

# HEALTH AND SOCIAL CARE ACT 2012

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## EXPLANATORY NOTES

### COMMENTARY ON SECTIONS

#### **Part 3 - Regulation of Health and Adult Social Care Services**

##### *Chapter 3 – Licensing*

742. This Chapter establishes a licensing regime for providers of health care services for the purposes of the NHS and provide Monitor with the necessary powers to run the regime. The regime gives Monitor the means to perform its main duty and carry out its functions; for example, it will provide a means for Monitor to collect information needed to set prices.
743. The Act gives Monitor powers to determine the licence criteria and conditions and gives it enforcement powers that enable it to ensure that providers comply with the requirements of their licences.
744. The Care Quality Commission currently registers providers of health and adult social care services to provide assurance that they meet essential levels of quality and safety. It will continue to exercise this role.
745. Monitor and the Care Quality Commission are required to co-operate and share information and they are required to establish a joint licensing/registration process.

#### **Licensing requirement**

##### *Section 81 - Requirement for health service providers to be licensed*

746. *Subsection (1)* stipulates that providers of health care services for the purposes of the NHS must hold a licence issued by Monitor. This does not include services provided for the purposes of the public health service.
747. *Subsection (2)* covers situations in which two or more legal persons are involved, in different capacities, in providing a service (eg. a prime contractor and subcontractor). It provides that, in this situation, regulations may set out who will be treated as the service provider for the purposes of the licensing regime. It is intended that this will be the person responsible for ensuring the service complies with the licensing requirements laid out in this (and any other relevant) legislation (eg. the prime contractor). This provision is based on section 10(2) of the Health and Social Care Act 2008, where the same provision is made for the purposes of registration with the Care Quality Commission.

##### *Section 82 - Deemed breach of requirement to be licensed*

748. This section provides that a licence holder is deemed to be in breach of the requirement to hold a licence if the organisation is required to register with the Care Quality Commission, but has not done so. The intention is that only providers who have

complied with a requirement to register with the Care Quality Commission should be able to hold a licence.

### ***Section 83 - Exemption regulations***

749. This section provides the power for the Secretary of State to make regulations exempting providers of NHS services from the requirement to hold a licence. The regulations would be subject to the negative resolution procedure in both Houses of Parliament.
750. Individuals, groups of providers, or providers of certain types of health care services could be exempted. Exemptions could be time-limited, and/or conditional. *Subsection (3)* gives examples of the sorts of conditions that could attach to an exemption. For example, a person granted an exemption may be required to comply with any direction given by Monitor about a matter specified in the exemption.
751. The intention is that exemptions will be used to focus licensing on appropriate parts of the health care sector - those where regulation of competition and pricing, or action to support continuity of services is most likely to have a strong positive impact. It is, for example, likely that the licensing regime would cover providers of accident and emergency services and secure mental health services. Exemptions might apply to, for example, smaller providers of family health services such as dentists, optometrists or primary medical care practices.
752. *Subsections (4) to (7)* provide for publication of the Secretary of State's intention to make exemption regulations and for representations to be made. The Secretary of State would have to give specific notice to Monitor, the NHS Commissioning Board, the Care Quality Commission and Healthwatch England (provided for in Chapter 1 of Part 5), as well as publishing more widely the proposal to make regulations, the effect of the regulations and the reasons for them. There must be a minimum period of 28 days, during which representations could be made, before the Secretary of State can make the regulations.
753. *Subsection (8)* provides that persons granted an exemption must be given notice of it. The Secretary of State must also publish exemptions granted.

### ***Section 84 - Exemption regulations: supplementary***

754. This section provides a mechanism for the Secretary of State to revoke or withdraw licensing exemptions. *Subsection (1)* provides that the exemption regulations themselves could be revoked in relation to an exemption granted to an individual provider, or amended in relation to regulations granting individual exemptions to more than one provider to enable any of the exemptions to be withdrawn. The Secretary of State can revoke or withdraw an exemption at the request of the provider, in accordance with the relevant exemption regulations themselves (for example if they provided for a conditional exemption), or if the Secretary of State considers it inappropriate for the exemption to continue.
755. *Subsection (2)* provides that exemption regulations granting an exemption to a group of providers could be revoked. Exemption regulations granting exemptions to more than one group of providers could also be amended to withdraw any of the exemptions. An exemption could be revoked or withdrawn either in accordance with the relevant exemption regulations themselves, or if the Secretary of State considers it inappropriate for the exemption to continue.
756. Under *subsection (3)*, the Secretary of State may by direction, withdraw an exemption for a particular provider within a group, whilst the exemption remained in place for the rest of that group. This may be done in accordance with the relevant exemption regulations, if the Secretary of State considered it inappropriate for the exemption to continue, or at the request of an individual provider.

757. When the exemption revocation or withdrawal is not at an individual provider's request, the Secretary of State must consult Monitor, the NHS Commissioning Board, the Care Quality Commission and Healthwatch England about the proposed withdrawal. If the exemption applies to an individual provider or providers within a group or type of providers that would remain exempt, the Secretary of State must also give notice to the provider(s) from whom he proposes to remove the exemption. If the exemption applied to a group or type of provider the notice of the proposal to remove the exemption must be published. The notice must state the Secretary of State's proposal and reasons for it, and specify a minimum 28-day period during which representations can be made.

### **Licensing procedure**

758. These sections provide for the procedure for applying for a licence, and for Monitor granting, refusing or revoking a licence.

#### ***Section 85 - Application for licence***

759. This section states that providers seeking a licence must apply to Monitor, who may require supporting information from them and specify the form in which applications may be made.

#### ***Section 86 - Licensing criteria***

760. This section requires Monitor to set and publish the criteria that a provider must meet in order to be granted a licence. *Subsection (2)* provides that Monitor may revise the criteria and must publish any revised version. This is intended to enable Monitor to adapt the licence criteria as the health care market develops. *Subsection (3)* requires that these criteria, and any subsequent revisions, be approved by the Secretary of State by order. Later provisions require that the first such order must be subject to the affirmative procedure. The additional requirement for the Secretary of State's approval of the criteria for granting licences is to provide a check on their appropriateness.

#### ***761. Section 87 - Grant or refusal of licence***

762. This section stipulates the process once an application for a licence has been made to Monitor. Where Monitor is satisfied that the provider has met the published criteria, it must approve the provider's application and, in accordance with *subsection (3)*, issue the licence to the applicant. If Monitor is not satisfied that the applicant meets the criteria, it must refuse the application.
763. *Subsection (4)* provides that licences are subject to both standard licence conditions and any special licence conditions. Further details about these types of conditions are in later sections. *Subsection (4)* also provides that licences granted to foundation trusts are subject to any licence conditions imposed under section 111 (imposition of licence conditions on NHS foundation trusts during the transitional period).

#### ***Section 88 - Application and grant: NHS foundation trusts***

764. This section provides that Monitor must treat an NHS foundation trust in existence at commencement of this section, or an NHS trust which becomes a foundation trust at a later date, as having made an application and met the criteria for a licence. As a result of this, the foundation trusts will not have to make a licence application. Foundation trusts will however still be regarded as applicants for the purpose of the power to include special conditions in an applicant's licence under section 95. Organisations have to go through a robust authorisation process in order to gain foundation trust status under Chapter 5 of Part 2 of the NHS Act. The automatic granting of licences to foundation trusts will limit the regulatory burden on them.

### **Section 89 - Revocation of licence**

765. This section provides Monitor with the powers to revoke a licence, either because the licence holder has requested this, or because the provider has failed to comply with a licence condition. A revocation provision is common to regulatory regimes that rely on a licence to deliver regulatory functions.
766. It is intended that Monitor will not automatically revoke the licence of a provider at their request where the continuity of services they are providing is required. In this way, providers of such services will not be able to avoid their obligations to provide such services simply by requesting revocation of their licence.
767. It is also intended that before revoking a licence for failure to comply with a condition of it, Monitor will first consider whether it could address the situation using its licence enforcement powers.

### **Sections 90, 91, 92 - Representations, notice and appeals**

768. The first of these sections requires Monitor to give the relevant provider advance notice when it proposes to either refuse or revoke a licence; and to state the reasons for its intended course of action. This notice must also specify the period within which the provider may make written representations to Monitor, allowing them the opportunity to make a case against Monitor's proposal if they wish to. This period must be at least 28 days.
769. The next section specifies that once Monitor reaches a decision to either refuse or revoke a licence, it must notify the relevant provider of its decision and explain the right of appeal. The section also stipulates when Monitor's decision to revoke a licence becomes final. This is (a) if an appeal is brought, when the appeal is concluded or abandoned; (b) when the provider declares its intention not to appeal; or (c) the day after the day that the period for bringing an appeal ended.
770. The last of these sections provides for the process for appeals to the First-tier Tribunal against a decision of Monitor to refuse a licence application or revoke a licence. The Tribunal is the main appeals Tribunal in the UK, run by the Tribunals Service and established by Parliament under the Tribunals, Courts and Enforcement Act 2007. It is also used for Care Quality Commission registration appeals and for other appeals relating to care standards and mental health issues. It is also used for appeals against decisions by other regulators, including the Office of Fair Trading and the Environment Agency.
771. *Subsection (2)* specifies the possible grounds for appeal as an error of fact a mistake in law or unreasonableness. The Tribunal may either confirm Monitor's decision, direct that Monitor's decision is not to have effect, or send the case back to Monitor for reconsideration.

### **Section 93 - Register of licence holders**

772. This section requires Monitor to keep and publish a register of licence holders. The register must contain such information as Monitor thinks necessary to keep the public informed about licence holders, including details of every licence granted or revoked. The information must be available to the public for inspection at Monitor's offices or available on request. However, there might be occasions on which it was not appropriate to release certain information to the public. *Subsection (5)* therefore provides for regulations setting out what information should not be accessible. *Subsection (6)* provides Monitor with power to charge a fee for providing a copy or extract of the register.
773. This section makes very similar provision to that for the register kept by the Care Quality Commission (see section 38 of the Health and Social Care Act 2008).

## **Licence conditions**

774. These sections make provision in relation to the two types of licence conditions that Monitor may set. Standard conditions will apply to all providers, or to all providers of a certain type (based on their nature, the services they provide, or the areas where they provide the services). Special conditions set individual requirements for individual providers. Creating different types of conditions gives potential providers some certainty over what a licence will entail (standard conditions), whilst enabling Monitor to tailor licences as appropriate (special conditions).

### **Section 94 - Standard conditions**

775. This section requires Monitor to set and publish the standard licence conditions. Standard conditions might include basic requirements necessary to support the regulator in exercising its functions, such as submitting the information about service provision that Monitor needs to set prices effectively.
776. Before determining the first set of standard conditions, Monitor must publish its draft standard conditions and consult the persons listed in *subsection (8)*.
777. *Subsections (2) to (6)* allow Monitor to set different standard conditions for different types of licences by reference to the nature of the provider, the services provided or the geographical area in which services are provided. Monitor could use this power to set additional licence conditions to apply to certain providers to ensure the continuity of certain services provided by them. For example, Monitor may set particular requirements on foundation trusts to ensure they are well governed, consistent with foundation trusts' duty to exercise their functions effectively, efficiently and economically, as necessary conditions of their continued ability to provide NHS services (see section 164). The intention is to enable Monitor to differentiate standard licence conditions, where necessary, to protect and promote patients' interests and to reflect particular statutory requirements as they may apply to foundation trusts and other types of healthcare provider. In addition, by differentiating standard licence conditions appropriately, Monitor may seek to achieve a fair playing field for providers.
778. *Subsections (4) to (6)* impose constraints on Monitor's ability to set different licence conditions relating to the nature of the provider. Subsection (5) allows for different standard licence conditions to be imposed in relation to governance to take account of differences in the status of different licence holders. Subsection (6) allows for different standard licence conditions to be imposed so as to achieve an equivalent regulatory burden on providers as a result of the licence, for example, where different standard licence conditions are appropriate to take account of differences in the burdens to which different types of provider are subject.
779. The Secretary of State is given the power in *subsection (10)* to reject Monitor's proposed first set of standard conditions, as a whole rather than as individual conditions.

### **Section 95 - Special conditions**

780. The power to include special licence conditions under *subsection (1)* is designed to address issues specific to particular licence holders, in situations where it would be problematic to define a description of relevant licences and applicable conditions, and hence to use standard licence conditions alone. For example, Monitor could use this provision to set licence conditions for a provider to secure continuity of NHS services in particular circumstances that Monitor considered were not captured within the standard licence conditions. Also by way of example, Monitor may set special licence conditions for a foundation trust (or other provider) which it considered were necessary in response to risks it identified; or to set special conditions prospectively so that those conditions would come into effect when interventions to secure the continuity of those services were required.

781. Monitor is able to include a special condition (or modify an existing one) if the applicant or licence holder consents. If that party does not agree and Monitor still wants the special condition or modification to be included in the licence, it may under section 101, make a reference to the Competition Commission, which will then investigate the appropriateness of including the special condition or making the modification.
782. Before including a special condition, or modifying one, Monitor must to comply with the notice requirements in *subsections (2) to (5)*.

### ***Section 96 - Limits on Monitor's functions to set or modify licence conditions***

783. This section specifies the purposes for which Monitor can set or modify licence conditions. Monitor would only be able to set licence conditions for the purposes specified in *subsection (2)*. For example, Monitor may use its licensing powers to support commissioners in securing continuity of services or to enable integration of services and co-operation between providers.
784. *Subsection (4)* provides that Monitor must not exercise its powers to set or modify conditions so as to unfairly advantage or disadvantage providers as a result of their having a particular status, including whether they are in the public or private sector.

### ***Section 97 - Conditions: supplementary***

785. *Subsection (1)* provides, by way of example, a non-exhaustive list of conditions that Monitor might include in licences. These include a requirement for licence holders to pay Monitor such fees as Monitor may determine in respect of the exercise of its licensing functions; a requirement that providers charge for services in accordance with the national tariff (see Chapter 4); and the conditions for securing the continued provision of NHS services. *Subsection (7)* gives Monitor the power to apply time restrictions to conditions, either by indicating when a condition should take effect or when it should end.
786. *Subsection (3)* specifies that Monitor must not use the powers it has under subsection (1) (c) to direct a licence holder to give access to its facilities to another provider.
787. *Subsection (4)(a)* provides that Monitor can require NHS foundation trusts and bodies which were former NHS trusts to notify the Office of Fair Trading if they intend to enter into a merger situation, being arrangements or transactions which would result in the trust's, or another business's, activities ceasing to be distinct. This provision is to ensure that the Office of Fair Trading has notice of mergers involving NHS foundation trusts, or former NHS trusts. *Subsection (4)(b)* specifies that this requirement no longer applies after five years from the date on which the condition was included in the licence.

### ***Section 98 – Conditions relating to the continuation of the provision of services etc.***

788. This section makes further provision about Monitor's licensing powers to support commissioners in securing continuity of health care services for the purposes of the NHS. *Subsection (1)* provides that Monitor may, in particular (but not by way of limitation), set conditions under section 97(1)(i)(i) requiring a licence holder: to provide information to commissioners and other persons as directed by Monitor; to allow Monitor to enter and inspect its premises; and to co-operate with persons appointed by Monitor to assist in the management of the licence holder's affairs, business and property. *Subsection (2)* requires commissioners to also co-operate with any such persons appointed by Monitor. Monitor may set such other licence conditions for the purposes of ensuring a provider continues to be able to provide NHS services under the terms of its licence as Monitor considers appropriate, subject to sections 94-96. This may include, for example, requirements relating to liquidity and, where appropriate, actions to ensure the provision of services is effective, efficient and economic in the long term.

789. Monitor could take a number of measures under licence conditions set under section 97(1)(i) to protect the continuity of NHS services in the case of a provider in financial difficulties (in “distress”). For example, Monitor could direct a provider in distress to appoint a “turnaround team”, or require a provider to provide information and access to their records and premises to a continuity of service planning team appointed by Monitor. The aim of such measures would be, wherever possible, to return the provider to normal operation as soon as possible and ensure the continuity of services which required protection.
790. *Subsection (3)* requires Monitor to carry out an on-going assessment of the risks to the continued provision of services to which a licence condition under section 97(1)(i), (j) or (k) applies. This enables Monitor to intervene early to assist providers to reduce any unacceptable risk.
791. *Subsection (4)* requires Monitor to publish guidance for licence holders on the requirements placed on them via licence conditions under section 97(1)(i), (j) or (k) for ensuring the continuity of services. Monitor must also publish guidance for commissioners of services subject to such conditions on the exercise of their functions in connection with the licence holders who provide those services. This could include guidance on their role in the turnaround of licence holders in distress, or in taking steps to plan for possible unsustainability of a licence holder. Before publishing such guidance (whether initially or as revised), Monitor must obtain the approval of the NHS Commissioning Board and the Secretary of State. *Subsection (5)* requires commissioners of services which are subject to continuity of service conditions to have regard to such guidance.

### ***Section 99 – Notification of commissioners where continuity of services is at risk***

792. This section provides for action to be taken by Monitor as part of its ongoing assessment of risk to the continuity of NHS health care services. It obliges Monitor to notify the NHS Commissioning Board and CCGs where it identifies significant risks to the provision of services and is satisfied that this is attributable to the way in which services are configured. *Subsection (5)* requires the Board and CCGs to have regard to such notifications when arranging for the continued provision of NHS health care services. It would be for commissioners to decide how best to respond to notifications under this section and section 126.

### ***Section 100 - Modification of standard conditions***

793. This section makes provision for modification of standard licence conditions in all providers’ licences or in licences of a particular description. Before making such a modification, Monitor must comply with the notice requirements set out in *subsections (2) to (5)*. These require Monitor to notify its intention to modify standard licence conditions and create the opportunity for those notified about the proposed modification to make representations.
794. Under *subsection (6)(a)* Monitor may make the modification if it received no objections from licence holders who would be affected by the change (relevant licence holders).
795. Where Monitor does receive representations from relevant licence holders, it may nonetheless make the modification if the proportion of licence holders objecting were below proportions specified by the Secretary of State in regulations made under *subsection (7)*. These regulations are subject to the affirmative Parliamentary procedure. Regulations must specify two proportions for these purposes. The first is the proportion of relevant licence holders who objected, expressed as a percentage of all relevant licence holders affected (the “objection percentage”). The second proportion is the number of relevant licence holders who objected, weighted according to their share of the supply of such services as may be prescribed (the “share of supply percentage”). This process is designed to enable Monitor to change standard licence conditions, but only where providers collectively do not have substantial objections to the proposed

change. Where the objection percentage and/or the share of supply percentage exceed those specified in the regulations, Monitor may only make the proposed change in accordance with section 101.

796. Other provisions of section 100 deal with situations where Monitor modifies the standard licence conditions. *Subsection (10)* provides that Monitor must publish the modifications. It also gives Monitor the power to make modifications to other conditions in a licence that might be required as a consequence. Thirdly, Monitor is also required to make the same modifications to future licences, where that is appropriate. The latter two requirements are to ensure consistency across licences.

### ***Section 101 – Modification references to the Competition Commission***

797. Under *subsection (2)* Monitor may make a reference to the Competition Commission when the applicant or licence holder refused to accept a proposal to include, modify or omit a special licence condition. Under *subsection (4)* a reference may also be made where Monitor is unable to modify the standard licence conditions because the number of licence holders objecting to the change exceeded one or both of the proportions set out in regulations made under section 100(7).
798. The Competition Commission is required to investigate and report on the matters contained in the reference from Monitor. Subsections (2) and (4) set the parameters for the Commission's investigations and reports under this section. In all cases, the Commission must consider whether any of the matters specified in the reference and which relate to the provision (or potential provision in the case of special licence conditions) of healthcare services are operating, or could be expected to operate, against the public interest. The Commission could not, therefore, consider references in terms of the impact on competition as an end in itself. Where a reference is made under subsection (2) and hence follows the refusal by an applicant or licence holder to include, modify or omit a special licence condition, the Commission must also investigate and report on whether the inclusion, modification or omission of a special condition in a licence would remedy or prevent the detriment to the public interest. Where a reference is made under subsection (4) and hence following objections from licence holders to proposals for standard licence conditions, the Commission must also investigate and report on whether the inclusion, modification or omission of standard licence conditions (applicable to all or a group of providers) would remedy or prevent the detriment to the public interest. Hence, in considering references from Monitor under this section, the Competition Commission's prime concern is whether the proposed licence condition or modifications would be in the public interest.
799. *Subsection (5)* gives effect to Schedule 10, which makes provision about investigations by the Competition Commission. Paragraph 7(2) of Schedule 10 requires Monitor to make changes to licence conditions in line with reports by the Commission following these investigations.
800. *Subsection (7)* enables Monitor to make incidental or consequential changes to the other conditions in a licence, where one or more conditions in the licence is changed following a reference to the Competition Commission under this section. Monitor must also modify the conditions in licences it issued in future, so that these conditions, as they would apply to all providers or all providers of a particular description, are the same. This provision avoids the need for Monitor to give notice and consult where it modifies standard licence conditions following a report by the Competition Commission under this section.

### ***Schedule 10 - References by Monitor to the Competition Commission***

801. Under paragraph 1, where Monitor makes a reference to the Competition Commission Monitor is able to change what is included in that reference by giving notice to the Commission. The Commission is obliged to accept the variation.

802. The intention of paragraph 2 is to enable Monitor to assist the Competition Commission by identifying in a reference or variation of a reference, any aspects of the referred matter that might have an adverse effect on the public interest, and by suggesting any alterations to licence conditions to avoid or remedy these effects. Paragraph 3 requires Monitor to publish any reference, or variation to a reference, and to send notice of a reference or variation to relevant applicants, licence holders and CCGs and to the NHS Commissioning Board (section 101(5)(a) refers).
803. [Paragraph 4](#) requires Monitor to provide relevant information and assistance to the Competition Commission and the Commission to take information supplied into account.
804. Under paragraph 5, a reference to the Competition Commission must specify a period – not longer than six months from the date of the reference – within which the Commission must report. The Commission’s report only has effect if it is made before the expiry of the period stated in the reference or at the end of an extended period. An extended period applies where the Commission sought this from Monitor and where Monitor is content that special reasons for extending the period existed. An extension may be for no more than six months and Monitor may grant only one extension. Monitor must send notice of the extension to the relevant persons, and publish the notice.
805. [Paragraph 6](#) requires the Commission, when reporting on a reference, to present definite conclusions, including details of any aspects it concludes might have negative impacts on the public interest. There must also be explanations as to how the inclusion, modification or omission of licence conditions could remedy or prevent those impacts.
806. This paragraph also requires that a conclusion in a report must have the agreement of at least two thirds of the group assigned to the investigation by the Competition Commission. If a member of the group disagreed with a conclusion, they may require the inclusion in the report of a statement of their disagreement and the reasons for it.
807. The Commission must ensure a copy of its report on a reference is sent to Monitor, who is then required to send a copy to the Secretary of State. Not less than 14 days after the Secretary of State received the copy under paragraph 6(6), Monitor is required to send a copy to applicants or licence holders affected by the conclusions in the report, the NHS Commissioning Board and CCGs likely to be affected by the matters to which the report relates. Monitor is required to publish the report within 24 hours of complying with this requirement.

### **Changes following report**

808. [Paragraph 7](#) requires Monitor to act on relevant recommendations made by the Competition Commission. Before doing so, Monitor must send a notice of the proposed changes to licence conditions to the relevant persons, explaining why it is taking such action, and publish the notice. The notice must specify a period – of at least 28 days from the date of publication - within which comments on the changes may be made. Once Monitor had considered the responses, it must notify the Commission, specifying the changes it proposes to make in response to the Commission’s report.
809. There would then be a four-week period, during which the Commission may direct Monitor (under paragraph 8) not to make the changes set out in the notice, or not to make some of the changes. Insofar as the Commission does not issue such directions, Monitor is required (under paragraph 7(11)) to make the changes it has proposed in response to the Commission’s report.

### **Competition Commission’s power to veto changes**

810. Under paragraph 8, the Competition Commission may apply to the Secretary of State asking him to direct that the four-week period for it to veto Monitor’s proposed changes to licence conditions be extended by 14 days.

811. Where the Commission vetoes changes proposed by Monitor, it must give notice of the changes Monitor proposed and its reasons for directing Monitor not to make them. The Commission is required to make any changes to licence conditions that it considers necessary to address any adverse effects to the public interest identified in its report that it considers would not be remedied or prevented by the changes proposed by Monitor. The Commission must give Monitor and other relevant persons (section 101(5)(a) refers) 28 days' notice of the changes it proposes to make, during which representations could be made. It must also publish the notice.
812. Once the changes had been made, the Commission must publish details of them and state why it had made them.

### **Disclosure**

813. [Paragraph 9](#) requires the Commission, before making a report or giving notice in relation to its power to veto Monitor's proposed changes, to ensure that no information harmful to the public interest, no sensitive commercial information and no information which might significantly harm an individual's interests is included.

### **Powers of investigation**

814. [Paragraph 10](#) provides that a number of investigative and enforcement powers under specified sections of Part 3 of the Enterprise Act 2002 apply, with specified modifications, for the purposes of references by Monitor to the Competition Commission.

### ***Section 102 - Modification of conditions by order under other enactments***

815. This section provides that the Office of Fair Trading, the Competition Commission and the Secretary of State, as relevant authorities, can modify standard conditions or conditions of a particular licence, by an order made under various specified provisions of the Enterprise Act 2002. This provision is to ensure that the licensing regime is consistent with measures taken under that Act, or can be modified as part of remedies imposed under that Act. The inclusion of a provision of this type is consistent with other regulatory regimes.

### ***Section 103 – Standard condition as to transparency of certain criteria***

816. The effect of this section is to require that Monitor must include a standard condition in all licences, which requires licence holders to act transparently in the setting and application of criteria for determining patient eligibility for particular services, for accepting or rejecting referrals, or determining the manner in which services are provided to that person. This is intended to ensure that providers act transparently in determining clinically appropriate care for patients and do not discriminate on non-clinical grounds. Nothing in this section will affect a person's entitlement to a particular treatment under the NHS. This transparency requirement will only operate wherever those services are subject to patient choice of provider. This will enable Monitor to minimise the scope for providers to make extra profits by 'cherry picking'- i.e. delivering a service only in less complex cases – by requiring them to be transparent about these matters. *Subsection (3)* specifies that certain powers conferred on Monitor, the Secretary of State, the Office of Fair Trading, and the Competition Commission by sections 100, 101 and 102 and Schedule 10 to modify licence conditions may not be used to omit such a condition from licences.

### **Enforcement**

817. [Sections 104 to 110](#) provide Monitor with the necessary powers to enforce the licensing regime. Whilst the Monitor and the Care Quality Commission will work jointly in relation to the licensing procedure, the two organisations have separate enforcement responsibilities. However, they are obliged to share information about

relevant enforcement actions taken. Monitor's enforcement powers are modelled on the set of civil sanctions for regulatory regimes laid down in Part 3 of the Regulatory Enforcement and Sanctions Act 2008.

#### ***Section 104 - Power to require documents and information***

818. *Subsection (1)* provides Monitor with a power to require persons listed in *subsection (2)* to provide to Monitor any information that it needs to carry out its regulatory functions (as specified in *subsection (4)*). This power would apply to commissioners, applicants for licences, licensees, providers of NHS services exempted from holding a licence, or providers operating without a licence when they should have one. Its purpose is to allow Monitor to obtain the information it would need to operate effectively and fulfil its functions. For example, Monitor could require a provider to submit information about its financial situation to support regulatory work to protect continuity of services, or about its prices to support tariff calculation.
819. Information might be needed from providers who are currently exempted from licensing if, for example, Monitor and the NHS Commissioning Board decided to extend the scope of tariff pricing to a new service, and needed information on the prices of these services to do so.

#### ***Section 105 - Discretionary requirements***

820. 'Discretionary requirements' are obligations which Monitor may place upon a provider of NHS services if it breached a licence condition, or failed to hold a licence when it is required to; or on any person who failed to provide Monitor with information under the previous section. Discretionary requirements are intended to act as an incentive to comply and a means of rectifying any problems.
821. *Subsection (2)* outlines the types of discretionary requirements that Monitor may impose. They are:
- a monetary penalty of such amount as Monitor may determine, up to 10% of turnover of the person in England ('variable monetary penalty');
  - action to cease the breach in question, or make sure it did not continue or happen again ('compliance requirement'). An example of this might be a requirement that a provider cease plans to dispose of an asset that was needed for the provision of a service, the continuity of which was required, or to take action to mitigate financial risk (in breach of a condition relating to financial viability) that would threaten the continuity of such services;
  - action to restore the position to what it was before the breach occurred ('restoration requirement'). For example, Monitor could require that a provider re-open a service that it had closed in breach of a licence condition.
822. The Secretary of State is given power by regulations to prescribe how turnover would be calculated for the purposes of the 10% limit on variable monetary penalties (*subsection (4)*).
823. *Subsection (3)* provides that Monitor must not impose discretionary requirements on a provider on more than one occasion in relation to the same breach, but Monitor may, however, take action to enforce the discretionary requirements it has imposed on a provider to remedy such a breach.
824. *Subsection (5)* provides that a penalty imposed under this section that is not paid in full accrues interest, but the total amount of interest charged may not exceed the amount of the penalty itself.

### **Section 106 - Enforcement undertakings**

825. 'Enforcement undertakings' are settlements offered by a person to rectify one or more breaches for which Monitor would otherwise be able to impose a discretionary requirement. Monitor could choose whether to accept the offered settlement, based on whether it was likely to constitute an appropriate remedy. This alternative to discretionary requirements provides an incentive for providers and others to take responsibility for proposing solutions to problems, and thus to be proactive about remedying breaches.
826. *Subsection (3)* specifies what types of enforcement undertakings Monitor may accept:
- action to cease the breach or to prevent the breach continuing or happening again;
  - action to restore the position to what it would have been before a breach occurred, so far as is possible;
  - action to benefit any licence holder or commissioner affected by a breach, which could be payment of money; or
  - other action as may be specified in regulations.
827. Once Monitor accepts an enforcement undertaking, it may only impose a discretionary requirement or revoke a licence if the licensee fails to comply with the undertaking, or any part of it (*subsection (4)*). *Subsection (5)* provides that where a provider has partially complied with an undertaking, Monitor must take the partial compliance into account when deciding whether to take further enforcement action.

### **Section 107 - Further provision about enforcement powers**

828. This section gives effect to Schedule 11, which provides further detail about both discretionary requirements and enforcement undertakings.

### **Schedule 11 - Further provision about enforcement powers**

#### **Part 1 - Discretionary requirements**

##### **Procedure**

829. The procedure for discretionary requirements follows that laid down in section 43 of the Regulatory Enforcement and Sanctions Act 2008.
830. **Paragraph 1** requires Monitor to give notice to a person of its intention to impose a discretionary requirement on them. The notice must provide specified details, including the grounds for the proposal to impose the requirement, and the notice period within which the person could make written representations, which must be at least 28 days, except where Monitor considers a shorter period is necessary to avoid or minimise further breaches of licence conditions. In these circumstances, Monitor may shorten the notice period, but not to less than five days. A shorter period might be necessary to, for example, require a provider of services subject to continuity of service conditions who had stopped providing those services, to restore them, where continuity of those services was required.
831. **Paragraph 2** provides that where, following expiry of the notice period, Monitor decides to impose a requirement, a second and final notice must be given to the person involved. This must include information about why the requirement is being imposed, the implications of failure to comply with the requirement, details of how any monetary penalty is to be paid and of the rights of appeal.
832. If Monitor wishes to impose a variable monetary penalty, it must give notice of this under paragraph 1 within five years of the breach occurring.

833. A person on whom Monitor imposes a discretionary requirement is able to appeal to the First-tier Tribunal (paragraph 3). During an appeal, the duty to fulfil the discretionary requirement(s) being appealed is suspended. There are a number of grounds for appeals:
- that the decision was based on a factual error;
  - that the decision was wrong in law;
  - that the amount of a variable monetary penalty was unreasonable;
  - that action required by Monitor was unreasonable (in the case of either compliance requirements or restoration requirements);
  - that the decision was unreasonable for any other reason.
834. [Paragraph 3\(4\)](#) specifies the measures the First-tier Tribunal may take following the appeal. It could confirm or withdraw the requirement in question, or vary it. Alternatively, the Tribunal has the same powers to act in relation to the breach(es) that gave rise to the appeal as Monitor has in relation to them. The third option is for the First –tier tribunal to remit the decision, or any matter relating to it, to Monitor for reconsideration.
835. [Paragraph 4](#) gives Monitor specific powers to withdraw or amend discretionary requirements that it has imposed.

### **Non-compliance penalties**

836. [Paragraph 5](#) gives Monitor the power to impose a monetary penalty (a “non-compliance penalty”) on a person who fails to comply with a compliance or restoration requirement, and to determine the amount of the monetary penalty. When proposing to impose such a penalty, Monitor must serve a “non-compliance notice” on the person concerned. This must include details of the monetary penalty and how and when it was to be paid, the grounds for imposing the penalty, the consequences of failing to pay the penalty and the right of appeal.
837. The period for payment must not be less than 28 days from the day after the date on which the notice is received. If the person on whom the notice was served complied with the compliance requirement within that period, the payment would cease to be due. If the person does not pay the fine within the specified payment period, Monitor may increase the non-compliance penalty by no more than 50%.
838. The grounds on which a person served with a non-compliance penalty could appeal to the First-tier tribunal are set out in paragraph 6(2). Penalties are suspended whilst an appeal was in progress. The Tribunal may confirm, change or withdraw a non-compliance penalty, or remit the decision to Monitor for reconsideration.

### **Recovery of financial penalties and payments of penalties etc. into Consolidated Fund**

839. Both variable monetary penalties and non-compliance penalties are recoverable summarily as a civil debt (paragraph 7). Monitor must pay money it received from penalties into the Consolidated Fund: it would not retain any element of the fines it imposed (paragraph 8).

## **Part 2 – Enforcement undertakings**

### **Procedure**

840. [Paragraphs 9](#) and [10](#) stipulate that Monitor must consult upon and then publish a procedure for entering into enforcement undertakings. It may revise that procedure but it would have to publish any revision. Monitor must also publish details of each enforcement undertaking it accepted, but with any commercial information or

information that Monitor considered would or might harm any person's legitimate business or personal interests redacted (paragraph 10).

### **Variation of terms**

841. A person giving an enforcement undertaking and Monitor may agree to vary the terms of an enforcement undertaking. This is intended to provide the flexibility to alter the agreement if necessary if, for example, a provider had good reasons for taking longer to carry out a remedial measure than was originally planned and agreed.

### **Compliance certificates**

842. If it is satisfied that a person had complied with an enforcement undertaking, Monitor must issue a compliance certificate (paragraph 12). Someone who had given an enforcement undertaking may apply for a certificate at any time.
843. [Paragraph 13](#) provides that an appeal to the First-tier Tribunal may be made against a decision of Monitor to refuse an application for a compliance certificate, on the grounds that the decision was based on an error in fact, was wrong in law, or was unfair or unreasonable. The Tribunal may confirm Monitor's decision or decide that it did not have effect.

### **Inaccurate, incomplete or misleading information**

844. If Monitor is satisfied that information supplied by a person in relation to an enforcement undertaking is inaccurate, misleading or incomplete, Monitor may treat the person as having failed to comply with the undertaking. If it did this, Monitor would have to revoke any compliance certificate given to that person in connection with the particular undertaking.

### ***Section 108 - Guidance as to use of enforcement powers***

845. This section requires Monitor to consult on and publish guidance about the way in which it will exercise its powers to impose discretionary requirements and to accept enforcement undertakings (*subsection (1)*). *Subsection (5)* provides that Monitor must have regard to the published guidance in exercising those powers. Guidance would give licensees and others a better understanding of the enforcement action that Monitor is likely to take in particular circumstances.
846. *Subsection (4)* provides that the guidance must include details of when Monitor is likely to impose a discretionary requirement and when it may not impose one, how it will decide the amount of variable monetary penalties, and how decisions may be appealed.

### ***Section 109 - Publication of enforcement action***

847. *Subsection (1)* provides that Monitor must include information in its annual report on discretionary requirements it has imposed and enforcement undertakings it has accepted during the financial year that the report covers. Under *subsection (2)* Monitor is not able to include information if it is satisfied that publication of it would or might significantly harm the legitimate business or personal interests of the person to whom the information relates.
848. *Subsection (3)* provides that Monitor is not to include in the report information about discretionary requirements that have been overturned on appeal.

### ***Section 110 - Notification of enforcement action***

849. This section provides that Monitor must notify the NHS Commissioning Board, affected CCGs and other relevant regulators of discretionary requirements it imposes and enforcement undertakings it accepts. This provision is designed to ensure that

information about provider performance, which may be relevant to the duties and functions of commissioners and other regulators, is shared appropriately.

## **Transitional provision**

### ***Section 111 - Imposition of licence conditions on NHS foundation trusts***

850. This and the following three sections provide Monitor with transitional intervention powers over all NHS foundation trusts.
851. *Subsections (1) and (2)* provide transitional powers for Monitor to impose such requirements on a foundation trust (in the form of additional licence conditions), as Monitor considers appropriate, to address a governance failing. Monitor can impose such requirements where it is satisfied that this is necessary to prevent or remedy a breach of a foundation trust's licence. *Subsection (1)* allows Monitor to impose licence conditions relating to governance on a foundation trust where it is satisfied that the governance of the trust will cause it to fail to comply with its licence conditions to provide NHS services. *Subsection (2)* specifies that the circumstances in which these powers may be used include those where the trust's directors, governors, or both, are failing to comply with conditions in the trust's licence, or are failing to reduce the risk of a breach of licence conditions. Monitor's transitional powers are intended to provide an additional safeguard to protect patients' interests by ensuring that foundation trusts are well-governed and exercise their functions consistently with their duty to do so effectively, efficiently and economically, in the early years of the new regulatory regime, when some foundation trust governors may be inexperienced and when some foundation trusts may be newly authorised.
852. *Subsection (3)* provides that any additional licence conditions imposed by Monitor under subsection (1) could continue in force until Monitor's transitional powers were repealed by Parliament by virtue of section 112.
853. *Subsections (5) and (6)* provide Monitor with further powers to take action where a foundation trust fails to comply with Monitor's requirements under subsection (1). Specifically, Monitor could intervene to require the trust to remove, replace on an interim basis, suspend or disqualify one or more directors or governors of the trust. If the trust failed to do so, Monitor could take such action itself.
854. *Subsection (7)* provides that Monitor's exercise of its transitional powers in subsection (5) is without prejudice to its ability to exercise powers to set and enforce requirements on foundation trusts, including requirements relating to governance, or requirements to ensure a foundation trust's continued ability to provide services for the purpose of the NHS. This clarifies that the transitional powers are in addition to Monitor's continuing non-transitional powers to intervene where a licence holder is in breach of licence conditions, for example, a requirement to maintain continuity of NHS services.
855. *Subsection (11)* repeals section 52 of the NHS Act (failing NHS foundation trusts) because Monitor will have permanent powers to protect the continuity of services through the modified regime for unsustainable foundation trusts. It also makes related consequential amendments.

### ***Section 112 – Duration of transitional period***

856. This section makes all foundation trusts subject to Monitor's transitional powers until the Secretary of State makes an order to release either some or all trusts from the powers. The first such order may not be made before 1 April 2016, or, in the case of a foundation trust authorised after 1 April 2014, before two years after the date of authorisation. The order would be subject to Parliamentary scrutiny under the negative resolution procedure, since those trusts being considered for release would have effective governance and would therefore be at low risk of needing intervention.

857. *Subsection (5)* provides for the section to be repealed when there are no longer any foundation trusts or NHS trusts which might become foundation trusts to which the powers might apply.

***Section 113 – Orders under section 112: criteria for deciding applicable trusts***

858. This section sets out the process to be followed when the Secretary of State decides to make an order to release foundation trusts from Monitor’s transitional intervention powers. *Subsection (1)* provides that the Secretary of State must notify Monitor where he proposes to make an order releasing trusts from the powers in this way.
859. *Subsection (2)* provides that, where Monitor receives a notification under subsection (1), it must develop criteria to decide which foundation trusts should be released from its transitional intervention powers. *Subsection (3)* requires Monitor to consult the Care Quality Commission and other appropriate persons and to obtain the Secretary of State’s approval for the criteria before applying them.
860. *Subsection (4)* requires that, following approval by the Secretary of State, Monitor must publish the criteria. Monitor must apply the criteria to decide which foundation trusts should be released from the transitional intervention powers. Monitor must notify the Secretary of State about which foundation trusts it has determined should be released from the transitional powers and publish a list of those trusts.
861. *Subsection (5)* provides for a situation where the Secretary of State did not approve the criteria developed by Monitor under subsection (2). Monitor would have to propose revised criteria to the Secretary of State and repeat the process in subsections (3) and (4).
862. *Subsection (6)* requires the Secretary of State, on receiving notification from Monitor under subsection (4), to review Monitor’s determination about the trusts to be released.

***Section 114 - Repeal of sections 112 and 113***

863. This section repeals the previous two sections when section 111 (Imposition of licence conditions on NHS foundation trusts) on transitional intervention powers is repealed. That section is repealed when it no longer has any effect in relation to any foundation trusts and there are no NHS trusts left in existence.