Title: Licensing exemptions **IA No:** 3122 **Lead department or agency:** Department of Health **Other departments or agencies:**	**Impact Assessment (IA)** **Date: 25/06/2013** **Stage:** Final **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Contact for enquiries:** Catherine Fiegehen, 226 Richmond House Tel: 020 7210 5569 email: catherine.fiegehen@dh.gsi.gov.uk

Summary: Intervention and Options

RPC Opinion: Not Applicable

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, One-Out?**	**Measure qualifies as**
£152m	£2m	£m	No	NA

What is the problem under consideration? Why is government intervention necessary?

As part of Monitor's new role as sector regulator for NHS services, the Health and Social Care Act 2012 gave Monitor the power to license all providers of NHS-funded healthcare services. The licence sets obligations on providers which they must meet in order to provide NHS services, and gives Monitor powers to take action if a provider were to breach one of those conditions. The Act also allows the Secretary of State to exempt providers from the requirement to hold a licence through regulations. These regulations will allow the Department to ensure that any additional regulatory burden placed on providers is proportionate to the benefits to patients of this additional regulation.

What are the policy objectives and the intended effects?

Our intention is to use regulations to exempt providers where the licence would bring little additional benefit or would result in unnecessary additional burden without significant additional benefit or reduced risk to patients' interests. Where providers are subject to similar or equivalent requirements which manage risk to patients' interests, they should be exempt from the requirement to hold a licence. The regulations should result in consistency and transparency in the application of regulatory requirements, ensuring that the licence allows for Monitor's and providers' resource to be prioritised where it will bring the most benefit for patients.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 0: Do nothing: This option would require all providers of NHS-funded services to be licensed.

Option 1: Preferred option. This option exempts certain providers from having to hold a licence based on: status as NHS trusts; provision of primary medical or dental services; provision of NHS nursing care as part of social care; income of less than £10m from services which are not exempt; or CQC registration status.

The preferred option will ensure that Monitor focuses its resources on providers that potentially have a greater impact on patients. It will save on costs to the system from having certain providers regulated by more than one organisation. The savings incurred from exempting providers relative to licensing them all is estimated in this assessment.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** 2016					
Does implementation go beyond minimum EU requirements?			NA		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** Yes	**< 20** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			Traded:	Non-traded:	

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs.

Signed by the responsible Minister: Earl Howe **Date:** 26th June 2013

Summary: Analysis & Evidence

Policy Option 1

Description: Preferred option. Exempt certain providers based on status as NHS trusts; provision of primary medical or dental services; provision of NHS nursing care; income of less than £10m; or CQC registration status.

FULL ECONOMIC ASSESSMENT

Price Base Year 2013	**PV Base Year** 2013	**Time Period Years**	**Net Benefit (Present Value (PV)) (£m)**		
			Low: Optional	**High:** Optional	**Best Estimate:** 152

COSTS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Cost** (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	Unquantified			

Description and scale of key monetised costs by 'main affected groups'

N/A

Other key non-monetised costs by 'main affected groups'

There is some risk of losing the benefits of licensing in relation to preventing behaviour that harms choice, competition and integration by exempt providers. However, there is limited scope for these providers to engage in this behaviour due to their size or oversight by other bodies, so we expect these costs to be low.

BENEFITS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Benefit** (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	152			**152**

Description and scale of key monetised benefits by 'main affected groups'

Exempt providers benefit in the instances where the licence would have placed them under additional regulatory burden. This results in benefits through administrative and compliance savings compared to the potential requirement to hold a licence. Patients benefit from providers not needing to reallocate resources from health care provision to administrative tasks.

Other key non-monetised benefits by 'main affected groups'

The overall system, and therefore patients, benefit from an exemption where providers are already subject to oversight from an existing organisation. Ensuring reduced duplication of oversight ensures efficiency in decision making and clarity for providers. Monitor would also benefit from reduction in administrative costs and ability to allocate resources more efficiently. This assessment only considers the one-off cost savings of exemptions. Recurring savings are not included.

Key assumptions/sensitivities/risks

Discount rate (%)

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			**In scope of OITO?**	**Measure qualifies as**
Costs:	**Benefits:** 2	**Net:**	Yes/No	N/A

Evidence Base (for summary sheets)

Introduction

1. The Health and Social Care Act 2012 (the 2012 Act) gave Monitor a new role as sector regulator, with a duty to protect and promote the interests of patients, through promoting the provision of health care services which is effective, efficient and economic, and which maintains or improves the quality of services. The 2012 Act sets out the licensing regime as a key tool for Monitor to exercise its functions to:
    - support commissioners to secure continuity of NHS services;
    - enforce prices for NHS services;
    - address anti-competitive behaviour by providers of services that is against patients' interests;
    - enable integrated care; and
    - oversee the governance of NHS foundation trusts.
2. The provider licence is made up of conditions and places enduring obligations on providers with which they must comply if they wish to provide NHS services. If a provider breaches a licence condition, Monitor will be able to take enforcement action. Monitor published its provider licence on 14 February 2013[1]. The licence is modular and contains seven sections, some of which will apply to all licence holders, some only to certain types of licence holders, for example NHS foundation trusts (FTs), and some only to providers providing certain types of services, for example providers of commissioner requested services (CRS)[2].
3. The licence covers:
    - General conditions which set out standard requirements for all licensees and include a fit and proper persons test and a requirement to hold CQC registration
    - Pricing conditions which make requirements around compliance with tariff prices, and other requirements to help Monitor fulfil its role over the national tariff
    - Choice and competition
    - Integration
    - Continuity of services conditions which set requirements to ensure patients' continued access to services in the case of a provider getting into financial difficulty
    - FT specific conditions which set requirements around FT governance

Exemptions from the requirement to hold a licence

4. The 2012 Act provides that the Secretary of State can make regulations to grant exemptions from the requirement to hold a Monitor licence. Such exemptions may relate to particular types of providers or to providers of particular types of services. The Secretary of State also retains the ability to withdraw exemptions from named providers or types of provider and would be able to do this if there was evidence that an exemption posed unacceptable risk to patients. Exemptions regulations enable the Department to set the parameters of licensing to ensure that regulation via the licence is targeted and proportionate.
5. The Department consulted on proposals about the possible content of exemptions regulations from 15 August to 22 October 2012[3]**.** As proposed in the consultation, the starting principle for

[1] http://www.monitor-nhsft.gov.uk/sites/default/files/publications/ToPublishLicenceDoc14February.pdf

[2] A service which commissioners have designated as in need of additional regulation to ensure patients' continued access will be known as a commissioner requested service (CRS) which will be subject to additional continuity of services licence conditions on the provider of that service

[3] https://www.gov.uk/government/publications/new-licensing-regime-for-providers-of-nhs-services-response-to-consultation--2

licence exemptions is that sector regulation should establish equivalent safeguards to protect patients' interests, irrespective of who provides those services.

6. The licence will impose requirements on providers of NHS services. Exemptions from the licence mean providers will not have to comply with requirements imposed through the licence. However depending on the type of provider, some of those requirements may not be applicable, or there may be similar requirements elsewhere through statutory or other means. We have proposed a targeted approach to the requirement to hold a licence, and therefore our exemptions policy, based on the following criteria:

    - realise the benefits of sector regulation to protect the safety and quality of healthcare services, and deal with the problems of poor access to services, high and inconsistent prices, inadequate information and ineffective integration of services, to the detriment of patient care;
    - ensure consistency and transparency in applying the principle of the new sector regulation system fairly so that providers can be confident that they are being held to account equally, whether they are NHS bodies, private businesses, social enterprises, charities or any other kind of organisation;
    - prioritise providers, where this is appropriate, for example, to focus resources where they are most needed and will give the most benefit;
    - ensure there is alignment and fit in the ways in which various bodies carry out their roles and functions in the new system, so as to avoid duplication where there is oversight elsewhere in the system, and to avoid unintended gaps in regulation; and
    - make sure any new regulatory burdens are necessary and proportionate, particularly for small enterprises and providers that may be subject to other forms of regulation.

7. These objectives seek to maximise the benefit from regulation and minimise its costs, whilst ensuring fairness between bodies doing similar roles.

8. In developing licence exemptions our first consideration is reducing risk to patients' interests. Licence exemptions are therefore based on these two key requirements:

Commissioner requested services (CRS) status

- A provider of a service that a commissioner has designated as in need of additional regulation to ensure patients' continued access (known as CRS) through the process set out in guidance by Monitor[4] will not be eligible for an exemption. The rationale is that where commissioners have designated a service as a CRS, Monitor must be able to intervene in order to secure continuity of that service. This requirement overrides the exemptions for small and micro providers, providers of primary care, of NHS Continuing Healthcare or NHS funded nursing care, and providers not required to register with CQC.

Care Quality Commission (CQC) registration status

- Protecting patient safety is the paramount consideration when determining the scope of healthcare regulation. Therefore the Department has decided to prioritise resource by ensuring that any provider who is not required to be registered with the CQC in respect of the NHS funded services it provides will be exempt from the requirement to hold a licence (unless the provider is providing a CRS, in which case they will require a licence, as set out above).
- The scope of CQC registration includes all providers that employ doctors or nurses as well as providers of specific services, including diagnostic testing. Annex A lists services and professions that are not currently subject to CQC registration. The effect of this is that organisations that only provide some of these services and do not employ doctors and nurses may be exempt from the requirement to register with CQC. These organisations

[4] http://www.monitor-nhsft.gov.uk/home/news-events-publications/our-publications/browse-category/guidance-health-care-providers-and-co-19

would also be exempt from the requirement to hold a licence. This position will be kept under review, and in particular we will consider potential changes to the scope of CQC registration.

9. Having taken these two requirements as our starting point we considered the categories of provider that would be captured and assessed them against criteria to determine whether licensing would be appropriate or whether an exemption would be a better fit.

10. To inform this process we also considered how the licence conditions would apply to the categories of provider. The tables below consider the provider types against our criteria. Alignment of licence conditions against provider type is considered in the later sections of this document (sections a to e) and in the risks and assumptions section.

Table 1: Licensed providers

	Licensed providers	
Criteria	**Foundation Trusts**	**Independent sector providers earning excess of £10m from NHS non-primary services**
Realise the benefits of sector regulation	FTs deliver services that affect a large number of patients. Significant potential benefits of sector regulation.	Larger providers are assumed to have the potential to affect a sufficient number of patients for regulation to be beneficial.
Ensure consistency and transparency	All FTs licensed effective from April 2013	This option ensures providers understand clearly the threshold for not being considered a small or micro provider
Prioritise providers	FTs deliver services that affect a large number of patients and there is no equivalent regulatory oversight. Effective regulation focused on critical health care providers.	Large independent providers affect significant numbers of patients, and there is not sufficent regulatory oversight elsewhere in the system. Regulating these providers through the licensing regime is therefore a priority.
Alignment and fit	There is no risk of duplication, as no other body will perform equivalent regulation or oversight for FTs.	Licensing medium and large providers ensures fit with government policy on regulatory burdens on small firms and ensures appropriate additional oversight relative to extent of potential impact on patients
Necessary and proportionate regulation	FTs are financially large and clinically essential providers of care. The costs of regulation are not great enough to justify exemption.	Licensing sufficiently large providers will ensure that the regulatory burden is proportionate to the risk posed by the provider.

Table 2: Exempt providers

	Exempt from licence				
Criteria	**NHS trusts**	**Small and micro providers (independent sector providers earning less than £10m in NHS non-primary income)**	**Primary care providers (earning less than £10m from NHS non-primary medical services)**	**Non-CQC registered providers**	**Social care providers**
Realise the benefits of sector regulation	There would be no additional benefits from regulation by Monitor as the NHSTDA will ensure trusts are subject to appropriate requirements equivalent to licence conditions.	Benefits from the regulation of small and micro providers are likely to be small because these providers deliver a small proportion of NHS services. Benefits would be realised through regulating large providers, which have a more significant impact on healthcare delivery.	Little additional benefits would be realised as NHS England holds contracts with primary care providers and has statutory duties which will ensure oversight equivalent to requirements in the licence and appropriate for these providers	No risks were identified with exempting these providers therefore there would be no additional benefits from licensing them	Monitor has no role over social care. Where such a provider has less than £10m of NHS services the benefits of regulation are likely to be small
Ensure consistency and transparency	Exempting NHS trusts avoids duplication of regulatory oversight, and therefore provides clarity for providers that any enforcement action against them will be undertaken by the NHSTDA.	Ensures providers understand clearly the threshold for being considered a small or micro provider	Avoids duplication of regulatory oversight, and therefore ensures NHS England, Monitor and primary care providers clearly understand their separate roles in the system.	Clear to non-CQC providers that they do not require a Monitor licence	Exemption ensures that providers of these levels of NHS services not provided as an integral part of social care are treated the same as other providers of these levels of services
Prioritise providers	Exempting NHS trusts would ensure regulatory resources are prioritised on providers who lack equivalent regulatory oversight and therefore have the potential to pose risks to patients.	Exempting small and micro providers will ensure regulatory resources are focused where they are most needed.	Exempting primary care providers would ensure regulatory resources are prioritised on providers who lack equivalent regulatory oversight and therefore have the potential to pose risks to patients.	These providers are not considered risky enough to be regulated by CQC and therefore should be de-prioritised	Exempting providers of small and micro levels of NHS services will enable regulatory resource to be prioritised
Alignment and fit	Exempting NHS trusts would ensure fit with the new system. It would avoid duplication and regulatory burden on providers.	Exempting small and micro providers ensures fit with other government policy.	Exempting the relevant primary care providers would ensure fit with the new system. It would avoid duplication and unnecessary regulatory burden.	Exempting these providers ensures consistency with the approach to quality regulation by CQC	Social care is outside Monitor's remit. Exemption of this type ensures consistency with other providers of these levels of NHS services not provided as an integral part of social care
Necessary and proportionate regulation	The NHSTDA will provide the necessary oversight for NHS trusts. This will consist of requiring NHS trusts to comply with equivalent conditions to Monitor's licence (especially in light of aspirant FTs)	Most independent sector providers would be considered small or micro organisations. The exemption proposed will ensure that the regulatory burden is proportionate to the risk posed by the provider.	Many of the licence conditions are either not applicable to primary care providers (eg pricing, continuity of services, FT-specific conditions) or equivalent to oversight from NHS England (eg recording and provision of information, ensure choice is offered)	These providers are not considered risky enough to be regulated by CQC and therefore should be de-prioritised	Exemption ensures that providers with small or micro levels of NHS provision are not unduly burdened in line with Government policy

Preferred option

11. The Government's preferred option is as follows.

Definition of provider

12. The licence holder will be the legal entity responsible for delivering NHS services to patients – the body receiving NHS funding and providing care directly to patients. This approach mirrors that for CQC registration.

Licensing exemptions

- All NHS foundation trusts are required to be licensed. This has been in effect from April 2013;
- All providers of designated Commissioner Requested Services (CRS) required to be licensed from April 2014, even if they would otherwise qualify for an exemption;
- Any provider not required to register with the Care Quality Commission exempt from the requirement to hold a licence from Monitor, unless providing a designated CRS;
- NHS trusts exempt from the requirement to hold a licence, but subject to equivalent requirements on pricing (where appropriate), choice and competition and integrated care, as a result of NHS Trust Development Authority supervision and oversight;

- Independent and voluntary sector providers of NHS-funded acute and mental health inpatient services, and community health services, to be licensed from April 2014, but with an exemption from this requirement for small and micro providers, determined by reference to a *de minimis* threshold based on NHS turnover of less than £10million;
- Providers of primary medical services and primary dental services under contract to NHS England (under Parts 4 and 5 of the National Health Service Act 2006) to be exempt from the requirement to hold a licence, but subject to standards equivalent to those in licence conditions, overseen by NHS England;
- GPs/dentists providing other types of services under contracts with commissioners other than NHS England (eg minor surgery clinics, diagnostic testing services, etc) will be subject to licensing in respect of these services from April 2014, but eligible for the *de minimis* threshold exemption;
- Care homes receiving NHS funding for providing nursing care will be exempt. Providers of other NHS-funded healthcare services in addition to nursing care (NHS Continuing Healthcare) will be subject to licensing in relation to those other services from April 2014 but eligible for the *de minimis* exemption. These exemptions are time limited to April 2015, and will be reviewed before then.
- With the exception of NHS trusts, exemptions are conditional on providers complying with Monitor's power to request information[1]. Where an exempt provider fails to comply with such information requirements, the 2012 Act allows Monitor to take enforcement action. Where an exempt provider consistently failed to comply, Monitor would be able to advise Secretary of State that the exemption be revoked.

Do nothing option

13. The Health and Social Care Act 2012 states that all providers of NHS funded services must hold a licence in order to provide services (section 81), unless exempt under regulations (section 83). In the absence of regulations setting out exemptions from the requirement to hold a licence, all providers of NHS services would be required to hold a licence in order to continue providing NHS services.
14. In the absence of regulations to define who is considered a provider there would be confusion over who should hold a licence and the risk of an approach which is not consistent with CQC registration. This would result in a more confusing and burdensome process for providers and Monitor when applying for and issuing licences.

Cost-Benefit analysis: Methodology

Identification of costs and benefits

15. For the purposes of this impact assessment we are considering the costs and benefits of an exemption (rather than the costs and benefits of regulation), compared to the 'do nothing' option. This means that, for providers, the benefits of a licence exemption are the administrative and compliance savings from not having to meet the requirements of the licence. When considering these savings, we need to consider the other requirements or regulations that the provider is under. In a number of cases, providers are already under similar requirements and therefore the licence exemption saves on administration but not on compliance. (In such situations, the cost of the exemption would be low, which is why it has been considered appropriate, see below.)

16. Monitor would benefit from an exemption by not incurring the costs of issuing a licence and enforcing compliance with its conditions.

[1] Section 104 of the 2012 Act

17. If a provider is exempt and there is no existing regulatory oversight of the issues in Monitor's licence, the benefits that would have been derived from licensing that provider would be lost. Such costs would fall on patients and taxpayers [in the event of discontinuity of services or the provider acting inappropriately]. Table 3 and 4 below identify the costs and benefits of exemptions in principle across all providers. In assessing whether particular providers or provider types should be licensed, we will assess the scale of the costs and benefits outlined here with respect to that provider/provider type.

Table 3: The potential costs of an exemption

	Cost of an exemption (benefits foregone from a licence)
To the provider	None.
To Monitor	None, but may impede effectiveness of the system if providers were able to act contrary to the requirements of the licence.
To patients and the NHS	Limited protection against anti-competitive behaviour and lack of integrated care
	Reduced protection against abuse of the NHS pricing system
	No opportunity for proactive intervention by Monitor to support continuity of services.

18. These are potential costs for an exemption of a provider of any type. Actual costs of exemption for a provider will depend on:

- The extent to which the provider is already under similar requirements from Monitor or other bodies;
- The incentives and opportunities a provider has to take action that would contravene a licence; and
- The potential magnitude of any infringement.
- These are discussed in more detail for each specific exemption.

19. The potential benefits of an exemption are presented below.

Table 4: The benefits of an exemption:

	Benefits of an exemption (Costs of a licence)
To the provider	A reduction in regulatory burden. Benefits will be the costs saved in licence fee, administration burden (including labour cost and potential additional specialist resources), and any compliance costs if there is no existing regulatory oversight (including labour cost and potential additional specialist resources).
To Monitor	Reduced implementation costs, allows resources to be focused on significant providers where risk of harm is higher and benefits are greater.
To patients and the NHS	Providers are more efficient, as any administrative and compliance costs are saved, benefiting patients. (As these impacts will be examined as savings to providers, they will not be discussed again as patient benefits in this IA.)

Quantification of costs and benefits:

20. To support its consultation on the licence, Monitor undertook an impact assessment of the likely costs and benefits incurred as a result of licensing providers of NHS services [2]. At the same time, the Department consulted on which providers should be exempt from the requirement to hold a licence.

21. This impact assessment draws heavily on the estimates of costs and benefits that Monitor developed for its consultation impact assessment. It also uses information from responses to the Department's consultation and data from other publicly available sources.

22. Monitor considered its costs to providers in the categories set out below, which follow the structure of the licence. In considering the costs and benefits of an exemption, we have therefore considered whether a particular licence condition or set of conditions would have applied to a category of provider had it been licensed, and whether a condition or set of conditions will apply to a category of provider through existing regulatory oversight if it is not required to hold a licence. In the latter case, there would be an administrative cost saving but not a compliance cost saving.

23. Where a condition would have applied through the licence *and* is not applied through existing regulatory oversight, an exemption would create savings for providers in terms of both administrative and compliance costs.

Table 5: Quantified costs from Monitor's consultation IA

Category	Quantified cost
General	Fit and proper persons Systems in place to ensure compliance
Pricing conditions	Recording information Publication of information (recurring costs; unknown frequency) Assuring information (recurring costs; frequency unknown) Engagement concerning local tariff modifications (recurring costs; frequency unknown)
Competition conditions	Not quantified
Integration conditions	Broadly defined prohibition – ensuring providers do not do anything that could reasonably be regarded as detrimental to enabling integrated care (recurring costs; unknown frequency)
Continuity of service (CoS) conditions	Application of CoS conditions - sets out how services may be designated as Commissioner Requested Services. If a licensee provides Commissioner Requested Services, the Continuity of Services Conditions apply Continuing provision of CRS (recurring costs; unknown frequency). Restrictions on assets Undertaking from controller Risk pool levy (recurring costs; unknown frequency and quantum) Availability of resources (recurring costs; unknown frequency)
Conditions on foundation	Not quantified

[2] http://www.monitor.gov.uk/sites/default/files/Final%20report%20IA.pdf

trusts	

Unquantified costs

24. The costs and corresponding savings included in this impact assessment as mentioned above are taken from Monitor's provider licence impact assessment. Whilst their assessment quantifies certain costs, there are also a large number of costs that are not quantified. In this assessment, there are two sets of unquantified costs:

    - Costs that are not quantified in Monitor's impact assessment; and
    - Recurring costs that were included in Monitor's assessment but, for the cost categories of relevance to exemptions, were more speculative in nature and dependent on certain assumptions. We felt it appropriate not to include them in our assessment. Only the one-off costs have been included.

25. The fact that there are unquantified costs should be taken into consideration when assessing the final costs included here. The major costs that fall under ii) above are summarised as follows:

Costs incurred by providers

26. Licence conditions that do not require explicit actions but allow Monitor to address undesirable actions are not quantified. This is because there is no data available concerning how likely a provider is to behave in a particular way and the magnitude of the impact if they did (which will depend entirely on the circumstances). These include the 'Choice and Competition' condition one-off costs.

27. The recurring costs attributable to the conditions that require providers to provide information to Monitor, such as pricing data are also not included. Since Monitor has been given the power in the 2012 Act to request information from licensed or exempt providers, the savings estimated in this assessment from an exemption are not affected by the exclusion of these recurring costs.

Costs incurred by Monitor

28. One-off costs faced by Monitor were not calculated in its impact assessment. Whilst recurring costs were included, these were rougher estimates and were not linked to the application of certain licence conditions. It is therefore difficult to tell whether such costs would be saved by not having to licence a certain provider type.

Costs incurred within the overall system

29. Where there are providers that must hold a Monitor licence and are also subject to oversight from another organisation, there are administrative costs associated with over-regulation. These would include duplication of work and any frictions caused by the two regulatory bodies disagreeing with one another. An exemption in this instance would therefore reflect savings to the whole system. These costs, and their corresponding savings, are unquantified but worth mentioning here.

FINAL POSITION: EXEMPTIONS BY PROVIDER TYPE.

30. The regulations grant exemptions to the need to hold a licence to the following groups of provider. We present the costs and benefits of this exemption using the framework set out in tables 3 and 4 above.

    a) NHS trusts

    b) Small and micro providers of NHS services

    c) Primary medical and dental service providers

    d) Providers of healthcare and adult social care

    e) Providers not CQC registered

a) NHS trusts

31. At July 2013, there are 100 NHS trusts[3].

32. We assessed that NHS trusts will not incur significant savings by not being subject to Monitor's licence. This is because many of Monitor's licence conditions would not have applied to NHS trusts and because the NHS Trust Development Authority (NHSTDA) will place similar requirements on NHS trusts to those that Monitor would have placed via its licence.

33. Therefore NHS trusts will be exempt from the requirement to hold a licence from Monitor.

Exemption savings and costs

34. The NHSTDA will be providing equivalent oversight to Monitor's licence to NHS trusts, and therefore it is unlikely that there will be any costs to patients associated with this exemption.

35. NHS trusts, which are all moving towards becoming FTs, are overseen and supported by the NHSTDA. The NHSTDA will operate a bespoke oversight and escalation regime, on behalf of the Secretary of State. The existence of the Unsustainable Provider Regime would make it inappropriate to apply licence conditions relating to continuity of services to NHS trusts because this would make them subject to two sets of processes governing the same issues. The NHSTDA will also oversee all other aspects of governance and performance in relation to NHS trusts.

36. The regulations therefore exempt NHS trusts from the requirement to hold a licence from Monitor, on the basis that the NHSTDA would operate a regime that would set similar requirements for NHS trusts to those contained in Monitor's licence. Agreements between the DH and Monitor and the NHSTDA respectively, and a memorandum of understanding between Monitor and the NHSTDA, will underpin these arrangements. Directions from the Secretary of State[4] to the NHSTDA require NHS trusts to comply, as appropriate, with equivalent conditions to those set by Monitor. With the NHSTDA ensuring NHS trusts comply with equivalent requirements, the exemption gives these providers a small saving in terms of administration costs (but this cannot be quantified).

37. Monitor may make some savings from not licensing NHS trusts but, as it will still have a role assisting the NHSTDA on matters such as competition investigations and in relation to its statutory powers, it is not possible to quantify this.

[3] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/194002/9421-2900878-TSO-NHS_Guide_to_Healthcare_WEB.PDF

[4] https://www.gov.uk/government/publications/nhs-trust-development-authority-directions-2013

b) Small and micro providers with an NHS turnover of less than £10m per year

38. The regulations exempt providers with annual NHS turnover of less than £10m. In terms of secondary care providers, this exemption mainly captures independent providers (i.e. private and voluntary sector) of acute, mental health and community healthcare services to the NHS. (Foundation trusts all have turnover well in excess of this amount and NHS trusts are exempt as per section a) above.)

39. It is established Government policy to protect small and micro-businesses from additional regulatory burdens. The Department therefore considered and consulted upon an exemption for such business. The analysis below shows that an exemption would reduce regulatory burdens whilst only introducing small risks, compared to licensing all providers.

40. We took the EU definition of small and micro businesses as our starting point and consulted on whether a threshold should consider both staff and turnover, or turnover.

Table 5: EU definition of small and micro businesses

Micro	Small	Medium
< 10 employees	< 50 employees	< 250 employees
≤ €2m turnover	≤ €10m turnover	≤ €50m turnover
≤ €2m balance sheet	≤ €10m turnover	≤ €43m turnover

41. Feedback from the consultation made it clear that including a staffing element to the threshold would risk not exempting some small or micro providers as staffing ratios are higher in healthcare than in most sectors and would be significantly below the turnover threshold. We therefore discarded the staff element of the threshold and will use a threshold of £10m NHS turnover as the most appropriate way to exempt small or micro providers of NHS services.

Exemption savings and costs

42. Based on an estimated 243 small and micro independent providers, we estimated how much in one-off costs these providers will save in total by not being subject to Monitor's licence. These figures apply the high to low estimated unit costs to the 243 average number of providers. This can be seen in table 6 below[5].

Table 6: Summary of costs saved by small and micro providers from licence exemption

Licence exemption one-off costs saved			
	High estimate	Med estimate	Low estimate
Small and micro providers	£3,287,790	£2,327,940	£1,368,090

43. In arriving at 243 providers we have made certain assumptions based on the data available.

44. Independent acute - HES online data for 2011-12 identifies around 200 independently owned sites providing NHS services[6]. Using Care Quality Commission data on site ownership we estimate that there are between 31 and 41 independent providers of acute services to the NHS.

[5] Expected medium one-off unit cost of condition requiring systems for compliance (£8,950) + expected medium one-off unit cost of fit and proper persons test (£630) = £9,580.
Estimated average number of exempt small and micro providers of NHS services = 242.
Expected medium one-off cost total saving = £9,580 x 242 = £2.3m
The '*Risks and assumptions*' section sets out more detail on the assumptions behind these costs.

[6] http://www.hscic.gov.uk/searchcatalogue?productid=9161&q=title%3a%22hospital+episode+statistics%22&sort=Relevance&size=10&page=1#top

Again, using HES, at least 12 of these account for fewer than 1000 treatment episodes each and so are likely to have an NHS turnover of less than £10 million. In addition, 7 of the 10 independent providers whose ownership couldn't be matched, undertake fewer than 1000 treatment episodes and so, if these are independent, they would be *de minimis*. We have used an estimate of between 12 and 22 exempt providers (average of 17).

45. Independent mental health – Laing's Healthcare Market Review, 2011-12 indicates that independent mental health hospitals earned £974m from NHS (and local authorities and government agencies) in 2010[7]. The smallest of the top 8 providers accounted for 2.3% of the market (private and publicly financed), which equates to £22.4m[8]. Therefore the top 8 will definitely require a licence. Outside the top 8 providers, and accounting for 22.3% (£217m) of the market are a further 148 hospitals. If these providers are distinct legal entities, they would each be earning income less than £10m. If the hospitals made up fewer than 148 legal entities, however, there may be providers that do earn over £10m. We have used an estimate of between 0 and 148 exempt providers (average of 74).

46. Independent community – The data in this area is even more limited. Just over £10bn is spent annually on community health care. Of this, 10% (£1bn) is provided by social enterprise - 44 social enterprises were spun out of PCTs. 20% (£2bn) by a small number of independent providers (eg. Care UK, Virgin Care, City Healthcare Partnership and Your Healthcare) and the remaining £7bn by NHS providers. It is therefore possible that all 44 social enterprises have a turnover of £10m and at least some must be of this size. It also seems reasonable that there would be a maximum of ten private providers requiring a licence (though some, such as Care UK, will have been counted under acute provision). However, there may be a number of small private providers which no data in available on. For the calculation we have used an estimate of 0 to 60 exempt providers (average of 30).

47. Independent ambulance – Data from CQC indicates that the total number of independent ambulances is approximately 244. We do not currently know how many of these would fall under the *de minimis* threshold. We have, therefore, used a range of 0-244 exempt providers (average of 122).

48. There will also be some savings to Monitor from not licensing these providers. It has not been possible to quantify these savings.

49. There are risks associated with exempting small and micro providers. By exempting small and micro providers, we create a risk that behaviour that is anti-competitive or prevents integration will not be addressed directly through the licence. However, anti-competitive behaviour by independent small and micro providers could be investigated under Monitor's concurrent competition powers. We do not think, therefore, that this presents a significant risk.

50. A potential risk is the abuse of a dominant position by a provider. It is unlikely, however, that a provider falling under the *de minimis* exemption will be large enough to hold a dominant position. Commissioners hold strong buyer power and are well placed to commission from other providers should they feel existing small providers are not acting in patients' interests. Low barriers to entry also help to prevent providers from abusing any market dominance they may have. But as these providers are small, any provider acting in detrimental ways is less likely to significantly affect patients.

51. Without the licence condition on integrated care, Monitor's duty under the 2012 Act to enable integrated care where this improves quality or efficiency, or reduces inequality would still remain. Monitor's powers in areas such as pricing and competition would act as its main tools for enabling integrated care.

52. Granted an exemption, small and micro providers would not need to meet the requirement set out in the licence for directors, governors or equivalent to be fit and proper persons. However, private small and micro providers are already precluded from appointing unfit directors under the Company Directors Disqualification Act 1986, and the Charities Act 1993 and Finance Act 2010 place some requirements on third sector providers.

[7] Table 5.3

[8] Table 5.5

53. Small providers will also not have to meet licence requirements to support choice. There may be a risk that patients of these providers are not made aware of the choices available, though public information is also available to support patients. There could also be a risk that these providers do not provide information about their own organisation to inform choice. However, in so far as they collaborate and compete with other organisations, they are likely to provide this information anyway.

c) Primary medical and dental services

54. All providers of NHS-funded primary medical and dental services[9] 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. 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.

55. Where these providers also provide other NHS funded services, they will be in scope of the licence in respect of those other services but eligible for the *de minimis* exemption where income from NHS services excluding primary medical and dental services is less than £10m per year.

56. For 2013/14, NHS England has delegated commissioning of certain local enhanced services to CCGS (as set out in guidance[10] from NHS England). Such arrangements would mean these services are exempt. However where CCGs, under their own commissioning powers, commission services from GP practices (which may be analogous to local enhanced services previously commissioned by primary care trusts), these services would not fall within this exemption. Depending on levels of NHS turnover, such services may qualify for the *de minimis* exemption.

57. Given the anticipated benefits and risks set out below, the case for exempting primary care providers is stronger than for licensing. While exempting these providers from the requirement to hold a licence means they are not subject to the licence conditions, there is oversight elsewhere in the system which will mitigate risk associated with this exemption to patients' interests. This oversight will in particular be provided by NHS England. NHS England is responsible for commissioning primary medical services and primary dental services, holds the contracts with providers of these services, and is therefore well placed to enforce standards equivalent to Monitor's standard licence conditions that are relevant to primary care providers. Further detail on oversight of and applicability of licence conditions to primary care providers is presented in the text below and towards the end of this IA under 'Risks and assumptions'. Furthermore, NHS England itself is under obligations to protect patient choice, avoid anti-competitive conduct and enable integration.

Exemption savings and costs

58. The main savings from not licensing these providers will be through reduced burdens. However, it should be noted when considering these "savings" that, although primary care is within the scope of the 2012 Act, costs of the magnitude being saved here were not anticipated in the impact assessment associated with the 2012 Act and therefore cannot be considered as savings relative to the position set out in it.

59. Using CQC data we have 7,633 as the total number of primary medical service providers and 8,039 as the total number of primary dental service providers. From these numbers, we estimated how much in one-off costs these providers will save by not being subject to Monitor's licence for between 7,583 and 7,633 primary medical providers[11] (average of 7,608) and 8,034

[9] Contracts held with NHS England under Part 4 or Part 5 of the 2006 Act

[10] http://www.england.nhs.uk/wp-content/uploads/2013/04/pri-med-care-ccg.pdf

[11] . It is understood that there are very few entirely private primary medical providers but exact information could not be obtained. The range of 0 to 50 over £10m is a rough estimate, based on Figure 1 of GPs per practice and registered patients. This shows that 31 practices have more than 15 GPs so might have significant non PMS/GMS NHS turnover.

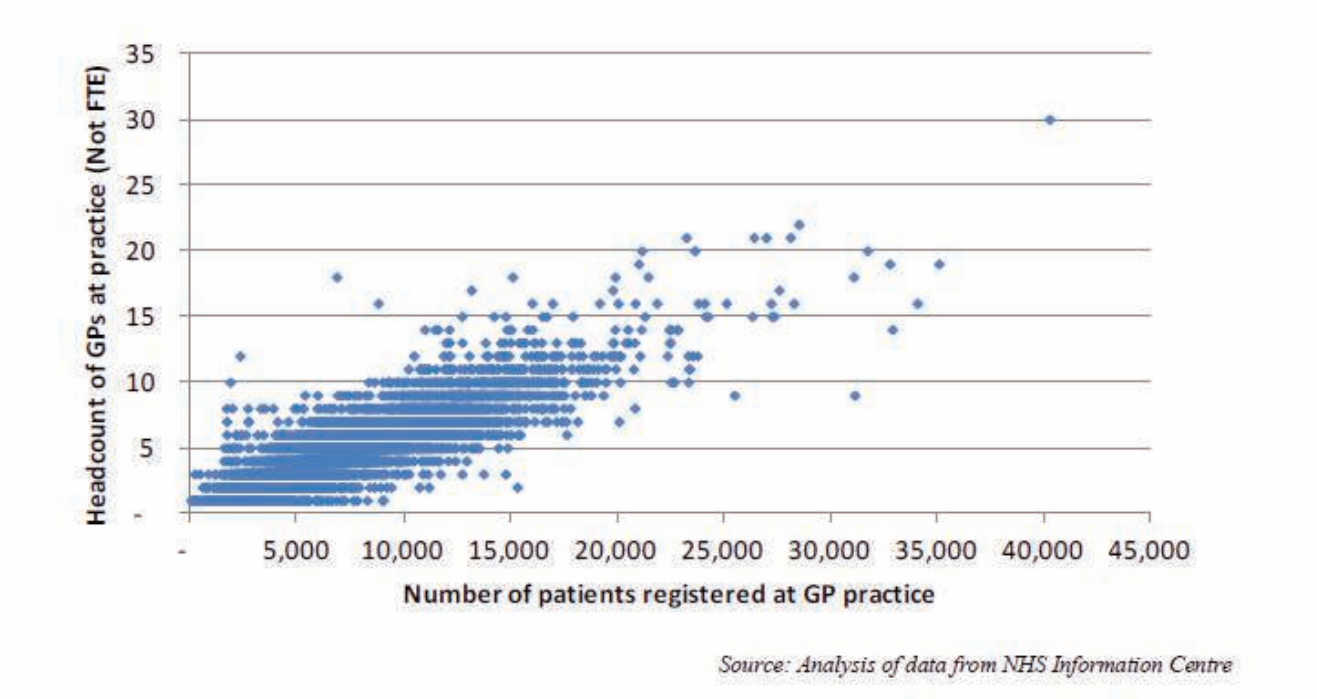
and 8,039 primary dental providers[12] (average of 8,037). The estimated quantifiable savings can be seen in the table below[13].

Table 7: Summary of costs saved by primary care providers from licence exemption

Licence exemption one-off costs saved			
	High estimate	Med estimate	Low estimate
Primary care	£211,670,085	£149,874,310	£88,078,535

60. Figure 1 below shows that the number of GPs per practice varies between one and thirty, and that the majority of practices have fewer than 15 practitioners. The average number of GPs per practice is 3 and the mode (most common) number of GPs per practice is two.

Figure 1: Distribution of number of GPs per practice by number of registered patients



61. Regarding the costs of an exemption, only some of the licence conditions are applicable to providers of primary care services. These are namely:

- Fit and proper persons test (general condition)
- Setting up compliance systems (general condition)
- Choice and competition conditions
- Integration condition

Fit and proper persons test

[12] It is understood that there are very few entirely private dental providers but exact information could not be obtained. DH officials advise, however, that there are only five large dental providers who could have a turnover greater than £10m.

[13] Expected medium one-off unit cost of condition requiring systems for compliance (£8,950) + expected medium one-off cost of fit and proper persons test (£630) = £9,580
Estimated average number of exempt primary care providers = 15,645
Expected medium one-off cost total saving = £9,580 x 15,645 = £150m
The '*Risks and assumption*' section sets out more detail on the assumptions behind these costs.

62. The test in the licence defines unfit persons as undischarged bankrupts, individuals who have served a prison sentence of three months or longer during the previous five years, and disqualified directors[14]. By virtue of being exempt, primary care providers would not have to meet the fit and proper persons test set by Monitor in the licence. However primary care enterprises are already precluded from appointing unfit directors under the Company Directors Disqualification Act 1986 – a requirement which is replicated in the licence. In the future, all providers may have to ensure that they undergo a fit and proper persons test in light of Government's response to the "Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry". Proposals are currently being reviewed by Monitor, the Care Quality Commission and the NHSTDA.

Compliance

63. Compliance systems in themselves do not create a benefit to patients, only in so far as they prevent a breach. Without such a system a primary care provider may have less awareness of their impact and, potentially, less information to support management.

Choice and competition

64. Exempting primary care providers from having to comply with the choice and competition licence conditions poses a limited risk to patients.

Choice

65. Choice is seen as an important tool in achieving efficiency and quality in services. Choice in the primary care market is centred on choice of GP and choice of secondary care provider at referral. Requirements around choice and competition both work together to provide a restraint against behaviour by providers or commissioners that is not in the best interests of patients.

66. The NHS Constitution sets out the current rights of patients to choice. Primary care providers must comply with the requirements as set out in the NHS Constitution. These rights include:

    - right to choice of GP practice, and to be accepted by that practice unless there are reasonable grounds to refuse
    - the right to express a preference for using a particular doctor within the GP practice and for the practice to try to comply
    - the right to make choices about the services commissioned by NHS bodies and to have information to support these choice
    - the right to choose the organisation that provides their NHS care when referred for the first outpatient appointment with a service led by a consultant (subject to certain exceptions)

67. Where choice is not being sufficiently offered, patients can report their concerns to their local Clinical Commissioning Group. CCGs will consider complaints about choice of secondary care services and must publish their complaints procedure. If they agree with the complaint, the Clinical Commissioning Group must make sure that the patient is offered a choice for that health service. NHS England is responsible for holding CCGs to account for fulfilling their statutory functions.

68. In certain circumstances, NHS England is the authority responsible for enabling choice. NHS England will consider complaints about not being offered a choice of GP practice, or choice of GP, or about health research.

69. In addition, the Procurement, Patient Choice and Competition Regulations give Monitor the power to take enforcement action to prevent and/or remedy breaches by commissioners of certain requirements relating to patient choice in the Responsibilities and Standing Rules Regulations.

Competition

[14] A person with an unexpired disqualification order under the Company Directors Disqualification Act 1986

70. There could be a risk of anti-competitive behaviour through collusion or abusing their position. Since no cases were made against primary care providers under the Principles and Rules for Co-operation and Competition, there is currently a lack of evidence to suggest that anti-competitive practice may be a significant problem with respect to primary care. Should there be an instance of anti-competitive behaviour within the primary care market, Monitor can exercise its concurrent power to enforce provisions of the Competition Act 1998.

71. Allowing new entry into the market and enabling patient choice also acts as a constraint to any collusive behaviour amongst providers. Following the Fair Playing Field review[15] Monitor has issued a call for evidence to help determine the extent to which the commissioning and provision of general practice and associated services is operating in the best interests of patients. This may have implications for Monitor's provider licence in the future.

72. The scope of any anti-competitive agreements between primary care providers and non-primary care providers is further limited by the licence. If the non-primary care provider engaged in this agreement were to be licensed, they would be in breach of Monitor's competition licence condition. The risk to patients would, therefore, be confined to the providers that are exempt under the *de minimis* threshold.

Integration

73. There is a risk that an exempt provider would act in a way that is against integration in patients' interests. However, NHS England could act if this was harming patients, as NHS England commissions primary care providers and has a duty to enable integration where this is in patients' interests.

74. Given the potential risks in issuing exemptions from the requirement to hold a licence, the Government has committed to reviewing licensing in 2016/17.

d) Providers of health care and adult social care

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

76. As at 2012, the CQC registered 12,461 social care providers in England.

77. In considering whether providers of both adult social care and NHS-funded healthcare should be required to hold a licence in respect of healthcare services, a key issue for the Department has been that a significant number of these types of providers are small or micro-businesses. Thus it seems likely that the majority would be exempt under the *de minimis* exemption in section b), although it is impossible to predict accurately how many that would cover in practice.

78. In the absence of this information, the Department sought feedback as to the likely impact on this group of providers of the proposals for *de minimis* exemptions. As part of our consultation on proposals for exemptions, we also discussed an alternative option of defining an exemption for providers that generate at least 50% of their income from adult social care activities. However at the time of the consultation, the question of which regulator should have oversight of the adult social care market had not been resolved and following the consultation we discarded this option.

79. It is clear that adopting a *de minimis* licensing exemption approach from April 2014 would risk pre-empting the implementation, subject to parliamentary approval of the Care Bill, of CQC's financial oversight regime for providers of adult social care. As we know some providers of adult social care also provide NHS funded services, there is a risk that this could lead to duplication

[15] http://www.monitor-nhsft.gov.uk/fpfr

and unnecessary additional burdens being placed on some providers of both adult social care and NHS funded healthcare, without clear benefits and protections for people receiving nursing care.

80. The Department published its response to the consultation on adult social care market oversight in May 2013 setting out our proposal to give CQC this responsibility. Given the role that CQC will have over providers of adult social care, the case for licensing these providers is currently unclear. In view of this, the regulations exempt providers of NHS continuing healthcare (CHC) and/or NHS-funded nursing care (FNC) as an integral part of a social care package. Providers of both adult social care and NHS funded healthcare will be licensed in respect of their NHS services only (apart from CHC or FNC). However they will be eligible for the *de minimis* exemption if income from these services is less than £10 million threshold. The regulations exclude income from CHC or FNC from the calculation of a provider's income for the purposes of the threshold. So, for example, a provider which has a total of £12 million NHS income per year, of which £2.5 million comes from CHC and FNC payments will be exempt from the requirement to hold a licence until at least April 2015, because disregarding the CHC and FNC payments will take the provider's NHS income from other sources below the £10 million *de minimis* threshold. If, however, only £1.5 million comes from CHC and FNC payments, and the remaining £10.5 million is from other sources, the provider would require a licence from April 2014 (unless the other NHS services provided attract an exemption in their own right, eg primary medical services).

81. This exemption for CHC and FNC will be time limited to April 2015 in the regulations and prior to the expiry date will be subject to a full review in the context of CQC's new role on adult social care market oversight. The exemption could then be retained, removed or amended to align with the market oversight decision.

e) Providers not CQC registered

82. There are a range of services and professions that are not registered by the CQC, essentially because they are pose a low risk to patients, because they are regulated by other bodies or because regulation would have a limited effect on their quality. These include:

- **primary ophthalmic services** (eg high street optometrists);
- **primary pharmaceutical services** (eg high street pharmacies);
- activity carried on **unpaid by a personal friend or family member** living in the same household;
- activity carried on by an establishment or agency required to be **registered and regulated by Ofsted** (eg children's homes);
- **provision of first aid**, even if by a health care professional who would otherwise be subject to CQC registration;
- medical and dental services provided by **the Armed Services**;
- **School nurses**, where they are directly employed and directed by the school; and
- Most of the **allied professionals** where they are not working within registered organisations.

83. The cost of excluding these providers from licensing is low as the only conditions in the licence which would introduce additional requirements are the general and integration conditions[16]. Responses to the consultation did not identify any risks associated with not including them in licensing. The benefit of excluding them is unknown but potentially very high, just in terms of avoiding administrative burdens, as there may be a large number of such providers. Because these providers are not CQC registered, we have do not have information about how many there are.

[16] PbR does not apply in these services and so data collection is not required. Such providers would not be providing CRS. The Competition Act would apply where there was risk of anti-competitive behaviour.

Risks and assumptions

84. There are some risks with this IA that mean that costs and benefits may differ from those set out here, though we have done our best to mitigate these through the use of ranges in the document:

- The exact numbers of providers affected are unknown within some groups. The Department has used a variety of sources, including responses to our consultation, to improve our estimates but these remain rough estimates in many places.
- For one-off costs of a licence, we have used the consultation level impact assessment prepared by Monitor to accompany its consultation on its licence. We have then adjusted these to take into account the final version of the licence. We have not included recurring costs in our assessment as the relevant ones appeared too speculative.
- Micro businesses may lose their exemption from the requirement to hold a licence if commissioners determine they provide commissioner requested services.
- The Secretary of State has the power to withdraw exemptions from a provider or from any type of provider, or providers of any type of services at any time.
- The following assumptions have been made in this impact assessment:

NHS trusts

85. In calculating the savings incurred by NHS trusts from being exempt, we have assumed the following major conditions will not contribute to any savings:

- The **general conditions** are not included as a saving. Many of the conditions will be replicated by the NHSTDA.
- All **pricing** conditions. As described in the NHSTDA Accountability Framework, NHS trusts will be required to comply with equivalent requirements overseen and enforced by the NHSTDA.
- The **Choice and Competition** and **Integrated Care** conditions will be replicated through the NHSTDA oversight model.
- The **Continuity of Services** conditions are not included as a saving since NHS trusts are subject to a separate performance management regime and the Unsustainable Provider Regime, overseen by NHSTDA and SoS.

Primary care providers

86. In calculating the savings incurred by primary care providers from being exempt, we have assumed the following major conditions will not contribute to any savings:

- Conditions related to the provision of information, whether it is general or pricing. Currently, contractors provide information to NHS England where it is required for the purposes of, or in connection with, the contract. In addition, Monitor has the power to request information from any provider when it relates to their functions, regardless of the provider holding a licence or not.
- **All pricing conditions**. Primary care services are not funded on tariff prices and so even if licensed, the compliance and information requirements would not apply.
- **Continuity of services** conditions. It is unlikely that these primary care providers will be delivering commissioner requested services, and therefore these conditions would not have placed extra burdens even if they were licensed.

Small and micro providers

87. In calculating the savings incurred by small and micro providers from being exempt, we have assumed the following major conditions will not contribute to any savings:

- **All pricing conditions.** All providers, regardless of licensed or exempt status, will be expected to provide tariff pricing information to Monitor when requested to get a reflective picture of costs in the sector. Monitor has been given this power under the 2012 Act.
- **Continuity of services conditions.** Since it is unlikely that exempt small and micro providers will deliver commissioner requested services, these conditions would not have placed extra burdens on this type of provider even if they were licensed.

Assumptions in calculation of quantified costs[17]

Condition G4: Fit and proper persons

- Unit cost of re-written contract = 35 hours of managers' time
- No high, medium or low estimate distinguished
- Unit cost = £630 per contract

Condition G6: Systems for compliance with licence conditions and related obligations

- Time needed to understand requirements of all licence conditions and related guidance = 4 to 8 person weeks of a manager's time per licensee (or 140-280 hours)
- Unit cost = £2,300-£4,700 per licensee (low to high estimate)
- Cost of implementing new systems. Including covering the need to set up management information systems and reporting lines, establishing terms of reference and other one-off costs. These were estimated by providers at between 140 and 420 person hours or approximately 1 to 3 months.
- Unit cost = £2,700-£8,200 per licensee (low to high estimate)
- Total unit cost = £5,000-£12,900

Review and evaluation

88. The Government remains fully committed to carrying out a full review of licensing. The objective of the review would be to establish whether licensing was achieving the intended objectives in the light of operational experience. Given this impact assessment has set out the assessment of risk in providing exemptions from the requirement to hold a licence, the review will include the exemptions regime.

89. In particular when looking at exemptions we will consider changes to the scope of CQC registration, changes in the NHS market. We will also consider existing sources of evidence such as complaints and whether and how information should be collected to inform any decision about exemptions as part of the review. The recommendation in Monitor's review of the fair playing field for Monitor to issue a call for evidence about the commissioning of general practice and associated services may also be able to inform our review.

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

[17] Source: Monitor's impact assessment of the licence conditions: http://www.monitor.gov.uk/sites/default/files/Final%20report%20IA.pdf

Wider impact assessments

Competition and small firms

91. These regulations exempt some providers of healthcare services to the NHS from the need to be licensed by Monitor. We consider several possible competition impacts but find that the risk of these is low:

    - Creation of barriers to entry – Exempt providers do not require a licence to deliver NHS services. These regulations therefore do not prevent small providers from contracting for NHS services alongside licensed providers.
    - Conferring an advantage on certain bodies – as a result of these exemptions, some providers will not need to comply with the requirements of the licence. The discussion in the main text of this document shows that this may give these providers a small saving in terms of reduced administrative burden and, in some cases, fewer behavioural obligations. However, this effect is small and, where some obligations have been removed, providers may choose to comply with them anyway as part of demonstrating the good quality of their offer to commissioners (for example, they may take positive steps to integrate their services with those of others in patients' interests).
    - Restricting bodies' ability or incentive to compete – these exemptions do not change providers' ability to compete, relative to the current level of competition. They do not place any new restrictions on price, quality or service. They do not alter providers' incentives to compete for patients or contracts in the areas in which commissioners are using competitive processes to commission services.
    - These regulations exempt those that provide less than £10m pa of services to the NHS. Thus all small providers are exempt. We expect that this will create some savings for them but will not impose any other costs.

92.

Health impact

93. The following table provides an assessment on the health impact of these regulations.

Table 8: health impact assessment

Will the proposal have a direct impact on health, mental health and wellbeing? For example would it cause ill health, affecting social inclusion, independence and participation? You should consider whether any socioeconomic or equalities groups* will be particularly affected.	There would be a positive impact. The regulations set out exemptions from a licensing regime that would be disproportionate for some providers. The regulations therefore ensure there are no unnecessary regulatory burdens, creating savings which providers can spend on healthcare services.
Will the policy have an impact on social, economic and environmental living conditions that would indirectly affect health? For example would it affect housing, transport, child development, education, good employment opportunities, green space or climate change? You should consider whether any socioeconomic or equalities groups* will be particularly affected.	No.
Will the proposal affect an individual's ability to improve their own health and wellbeing? For example will it affect their ability to be physically active, choose healthy food, reduce drinking and smoking? You should consider whether any socioeconomic or equalities groups* will be particularly affected.	No. The exemptions proposals will ensure proportionate and targeted regulation, and would not affect patients directly.
Will there be a change in demand for or access to health and social care services? For example: Primary Care, Hospital Care, Community Services, Mental Health and Social Services? You should consider whether any socioeconomic or equalities groups* will be particularly affected.	No – the policy will not change demand for access to services.
Will the proposal have an impact on global health?	No.

***Equalities groups such as race, gender, health, disability, sexual orientation, age, religion or belief.**

Environmental impact

94. We do not consider that this policy has any direct adverse environmental effects.

Rural impact

95. Providers of services in these types of areas may be less likely to benefit from an applicable exemption as a result of the provisions around commissioner requested services. This is because commissioners in rural areas may designate a greater number of services to be additionally licensed under the continuity of service conditions as there are likely to be fewer alternative providers. However, protecting patients' interests should take priority and the benefit of additional regulation to secure continuity of services would outweigh the costs of any additional burden.

96.

ANNEX A: Services and professions not subject to CQC registration

Services

- **primary ophthalmic services** (eg high street optometrists);
- **primary pharmaceutical services** (eg high street pharmacies);
- activity carried on **unpaid by a personal friend or family member** living in the same household;
- activity carried on by an establishment or agency required to be **registered and regulated by Ofsted** (eg children's homes);
- **provision of first aid**, even if by a health care professional who would otherwise be subject to CQC registration;
- medical and dental services provided by **the Armed Services**;
- **School nurses**, where they are directly employed and directed by the school.

Professions

- Arts therapists
- some chiropodists and podiatrists
- Chiropractors
- Dietitians
- Occupational therapists
- Orthoptists;
- Osteopaths;
- Physiotherapists;
- Prosthetists and Orthotists;
- Psychotherapists and Counsellors
- Speech and language therapists