

# Enforcement Guidance

**28 March 2013**

*Monitor's enforcement guidance explains the action we can take to enforce compliance with the provider licence and other regulatory obligations on providers and others required to provide Monitor with information needed to perform its functions. It sets out the proposed process for prioritising issues, deciding on the action to take and seeking input from stakeholders on our proposed actions.*



## Foreword



The Health and Social Care Act 2012 (the Act) makes changes to the way health care is regulated, including expanding Monitor's role by giving us a number of additional responsibilities. As part of these changes we are given a new main duty to protect and promote the interests of people who use health care services by promoting the provision of services which is economic, efficient and effective, and maintains or improves the quality of the services.

As the foundation of our new role, the Act requires that Monitor issue licences for providers of NHS services and also gives Monitor powers to enforce this licence. These powers enable Monitor to investigate potential breaches of the licence and then to either impose requirements on NHS service providers where we find actual breaches, or accept undertakings from the provider, to make sure they return to compliance. The requirements we can impose range from obliging providers to take steps to restore compliance, requiring providers to restore the position before the breach or obliging them to pay a financial penalty. In exceptional circumstances, we can also consider revoking a licence.

Some of the enforcement powers of the Act can also be exercised against those who are not licence holders - such as those operating without a licence when required to hold one, and those in breach of a requirement to provide Monitor with information. The Act separately gives Monitor concurrent powers with the Office of Fair Trading to apply competition law in the health care sector in England.

This document sets out guidance on how we will exercise our enforcement powers. As examples, this guidance will apply to:

- complaints from a commissioner that a provider has acted unreasonably in refusing to supply a service as a Commissioner Requested Service, in breach of its licence;
- complaints that a provider is not charging in line with the national tariff as required by its licence;
- complaints that a provider has acted anti-competitively in breach of its licence and/or competition law;
- investigations into whether an NHS foundation trust may be in breach of its licence conditions about governance; and
- failures, by those obliged to do so, to provide information to Monitor.

In this document we explain when we may formally investigate potential breaches, the processes we are likely to follow, and the factors that we may consider when deciding what requirements to impose should Monitor find a breach of the provider licence.

We are very grateful for the support and engagement of stakeholders in helping develop this guidance through the recent consultation. This is a new enforcement framework which we will develop and refine over time as we learn through practice. But we are keen to start with an effective regime building on regulatory experience to date.



**Adrian Masters**  
**Managing Director of Sector Development**

# 1 Introduction

The Health and Social Care Act 2012 (the Act) makes changes to the way providers of NHS health care services will be regulated and gives Monitor new duties and powers. Further information on our role can be found on our website: [www.monitor.gov.uk](http://www.monitor.gov.uk)

This guidance covers the general approach that Monitor will take to using our provider licence enforcement and competition law powers over health care providers. Parts of it apply to others who may be required to supply Monitor with information. This document explains:

- when Monitor may decide to take action, and what action we might take;
- how Monitor is likely to decide what kind of sanctions to impose using our powers under the Act; and
- the high-level processes Monitor intends to follow when taking enforcement action.

This guidance is designed to provide information about how Monitor generally expects to go about our enforcement work. The circumstances in some cases may make it appropriate for us to depart from the guidance.

We have written this guidance to be as clear as possible, and have tried to use straightforward language and avoided quoting sections of the Act where possible; this means that, sometimes, we do not use the exact wording used in the Act which would, of course, override this guidance.

All of this guidance is relevant to providers of NHS health care services in England. The sections that cover competition law are relevant to all providers of health care services in England. The sections covering enforcement action under sections 105 and 106 of the Act apply also to others where they may be in breach of a requirement to provide Monitor with information; this applies to the NHS Commissioning Board and clinical commissioning groups. This guidance does not cover Monitor's approach to using our enforcement powers under the [\*National Health Service \(Procurement, Patient Choice and Competition\) \(No. 2\) Regulations 2013\*](#).

As we move from the current framework of regulating NHS foundation trusts through their terms of Authorisation to regulating them through the licence, we are following a similar approach to that set out in this guidance in 'translating' breaches of terms of the Authorisation into appropriate regulatory action under the licence, to take effect as the licence comes into force. We are working closely with the NHS foundation trusts affected by this to achieve a smooth transition.

## 1.1 Scope of the guidance

The Act requires Monitor to introduce a licence for providers of NHS health care services, the standard conditions for which are available [here](#). The Act gives Monitor associated enforcement powers under sections 105 and 106. Monitor may use these specific enforcement powers to ensure that any provider that should hold a licence does in fact hold one, all licensed providers comply with their licence conditions and all providers and others who may be obliged to comply with requests from Monitor to provide information.

Section 89 of the Act gives Monitor the power to revoke a provider's licence if we are satisfied that the provider has failed to comply with a licence condition. Some of this guidance also applies to investigations which may result in revocation of a licence under section 89 of the Act.

Section 111 of the Act gives Monitor additional specific powers to take action where the governance of an NHS foundation trust is such that it is failing, or will fail, to comply with one or more of the conditions in its licence. These powers are in addition to those described above. Some of this guidance also applies to investigations which may result in an intervention under section 111 of the Act.

When carrying out the above functions, Monitor will seek to ensure that the enforcement actions we take enable us to best achieve our main duty to protect and promote the interests of people that use health care services (health care service users) by promoting the provision of health care services which is economic, efficient and effective, and maintains or improves the quality of the services.

The Act gives Monitor concurrent powers with the Office of Fair Trading (OFT) to apply competition law in relation to the provision of health care services in England meaning that either Monitor or the OFT may act in relation to a particular case. Some of this guidance also has relevance to investigations that Monitor may carry out under the Competition Act 1998 (the Competition Act) and the Treaty on the Functioning of the European Union (the TFEU). It gives an overview of the investigation process we intend to follow and contains links to information published by the OFT. Monitor and the OFT will decide on a case-by-case basis which organisation is best placed to investigate an issue. We may, in the future, publish more detailed guidance on Monitor's procedures around applying competition law.

This guidance also describes how we will prioritise our enforcement work in order to make the best use of resources. We intend to apply the same principles for prioritising all of our decisions that potentially involve a significant amount of resource to a case or project.

**Table 1.1 Monitor’s enforcement powers**

How this guidance applies to Monitor’s different enforcement powers:

Regulatory action	Informal action	Enforcement undertakings (section 106)	Discretionary requirements (section 105)	Section 111 new licence condition	Section 111 remove, suspend or disqualify directors / governors	Revoking a provider’s licence (section 89)	Competition law (section 72)
Section of guidance							
2.2 Prioritisation	✓	✓	✓	✓	✓	✓	✓
2.3 Informal or formal action	✓	✓	✓	✓	✓	✓	✓
3.2 to 3.4 Imposing discretionary requirements			✓	✓	✓	✓	
3.5 Accepting enforcement undertakings		✓					
4.2.1 Case initiation	✓	✓	✓	✓	✓	✓	✓
4.2.2 Investigations	✓	✓	✓		✓	✓	✓
4.2.3 Case updates	✓	✓	✓	✓	✓	✓	✓
4.2.4 Entering into enforcement undertakings		✓					
4.2.5 Discretionary requirements			✓				
4.3 Procedures for licence revocation						✓	
4.4 Actions under section 111 of the Act (applies to NHS foundation trusts)				✓	✓		
4.5 Investigations under competition law							✓
5 Decision making	✓	✓	✓	✓	✓	✓	✓
6.2 Rights of appeal		✓*	✓			✓	✓

**\* Right of appeal for enforcement undertakings is only in relation to a refusal by Monitor to issue a certificate of compliance with undertakings.**

## 1.2 Monitor's enforcement powers

In this section we explain the different enforcement powers that the Act gives Monitor. More details of Monitor's enforcement powers are in the Annex. This section outlines:

### **Licence enforcement**

- what discretionary requirements are and when Monitor may impose them - section 105 of the Act;
- what enforcement undertakings are and when Monitor may accept them - section 106 of the Act;
- Monitor's power to revoke a provider's licence - section 89 of the Act;
- Monitor's powers to impose additional licence conditions on an NHS foundation trust, and to require a foundation trust to remove, suspend or disqualify one or more of its directors and/or governors - section 111 of the Act; and

### **Competition law enforcement**

- Monitor's powers to apply competition law.



## Licence enforcement

### *Discretionary requirements under the Act*

Where Monitor finds that a provider is breaching, or has breached, one or more of its licence conditions, or has not met a requirement to hold a licence, or has failed to provide Monitor with information we require, Monitor may impose one or more of the 'discretionary requirements' specified in section 105 of the Act. Monitor may also impose such requirements on others in breach of a requirement to provide us with information.

The discretionary requirements that Monitor may impose are:

- **compliance requirements** which require a provider to take such steps as we may specify to ensure that the breach in question does not continue or recur;
- **restoration requirements** which require a provider to take such actions as we may specify to restore the situation to what it would have been, absent the breach; and
- **variable monetary penalties** which require a provider to pay a penalty.

The Act requires us to explain in guidance how we intend to exercise our powers to impose discretionary requirements including:

- when we are likely to impose a discretionary requirement - see Chapter 3;
- when we may not impose a discretionary requirement - see Chapter 3;
- the matters we are likely to take into account in determining a variable monetary penalty, including any discounts for voluntary reporting - see Chapter 3; and
- a provider's rights to make representations and rights of appeal - see Chapter 6.

### *Enforcement undertakings under the Act*

If Monitor has reasonable grounds to suspect that a provider is breaching, or has breached, one or more of its licence conditions, or has not met a requirement to hold a licence, or has failed to provide Monitor with information we required, we may also accept 'enforcement undertakings', as described in section 106 of the Act. Monitor may also accept such undertakings from others in breach of a requirement to provide us with information.

Enforcement undertakings are actions that providers commit themselves to taking and which Monitor may decide to accept. They would usually be used as an alternative to investigating further with the attendant possibility of imposing discretionary requirements.

An enforcement undertaking may include one or more of the following commitments:

- action to ensure that the breach does not continue or recur;
- action to ensure that the position is, so far as possible, restored to what it would have been, absent the breach;
- action, including the payment of a sum of money, to benefit any other licensee affected by the breach, any provider of NHS health care services affected by the breach, or any commissioner of NHS health care services affected by the breach; or
- action of such a description as may be prescribed.

The Act requires us to include in our guidance information about how we intend to exercise our powers to accept enforcement undertakings - see Chapters 3 and 4.

### ***Revoking a provider's licence***

Monitor may also revoke a provider's licence if we are satisfied that the provider has failed to comply with a licence condition, as set out in section 89 of the Act.

### ***Powers to impose additional licence conditions on NHS foundation trusts***

Monitor has additional specific powers to take action where the governance of an NHS foundation trust is such that it is failing, or will fail, to comply with one or more of the conditions in its licence.

There are two parts to these powers:

- I. where Monitor is satisfied that an NHS foundation trust's directors and/or governors are failing to (a) secure compliance with conditions in the foundation trust's licence, or (b) take steps to reduce the risk of a breach of a condition in the foundation trust's licence under section 111 of the Act, Monitor may include in the licence such conditions relating to governance as Monitor considers appropriate; and
- II. where Monitor is satisfied that the NHS foundation trust has breached, or is breaching, an additional licence condition that was included under section 111 of the Act, we may use our powers to require the foundation trust to remove, suspend or disqualify one or more of the foundation trust's directors and/or governors or, if the foundation trust does not do so, Monitor may make such changes.

## Competition law

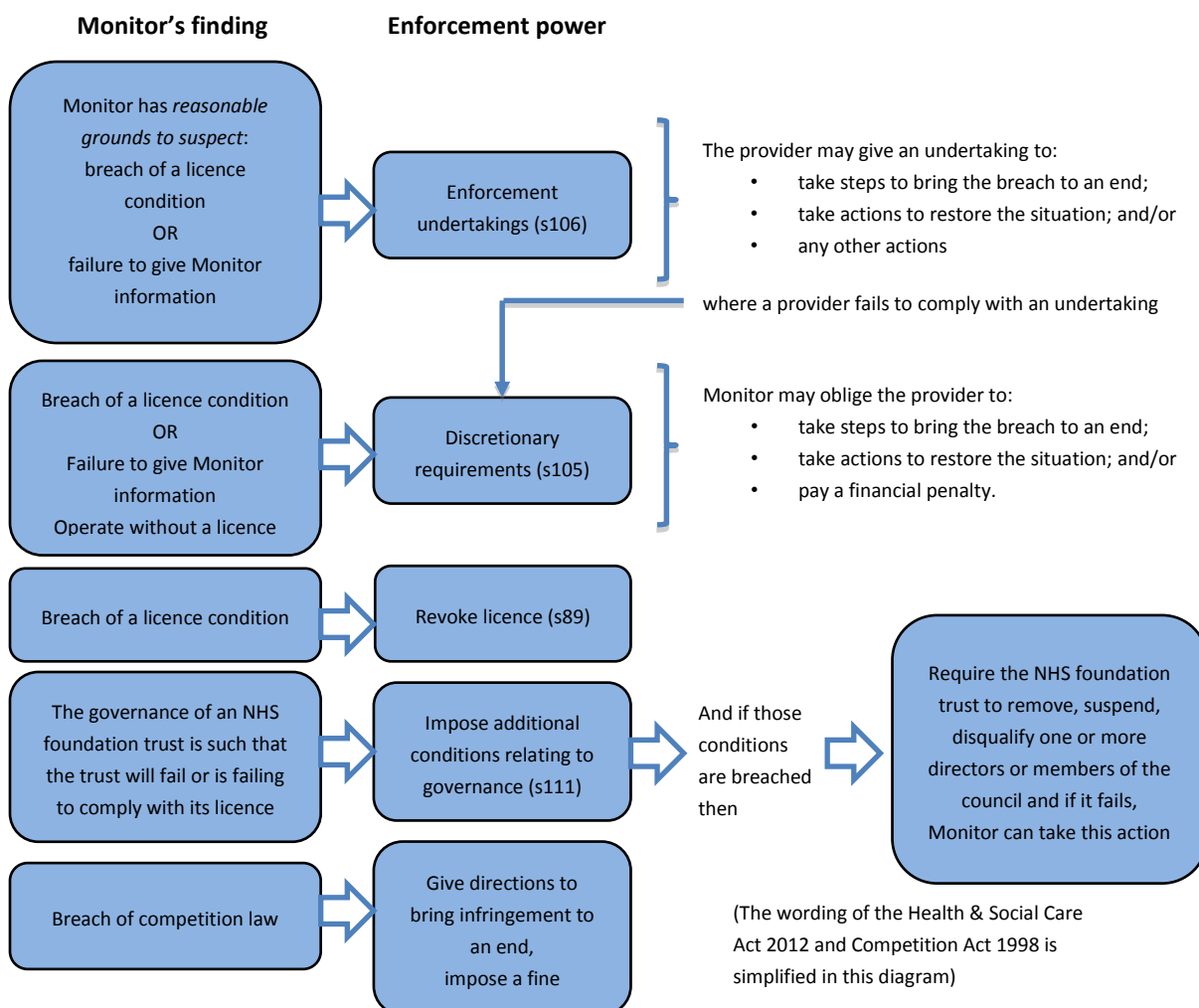
Monitor has concurrent powers with the OFT to apply UK and European competition law to providers in the health care sector in England. Where Monitor establishes an infringement of the Competition Act and/or Articles 101/102 of the TFEU, our enforcement powers include:

- giving directions to bring an infringement to an end; and
- imposing financial penalties.

Before any finding of infringement, Monitor may accept binding commitments offered to us by an undertaking.

Monitor's powers to apply competition law are not limited to the NHS but apply to all undertakings involved in the provision of health care services in England. Further information on what constitutes an 'undertaking' can be found [here](#).

### Overview of Monitor's formal provider enforcement powers (simplified)



### 1.3 About this document

**Chapter 2** explains how Monitor is likely to decide whether to take action, and what kind of action we might decide to take.

**Chapter 3** is about enforcement actions and explains the factors Monitor will take into account when deciding which, if any, discretionary requirements to impose or what, if any, enforcement undertakings we will accept. This chapter also covers the matters Monitor may take into account when imposing a variable monetary penalty.

**Chapter 4** describes the processes that Monitor will follow if we decide to investigate formally a potential breach. This includes the procedures for gathering information, the information that parties may receive about the investigation process, and the opportunity for the affected party to make representations.

**Chapter 5** outlines the decision-making procedures that Monitor will follow.

**Chapter 6** explains what rights of appeal exist if the affected party wishes to contest a Monitor enforcement decision or a competition law decision.

## 2 Prioritisation

This chapter sets out the prioritisation framework that we intend to follow to make sure Monitor focuses on the issues that best enable us to meet our duties and to make use of our resources.

### 2.1 Prioritisation framework

Monitor intends to apply this prioritisation framework to decisions about whether to pursue enforcement action and to all other significant cases where Monitor has discretion over whether to act. We will use this framework to inform our decisions on whether or not to begin cases, and to continue with them once under way. In developing this framework, Monitor has considered the approaches taken by other regulators, many of which also use prioritisation frameworks.

When assessing priorities for enforcement action, we would expect to draw on a range of information, including but not limited to: intelligence and information that Monitor may collect directly; information from patient representative bodies and commissioners; any complaints and representations made to Monitor; and information from providers themselves, including, for example, monitoring information supplied to us.

In weighing up the benefits and costs of taking action, we will consider, amongst any other relevant factors:

#### *The likely benefits to health care service users*

Our key consideration will be the expected benefit of our work for health care service users. When we decide whether to devote resources to a matter, we will consider all types of benefits that our actions may generate or protect. Such benefits may include:

- **Direct benefits to health care service users.** We intend to consider the impact of our actions on the quality of health care services, access to care and value for money spent on health care. We will consider both the short and longer term impacts of our proposed interventions.
- **Indirect benefits to health care service users.** We will consider whether a particular action in one area may lead to a wider, more general, benefit to health care service users. This might arise by reducing the likelihood of future breaches by the provider in question. This might also arise, for example, by prompting positive changes in the general behaviour of providers, commissioners or health care service users. For example, enforcement action considered appropriate in relation to one provider's breach of the provider conditions may also:

- deter similar breaches by other providers;
- help other providers understand how obligations apply in certain circumstances;
- enable commissioners to obtain better information about the strengths and capabilities of particular providers or effective ways to procure health care services;
- enable health care service users to become better informed about their rights and empowered to make choices;
- increase confidence in the functioning of the health care sector more generally which may lead to more providers and expansion of the sector; and
- help Monitor to identify that certain aspects of the sector may not be working well for health care service users, resulting in future policy improvements.

In assessing how much an action may benefit health care service users, we will be mindful of the **likelihood of success**. When we decide whether Monitor should take action about a suspected breach of a licence condition, we may assess, for example, whether there is a risk that Monitor might be unable to gather the evidence to be satisfied that a condition has been breached.

In determining the potential benefits of an intervention by Monitor, we will also consider whether we can achieve the best outcome for health care service users by ourselves acting or acting together with another organisation, or whether another organisation has regulatory tools that could tackle an issue more effectively, or is already taking steps that are likely to address the potential harm. For example, the Care Quality Commission, the Office of Fair Trading, the Charity Commission, the NHS Commissioning Board, the NHS Trust Development Authority, and the Advertising Standards Authority are all also able to take action within the health care sector.

If the breach relates to enabling integrated care, we will also consider the potential for action to reduce inequalities, in line with our duty under the Act.

### ***The likely costs of taking action***

To ensure that we make the best possible use of our resources, we will also consider the cost of any action. We will think about the resources needed to take a particular course of action and compare them to the potential benefits. We propose to consider staff and non-staff costs, and the likely duration of the work.

We also recognise that the actions we take may be costly for other organisations in the health care sector. So we intend to consider the impact of our possible actions on providers, and other parties, and will pay close attention to whether the burden they would impose is in proportion to the scale of the problem they aim to correct.

### *Deciding whether to take formal or informal action*

When called on to act, Monitor may need to choose between taking informal action, formal action, or no action at all. We may also consider responding to a problem in ways that do not involve the use of our enforcement powers. For example, we may decide to review the situation, review our own policy approach, or consider addressing the matter by using other powers such as the power to set prices for some NHS services.

Even when a matter could appropriately be addressed by using Monitor's formal enforcement powers, it may still be appropriate to deal with it informally and give providers an opportunity to address any issues without a formal investigation. Monitor's decision on whether to take formal or informal action will take into account the individual circumstances of the matter in hand. We will make our decisions based on what is in the interests of health care service users in line with our main duty. Relevant considerations may include:

- the impact of the breach or potential breach on health care service users;
- whether the provider has already taken steps that suggest the breach is unlikely to recur, for example by:
  - notifying the breach to Monitor as soon as it was identified; or
  - voluntarily taking action to end the breach and limit the risk of similar future breaches;
- the context in which the breach has occurred. For example, we might consider: whether the conduct involves repeated breaches of the same condition; a provider that is repeatedly breaching different conditions; whether other regulators or relevant stakeholders have relevant concerns about the provider; a provider's history of responding to breaches; the likelihood that the action being considered resulting in compliance and the speed at which it will result in compliance; whether the type of breach is thought to be widespread in the health care sector; and/ or
- whether any third parties (e.g. other regulators or litigants) are taking relevant action in relation to the same breach.

If Monitor considers that informal action is preferred over formal action, or as a first attempt to resolve a matter before moving to formal action, such informal action may involve one or more of the following:

- providing guidance, or working with providers to support them in maintaining or restoring compliance. For example, this may include the use of agreed action plans containing specific milestones and deadlines;
- issuing an advisory letter to explain a provider's obligations and what action may be advisable to maintain compliance; and
- issuing a warning letter which sets out Monitor's concerns, and notifying the provider that if it does not take action Monitor may commence a formal investigation.

In choosing the most effective response to a potential issue, we will consider which option is likely to create the most potential benefit to health care service users, with proportionate potential costs to Monitor and the sector, in line with the principles outlined above.



## 3 Imposing discretionary requirements and accepting enforcement undertakings

### 3.1 Introduction

Monitor may impose discretionary requirements where we are satisfied that a provider is, or was, in breach of a licence condition, or the requirement to hold a licence, or a requirement to supply Monitor with information. A provider subject to a formal investigation may offer Monitor an enforcement undertaking which Monitor may accept instead of investigating further and, potentially, imposing discretionary requirements. Monitor may also accept enforcement undertakings from, others in breach of a requirement to provide us with information.

This chapter outlines:

- the nature of the discretionary requirements that Monitor may impose;
- the factors that Monitor may consider in determining what requirements are needed;
- issues relevant to each requirement and how they may be implemented, including the factors that Monitor may take into account when setting a variable monetary penalty; and
- when Monitor may accept enforcement undertakings.

### 3.2 Discretionary requirements

Discretionary requirements are formally specified in the Act and may be a:

- **Compliance requirement:** A compliance requirement is an instruction from Monitor to the provider to take specified steps within a set period to secure that the breach not continue or recur. The principal focus of a compliance requirement is to secure compliance;
- **Restoration requirement:** A restoration requirement obliges the provider 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, absent the breach. Restoration requirements may also be used to compensate any affected party, including health care service users and other providers. Such a requirement could require, for example, that the provider gives up any gains it has made from the breach and restores the position of those who have suffered harm as a result; and

- **Variable monetary penalty:** Variable monetary penalties require a provider to pay a financial penalty of such amount as Monitor may specify. The variable monetary penalty must not exceed 10% of the provider's turnover in England.

Discretionary requirements may be used in combination in relation to the same breach, where appropriate. However, Monitor must not impose discretionary requirements on more than one occasion in relation to the same breach.

### 3.3 Deciding what kind of discretionary requirements to impose

In considering what, if any, discretionary requirements to impose, Monitor's aim is to ensure that any action we take promotes compliance and fulfils Monitor's main duty to protect and promote the interests of people who use health care services, by promoting the provision of health care services which is economic, efficient and effective, and maintains or improves the quality of the services. We will ensure also that we take into account all our other duties as appropriate in exercising our enforcement functions.

In deciding what action is most appropriate in the circumstances of the individual case and which requirements, if any, to impose, we intend to consider, amongst other relevant considerations:

- the seriousness of the breach;
- ensuring provider compliance;
- deterring similar breaches;
- restoring the position to what it would have been without the breach; and
- the proportionality of the remedy to the nature of the breach.

Monitor may decide not to impose a discretionary requirement if we conclude that:

- the breach caused (or was capable of causing) no harm or harm that is not material;
- a discretionary requirement is not required to ensure provider compliance;
- a discretionary requirement is not required to restore the position to what it would have been without the breach; and
- a discretionary requirement is not required to deter similar breaches.

Monitor may also decide not to impose a discretionary requirement if we conclude that the only suitable discretionary requirement would be disproportionate to the nature of the breach.

## *Seriousness*

Monitor will take into account a range of relevant factors in assessing seriousness, including:

- the nature and the scale of the harm that a breach or potential breach has caused or is capable of causing to health care service users. Monitor intends to assess:
  - who has been or is likely to be affected;
  - the extent to which any harm could be reversed or remedied;
  - the number of health care service users affected, or potentially affected, whether directly or indirectly;
  - the actual or potential impact on those health care users;
  - the duration of any harmful effects of potential effects;
- whether the provider knew or should have known that its actions would risk non-compliance; and/or
- whether the provider has committed a breach before.

The more serious the breach, the more likely Monitor will be to impose discretionary requirements.

## *Ensuring provider compliance*

Monitor will consider what action may be needed to ensure: that a breach not continue; and/or that the provider end the breach and not repeat it. Monitor will also consider what forms of intervention may be needed to deter similar breaches from recurring.

In considering whether requirements are needed to ensure that a breach not continue, Monitor proposes to assess, amongst other relevant factors:

- whether the breach has been brought to an end;
- if the breach is continuing, what steps the provider has taken and/or proposes to take voluntarily in order to bring the breach to an end;
- whether, if the provider has proposed voluntary steps, it would still be beneficial to ensure that the breach does not continue by imposing requirements relating to those proposed steps;
- whether there are other steps which Monitor considers should be taken in order to ensure that the breach not continue; and

- whether any third parties (e.g. other regulators or litigants) are taking relevant action in relation to the same breach.

If Monitor considers that discretionary requirements are needed to ensure a breach not continue, it is likely that Monitor will impose a compliance requirement.

In considering whether requirements are needed to deter further breaches by the provider, Monitor proposes to assess, amongst other relevant factors:

- Whether the provider knew, or should have known, that its actions would risk non-compliance; this may include evidence that the breach was genuinely accidental and that the provider has already taken steps to avoid non-compliance;
- How much the provider has gained, or is expected to gain, from the breach - relevant benefits may include financial and other benefits such as reputational benefits;
- Whether the provider has taken steps that suggest the breach in question will not recur - this could be, for example, by:
  - notifying the breach to Monitor as soon as it was identified;
  - voluntarily taking effective steps to ensure that the breach is remedied and to limit the risk of further breaches taking place in future;
  - cooperating generally with Monitor's enquiries and requirements; or
  - taking action to compensate those affected.
- Whether the breach could represent part of a pattern of non-compliance, emerging or otherwise, such that Monitor considers that imposing requirements is necessary to incentivise compliance in the future; and
- Whether any third parties (e.g. other regulators or litigants) are taking relevant action in relation to the same breach.

Monitor is likely to impose a discretionary requirement if we are satisfied that it is needed to deter future breaches. A compliance requirement is likely to be appropriate if there are practical steps which Monitor could require of the provider in order to ensure that the breach not recur. The greater the risk of future breach, the greater the likelihood that Monitor will impose a variable monetary penalty (whether instead of or in addition to other discretionary requirements) in order to deter a recurrence.

### ***Deterring similar breaches by other providers***

In order to deter similar breaches by other providers, Monitor will consider how the action we take in one case might also affect the incentives on other providers to comply. For example, Monitor may find it appropriate to adjust the severity of the requirements we impose according to:

- the extent to which the type of breach under consideration is thought to be widespread in the health care sector;
- the extent of harm the type of breach has caused (or is capable of causing) to health care service users; or
- whether previous sanctions have been effective or ineffective in deterring others from taking similar action.

If Monitor considers that it is necessary to adjust the proposed discretionary requirements in order to deter similar breaches by other providers, it is likely that Monitor would impose (or increase) a variable monetary penalty. However, in appropriate cases the objective of deterring similar breaches by other providers may be met through the imposition of, or modifications to, a compliance requirement or a restoration requirement.

### ***Restoring the position to what it would have been without the breach***

Monitor will consider whether it would be desirable and feasible to take steps to restore the position to what it would have been without the breach. If so, Monitor may impose a restoration requirement.

Restoration could require a provider to give up any gains it has made from a breach and restore the position of those who have suffered harm as a result. Restoration requirements may be financial or non-financial.

Where a breach of a regulatory requirement causes harm to another party, Monitor considers that a restoration requirement may have a number of advantages. It might be used to ensure that parties do not profit from a breach, and it may deter others from similar conduct in future. It may also compensate any affected parties.

However, there may be some practical limits to Monitor's ability to impose restoration requirements. For example, it may be difficult to establish which parties (whether individuals or categories of parties) have been harmed by a breach, or the extent of any such harm.

## **Proportionality**

Monitor will ensure the action we take is proportionate and reasonable in the circumstances at hand, and that we balance the need to deter harmful conduct with the need to ensure the continued provision of health care services to health care service users.

Before imposing a requirement, Monitor therefore proposes to consider:

- the specific circumstances of the relevant provider;
- how any requirement is likely to affect the provider's delivery of health care services; and

In particular, Monitor will consider the impact of a particular requirement on the provider's future financial viability. We propose to consider factors such as:

- the cost of the requirement to the provider;
- the provider's current financial position;
- how much the provider has gained from the relevant breach;
- whether a requirement is likely to cause the provider financial hardship or distress that could:
  - threaten service continuity; or
  - cause further harm to health care service users by reducing competition and choice in the market; or
  - any wider harm to health care service users that might arise from reducing the resources available to the provider in line with our main duty.

### **3.4 Variable monetary penalties**

This section sets out the factors which Monitor will consider when deciding on the appropriate amount of a variable monetary penalty.

Variable monetary penalties may require a provider to pay a monetary penalty to Monitor which Monitor must pay into the Government Consolidated Fund. The variable monetary penalty must not exceed 10% of the provider's turnover in England. The Department of Health has published its intended definition of 'turnover' for these purposes, which is available [here](#).

An important objective of imposing a penalty is deterring similar conduct in future. The amount of any penalty must be sufficient to ensure that it will act as an effective incentive to compliance, having regard to the seriousness of the breach. The factors Monitor will take into account, therefore, include amongst other relevant considerations:

- the seriousness of the breach;
- ensuring provider compliance;
- deterring similar breaches by other providers; and
- the proportionality of a variable monetary penalty to the nature of the breach.

The factors relevant to each of these considerations are described in section 3.3 above.

As well as these matters, Monitor will consider any relevant aggravating and mitigating factors. Penalties are likely to be higher when we identify one or more aggravating factors. Aggravating factors could be, but are not limited to, where:

- Monitor has previously imposed a discretionary requirement on, or accepted an enforcement undertaking from, the relevant provider concerning similar or related matters;
- there is a positive intent to contravene, in that the provider must have been aware, or could not reasonably have been unaware, that its conduct would lead to a breach; or
- a provider has not cooperated with Monitor's investigation.

Penalties are likely to be lower when we identify relevant mitigating factors. Mitigating factors could be, but are not limited to, where:

- a provider takes timely and effective action to remedy the effects of a breach, including action to restore any actual or potential harm caused;
- a provider self-reports a breach; or
- a provider has cooperated fully with Monitor's investigation and requirements.

### 3.5 Enforcement undertakings

A provider may offer an enforcement undertaking during the course of a formal investigation. Monitor may accept the undertaking if we have reasonable grounds to suspect that the provider is, or was, in breach of a licence condition, the requirement to hold a licence, or a requirement to supply Monitor with information. An enforcement undertaking may include a commitment to take steps to secure that the breach in question does not continue or recur. A provider may also undertake to restore the position to what it would have been had the breach in question not occurred, or action (including the payment of a sum of money) to benefit any other licence holder or commissioner affected by the breach.

The decision whether to accept an enforcement undertaking, rather than to continue an investigation and potentially impose discretionary requirements, is at Monitor's discretion and will depend on the circumstances. In considering an enforcement undertaking offered by a provider, Monitor intends to take into account the factors outlined in section 3.3 above.

Agreed enforcement undertakings may be less burdensome on the provider than the discretionary requirements which Monitor would otherwise have imposed. This is in recognition of:

- the cooperation demonstrated by that provider; and
- the fact that Monitor is then able to devote resources to other matters on the basis that Monitor can stop pursuing an investigation or parts of an investigation.

We intend to maintain a register of enforcement undertakings. We are likely to require providers that have given undertakings report on compliance. Any reporting commitments will be agreed as part of the agreement of the enforcement undertaking as a whole.

If the relevant provider complies with the enforcement undertaking, Monitor cannot take further action in relation to the relevant breach or suspected breach. For example, having accepted undertakings which are then complied with, Monitor cannot seek to impose additional discretionary requirements or to revoke the provider's licence in relation to the same breach.

Failing, or partially failing, to comply with an enforcement undertaking accepted by Monitor may result in the imposition of a discretionary requirement.



## 4 Enforcement - case procedures

### 4.1 Introduction

This chapter outlines the general procedures that Monitor intends, in general, to follow when conducting an investigation that may result in us taking formal enforcement action.

This chapter focuses first on the procedures relevant to licence enforcement and to imposing discretionary requirements or accepting enforcement undertakings. Under schedule 11 of the Act, Monitor is bound to follow certain processes when taking such enforcement action.

This chapter also outlines:

- the processes relevant to licence revocation;
- the processes Monitor intends to follow when using our additional powers where the governance of an NHS foundation trust is such that it is failing, or will fail, to comply with one or more of its licence conditions; and
- an introduction to the processes relevant to enforcement under competition law.

As we explained earlier, we are following a similar approach to that set out in this guidance in ‘translating’ breaches of NHS foundation trusts’ terms of Authorisation into appropriate regulatory action under the licence, to take effect as the licence comes into force. The processes we follow, however, are likely to be more bespoke than the case procedures set out in this section. For example, we do not intend to publish case initiations or consult on draft findings for this transition activity. We are currently working closely with the relevant foundation trusts.

### 4.2 Enforcement procedures

#### 4.2.1 Case initiation

When we become aware of a potential breach, we will consider how to proceed in accordance with our prioritisation principles - see chapter 2. Where we decide to begin an investigation of a potential breach, we will notify the relevant party or parties and set out what Monitor is investigating, the key contacts at Monitor, and the expected timetable for the investigation.

Information about the investigation will, where appropriate, be published on Monitor’s website. Monitor considers that publication of case details will generally be beneficial, as it will help to highlight issues that are of concern to Monitor and deter inappropriate conduct, and help ensure that all interested parties are aware of an issue and can provide relevant information.

### **4.2.2 Investigation**

Once Monitor has decided to start a formal investigation, we may use our powers under the Act to gather information – see section 104 of the Act. These powers allow us to ask parties specified in the Act (licence holders, provider licence applicants, providers who are exempt from requiring a licence, providers who should hold a provider licence, the NHS Commissioning Board and clinical commissioning groups) for any information, documents or other items Monitor considers are necessary or expedient to have in order to perform our regulatory functions.

Information includes information, documents or records kept by means of a computer. Monitor also has the power to require the provision of the information, documents or records in legible form. The Monitor provider licence will also require licence holders to provide Monitor with such information as we consider necessary to fulfil our licensing functions, which can be used in addition to or instead of the powers specified in section 104 of the Act.

During the course of an investigation, Monitor may need to issue several information requests to determine whether a provider has breached its obligations or for any other appropriate reason. Monitor will try to limit the burdens placed on parties to an investigation, as much as possible, and ensure that our information gathering is focused and proportionate - in line with our obligations under section 68 of the Act.

At any point during an investigation, Monitor may close a case without further action if, for example, we consider that there is insufficient evidence of a breach or that a formal investigation should no longer be prioritised. Where we consider it appropriate, we will also publish our reasons for making such decisions on our website.

There is no specific time period within which Monitor must complete an investigation, and how long an investigation lasts will vary depending on the complexity of the issue and how much relevant information is available. But when an investigation is opened, we will provide parties with our expected timescales and provide updates to the timescale as appropriate.

### **4.2.3 Case updates**

In longer running cases, we intend to give the relevant parties regular updates about how the investigation is progressing, and when key decisions are likely to be taken.

We intend to:

- keep the parties to the investigation informed about the expected timetable and any changes; and

- provide regular case updates to parties, for example, each month, by telephone or in writing.

We will also offer providers under investigation the opportunity to meet representatives of the case team at appropriate intervals, for example every four to six months to ensure that parties have the opportunity to raise points directly with us and to discuss the progress of an investigation.

#### ***4.2.4 Entering into enforcement undertakings***

This section sets out our proposed procedure for entering into enforcement undertakings, which we are required to publish in accordance with schedule 11 of the Act.

Where Monitor considers it appropriate we may discuss with the provider the possibility of accepting an enforcement undertaking. A provider may offer an enforcement undertaking at any point during the course of an investigation, up until a final decision is made as to whether the provider has acted in breach and as to any discretionary requirement, although the closer an investigation is to its conclusion, the smaller the resource saving to be made by accepting undertakings - see section 3.5.

**Offering an enforcement undertaking** Where a provider wishes to offer an enforcement undertaking, it should first discuss this with the case team. If after this it wishes to do so, it should write to the case team setting out the commitments it is offering, any timescales for implementing the commitments and their anticipated impact. If Monitor thinks that an enforcement undertaking may be an appropriate way to resolve a matter, we may invite a provider to consider making an offer of an enforcement undertaking. When a provider makes such an offer, Monitor expects that we will normally respond by telling the provider that we either:

- do not consider it appropriate to enter into discussions about undertakings at that time and intend to continue the formal investigation; or
- consider it appropriate to enter into discussions about undertakings.

In some circumstances, Monitor is likely to wish to continue with an investigation until we can be satisfied that an enforcement undertaking may or may not be an appropriate way forward. In most circumstances, Monitor will tell the provider when we expect to be in a position to respond to an offer of an enforcement undertaking.

When undertakings have been offered and Monitor considers they may be an appropriate way to resolve the matter; we are likely to discuss the form and content of the undertaking offered with

the provider, and invite the parties to make any changes that we consider necessary. In deciding whether to accept enforcement undertakings, Monitor will assess the proposed undertaking by referring to the factors outlined in section 3.3 above.

**Accepting an enforcement undertaking** Where Monitor has received a proposed enforcement undertaking that we think may represent an appropriate resolution of the matter we may seek views on whether it is appropriate. When we choose to seek views, we will also give reasons why we propose to accept the draft enforcement undertaking, referring to the factors outlined in section 3.3.

Seeking views may range from formal and extensive public engagement to more informal, brief engagement with third parties. The decision on whether to seek views will be made on a case-by-case basis. In deciding whether to seek views we will consider all relevant matters including whether it is in the interests of health care service users to take action quickly, for example where there is a concern about patient safety, as well as any benefits of wider engagement. We will also consider the factors outlined in section 3.3.

After seeking views, Monitor would then need to decide whether the proposed undertakings should be modified, accepted, or rejected.

**After an enforcement undertaking has been accepted** Where Monitor accepts an enforcement undertaking, we are under a legal obligation to publish it. That means Monitor cannot accept an enforcement undertaking on the basis that any of the terms of the undertaking will be kept confidential. We can only withhold from publication any part of an enforcement undertaking which contains information which is:

- commercial, information whose disclosure would or might significantly harm the legitimate business interests of the affected party; or
- information about the private affairs of an individual, where disclosure would or might significantly harm that person's interests.

The terms of an enforcement undertaking - including, in particular, the action it specifies and the period within which the action must be taken - may be varied if both Monitor and the provider agree.

Where Monitor is satisfied that a provider has complied with an enforcement undertaking, we must issue a certificate to that effect – this is called a compliance certificate. A provider who has given an enforcement undertaking can apply to Monitor at any time for a compliance certificate,

including in the application evidence to demonstrate that the provider has satisfactorily met the compliance requirement, and other relevant information to be required and specified by Monitor. Monitor must decide whether or not to issue a compliance certificate, and give notice to the applicant of the decision within 14 days after the day on which we receive the application. There is a right of appeal from a decision to refuse this application.

If at any point Monitor considers that a provider who has given an enforcement undertaking has supplied inaccurate, misleading or incomplete information in relation to the undertaking then we may treat the provider as having failed to comply with the undertaking. In that case, after giving notice, Monitor may revoke any compliance certificate given to that provider.

**Table 4.1 summarises the process for entering into enforcement undertakings**

1	Monitor informs the provider in writing that we have launched formal enforcement action in relation to a suspected breach.
2	If it wishes, the provider contacts the case team to discuss the possibility of undertakings and following this it writes to Monitor with an outline of a proposed enforcement undertaking. The provider may also write to Monitor with an outline of a proposed undertaking after an invitation from Monitor to do so.
3	Monitor responds to the provider indicating, if necessary, whether the matter is suitable for an enforcement undertaking and the terms and timescales on which discussions might proceed.
4	Discussions on an enforcement undertaking may proceed based on the provider's offer at 2 above and/or alternative suggestions made by Monitor.
5	If provisional agreement is reached, Monitor may seek views as set out above if it considers this appropriate.
6	Following consideration of views if sought Monitor either: <ul style="list-style-type: none"> <li>• accepts the enforcement undertaking – with any necessary and agreed modifications – and closes our investigation; or</li> <li>• rejects the proposed undertakings and continues our investigation.</li> </ul>
7	Monitor will publish the agreed enforcement undertaking.

## **4.2.5 Discretionary requirements**

### ***Notice of Intent***

Under schedule 11 of the Act, if Monitor intends to impose a discretionary requirement on a provider we must issue the provider with a 'Notice of Intent' containing the following information:

- the proposal to impose a discretionary requirement;
- the effect of the discretionary requirement;
- the grounds for making the proposal - a statement of the evidence and reasoning behind the proposal as well as our preliminary conclusion;
- an explanation of the effect of section 106 of the Act (enforcement undertakings), including whether we have considered an enforcement undertaking, or may be considering them;
- the circumstances (if any) in which Monitor may not impose the requirement; and
- the period for making representations ('notice period').

Where Monitor is considering imposing discretionary requirements, we may seek views on whether they are appropriate. When we choose to seek views, we will also give reasons for our proposals, referring to the factors outlined in section 3.3.

Seeking views may range from formal and extensive public engagement to more informal, brief engagement with third parties. The decision on whether to seek views will be made on a case-by-case basis. In deciding whether to seek views we will consider all relevant matters including whether it is in the interests of health care service users to take action quickly, for example where there is a concern about patient safety, as well as any benefits of wider engagement. We will also consider the factors outlined in section 3.3.

After seeking views, Monitor would then need to decide whether the proposed requirements should be imposed and in the original or modified form.

### ***Making representations to Monitor***

Under schedule 11 of the Act, on receiving a Notice of Intent, the relevant parties will be invited to submit representations to Monitor in writing and in person within a specified period, known as the 'notice period' of at least 28 days from the day after the Notice of Intent was received.

On request, providers may also make oral representations to the relevant decision-makers within Monitor.

In certain circumstances, Monitor may reduce the notice period to a minimum of five days. This may be the case, as specified in schedule 11, where:

- Monitor is proposing a compliance requirement or restoration requirement; and
- Monitor considers that a shorter notice period is necessary to prevent or minimise further breaches.

### *Final notice*

Under schedule 11 of the Act, after the end of the notice period, Monitor must decide whether to impose the discretionary requirement, with or without modification, or impose any other discretionary requirement.

If, after issuing the Notice of Intent, Monitor has become aware of new information which the provider should in fairness be given an opportunity to comment on before Monitor decides whether to impose a discretionary requirement, Monitor will make arrangements for the provider to be given that opportunity.

If the decision-makers - see chapter 5 - decide to impose a discretionary requirement Monitor will issue a further notice, known as a 'final notice'. The final notice will contain the following information:

- the discretionary requirement which Monitor has decided to impose;
- the effect of the discretionary requirement;
- the reasons for imposing the requirement;
- the consequences of failing to comply with the requirement; and
- the right of appeal.

Although we are not required by the Act to do so, we expect that Monitor will always publish final notices unless the circumstances of the case make this inappropriate. Where appropriate, we will consider the need to obtain confirmation of factual accuracy prior to publication.

If Monitor imposes a variable monetary penalty, the final notice, as specified in schedule 11 of the Act, will also contain the following information:

- how to make the payment;
- the period within which payment must be made;
- any discount for early payment; and
- the rate of interest payable for late payment.

The provider will have a minimum period of 28 days, as specified in schedule 11 of the Act, from the day after the final notice was received to pay a monetary penalty. A monetary penalty may not be imposed unless the Notice of Intent was issued within five years of the last day of the period in which the licensee was in breach.

Any financial penalty paid to Monitor will be transferred to the [Government Consolidated Fund](#). Under schedule 11 of the Act, if the provider does not pay a monetary penalty imposed by Monitor within the specified time, interest may be payable and, in addition to any other action to recover these amounts due, Monitor may take action to collect the money, and any interest owed, through the civil courts as a civil debt.

#### *After the decision*

Under schedule 11 of the Act, Monitor has some freedom to change a discretionary requirement after we have given a final notice. At that stage, Monitor may still:

- withdraw the requirement;
- reduce the amount of any variable monetary penalty;
- extend the time allowed for paying the penalty; or
- extend the time for taking steps specified in a compliance or restoration requirement.

Although we are not required to do so, we expect that where Monitor has decided to take any of the above steps, we will always publish notices setting out the steps decided on and our reasons for taking any of these steps, unless the circumstances of the case would make this inappropriate.

The provider may appeal a decision to impose a discretionary requirement. This is explained in chapter 6.



## *Non-compliance penalties*

Under schedule 11 of the Act, if the provider fails to comply with a compliance or restoration requirement that Monitor has imposed, we may take further action against the provider.

Monitor may impose a financial penalty known as a 'non-compliance penalty' on the provider.

If we decide to take this action, we will first issue a 'non-compliance notice', as specified in schedule 11 of the Act, setting out:

- the amount of the non-compliance penalty;
- the reasons for imposing the non-compliance penalty;
- how to pay the non-compliance penalty;
- the period within which a provider must pay;
- any discount for early payment;
- the consequences of late payment; and
- the right of appeal.

Although we are not required to do so, we expect that Monitor will always publish non-compliance notices unless the circumstances of the case would make this inappropriate. Where appropriate, we will consider the need to obtain confirmation of factual accuracy prior to publication.

If any part of the original payment demanded is not paid by the deadline, Monitor may under schedule 11 of the Act increase the amount payable by up to 50% of the amount of the original penalty.

As with discretionary requirements, under schedule 11 of the Act Monitor has discretion to reduce the amount of the penalty or extend the payment period of a non-compliance penalty. We may make such changes at any time in the process after we have imposed a non-compliance penalty.

Payments from non-compliance penalties are recoverable as civil debts and we will pay them into the Government Consolidated Fund.

The provider can appeal against Monitor's decision to impose a non-compliance penalty. The process for appealing is explained in chapter 6.

### 4.3 Procedures for licence revocation

As outlined in section 1.2, Monitor may revoke a provider's licence if we are satisfied that the provider has failed to comply with a licence condition – see section 89 of the Act. In making the decision that a provider has failed to comply with its licence condition, we intend the following parts of this proposed guidance to apply:

- Chapter 2 - deciding whether a matter is a priority;
- Chapter 4, section 4.2 - case initiation, investigation and case updates;
- Chapter 5 - decision making; and
- Chapter 6 - appeals.

Monitor expects that we would consider revoking a provider's licence only rarely, as to do so would prevent a provider from continuing to provide NHS health care services where it is obliged to hold a licence. If Monitor considers it appropriate to do so, we will consider revoking a provider's licence.

In considering whether to revoke a licence, Monitor's aim will be to fulfil Monitor's main duty to protect and promote the interests of people who use health care services by promoting the provision of health care services which is economic, efficient and effective, and maintains or improves the quality of the services. We intend to consider, amongst any other relevant factors, the following factors as set out in section 3.3 above, that is:

- the seriousness of the breach;
- ensuring provider compliance;
- deterring similar breaches; and
- the proportionality of the remedy to the nature of the breach.

Monitor considers that it would normally only be appropriate to revoke a licence if we are satisfied that the objectives could not be met through the imposition of discretionary requirements (or the acceptance of enforcement undertakings).

#### ***Case initiation, investigation, case update***

We propose that the processes relevant to licence revocation will be as we set out in sections 4.2.1, 4.2.2, and 4.2.3.

### ***Notice of Intent (section 90)***

Where Monitor proposes to revoke a licence, we must give notice to the provider setting out our reasons for proposing to revoke the licence and the time that the licensee has to make representations - see section 90 of the Act. Monitor may take such action only where we are satisfied that a licence holder has failed to comply with a condition of its licence.

Monitor must provide the licence holder with no less than 28 days from date of receipt, within which representations may be made. Providers may, on request, also make oral representations to relevant decision-makers (see chapter 5 below) within Monitor.

Where Monitor is proposing this action, we may seek views on whether it is appropriate. When we choose to seek views, we will also give reasons for our proposal, referring to the factors outlined in section 3.3.

Seeking views may range from formal and extensive public engagement to more informal, brief engagement with third parties. The decision on whether to seek views will be made on a case-by-case basis. In deciding whether to seek views we will consider all relevant matters including whether it is in the interests of health care service users to take action quickly, for example where there is a concern about patient safety, as well as any benefits of wider engagement. We will also consider the factors outlined in section 3.3.

After seeking views, Monitor would then need to decide whether to take the proposed action or other action.

### ***Notice of Decision (section 91)***

Having considered the licence holder's representations Monitor will issue a Notice of Decision confirming whether or not the provider's licence has been revoked. Under section 91 of the Act, the Notice of Decision must explain the provider's right of appeal (see chapter 6 below).

A licence revocation can only have effect once the licensee's right to appeal has ended or once an appeal has been confirmed by the First-Tier Tribunal or the appeal has been abandoned – see sections 91 and 92 of the Act (see chapter 6 below).

Although we are not required by the Act, we expect that Monitor will always publish final notices unless the circumstances of the case mean that this would be inappropriate.

The licensee can appeal against Monitor's decision to revoke its licence. The process for appealing is explained in chapter 6.

## 4.4 Procedures for imposing additional licence conditions on NHS foundation trusts and removing, suspending or disqualifying directors or governors of NHS foundation trusts

We intend that the following parts of this proposed guidance apply to Monitor's actions under section 111 of the Act:

- Chapter 2 - deciding whether a matter is a priority;
- Chapter 4, section 4.2 - case initiation, investigation and case updates; and
- Chapter 5 - decision making.

As outlined in section 1.2, there are two parts to Monitor's powers under section 111:

- I. where Monitor is satisfied that an NHS foundation trust's directors and/or governors are failing to (a) secure compliance with conditions in the foundation trust's licence, or (b) take steps to reduce the risk of a breach of a condition in the foundation trust's licence under section 111 of the Act, Monitor may include in the licence such conditions relating to governance as Monitor considers appropriate; and
- II. where Monitor is satisfied that the NHS foundation trust has breached or is breaching an additional licence condition that was included under section 111 of the Act, we may use our powers to require the foundation trust to remove, suspend or disqualify one or more of the foundation trust's directors and/or governors or, if the foundation trust does not do so, Monitor may make such changes.

A separate process must be followed to exercise the second power. The process that Monitor proposes to follow is set out below.

### ***Case initiation, investigation, case update***

We propose that the processes relevant to section 111 actions will be as we set out in sections 4.2.1, 4.2.2, and 4.2.3.

### ***Notice of Intent (section 111)***

If Monitor is minded to impose an additional licence condition on a foundation trust, Monitor will issue a notice to the foundation trust informing it of:

- the proposal to impose additional licence conditions;
- the anticipated effect of the additional licence conditions;

- any incidental or consequential modifications which may be necessary or expedient to other licence conditions in consequence of the additional licence conditions;
- the grounds for making the proposal; and
- the period for making representations ('notice period').

Monitor would follow the same procedure in the event that we were minded to vary any such licence condition.

Where Monitor is proposing such action, we may seek views on whether it is appropriate. When we choose to seek views, we will also give reasons for our proposals, referring to the factors outlined in section 3.3.

Seeking views may range from formal and extensive public engagement to more informal, brief engagement with third parties. The decision on whether to seek views will be made on a case-by-case basis. In deciding whether to seek views we will consider all relevant matters including whether it is in the interests of health care service users to take action quickly, for example where there is a concern about patient safety, as well as any benefits of wider engagement. We will also consider the factors outlined in section 3.3.

After seeking views, Monitor would then need to decide whether the proposed condition should be modified, retained or not included.

If Monitor is satisfied that a foundation trust has not complied with additional licence conditions and Monitor is minded to require a foundation trust to remove, suspend or disqualify one or more of its directors and/or governors, we will issue a notice to the foundation trust informing it of:

- the proposal to require the foundation trust to remove, suspend or disqualify one or more of its directors and/or governors;
- the grounds for making the proposal; and
- the period for making representations ('notice period').

### ***Final notice (section 111)***

At the end of the notice period, if Monitor has not changed its view following the foundation trust's representations, Monitor would issue a final notice.

If the decision-makers - see chapter 5 - decide to impose an additional licence condition, Monitor will issue a further notice, known as a 'final notice of additional licence conditions'. This notice will contain the following information:

- the licence conditions which Monitor has decided to impose; any incidental or consequential modifications which must be made to other licence conditions;
- the anticipated effect of the additional licence conditions;
- the reasons for imposing the additional licence conditions; and
- the consequences of failing to comply with them.

Monitor would follow the same procedure in the event that we decided to vary any such licence condition.

If the decision-makers - see chapter 5 - decide to impose governance changes, Monitor will issue a further notice, known as a 'final notice of governance changes'. It will contain the following information:

- the requirements of the foundation trust to remove, suspend or disqualify one or more of its directors and/or governors and appoint interim governors or directors;
- the reasons for imposing them; and
- the consequences of failing to comply with them.

Although we are not required to do so, we expect that Monitor will always publish final notices unless the circumstances of the case mean that this would be inappropriate.

Should the foundation trust not comply with this notice, Monitor will, if it considers appropriate, itself implement one or more of the requirements set out in the notice.

### **4.5 Procedures for investigations under competition law**

Where Monitor suspects anti-competitive behaviour in the health care sector in England, we may decide to use our powers under the provider licence, or apply the prohibitions on anti-competitive agreements and abuse of a dominant position set out in the Competition Act and Articles 101 and 102 of the Treaty on the functioning of the European Union.

Monitor will have concurrent powers to apply competition law, meaning that either Monitor or the OFT could act in relation to a particular case. Monitor and the OFT will decide which organisation is best placed to investigate an issue on a case-by-case basis.

As far as possible, we intend that the procedures Monitor follows are consistent whether taking action under the Act or the Competition Act or the TFEU. But when Monitor takes action under the Competition Act, we must adhere to the same statutory rules that the OFT would if it were taking the case (see Competition Act 1998 (Office of Fair Trading's Rules) Order 2004 Statutory Instrument 2751 of 2004 <http://www.legislation.gov.uk/uksi/2004/2751/contents/made>). Similarly, when enforcing Articles 101 and 102 of the TFEU, Monitor must comply with the requirements in European Union Regulation 1/2003.

In any enforcement proceedings under the Competition Act, Monitor will also be required to have regard to:

- the OFT's guidance on the circumstances in which it may be appropriate to accept binding commitments. This is contained in an annex to the OFT's Enforcement Guidelines, see [http://www.offt.gov.uk/shared\\_offt/business\\_leaflets/ca98\\_guidelines/oft407.pdf](http://www.offt.gov.uk/shared_offt/business_leaflets/ca98_guidelines/oft407.pdf).
- the OFT's guidance as to the appropriate amount of a penalty, see [http://www.offt.gov.uk/shared\\_offt/business\\_leaflets/ca98\\_guidelines/oft423.pdf](http://www.offt.gov.uk/shared_offt/business_leaflets/ca98_guidelines/oft423.pdf).

The following sections of this proposed guidance are also relevant to investigations under the Competition Act or TFEU:

- Chapter 2 - deciding whether a matter is a priority;
- Chapter 4, section 4.2 - case initiation and case updates;
- Chapter 5 - decision making; and
- Chapter 6 - appeals.

We may, in the future, publish more detailed guidance on Monitor's procedures in applying competition law.

## **5 Decision-making for enforcement cases**

### **5.1 Introduction**

This chapter sets out Monitor's proposed approach to taking three key decisions relevant to formal enforcement:

- I. the decision to formally investigate a potential breach or infringement;
- II. the decision to provisionally find a breach and to issue, for example, a 'Notice of Intent'; and
- III. the decision to find a breach and to issue, for example, a 'final notice'.

### **5.2 The decisions to launch a formal investigation and to make a provisional finding**

The first two decisions relevant to a formal investigation are: whether to formally investigate a matter; and whether to make a provisional finding that there has been a breach or infringement.

In both cases, Monitor proposes the decisions are taken by a senior staff member in the Monitor group, advised by technical experts as appropriate, responsible for the enforcement action. This person will oversee the investigation up to and including any provisional finding, and take decisions about whether or not enforcement undertakings should be accepted in relation to breaches of obligations by providers, or commitments in competition law cases.

### **5.3 The decision to find a breach or infringement**

For final decisions concerning a breach or an infringement, Monitor proposes that a decision-making committee comprising a number of Monitor's senior staff would take the decision as to whether there has been a breach/infringement, and what sanctions, if any, should be imposed.

The membership of the decision-making committee will be decided on a case-by-case basis, to suit the matter in hand and reflect the risk and complexity involved. It may involve staff from any discipline throughout Monitor. Monitor's Board may decide that it forms the decision-making committee in relation to enforcement matters that are of particular significance to health care service users. In other cases, Monitor's Executive team may form the decision-making committee, or it may be made up of other members of Monitor's senior staff.

However the final decision-making committee is composed, the majority of the decision makers on the committee would not have had any significant prior involvement in the investigation – that is, they would bring a 'fresh pair of eyes' to the matter. The senior staff member responsible for



the first two decision-making points (decision to investigate and provisional finding) and other members of the investigating team may participate in the discussions around making the final decision, but will not be members of the decision-making committee for the purpose of making the decision. It is noted in this context that Monitor has processes in place for decision-makers to declare where necessary any conflicts of interest.

If a party offers an enforcement undertaking after a provisional finding, the decision-making committee would take the decision as to whether that undertaking should be accepted.

To ensure that parties have the opportunity to make representations directly to decision-makers, members of the decision-making committee would hear any oral representations made in response to a provisional finding.

## 6 Rights of appeal

### 6.1 Introduction

This chapter outlines the decisions that are appealable and the appeal processes as specified by law.

### 6.2 Provider enforcement

A provider may appeal a decision to impose a discretionary requirement, the imposition of a non-compliance penalty or the refusal by Monitor to issue a certificate of compliance in relation to an enforcement undertaking to the First-tier Tribunal.

The First-tier Tribunal is a specialist judicial body established under the Courts and Enforcement Act 2007. The main function of the First-tier Tribunal is to hear and decide appeals in specified areas of law (see <http://www.justice.gov.uk/tribunals>).

#### *Discretionary requirements*

A provider has a right of appeal to the First-tier Tribunal against a decision to impose a discretionary requirement. An appeal may be brought on one or more of the following grounds:

- that the decision was based on an error of fact;
- that the decision was wrong in law;
- that the amount of a variable monetary penalty is unreasonable;
- that the nature of a compliance requirement or restoration requirement is unreasonable; or
- that the decision was unreasonable for any other reason.

Once the provider has lodged an appeal, the discretionary requirement will be suspended until the appeal is determined.

When the Tribunal reaches a decision on the appeal, it may take any of the following actions:

- confirm, vary or withdraw the discretionary requirement;
- take such steps as Monitor could take in relation to the breach; or
- remit the decision whether to confirm the requirement, or any matter relating to the decision, to Monitor.

### ***Non-compliance penalties***

A provider may appeal to the First-tier Tribunal against one of Monitor's decisions to impose a non-compliance penalty on any of the following grounds:

- that the decision was based on an error of fact;
- that the decision was wrong in law; or
- that the decision was, or the amount of the penalty is, unfair or unreasonable.

If the provider lodges an appeal, the non-compliance penalty will be suspended until the appeal is determined.

When making a decision on the appeal, the Tribunal may take the following action:

- confirm, vary or withdraw the non-compliance penalty; or
- remit the decision whether to confirm the penalty, or any matter relating to that decision, to Monitor.

### ***Enforcement undertakings***

A provider may appeal, to the First-tier Tribunal, a refusal from Monitor to meet a request for a certificate of compliance on the following grounds:

- the decision was based on an error of fact;
- the decision was wrong in law; or
- the decision was unfair or unreasonable.

In making a decision on the appeal, the Tribunal may either confirm Monitor's decision or direct that it is not to have effect.

## **6.3 Licence revocation**

A licensee has a right of appeal to the First-tier Tribunal against a decision to revoke a licence under section 89(b). An appeal may be brought on one or more of the following grounds:

- that the decision was based on an error of fact;
- that the decision was wrong in law; or
- that the decision was unreasonable.

Once the provider has lodged an appeal, the licence revocation does not take effect until the appeal is confirmed or abandoned.

When making a decision on the appeal, the Tribunal may take any of the following actions:

- confirm Monitor's revocation decision;
- direct that Monitor's revocation decision is not to have effect; or
- remit the revocation decision to Monitor.

## **6.4 Competition law enforcement**

Monitor's Competition Act and TFEU decisions may be appealed to the Competition Appeal Tribunal. Appeals can be brought by addressees of Monitor's decisions and by third parties with a sufficient interest. Appealable decisions include decisions as to whether there has been a competition law infringement; interim measures' decisions; and decisions on the imposition of, or the amount of, a penalty (see <http://www.catribunal.org.uk/242/About-the-Tribunal.html#Appeal-under-CA98>).

The Competition Appeal Tribunal was created by section 12 and Schedule 2 to the Enterprise Act 2002 which came into force on 1 April 2003. The Competition Appeal Tribunal is a specialist judicial body with cross-disciplinary expertise in law, economics, business and accountancy whose function is to hear and decide cases involving competition or economic regulatory issues.

The Competition Appeal Tribunal has wide powers to determine most appeals under competition law on their merits and may:

- confirm or set aside all or part of the decision;
- remit the matter to Monitor;
- impose, revoke or vary the amount of any penalty;
- give such directions, or take such other steps as Monitor could have given or taken; or
- make any other decision which Monitor could have made.

## **Annex      Monitor's powers of enforcement under the Health and Social Care Act 2012**

### **1.      Competition**

#### ***Functions under the Competition Act (section 72)***

Monitor and the Office of Fair Trading have concurrent functions under Part 1 of the Competition Act, relating to the provision of health care services in England where:

- a) agreements, decisions or concerted practices are anti-competitive (anti-competitive practices); or
- b) there are abuses of a dominant position in a market (abuse of dominant position).

These powers relate to the Competition Act and the TFEU.

#### ***Functions under Part 4 of the Enterprise Act 2002 (section 73)***

Monitor and the Office of Fair Trading have concurrent functions under Part 4 of the Enterprise Act 2002 (market investigations), relating to activities which concern the provision of health care services in England.

### **2.      Licensing procedure**

#### ***Licence revocation (section 89)***

Monitor may revoke a provider's licence on the application of the licensee, or if Monitor is satisfied that the licensee has failed to comply with a condition of its licence.

Monitor must give notice to the licensee if we propose to revoke its licence. The notice must set out Monitor's reasons for its proposal; and specify the period (not less than 28 days from the date of receipt) within which representations about it may be made to Monitor.

#### ***Right to make representations (section 90)***

Monitor must give notice to the licensee if we propose to revoke its licence. That notice must:

- a) set out Monitor's reasons for our proposal; and
- b) specify the period (not less than 28 days beginning with the day after that on which the notice is received), for representations to be made on it to Monitor.

### ***Notice of decisions (section 91)***

If Monitor decides to revoke a licence, we must give notice of our decision to the licensee. The notice must explain the right of appeal against that decision.

The decision will take effect when we specify, subject to not being a day earlier than:

- a) the day on which a decision on appeal (if made) is confirmed or the appeal is abandoned;
- b) the day on which Monitor receives notification that the licensee does not intend to appeal (before the end of the period for bringing an appeal); or
- c) the day after the period for bringing an appeal.

### ***Appeals to the Tribunal (section 92)***

An appeal may be made to the First-tier Tribunal against Monitor's decision to revoke a licence.

The grounds for an appeal are that the decision was:

- a) based on an error of fact;
- b) wrong in law; or
- c) unreasonable.

On hearing the appeal, 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.

## **3. Enforcement**

### ***Information provision (section 104)***

Monitor may require a person (any provider of NHS health care services in England whether licensed or not, the NHS Commissioning Board and a Clinical Commissioning Group) to provide us with any information, documents, records or other items which we consider is necessary or expedient for our functions. This includes information, documents or records kept by means of a computer and Monitor has the power to require the provision of the information, documents or records in legible form.

### ***Discretionary requirements (section 105)***

Monitor may impose one or more discretionary requirements on a person if Monitor is satisfied that the person:

- a) has provided, or is providing, an NHS health care service without either a licence or an exemption to hold a licence;
- b) is a provider licensee who is in breach of a licence condition; or
- c) is in breach of a requirement to provide information.

Discretionary requirement means:

- a) a requirement to pay a monetary penalty to Monitor (a “variable monetary penalty”).  
The variable monetary penalty must not exceed 10% of the person’s turnover in England, such amount to be calculated in the manner set out in regulations by the Department of Health. If all or part of a variable monetary penalty is not paid by the time required, the unpaid balance carries interest at the rate specified in section 17 of the Judgments Act 1838; subject to the total interest not exceeding the amount of the penalty;
- b) a requirement to take such steps, within such period, to secure that the breach in question does not continue or recur (a “compliance requirement”); or
- c) a requirement to take such steps, within such period, 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 (a “restoration requirement”).

Monitor must not impose discretionary requirements on a person on more than one occasion in relation to the same breach.

### ***Enforcement undertaking requirements (section 106)***

Monitor may accept an enforcement undertaking from a person if Monitor has reasonable grounds to suspect that the person:

- a) has or is providing, an NHS health care service without either a licence or an exemption to hold a licence;
- b) is a licensee who has or is providing, an NHS health care service in breach of a licence condition; or
- c) is in breach of a requirement to provide information.

An enforcement undertaking is that a specified action will be taken within a specified period. The action must be:

- a) to secure that the breach does not continue or recur;

- b) to secure that the position is, so far as possible, restored to what it would have been if the breach 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;
  - (ii) any commissioner of NHS health care services which is affected by the breach; or
- d) action of such a description as may be allowed in regulations to be made by the Department of Health.

Where Monitor accepts an enforcement undertaking, unless the person has failed to comply with the undertaking or any part of it:

- a) Monitor may not impose any discretionary requirement which we would otherwise have power to impose in respect of the breach; and
- b) Monitor may not revoke that person's licence if the breach is a breach of a licence condition.

Where the person has complied with only part of an enforcement undertaking, Monitor must take the partial compliance into account in deciding whether:

- a) to impose a discretionary requirement on the person; or
- b) to revoke the person's licence, if the breach is a breach of a licence condition.

### ***Further provision about enforcement powers (section 107)***

Monitor must follow schedule 11 provisions about procedures for discretionary requirements and enforcement undertakings.

### ***Guidance on use of enforcement powers (section 108)***

Monitor must publish guidance about how we intend to impose discretionary requirements, accept enforcement undertakings and the procedures we will follow to do so. Monitor may revise the guidance. Monitor must consult persons we consider appropriate before publishing or revising the guidance.

The guidance, in regard to discretionary requirements, 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); and
- d) rights to make representations and rights of appeal.

Monitor must have regard to the guidance or revised guidance in imposing discretionary requirements and accepting enforcement undertakings.

#### ***Publication of enforcement action (section 109)***

Monitor must include, in our annual report, information about:

- a) cases in which a discretionary requirement has been imposed during the financial year of the report (except if it was overturned on appeal); and
- b) cases in which an enforcement undertaking has been accepted during that financial year.

But Monitor must not include information which we are satisfied is:

- a) commercial information where its disclosure might significantly harm the legitimate business interests of the relevant provider; or
- b) information relating to the private affairs of an individual where its disclosure might significantly harm that person's interests.

#### ***Notification of enforcement action (section 110)***

As soon as is practicable after imposing a discretionary requirement or accepting an enforcement undertaking, Monitor must notify:

- a) the NHS Commissioning Board;
- b) Clinical Commissioning Groups who are likely to be affected by the requirement or undertaking; and
- c) any person exercising regulatory functions in relation to the relevant provider.

#### **4. Imposition of licence conditions on NHS foundation trusts and removing, suspending or disqualifying directors or governors of NHS foundation trusts (section 111)**

Where Monitor is satisfied that the governance of an NHS foundation trust is such that the foundation trust will fail to comply with the conditions of its licence, Monitor may include a governance condition(s) in its licence that we consider is appropriate to reduce that risk.

This includes where Monitor is satisfied that the council of governors, the board of directors or the council of governors and board of directors together are failing:

- a) to secure compliance with conditions in the foundation trust's licence; or
- b) to take steps to reduce the risk of a breach of a condition in the foundation trust's licence.

Monitor may modify such a condition once it has been included.

Such a condition will have effect until the Secretary of State for Health orders that section 111 of the Act ceases to have effect.

Where Monitor is satisfied that the trust has breached or is breaching this new condition Monitor may by notice require the foundation 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 of governors from office as a director or member for a set period; or
- c) disqualify one or more of the directors or members of the council of governors from holding office as a director or member for a set period.

Where Monitor is satisfied that a foundation trust has failed or is failing to comply with such a notice, Monitor may do one or more of the things which we required the foundation trust to do.

Where Monitor includes a condition, we may also make such incidental or consequential modifications as we consider necessary or expedient to any other condition of the licence concerned which is affected.

Monitor can also, in relation to such a condition, use the enforcement powers under sections 105 and 106 of the Act.

Where Monitor includes a condition 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.



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