



# Health and Social Care Act 2012

## 2012 CHAPTER 7

### PART 3

#### REGULATION OF HEALTH AND ADULT SOCIAL CARE SERVICES

### CHAPTER 3

#### LICENSING

#### *Licensing requirement*

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

- (1) Any person who provides a health care service for the purposes of the NHS must hold a licence under this Chapter.
- (2) Regulations may make provision for the purposes of this Chapter for determining, in relation to a service provided by two or more persons acting in different capacities, which of those persons is to be regarded as the person who provides the service.

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

- (1) This section applies where a licence holder—
  - (a) in providing a health care service for the purposes of the NHS, carries on a regulated activity (within the meaning of Part 1 of the Health and Social Care Act 2008), but
  - (b) is not registered under Chapter 2 of Part 1 of that Act in respect of the carrying on of that activity.
- (2) The licence holder is to be regarded as providing the service in breach of the requirement under section 81 to hold a licence.

### **83 Exemption regulations**

- (1) Regulations (referred to in this section and section 84 as “exemption regulations”) may provide for the grant of exemptions from the requirement under section 81 in respect of—
  - (a) a prescribed person or persons of a prescribed description;
  - (b) the provision of a prescribed health care service or a health care service of a prescribed description.
- (2) Exemption regulations may grant an exemption—
  - (a) either generally or to the extent prescribed;
  - (b) either unconditionally or subject to prescribed conditions;
  - (c) indefinitely, for a prescribed period or for a period determined by or under the exemption.
- (3) Conditions subject to which an exemption may be granted include, in particular, conditions requiring any person providing a service pursuant to the exemption—
  - (a) to comply with any direction given by Monitor about such matters as are specified in the exemption or are of a description so specified,
  - (b) except to the extent that Monitor otherwise approves, to do, or not to do, such things as are specified in the exemption or are of a description so specified (or to do, or not to do, such things in a specified manner), and
  - (c) to refer for determination by Monitor such questions arising under the exemption as are specified in the exemption or are of a description so specified.
- (4) Before making exemption regulations the Secretary of State must give notice to—
  - (a) Monitor,
  - (b) the National Health Service Commissioning Board, and
  - (c) the Care Quality Commission and its Healthwatch England committee.
- (5) The Secretary of State must also publish a notice under subsection (4)
 

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- (6) A notice under subsection (4) must—
  - (a) state that the Secretary of State proposes to make exemption regulations and set out their proposed effect,
  - (b) set out the Secretary of State’s reasons for the proposal, and
  - (c) specify the period (“the notice period”) within which representations with respect to the proposal may be made.
- (7) The notice period must be not less than 28 days beginning with the day after that on which the notice is published under subsection (5)
 

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- (8) Where an exemption is granted the Secretary of State—
  - (a) if the exemption is granted to a prescribed person, must give notice of it to that person, and
  - (b) must publish the exemption.

## **84 Exemption regulations: supplementary**

- (1) Regulations may revoke exemption regulations by which an exemption was granted to a person, or amend such regulations by which more than one exemption was so granted so as to withdraw any of the exemptions—
  - (a) at the person’s request,
  - (b) in accordance with any provision of the exemption regulations by which the exemption was granted, or
  - (c) if the Secretary of State considers it to be inappropriate for the exemption to continue to have effect.
- (2) Regulations may revoke exemption regulations by which an exemption was granted to persons of a prescribed description, or amend such regulations by which more than one exemption was so granted so as to withdraw any of the exemptions—
  - (a) in accordance with any provision of the exemption regulations by which the exemption was granted, or
  - (b) if the Secretary of State considers it to be inappropriate for the exemption to continue to have effect.
- (3) The Secretary of State may by direction withdraw an exemption granted to persons of a description prescribed in exemption regulations for any person of that description—
  - (a) at the person’s request,
  - (b) in accordance with any provision of the exemption regulations by which the exemption was granted, or
  - (c) if the Secretary of State considers it to be inappropriate for the exemption to continue to have effect in the case of the person.
- (4) Subsection  
(5)  
applies where the Secretary of State proposes to—
  - (a) make regulations under subsection  
(1)(b)  
or  
(c)  
(2)  
, or
  - (b) give a direction under subsection  
(3)(b)  
or  
(c)  
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- (5) The Secretary of State must—
  - (a) consult the following about the proposal—
    - (i) Monitor;
    - (ii) the National Health Service Commissioning Board;
    - (iii) the Care Quality Commission and its Healthwatch England committee;
  - (b) where the Secretary of State is proposing to make regulations under subsection (1)(b) or (c), give notice of the proposal to the person to whom the exemption was granted;

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- (c) where the Secretary of State is proposing to make regulations under subsection (2), publish the notice;
  - (d) where the Secretary of State is proposing to give a direction under subsection (3)(b) or (c), give notice of the proposal to the person from whom the Secretary of State proposes to withdraw the exemption.
- (6) The notice must—
- (a) state that the Secretary of State proposes to make the regulations or give the direction (as the case may be),
  - (b) set out the Secretary of State’s reasons for the proposal, and
  - (c) specify the period within which representations with respect to the proposal may be made.
- (7) The period so specified must be not less than 28 days beginning with the day after that on which the notice is received or (as the case may be) published.

### *Licensing procedure*

#### **85 Application for licence**

- (1) A person seeking to hold a licence under this Chapter must make an application to Monitor.
- (2) The application must be made in such form, and contain or be accompanied by such information, as Monitor requires.

#### **86 Licensing criteria**

- (1) Monitor must set and publish the criteria which must be met by a person in order for that person to be granted a licence under this Chapter.
- (2) Monitor may revise the criteria and, if it does so, must publish them as revised.
- (3) Monitor may not set or revise the criteria unless the Secretary of State has by order approved the criteria or (as the case may be) revised criteria.

#### **87 Grant or refusal of licence**

- (1) This section applies where an application for a licence has been made under section 85.
- (2) If Monitor is satisfied that the applicant meets the criteria for holding a licence for the time being published under section 86 it must as soon as reasonably practicable grant the application; otherwise it must refuse it.
- (3) On granting the application, Monitor must issue a licence to the applicant.
- (4) A licence issued under this section is subject to—
  - (a) such of the standard conditions (see section 94) as are applicable to the licence,
  - (b) such other conditions included in the licence by virtue of section 95 (referred to in this Chapter as “the special conditions”), and
  - (c) any conditions included in the licence by virtue of section 111 (imposition of licence conditions on NHS foundation trusts during transitional period).

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

- (1) This section applies where an NHS trust becomes an NHS foundation trust pursuant to section 36 of the National Health Service Act 2006 (effect of authorisation of NHS foundation trust).
- (2) The NHS foundation trust is to be treated by Monitor as having—
  - (a) duly made an application for a licence under section 85, and
  - (b) met the criteria for holding a licence for the time being published under section 86.
- (3) An NHS foundation trust in existence on the day on which this section comes into force is to be treated for the purposes of this section as having become an NHS foundation trust pursuant to section 36 of the National Health Service Act 2006 on that day.

## **89 Revocation of licence**

Monitor may at any time revoke a licence under this Chapter—

- (a) on the application of the licence holder, or
- (b) if Monitor is satisfied that the licence holder has failed to comply with a condition of the licence.

## **90 Right to make representations**

- (1) Monitor must give notice—
  - (a) to an applicant for a licence under this Chapter of a proposal to refuse the application;
  - (b) to the licence holder of a proposal to revoke a licence under section 89  
(b)
- (2) A notice under this section must—
  - (a) set out Monitor's reasons for its proposal;
  - (b) specify the period within which representations with respect to the proposal may be made to Monitor.
- (3) The period so specified must be not less than 28 days beginning with the day after that on which the notice is received.

## **91 Notice of decisions**

- (1) This section applies if Monitor decides to—
  - (a) refuse an application for a licence under section 87, or
  - (b) revoke a licence under section 89  
(b)
- (2) Monitor must give notice of its decision to the applicant or the licence holder (as the case may be).
- (3) A notice under this section must explain the right of appeal conferred by section 92.
- (4) A decision of Monitor to revoke a licence under section 89

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- (b) takes effect on such day as may be specified by Monitor, being a day no earlier than—
- (a) if an appeal is brought under section 92, the day on which the decision on appeal is confirmed or the appeal is abandoned,
  - (b) where the licence holder notifies Monitor before the end of the period for bringing an appeal under section 92 that the licence holder does not intend to appeal, the day on which Monitor receives the notification, or
  - (c) the day after that period.

## **92 Appeals to the Tribunal**

- (1) An appeal lies to the First-tier Tribunal against a decision of Monitor to—
  - (a) refuse an application for a licence under section 87, or
  - (b) revoke a licence under section 89
- (2) The grounds for an appeal under this section are that the decision was—
  - (a) based on an error of fact,
  - (b) wrong in law, or
  - (c) unreasonable.
- (3) On an appeal under this section, the First-tier Tribunal may—
  - (a) confirm Monitor’s decision,
  - (b) direct that the decision is not to have effect, or
  - (c) remit the decision to Monitor.

## **93 Register of licence holders**

- (1) Monitor must maintain and publish a register of licence holders.
- (2) The register may contain such information as Monitor considers appropriate for the purpose of keeping members of the public informed about licence holders including, in particular, information about the revocation of any licence under this Chapter.
- (3) Monitor must secure that copies of the register are available at its offices for inspection at all reasonable times by any person.
- (4) Any person who asks Monitor for a copy of, or an extract from, the register is entitled to have one.
- (5) Regulations may provide that subsections
  - (3)
  - and
  - (4)
 do not apply—
  - (a) in such circumstances as may be prescribed, or
  - (b) to such parts of the register as may be prescribed.
- (6) A fee determined by Monitor is payable for the copy or extract except—
  - (a) in such circumstances as may be prescribed, or

- (b) in any case where Monitor considers it appropriate to provide the copy or extract free of charge.

### *Licence conditions*

## **94 Standard conditions**

- (1) Monitor must determine and publish the conditions to be included in each licence under this Chapter (referred to in this Chapter as “the standard conditions”).
- (2) Different standard conditions may be determined for different descriptions of licences.
- (3) For the purposes of subsection (2) a description of licences may, in particular, be framed wholly or partly by reference to—
  - (a) the nature of the licence holder,
  - (b) the services provided under the licence, or
  - (c) the areas in which those services are provided.
- (4) But different standard conditions must not be determined for different descriptions of licences to the extent that the description is framed by reference to the nature of the licence holder unless Monitor considers that at least one of requirements 1 and 2 is met.
- (5) Requirement 1 is that—
  - (a) the standard conditions in question relate to the governance of licence holders, and
  - (b) it is necessary to determine different standard conditions in order to take account of differences in the status of different licence holders.
- (6) Requirement 2 is that it is necessary to determine different standard conditions for the purpose of ensuring that the burdens to which different licence holders are subject as a result of holding a licence are broadly consistent.
- (7) Before determining the first set of the standard conditions Monitor must consult the persons mentioned in subsection (8) on the conditions it is proposing to determine (“the draft standard conditions”).
- (8) Those persons are—
  - (a) the Secretary of State,
  - (b) the NHS Commissioning Board Authority,
  - (c) every Primary Care Trust,
  - (d) the Care Quality Commission, and
  - (e) such other persons as are likely to be affected by the inclusion of the conditions in licences under this Chapter as Monitor considers appropriate.
- (9) Monitor must also publish the draft standard conditions.
- (10) The Secretary of State may direct Monitor not to determine that the standard conditions will be the draft standard conditions.
- (11) If, at the time Monitor discharges the function under subsection (7)

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, the day specified by the Secretary of State for the purposes of section 14A of the National Health Service Act 2006 has passed or section 9 or 181 has come into force—

- (a) in the case of section 14A of the National Health Service Act 2006, the reference in subsection (8)(c) to every Primary Care Trust is to be read as a reference to every clinical commissioning group;
- (b) in the case of section 9, the reference in subsection (8)(b) to the NHS Commissioning Board Authority is to be read as a reference to the National Health Service Commissioning Board;
- (c) in the case of section 181, the reference in subsection (8)(d) to the Care Quality Commission is to be read as including a reference to its Healthwatch England committee.

## 95 Special conditions

- (1) Monitor may—
  - (a) with the consent of the applicant, include a special condition in a licence under this Chapter, and
  - (b) with the consent of the licence holder, modify a special condition of a licence.
- (2) Before including a special condition or making such modifications Monitor must give notice to—
  - (a) the applicant or the licence holder (as the case may be),
  - (b) the Secretary of State,
  - (c) the National Health Service Commissioning Board,
  - (d) such clinical commissioning groups as are likely to be affected by the proposed inclusion or modifications, and
  - (e) the Care Quality Commission and its Healthwatch England committee.
- (3) Monitor must also publish the notice under subsection (2).
- (4) The notice under subsection (2) must—
  - (a) state that Monitor proposes to include the special condition or make the modifications and set out its or their proposed effect,
  - (b) set out Monitor’s reasons for the proposal, and
  - (c) specify the period (“the notice period”) within which representations with respect to the proposal may be made to Monitor.
- (5) The notice period must be not less than 28 days beginning with the day after that on which the notice is published under subsection (3).
- (6) In this section, a reference to modifying a condition includes a reference to amending, omitting or adding a condition.



## 96 Limits on Monitor’s functions to set or modify licence conditions

- (1) This section applies to the following functions of Monitor—
- (a) the duty to determine the standard conditions to be included in each licence under this Chapter or in licences of a particular description (see section 94);
  - (b) the powers to include a special condition in a licence and to modify such a condition (see section 95);
  - (c) the power to modify the standard conditions applicable to all licences, or to licences of a particular description (see section 100).
- (2) Monitor may only exercise a function to which this section applies—
- (a) for the purpose of regulating the price payable for the provision of health care services for the purposes of the NHS;
  - (b) for the purpose of preventing anti-competitive behaviour in the provision of health care services for those purposes which is against the interests of people who use such services;
  - (c) for the purpose of protecting and promoting the right of patients to make choices with respect to treatment or other health care services provided for the purposes of the NHS;
  - (d) for the purpose of ensuring the continued provision of health care services for the purposes of the NHS;
  - (e) for the purpose of enabling health care services provided for the purposes of the NHS to be provided in an integrated way where Monitor considers that this would achieve one or more of the objectives referred to in subsection (3);
  - (f) for the purpose of enabling the provision of health care services provided for the purposes of the NHS to be integrated with the provision of health-related services or social care services where Monitor considers that this would achieve one or more of the objectives referred to in subsection (3);
  - (g) for the purpose of enabling co-operation between providers of health care services for the purposes of the NHS where Monitor considers that this would achieve one or more of the objectives referred to in subsection (3);
  - (h) for purposes connected with the governance of persons providing health care services for the purposes of the NHS;
  - (i) for purposes connected with Monitor’s functions in relation to the register of NHS foundation trusts required to be maintained under section 39 of the National Health Service Act 2006;
  - (j) for purposes connected with the operation of the licensing regime established by this Chapter;
  - (k) for such purposes as may be prescribed for the purpose of enabling Monitor to discharge its duties under section 62.
- (3) The objectives referred to in subsection (2)(e)
- (f)

and

(g)

are—

- (a) improving the quality of health care services provided for the purposes of the NHS (including the outcomes that are achieved from their provision) or the efficiency of their provision,
  - (b) reducing inequalities between persons with respect to their ability to access those services, and
  - (c) reducing inequalities between persons with respect to the outcomes achieved for them by the provision of those services.
- (4) Monitor must not exercise a function to which this section applies in a way which it considers would result in a particular licence holder or holders of licences of a particular description being put at an unfair advantage or disadvantage in competing with others in the provision of health care services for the purposes of the NHS as a result of—
- (a) being in the public or (as the case may be) private sector, or
  - (b) some other aspect of its or their status.

(5) In subsection

(2)(f)

, “health-related services” and “social care services” each have the meaning given in section 62

(11)

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## 97 **Conditions: supplementary**

- (1) The standard or special conditions of a licence under this Chapter may, in particular, include conditions—
- (a) requiring the licence holder to pay to Monitor such fees of such amounts as Monitor may determine in respect of the exercise by Monitor of its functions under this Chapter,
  - (b) requiring the licence holder to comply with any requirement imposed on it by Monitor under Chapter 6 (financial assistance in special administration cases),
  - (c) requiring the licence holder to do, or not to do, specified things or things of a specified description (or to do, or not to do, any such things in a specified manner) within such period as may be specified in order to prevent anti-competitive behaviour in the provision of health care services for the purposes of the NHS which is against the interests of people who use such services,
  - (d) requiring the licence holder to give notice to the Office of Fair Trading before entering into an arrangement under which, or a transaction in consequence of which, the licence holder’s activities, and the activities of one or more other businesses, cease to be distinct activities,
  - (e) requiring the licence holder to provide Monitor with such information as Monitor considers necessary for the purposes of the exercise of its functions under this Part,
  - (f) requiring the licence holder to publish such information as may be specified or as Monitor may direct,

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- (g) requiring the licence holder to charge for the provision of health care services for the purposes of the NHS in accordance with the national tariff (see section 116),
  - (h) requiring the licence holder to comply with other rules published by Monitor about the charging for the provision of health care services for the purposes of the NHS,
  - (i) requiring the licence holder—
    - (i) to do, or not to do, specified things or things of a specified description (or to do, or not to do, any such things in a specified manner) within such period as may be specified in order to ensure the continued provision of one or more of the health care services that the licence holder provides for the purposes of the NHS,
    - (ii) to give Monitor notice (of such period as may be determined by or under the licence) of the licence holder’s intention to cease providing a health care service for the purposes of the NHS, and
    - (iii) if Monitor so directs, to continue providing that service for a period determined by Monitor,
  - (j) about the use or disposal by the licence holder of assets used in the provision of health care services for the purposes of the NHS in order to ensure the continued provision of one or more of the health care services that the licence holder provides for those purposes, and
  - (k) about the making by the licence holder of investment in relation to the provision of health care services for the purposes of the NHS in order to ensure the continued provision of one or more of the health care services that the licence holder provides for those purposes.
- (2) In subsection  
(1)  
“specified” means specified in a condition.
- (3) Monitor must not include a condition under subsection (1)(c) that requires the licence holder (A) to provide another licence holder with access to facilities of A.
- (4) A condition under subsection  
(1)(d)  
—
  - (a) may be included only in the licence of an NHS foundation trust or a body which (or part of which) used to be an NHS trust established under section 25 of the National Health Service Act 2006, and
  - (b) ceases to have effect at the end of the period of five years beginning with the day on which it is included in the licence.
- (5) The references in subsection  
(1)(d)  
to the activities of a licence holder or other business include a reference to part of the activities concerned.
- (6) The references in subsections  
(1)(d)  
and  
(5)  
to the activities of a business include a reference to the activities of an NHS foundation trust in so far as its activities would not otherwise be the activities of a business.

- (7) A condition of a licence under this Chapter may provide that it is to have effect, or cease to have effect, at such times and in such circumstances as may be determined by or under the conditions.

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

- (1) The things which a licence holder may be required to do by a condition under section 97(1)(i)(i) include, in particular—
- (a) providing information to the commissioners of services to which the condition applies and to such other persons as Monitor may direct,
  - (b) allowing Monitor to enter premises owned or controlled by the licence holder and to inspect the premises and anything on them, and
  - (c) co-operating with such persons as Monitor may appoint to assist in the management of the licence holder's affairs, business and property.
- (2) A commissioner of services to which a condition under section 97(1)(i), (j) or (k) applies must co-operate with persons appointed under subsection (1)(c) in their provision of the assistance that they have been appointed to provide.
- (3) Where a licence includes a condition under section 97(1)(i), (j) or (k), Monitor must carry out an ongoing assessment of the risks to the continued provision of services to which the condition applies.
- (4) Monitor must publish guidance—
- (a) for commissioners of a service to which a condition under section 97(1)(i), (j) or (k) applies about the exercise of their functions in connection with the licence holders who provide the service, and
  - (b) for such licence holders about the conduct of their affairs, business and property at a time at which such a condition applies.
- (5) A commissioner of services to which a condition under section 97(1)(i), (j), or (k) applies must have regard to guidance under subsection (4)(a).
- (6) Monitor may revise guidance under subsection (4) and, if it does so, must publish the guidance as revised.
- (7) Before publishing guidance under subsection (4) or (6), Monitor must obtain the approval of—
- (a) the Secretary of State, and
  - (b) the National Health Service Commissioning Board.

**99 Notification of commissioners where continuation of services at risk**

- (1) This section applies where Monitor—
- (a) takes action in the case of a licence holder in reliance on a condition in the licence under section 97(1)(i), (j) or (k), and
  - (b) does so because it is satisfied that the continued provision for the purposes of the NHS of health care services to which that condition applies is being put at significant risk by the configuration of certain health care services provided for those purposes.
- (2) In subsection (1), a reference to the provision of services is a reference to their provision by the licence holder or any other provider.

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- (3) Monitor must as soon as reasonably practicable notify the National Health Service Commissioning Board and such clinical commissioning groups as Monitor considers appropriate—
  - (a) of the action it has taken, and
  - (b) of its reasons for being satisfied as mentioned in subsection (1)(b).
- (4) Monitor must publish for each financial year a list of the notifications under this section that it has given during that year; and the list must include for each notification a summary of Monitor’s reasons for being satisfied as mentioned in subsection (1)(b).
- (5) The Board and clinical commissioning groups, having received a notification under this section, must have regard to it in arranging for the provision of health care services for the purposes of the NHS.

## **100 Modification of standard conditions**

- (1) Monitor may, subject to the requirements of this section, modify the standard conditions applicable to all licences under this Chapter or to licences of a particular description.
- (2) Before making any such modifications Monitor must give notice to—
  - (a) each relevant licence holder,
  - (b) the Secretary of State,
  - (c) the National Health Service Commissioning Board,
  - (d) every clinical commissioning group, and
  - (e) the Care Quality Commission and its Healthwatch England committee.
- (3) Monitor must also publish the notice under subsection [\(2\)](#).
- (4) The notice under subsection [\(2\)](#) must—
  - (a) state that Monitor proposes to make the modifications,
  - (b) set out the proposed effect of the modifications,
  - (c) set out Monitor’s reasons for the proposal, and
  - (d) specify the period (“the notice period”) within which representations with respect to the proposal may be made to Monitor.
- (5) The notice period must be not less than 28 days beginning with the day after that on which the notice is published under subsection [\(3\)](#).
- (6) Monitor may not make any modifications under this section unless—
  - (a) no relevant licence holder has made an objection to Monitor about the proposal within the notice period, or
  - (b) subsection [\(7\)](#) applies to the case.

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- (7) This subsection applies where—
- (a) one or more relevant licence holders make an objection to Monitor about the proposal within the notice period,
  - (b) the objection percentage is less than the percentage prescribed for the purposes of this paragraph, and
  - (c) the share of supply percentage is less than the percentage prescribed for the purposes of this paragraph.
- (8) In subsection (7)
- (a) the “objection percentage” is the proportion (expressed as a percentage) of the relevant licence holders who objected to the proposals;
  - (b) the “share of supply percentage” is the proportion (expressed as a percentage) of the relevant licence holders who objected to the proposals, weighted according to their share of the supply in England of such services as may be prescribed.
- (9) Regulations prescribing a percentage for the purposes of subsection (7)(c) may include provision prescribing the method to be used for determining a licence holder’s share of the supply in England of the services concerned.
- (10) Where Monitor modifies the standard conditions applicable to all licences or (as the case may be) to licences of a particular description under this section, Monitor—
- (a) may also make such incidental or consequential modifications as it considers necessary or expedient of any other conditions of a licence which is affected by the modifications,
  - (b) must make (as nearly as may be) the same modifications of those conditions for the purposes of their inclusion in all licences or (as the case may be) licences of that description granted after that time, and
  - (c) must publish the modifications.
- (11) In this section and section 101, “relevant licence holder”—
- (a) in relation to proposed modifications of the standard conditions applicable to all licences, means any licence holder, and
  - (b) in relation to proposed modifications of the standard conditions applicable to licences of a particular description, means a holder of a licence of that description.
- (12) In this section, a reference to modifying a condition includes a reference to amending, omitting or adding a condition.

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

- (1) Subsection (2) applies where—
- (a) Monitor has given notice under section 95(2) of a proposal to include a special condition in a licence or modify such a condition, and
  - (b) the applicant or (as the case may be) licence holder concerned has refused consent to the inclusion of the condition or the making of the modifications.

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- (2) Monitor may make a reference to the Competition Commission which is so framed as to require the Commission to investigate and report on the questions—
- (a) whether any matters which relate to the provision, or proposed provision, of a health care service for the purposes of the NHS by the applicant or (as the case may be) licence holder concerned and which are specified in the reference, operate, or may be expected to operate, against the public interest, and
  - (b) if so, whether the effects adverse to the public interest which those matters have or may be expected to have could be remedied or prevented by the inclusion of a special condition in the applicant's licence or by modifications of a special condition of the licence holder's licence.
- (3) Subsection (4) applies where—
- (a) Monitor has given notice under section 100(2) of a proposal to make modifications to the standard conditions applicable to all licences under this Chapter, or to licences of a particular description, and
  - (b) section 100 operates to prevent Monitor from making the modifications.
- (4) Monitor may make a reference to the Competition Commission which is so framed as to require the Commission to investigate and report on the questions—
- (a) whether any matters which relate to the provision of health care services for the purposes of the NHS by the relevant licence holders, and which are specified in the reference, operate, or may be expected to operate, against the public interest, and
  - (b) if so, whether the effects adverse to the public interest which those matters have or may be expected to have could be remedied or prevented by modifications of the standard conditions applicable to all licences under this Chapter, or to licences of a particular description.
- (5) Schedule 10 (which makes further provision about references to the Competition Commission) has effect in relation to a reference under subsection
- (2)  
or  
(4)  
; and, for that purpose, the relevant persons are—
- (a) in paragraphs 3, 6(6) and 7(6)—
    - (i) the applicant or licence holder concerned or (as the case may be) relevant licence holders,
    - (ii) the National Health Service Commissioning Board, and
    - (iii) such clinical commissioning groups as are likely to be affected by matters to which the reference relates,
  - (b) in paragraph 5(6), the applicant or licence holder concerned or (as the case may be) relevant licence holders, and
  - (c) in paragraph 8(10)—
    - (i) the applicant or licence holder concerned or (as the case may be) relevant licence holders,
    - (ii) Monitor,
    - (iii) the National Health Service Commissioning Board, and
    - (iv) such clinical commissioning groups as are likely to be affected by the proposal concerned.

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- (6) In investigating the question under subsection (2)(a) or (4)(a) the Competition Commission must have regard to—
  - (a) the matters in respect of which Monitor has duties under section 62, and
  - (b) the matters to which Monitor must have regard by virtue of section 66.
- (7) Where the standard conditions applicable to all licences or (as the case may be) to licences of a particular description are modified pursuant to a reference made under subsection (4), Monitor—
  - (a) may also make such incidental or consequential modifications as it considers necessary or expedient of any other conditions of a licence which is affected by the modifications,
  - (b) must make (as nearly as may be) the same modifications of those conditions for the purposes of their inclusion in all licences or (as the case may be) licences of that description granted after that time, and
  - (c) must publish any modifications made under this subsection.
- (8) In this section, a reference to modifying a condition includes a reference to amending, omitting or adding a condition.

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

- (1) This section applies where the Office of Fair Trading, Competition Commission or Secretary of State (the “relevant authority”) makes a relevant order.
- (2) A relevant order may modify—
  - (a) the conditions of a particular licence, or
  - (b) the standard conditions applicable to all licences under this Chapter or to licences of a particular description.
- (3) The modifications which may be made by a relevant order are those which the relevant authority considers necessary or expedient for the purpose of giving effect to, or taking account of, any provision made by the order.
- (4) In this section “relevant order” means—
  - (a) an order under section 75, 83 or 84 of, or paragraph 5, 10 or 11 of Schedule 7 to, the Enterprise Act 2002 where one or more of the enterprises which have, or may have, ceased to be distinct enterprises were engaged in the provision of health care services for the purposes of the NHS;
  - (b) an order under any of those provisions of that Act where one or more of the enterprises which will or may cease to be distinct enterprises is engaged in the provision of health care services for the purposes of the NHS;
  - (c) an order under section 160 or 161 of that Act where the feature, or combination of features, of the market in the United Kingdom for goods or services which prevents, restricts or distorts competition relates to—
    - (i) the commissioning by the National Health Service Commissioning Board or a clinical commissioning group of health care services for the purposes of the NHS, or
    - (ii) the provision of those services.
- (5) The modification under subsection (2)(a)



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of part of a standard condition of a licence does not prevent any other part of the condition from continuing to be regarded as a standard condition for the purposes of this Chapter.

- (6) Where the relevant authority modifies the standard conditions applicable to all licences or (as the case may be) to licences of a particular description under this section, the relevant authority—
- (a) may, after consultation with Monitor, make such incidental or consequential modifications as the relevant authority considers necessary or expedient of any other conditions of any licence which is affected by the modifications,
  - (b) must also make (as nearly as may be) the same modifications of those conditions for the purposes of their inclusion in all licences or (as the case may be) licences of that description granted after that time, and
  - (c) must publish any modifications it makes under paragraph (b)
- (7) Expressions used in subsection (4) and in Part 3 or (as the case may be) Part 4 of the Enterprise Act 2002 have the same meaning in that subsection as in that Part.
- (8) In this section, a reference to modifying a condition includes a reference to amending, omitting or adding a condition.

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

- (1) The standard conditions applicable to any licence under this Chapter must include a condition requiring the licence holder to—
- (a) set transparent eligibility and selection criteria, and
  - (b) apply those criteria in a transparent way to persons who, having a choice of persons from whom to receive health care services for the purposes of the NHS, choose to receive them from the licence holder.
- (2) “Eligibility and selection criteria”, in relation to a licence holder, means criteria for determining—
- (a) whether a person is eligible, or is to be selected, to receive health care services provided by the licence holder for the purposes of the NHS, and
  - (b) if the person is selected, the manner in which the services are provided to the person.
- (3) The following powers must not be exercised so as to omit the condition mentioned in subsection (1) from any licence under this Chapter—
- (a) the powers conferred on Monitor by sections 100, 101(7) and paragraph 7(2) of Schedule 10 to modify the standard conditions applicable to all licences, or to licences of a particular description,
  - (b) the power conferred on the Competition Commission by paragraph 8(5) of that Schedule to modify those conditions, and
  - (c) the powers conferred by section 102 on the Office of Fair Trading, Competition Commission and Secretary of State to modify those conditions or the conditions of a particular licence.

### *Enforcement*

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

- (1) Monitor may require a person mentioned in subsection (2) to provide it with any information, documents, records or other items which it considers it necessary or expedient to have for the purposes of any of its regulatory functions.
- (2) The persons are—
  - (a) an applicant for a licence under this Chapter,
  - (b) a licence holder,
  - (c) a person who has provided, or is providing, a health care service for the purposes of the NHS in accordance with an exemption by virtue of section 83 from the requirement to hold a licence under this Chapter,
  - (d) a person who has provided, or is providing, a health care service for the purposes of the NHS in breach of that requirement,
  - (e) the National Health Service Commissioning Board, and
  - (f) a clinical commissioning group.
- (3) The power in subsection (1) includes, in relation to information, documents or records kept by means of a computer, power to require the provision of the information, documents or records in legible form.
- (4) For the purposes of subsection (1) Monitor’s regulatory functions are its functions under—
  - (a) this Chapter,
  - (b) Chapters 4 to 6,
  - (c) Chapter 5 of Part 2 of the National Health Service Act 2006 (NHS foundation trusts), and
  - (d) Chapter 5A of that Part of that Act (trust special administration).

#### **105 Discretionary requirements**

- (1) Monitor may impose one or more discretionary requirements on a person if Monitor is satisfied that the person—
  - (a) has provided, or is providing, a health care service for the purposes of the NHS in breach of the requirement to hold a licence under this Chapter (see section 81),
  - (b) is a licence holder who has provided, or is providing, a health care service for the purposes of the NHS in breach of a condition of the licence, or
  - (c) is in breach of a requirement imposed by Monitor under section 104.
- (2) In this Chapter, “discretionary requirement” means—
  - (a) a requirement to pay a monetary penalty to Monitor of such amount as Monitor may determine (referred to in this Chapter as a “variable monetary penalty”),

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- (b) a requirement to take such steps within such period as Monitor may specify, to secure that the breach in question does not continue or recur (referred to in this Chapter as a “compliance requirement”), or
  - (c) a requirement to take such steps within such period as Monitor may specify, to secure that the position is, so far as possible, restored to what it would have been if the breach in question was not occurring or had not occurred (referred to in this Chapter as a “restoration requirement”).
- (3) Monitor must not impose discretionary requirements on a person on more than one occasion in relation to the same breach.
- (4) A variable monetary penalty must not exceed 10% of the turnover in England of the person on whom it is imposed, such amount to be calculated in the prescribed manner.
- (5) If the whole or any part of a variable monetary penalty is not paid by the time it is required to be paid, the unpaid balance from time to time carries interest at the rate for the time being specified in section 17 of the Judgments Act 1838; but the total interest must not exceed the amount of the penalty.

## **106 Enforcement undertakings**

- (1) Monitor may accept an enforcement undertaking from a person if Monitor has reasonable grounds to suspect that the person—
- (a) has provided, or is providing, a health care service for the purposes of the NHS in breach of the requirement to hold a licence under this Chapter,
  - (b) is a licence holder who has provided, or is providing, a health care service for the purposes of the NHS in breach of a condition of the licence, or
  - (c) is in breach of a requirement imposed by Monitor under section 104.
- (2) In this Chapter, “enforcement undertaking” means an undertaking from a person to take such action of a kind mentioned in subsection
- (3) as may be specified in the undertaking within such period as may be so specified.
- (3) The specified action must be—
- (a) action to secure that the breach in question does not continue or recur,
  - (b) action to secure that the position is, so far as possible, restored to what it would have been if the breach in question was not occurring or had not occurred,
  - (c) action (including the payment of a sum of money) to benefit—
    - (i) any other licence holder affected by the breach, or
    - (ii) any commissioner of health care services for the purposes of the NHS which is affected by the breach, or
  - (d) action of such a description as may be prescribed.
- (4) Where Monitor accepts an enforcement undertaking then, unless the person from whom the undertaking is accepted has failed to comply with the undertaking or any part of it—
- (a) Monitor may not impose on that person any discretionary requirement which it would otherwise have power to impose by virtue of section 105 in respect of the breach to which the undertaking relates, and
  - (b) if the breach to which the undertaking relates falls within subsection
- (1)(b)

, Monitor may not revoke that person's licence under section 89

(b)

- (5) Where a person from whom Monitor has accepted an enforcement undertaking has failed to comply fully with the undertaking but has complied with part of it, Monitor must take the partial compliance into account in deciding whether—
- (a) to impose a discretionary requirement on the person in respect of the breach to which the undertaking relates, or
  - (b) if the breach to which the undertaking relates falls within subsection (1)(b), to revoke the person's licence under section 89(b).

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

Schedule 11 (Part 1 of which makes further provision about discretionary requirements and Part 2 of which makes further provision about enforcement undertakings) has effect.

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

- (1) Monitor must publish guidance about how it intends to exercise its functions under sections 105 and 106 and Schedule 11.
- (2) Monitor may revise the guidance and, if it does so, must publish the guidance as revised.
- (3) Monitor must consult such persons as it considers appropriate before publishing or revising the guidance.
- (4) Guidance relating to Monitor's functions under section 105 must include information about—
  - (a) the circumstances in which Monitor is likely to impose a discretionary requirement,
  - (b) the circumstances in which Monitor may not impose a discretionary requirement,
  - (c) the matters likely to be taken into account by Monitor in determining the amount of any variable monetary penalty to be imposed (including, where relevant, any discounts for voluntary reporting of breaches in respect of which a penalty may be imposed), and
  - (d) rights to make representations and rights of appeal.
- (5) Monitor must have regard to the guidance or (as the case may be) revised guidance in exercising its functions under sections 105 and 106 and Schedule 11.

### **109 Publication of enforcement action**

- (1) Monitor must include information about the following in its annual report—
  - (a) the cases in which a discretionary requirement has been imposed during the financial year to which the report relates, and
  - (b) the cases in which an enforcement undertaking has been accepted during that financial year.

- (2) But Monitor must not include information which it is satisfied is—
  - (a) commercial information the disclosure of which would, or might, significantly harm the legitimate business interests of the person to whom it relates;
  - (b) information relating to the private affairs of an individual the disclosure of which would, or might, significantly harm that person’s interests.
- (3) The reference in subsection (1)(a) to cases in which a discretionary requirement has been imposed does not include a reference to a case where a discretionary requirement has been imposed but overturned on appeal.

#### **110 Notification of enforcement action**

- (1) As soon as reasonably practicable after imposing a discretionary requirement or accepting an enforcement undertaking Monitor must notify the following of that fact—
  - (a) the National Health Service Commissioning Board,
  - (b) such clinical commissioning groups as are likely to be affected by the imposition of the requirement or the acceptance of the undertaking, and
  - (c) any person exercising regulatory functions in relation to the person on whom the discretionary requirement was imposed or from whom the enforcement undertaking was accepted.
- (2) In subsection (1) “regulatory functions” has the same meaning as in the Legislative and Regulatory Reform Act 2006 (see section 32 of that Act).

#### *Transitional provision*

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

- (1) Where Monitor is satisfied that the governance of an NHS foundation trust is such that the trust will fail to comply with the conditions of its licence, Monitor may include in the licence such conditions relating to governance as it considers appropriate for the purpose of reducing that risk.
- (2) The circumstances in which Monitor may be satisfied as mentioned in subsection (1) include circumstances where it is satisfied that the council of governors, the board of directors or the council of governors and board of directors taken together are failing—
  - (a) to secure compliance with conditions in the trust’s licence, or
  - (b) to take steps to reduce the risk of a breach of a condition in the trust’s licence.
- (3) A condition included under subsection (1) has effect until this section ceases, by virtue of section 112, to have effect in relation to the trust.
- (4) Monitor may modify a condition included under subsection (1).
- (5) Where Monitor is satisfied that the trust has breached or is breaching a condition included under subsection (1), Monitor may by notice require the trust to—
  - (a) remove one or more of the directors or members of the council of governors and appoint interim directors or members of the council;
  - (b) suspend one or more of the directors or members of the council from office as a director or member for a specified period;

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- (c) disqualify one or more of the directors or members of the council from holding office as a director or member for a specified period.
- (6) Where Monitor is satisfied that a person has failed or is failing to comply with a notice under subsection
  - (5), Monitor may do one or more of the things which it may require the trust to do under that subsection.
- (7) Subsection
  - (5) does not prevent Monitor from exercising in relation to a condition included in a licence under subsection (1) the powers conferred by sections 105 and 106 (breach of licence condition etc: enforcement powers which apply during and after period in which this section and sections 112 to 114 have effect).
- (8) Where Monitor includes a condition under subsection (1), it may also make such incidental or consequential modifications as it considers necessary or expedient of any other condition of the licence concerned which is affected.
- (9) Where Monitor includes a condition under subsection (1) by modifying a standard condition of the licence concerned, the modification does not prevent any other part of the condition from continuing to be regarded as a standard condition for the purposes of this Chapter.
- (10) In this section, a reference to failing to discharge functions includes a reference to failing to discharge those functions properly.
- (11) Omit section 52 of the National Health Service Act 2006 (failing NHS foundation trusts); and in consequence of that, omit—
  - (a) section 39(2)(f) of that Act (copy of notice under section 52 of that Act to be on register), and
  - (b) paragraph 22(1)(f) of Schedule 7 to that Act (copy of that notice to be available for public inspection).

## **112 Duration of transitional period**

- (1) Section 111 ceases to have effect in relation to an NHS foundation trust on such day as the Secretary of State may by order specify.
- (2) Different days may be appointed in relation to different NHS foundation trusts.
- (3) A day specified under subsection (1) must not—
  - (a) in the case of an NHS foundation trust authorised on or before 1 April 2014, be before 1 April 2016;
  - (b) in the case of an NHS foundation trust authorised after 1 April 2014, be before the end of the period of two years beginning with the day on which the trust was authorised.
- (4) In this section, a reference to being authorised is a reference to being given an authorisation under section 35 of the National Health Service Act 2006.
- (5) Section 111 is repealed as soon as there are—
  - (a) no NHS foundation trusts in relation to which it has effect, and

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- (b) no NHS trusts in existence (whether because they had all ceased to exist without section 179 having come into force or there are none continuing in existence by virtue of subsection (3) of that section).

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

- (1) Where the Secretary of State proposes to make an order under section 112, the Secretary of State must notify Monitor.
- (2) Monitor, having received a notification under subsection (1), must set the criteria that are to be applied for the purpose of determining to which NHS foundation trusts the order should apply.
- (3) Before setting criteria under subsection (2), Monitor must—
  - (a) consult the Care Quality Commission and such other persons as Monitor considers appropriate, and
  - (b) obtain the approval of the Secretary of State.
- (4) If the Secretary of State approves the proposed criteria, Monitor must—
  - (a) publish the criteria,
  - (b) determine, by applying the criteria, to which trusts the order should apply,
  - (c) notify the Secretary of State of its determination, and
  - (d) publish a list of the trusts concerned.
- (5) If the Secretary of State does not approve the proposed criteria, Monitor must propose revised criteria; and subsections (3)(b) and (4) apply in relation to the proposed revised criteria as they apply in relation to the criteria previously proposed.
- (6) The Secretary of State, having received a notification under subsection (4)(c), must review Monitor’s determination under subsection (4)(b).

### **114 Repeal of sections 112 and 113**

- (1) Sections 112 and 113 are repealed immediately after section 111 is repealed; and in consequence of that—
  - (a) in section 67(2)(a), omit “or under sections 111 and 113 of this Act (imposition of licence conditions on NHS foundation trusts during transitional period)”,
  - (b) omit section 67(3),
  - (c) in section 87(4), after paragraph (a) insert “and”, and
  - (d) in section 87(4), omit paragraph (c) and the preceding “and”.
- (2) This section is repealed immediately after sections 112 and 113 are repealed.