence was granted or refused. If the application was withdrawn before a decision to grant or refuse was made by us, please state the applicant name, the date of the application and the reason why the application was withdrawn.

Section 7: Licence application declaration and submission

Key contact

2.92. All organisations other than individuals should have a key contact. This is a person who will act as the main contact with us. The key contact must be a person who has the authority to complete the application and who we can contact if we need further clarification or information relating to your application.

Declaration

- 2.93. The person who submits an application must sign the declaration on the application. For an applicant who is an individual, that individual signs the declaration. Where an organisation is submitting an application, a person (that is, the key contact) who has been duly authorised to do so must make the required declaration.
- 2.94. Pursuant to the declaration, the individual or key contact must:
 - acknowledge that they have has the authority to submit the application
 - confirm that the information provided on the application is accurate, complete and not misleading, to the best of the applicant's knowledge and belief at the time of entry (for non-individuals this means to the best of the key contact's knowledge and belief)
 - undertake that where information entered on the application is no longer accurate, complete and not misleading, updated information, which is accurate, complete and not misleading, will be provided promptly to NHS **Improvement**
 - acknowledge that NHS Improvement will use the information provided on the form, including personal data, and any other relevant information that NHS Improvement obtains or receives, for the purpose of performing its regulatory functions.
- 2.95. When signing the declaration, you must include the date on which the declaration is made. This should be entered in the (dd/mm/yy) format.
- 2.96. Before submitting your application, you will be asked if you consent, by ticking the relevant box, to the receipt of formal notices electronically, and that the email address provided in response to question 1.3 can be used for that purpose.²⁰
- 2.97. We may share the information you provide on the application with other regulators and public bodies, including CQC. In particular, we have an obligation to share information with CQC where that information would assist CQC with the exercise of its functions.21

²⁰ See the 2012 Act, ss148-9.

²¹ See the 2012 Act. s288.

2.98. If any of the information you have provided changes before you receive a Notice of Decision, pursuant to this declaration you must inform us as soon as reasonably practical.

Submitted applications

- 2.99. We will send you an email confirming receipt of your application.
- 2.100. Following this, your application is assessed. If we require additional information we will ask you for it; please provide us with it promptly.
- 2.101. In some circumstances, we may contact an applicant to state that we are unable to consider the application. This could be because the answers given under Section 3 of the application form demonstrate that the provider is exempt, or because of inconsistencies in the application. An applicant will be advised as to how to proceed if this is the case.

Amended applications

- 2.102. Once you have submitted your application, NHS Improvement will process it. If we require further information, we will let you know. If you subsequently need to amend any details of your application, please send the full details of the requested amendments by email to NHS Improvement's licensing team at NHSI.Licensing@nhs.net. If you want to change the email address we hold for correspondence, please confirm also if you agree for this new address to be used by NHS Improvement to send you formal legal notices as well as for administrative purposes (see paragraph 2.96).
- 2.103. If you want to change the correspondence address of the key contact, you will need to provide us with all the relevant key contact details (see paragraphs 2.20 to 2.22).

Incomplete applications

2.104. We cannot process incomplete applications. These will be rejected and we will let you know if this is the case. We strongly advise you to take care to complete your application fully and accurately, as gaps or inaccuracies will delay your application.

- 2.105. If your application is incomplete we will request further information from you. Failure to provide the requested information without a reasonable explanation will be deemed as your withdrawal from the application process (also see paragraphs 2.107 and 2.108).
- 2.106. Please note that it remains the provider's responsibility to ensure compliance with all the legal rules of the licensing regime, including compliance with the requirement to hold a licence if applicable. If you fail to obtain a licence when you are required to do so, you will be acting in breach of legal rules and you could be subject to enforcement action including, potentially, being fined.

Withdrawn applications

- 2.107. If at any point in the application process, you want to withdraw your application, we ask you to confirm this by email, with the reasons why you are withdrawing your application to: NHSI.Licensing@nhs.net.
- 2.108. If you withdraw your application before we make our final decision to grant or refuse a licence, this may lead to further information requests and/or action from us: for example, if we consider that you may not be exempt from the requirement to hold a licence.

Notice of Decision

- 2.109. If NHS Improvement is satisfied that the applicant meets criteria 1 and 2, as soon as reasonably practicable we grant the application and send a Notice of Decision.²² We aim to issue a decision within 20 working days of accepting a fully completed application, unless gueries or concerns are raised which cannot be addressed in that timeframe.
- 2.110 If the decision is to issue a licence, this is sent by email to the applicant or in the case of a non-individual, the key contact. The Register of Licence Holders on NHS Improvement's website is also updated.

²² See the 2012 Act. s87.

3. Information requested following grant of licence

3.1. If a licence is granted, you will be asked to send us additional information within one month of this grant. The information sought includes financial information, the nature of your contractual arrangements, compliance with CQC conditions as well as information regarding CRS, if relevant.

Information to be provided by all licensed providers

The value of your applicable turnover and total turnover in £ for the relevant business year.

- 3.2. The definition of 'applicable turnover' for the purpose of this calculation is the same as used in relation to the *de minimis* exemption to the requirement to hold a licence. This is set out in Section 7 of the exemptions guidance and is explained in paragraphs 2.45 to 2.48 of this guidance.
- 3.3. Total turnover is the total turnover of the provider in the previous business year.

CRS revenue disclosures

3.4. We require this information to understand what proportion of the provider's turnover is derived from the provision of NHS healthcare services.

Information to be provided only by CRS providers

3.5. We require information about the value and nature of CRS as well as the way in which they are delivered. We seek information, in particular, on whether or not CRS are provided by prime contractors or subcontractors as well as the information regarding who has commissioned CRS. We also seek information regarding the financial position of providers of CRS.

The list of services designated as CRS in the specified format and the value in £ of the CRS you have been contracted to deliver by the commissioner at the time you submit this information to NHS Improvement.

3.6. You need to provide us with a list of all the services you provide which have been formally designated by a commissioner as CRS, and state the annual contractual value of the CRS you have been contracted to deliver. This information should be current: that is, the annual contractual value on the date the information is submitted.

Other CRS disclosures

If you are providing healthcare services (excluding CRS) to the NHS as a prime contractor, have you entered into subcontracting arrangements with one or more other providers for them to provide part or all of these services?

If you are providing CRS as a prime contractor, have you entered into subcontracting arrangements with one or more other providers for them to provide part or all of these services? If so, please provide the specified details.

Ultimate controller undertaking in accordance with the requirements of condition CoS4 of the NHS provider licence.

3.7. Under Continuity of Services licence condition 4 (CoS4), a CRS provider that has an ultimate controller must provide an undertaking declaration from its ultimate controller. We will provide a template for the undertaking.

Last available credit rating (if you have one).

3.8. Please provide your latest credit rating, as well as the date of that credit rating, if you have one. If you do not have a credit rating, you do not have to provide this information.

Information relating to your transactions.

Information relating to your financial plans.

Last full set of annual report and accounts.

Governance arrangements for NHS-controlled providers

3.9. We will contact you when the requirement to make your first corporate governance statement falls due.23

Exceptional events

3.10. We request routine information about your planned transactions, as well as about your financial planning generally.

²³ Under condition CP1(8)(a) of the NHS controlled provider licence.

4. Representations and appeals

- 4.1. We must refuse an application for a licence where the licence grant criteria are not met.²⁴ In such cases, NHS Improvement gives a Notice of Proposal to Refuse (including its reasons) and specifies the period within which the applicant may make representations to us with respect to the above Notice. This period will be no less than 28 days. 25
- 4.2. If we do not accept your representations, we confirm our proposal through a Notice of Decision to Refuse. You can appeal against our decision to the Care Standards jurisdiction of the First-tier Tribunal, which is an independent tribunal.26
- The Notice of Decision explains the right of appeal.²⁷ Appeals may be made 4.3. based on errors of fact, errors of law or on the unreasonableness of a decision. More information on the First-tier Tribunal is available. The tribunal service's address is:

Care Standards Tribunal

HM Courts and Tribunals Service

1st Floor

Darlington Magistrates' Court

Parkgate

DL1 1RU

²⁴ The 2012 Act, s87.

²⁵ The 2012 Act, s.90

²⁶ The 2012 Act, s.92

²⁷ The 2012 Act, s.91(3)

5. Compliance

- 5.1. Licensed persons have a duty to make sure that the regulated activities they are responsible for are carried out and managed in a way that complies with their licence conditions. 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 apply to an individual provider. The conditions specific to NHS-controlled providers are given in Guidance on our oversight of NHS-controlled providers and the full NHS-controlled providers licence conditions.
- 5.2. We have powers, under the 2012 Act, to take action against actual or suspected licence breaches. These include the power to take action to stop a breach continuing, rectify the breach and/or to impose a fine. We also have the power to revoke a licence. Our enforcement guidance sets out the principles we follow in taking enforcement action.

6. Associated documents

The Health and Social Care Act 2012

The National Health Services Act 2006

The National Health Service (Approval of Licensing Criteria) Order 2013 and explanatory memorandum

The National Health Service (Licence Exemptions, etc.) Regulations 2013 and explanatory memorandum

The National Health Service (Licence Exemptions, etc) Amendment Regulations 2015

Protecting and promoting patients' interests: Licence exemptions: guidance for providers (Department of Health and Social Care document)

NHS Improvement publications

Enforcement guidance

The new NHS provider licence and its annex NHS provider licence standard conditions

Guidance for commissioners on ensuring the continuity of health care services

Risk assessment framework: addendum for assessing risk at independent providers of commissioner requested services

NHS Oversight Framework for NHS providers

Contact us:

NHSI.Licensing@nhs.net

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