



Enforcement guidance on the Procurement, Patient Choice and Competition Regulations

About Monitor

Monitor is the sector regulator for health services in England. Our job is to protect and promote the interests of patients by ensuring that the whole sector works for their benefit.

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Foreword

The Health and Social Care Act 2012 (the 2012 Act) made Monitor the sector regulator for health care services in England and gave us a responsibility for enforcing rules on procurement, patient choice and competition. These rules provide a legal framework, the aim of which is to benefit people who use health care services.

In this document we focus on providing guidance for commissioners on the National Health Service (Procurement, Patient Choice and Competition) (No. 2) Regulations 2013. These regulations are also sometimes referred to as the “section 75 regulations” or “the commissioner regulations”. While the regulations replace the previous administrative rules governing the procurement of NHS-funded services set out by the Department of Health (in Principles and rules for cooperation and competition and Procurement guide for commissioners of NHS-funded services), the substance of the former rules is preserved within them.

The new regulations are designed to ensure that NHS England and clinical commissioning groups procure high quality and efficient health care services that meet the needs of patients and protect patient choice. They also prohibit commissioners from engaging in anti-competitive behaviour unless this is in the interests of health care service users.

It is for the commissioner to decide which services to procure and how best to secure them in the interests of patients. For this reason, the regulations set out a principles-based framework to enable commissioners to decide in individual cases what is best for the people they serve. Monitor’s role is to ensure that the framework is respected so that decisions are taken in patients’ interests.

Previously, the independent Co-operation and Competition Panel (CCP) advised on compliance with the Principles and Rules. Since 1 April 2013, the CCP has provided advice to Monitor on the new regulations. Monitor will continue to provide informal advice to interested parties on the application of the regulations (just as advice on the Principles and rules was previously available from the CCP).

The Procurement, Patient Choice and Competition Regulations apply alongside the existing Public Contracts Regulations 2006. The new regulations, however, are a bespoke set of rules for the health care sector and provide a mechanism for Monitor, as sector regulator, to investigate complaints and take enforcement action. The regulations are designed as an accessible and effective alternative to challenging decisions in the courts.

For our part, we will ensure that our enforcement action is proportionate and consistent with our duties under the 2012 Act. In developing this guidance, we have had regard to

the Hampton Principles of Good Regulation, and we will ensure that our enforcement action under the Procurement, Patient Choice and Competition Regulations is consistent with these principles. We recognise that the sector has been in a period of transition, with commissioning responsibilities transferred to clinical commissioning groups and NHS England.

In preparing the guidance, we consulted the Department of Health and NHS England, ran a series of workshops with commissioners and held an eight-week public consultation between May and July 2013. We have since acted on the feedback that we received, and the Secretary of State for Health has given his approval to the guidance.

The guidance is in two parts: one dealing with substance and one with enforcement. We have also published a series of case studies which consider how the regulations might apply to a number of hypothetical scenarios. We will continue to work closely with NHS England to ensure that our guidance and NHS England's forthcoming guidance on procurement for commissioners are aligned.

Section 1: Introduction

The Procurement, Patient Choice and Competition Regulations¹ include a number of regulations that commissioners must comply with that are designed to:

- ensure that commissioners secure high-quality, efficient NHS health care services that meet the needs of people who use the services;
- protect the rights of patients to choose who provides their health care in certain circumstances; and
- prevent anti-competitive behaviour by commissioners unless this is in the interests of patients.

The Procurement, Patient Choice and Competition Regulations also give Monitor associated enforcement powers, including the power to enforce certain requirements that commissioners must comply with relating to patient choice set out in the Responsibilities and Standing Rules Regulations.²

The guidance sets out the general approach that we propose to take in using our enforcement powers under the Procurement, Patient Choice and Competition Regulations.

This guidance is statutory guidance published in accordance with section 78 of the Health and Social Care Act 2012 (the 2012 Act). In preparing the guidance, we consulted the Department of Health and NHS England, ran a series of workshops with commissioners and held an eight-week public consultation between May and July 2013.³

We have written this guidance to be as clear as possible. We have tried to use straightforward language and have avoided quoting sections of the Procurement, Patient Choice and Competition Regulations where possible. This means that we do not always use the exact wording from the regulations.

¹ The National Health Service (Procurement, Patient Choice and Competition) (No 2) Regulations 2013 (SI. 2013 No.500), which were made on 6 March 2013, replace the National Health Service (Procurement, Patient Choice and Competition) Regulations 2013 (SI. 2013 No.257), which were made on 11 February 2013. The Regulations were made pursuant to sections 75, 76, 77 and 304(9) and (10) of the Health and Social Care Act 2012.

² The National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012 (SI. 2012 No.2996).

³ The 2012 Act requires Monitor to consult with NHS England and such other persons as Monitor considers appropriate before publishing the guidance.

Monitor expects to follow the approach set out in this guidance when exercising its enforcement powers under the regulations. However, this guidance should not be treated as a statement of the law. The 2012 Act and the regulations ultimately override this guidance. The circumstances of some cases may also make it appropriate for us to depart from this guidance. If we depart from this guidance, we will explain our reasons for doing so.

1.1 Monitor's functions

Monitor's main duty is to protect and promote the interests of people who use health care services. We do this by promoting the provision of health care services that is economic, efficient and effective and that maintains or improves the quality of services.

Monitor's functions include making sure that: public sector providers are well led so that they can provide high-quality care to local communities; essential NHS services continue if a provider gets into difficulty; the NHS payment system rewards quality and efficiency; licensed providers do not behave in a way that is detrimental to the delivery of integrated care; and the commissioning of services, patient choice and competition work well for patients.

This guidance is concerned with our role in ensuring that the commissioning of services, patient choice and competition work well for patients.

1.2 Scope of guidance

1.2.1 Who does the guidance apply to?

The guidance is relevant to **clinical commissioning groups (CCGs)** and **NHS England**⁴ who are required to comply with the Procurement, Patient Choice and Competition Regulations and the Responsibilities and Standing Rules Regulations. In the guidance we refer to NHS England and CCGs collectively as commissioners.

It is also relevant to providers, patients and other third parties that are contemplating making or have made a complaint to Monitor about a commissioner's conduct under the Procurement, Patient Choice and Competition Regulations. Guidance on how to make a complaint, including where to send a complaint and who to speak to, is available on our website.⁵

⁴ The National Health Service Commissioning Board, which is established by section 1H of the National Health Service Act 2006, is referred to in this guidance as NHS England.

⁵ www.monitor.gov.uk

1.2.2 What legislative requirements does the guidance cover?

This guidance covers Monitor's approach to taking enforcement action to prevent and/or remedy breaches of the Procurement, Patient Choice and Competition Regulations.

It also covers our approach to taking enforcement action to prevent and/or remedy breaches of those requirements relating to patient choice in the Responsibilities and Standing Rules Regulations.

The guidance also describes how we propose to prioritise our enforcement work in this area.

This guidance does not cover Monitor's use of its other enforcement powers, such as action taken to enforce the NHS provider licence, or powers under the Competition Act 1998 and/or the Treaty on the Functioning of the European Union. Guidance on how we use our other enforcement powers is available [here](#).⁶

1.2.3 Where can I find out more about what the regulations require commissioners to do?

This document does not provide guidance on the substantive requirements of the Procurement, Patient Choice and Competition Regulations.

We have also published guidance on how to comply with the Procurement, Patient Choice and Competition Regulations; our *Substantive guidance on the Procurement, Patient Choice and Competition Regulations* is available on the Monitor website.

Commissioners are required to comply with various other legislative requirements in addition to the requirements in the Procurement, Patient Choice and Competition Regulations, for example, on preparing joint strategic needs assessments (JSNAs) to identify the current and future health and social care needs of the population in their area⁷ and for preparing joint health and wellbeing strategies (JHWSs) for meeting those needs.⁸ Typically, the preparation of the JSNA and the JHWS will be key steps taken by a commissioner to ensure that the services that it then seeks to procure meet the needs of people who use the services, consistent with its procurement objective under the Regulations (Regulation 2).⁹ If a commissioner has acted consistently with relevant

⁶ www.monitor.gov.uk/home/news-events-publications/our-publications/browse-category/guidance-health-care-providers-and-co-7

⁷ See section 116 of the Local Government and Public Involvement in Health Act 2007.

⁸ See section 116A of the Local Government and Public Involvement in Health Act 2007.

⁹ See Regulation 2 of the Procurement, Patient Choice and Competition Regulations. This objective is to secure the needs of people who use the services and improve the quality and efficiency of the services, including through the services being provided in an integrated way.

guidance on the preparation of JSNAs and JHWSs from the Secretary of State and in NHS England's *Guidance for commissioners on the procurement of NHS-funded health care services in England*, this is likely to be strong evidence that it has acted reasonably and in compliance with Regulation 2.

NHS England's *Guidance for commissioners on the procurement of NHS-funded health care services in England* complements Monitor's guidance. NHS England's guidance provides an overview of the different procurement approaches that commissioners may adopt in appropriate circumstances and outlines some of the key considerations when undertaking a procurement process. It also provides advice on compliance with other legislative requirements, including EU procurement law and the Public Services (Social Value) Act 2012. We will have regard to NHS England's guidance when carrying out investigations under the Procurement, Patient Choice and Competition Regulations.

1.3 Monitor's investigation and enforcement powers

The Procurement, Patient Choice and Competition Regulations give Monitor the following investigation and enforcement powers:

- **Regulation 13** gives Monitor the power to investigate potential breaches of Regulations 2 to 12 of the Procurement, Patient Choice and Competition Regulations or Regulations 39, 42 or 43 of the Responsibilities and Standing Rules Regulations. It also gives Monitor the power to require a commissioner to provide Monitor with information that it may require for the purposes of carrying out an investigation.
- **Regulation 14** gives Monitor the power to declare that an arrangement (or a term or condition of an arrangement) for NHS health care services is ineffective if we are satisfied that there has been a sufficiently serious breach of certain requirements in the Procurement, Patient Choice and Competition Regulations.
- **Regulation 15** gives Monitor the power to issue a wide range of directions. These include the power to direct a commissioner to put in place measures to prevent breaches, remedy breaches or mitigate the effects of breaches; to vary or withdraw an invitation to tender for the provision of NHS health care services and to vary an arrangement for such services in certain circumstances.
- **Regulation 16** also gives Monitor the power to accept an undertaking from a commissioner to take any action that could have been the subject matter of a direction under Regulation 15.

1.4 Structure of guidance

Section 2 explains how we are likely to decide whether to take action, and what action we may take.

Section 3 explains the factors we will take into account when deciding whether to make a declaration of ineffectiveness and what, if any, directions to make or undertakings to accept.

Section 4 describes the processes that we follow when we decide to open a formal investigation. This includes the procedures for gathering information, the information that a commissioner may receive about the investigation process, and the opportunity for the affected commissioner to make representations.

Section 5 outlines the decision-making procedures that we follow.

Section 2: How we are likely to decide whether to take action and what action we may take

This section explains how we are likely to decide whether to take action and what action we might take. In taking these decisions, Monitor applies a prioritisation framework to make sure that we focus our activities on those issues that enable us to make the best use of our resources consistent with our main duty to protect and promote the interests of people who use health care services.

2.1 Prioritisation framework

We apply this prioritisation framework to inform our decisions on whether or not to open an investigation (whether following a complaint, or on our own initiative for investigations into breaches of the prohibition on anti-competitive behaviour) and whether or not to continue an investigation once underway.

This prioritisation framework is the same as that applied by us when considering enforcement action under our other powers, including investigations into breaches of the conditions of the NHS provider licence.

The rest of this section sets out how this framework applies in the specific context of action taken under the Procurement, Patient Choice and Competition Regulations.

Monitor is not able to investigate a complaint where the complainant has initiated proceedings against a commissioner under the Public Contracts Regulations 2006 (by issuing a claim form).¹⁰

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

2.1.1 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 will consider the impact of our actions on the quality of health care services, access to care and value for money

¹⁰ Regulation 13(3) of the Procurement, Patient Choice and Competition Regulations.

spent on health care. We will consider both the short and longer-term impact of our proposed interventions.

- **Indirect benefits to health care service users.** We will consider whether a particular action in one area may lead to wider, more general benefits to health care service users. This might arise by reducing the likelihood of any future breaches by the commissioner in question. This might also arise, for example, by prompting positive changes in the general behaviour of commissioners, providers or health care service users. For example, enforcement action considered appropriate in relation to one commissioner may:
 - deter similar breaches by other commissioners;
 - help other commissioners to understand how obligations apply in certain circumstances;
 - increase awareness among providers and health care service users of commissioners' obligations;
 - increase confidence in the functioning of the health care sector; and
 - help Monitor to identify aspects of the sector that may not be working well for health care service users, resulting in future policy improvements.

If the breach relates to one of the requirements in the Procurement, Patient Choice and Competition Regulations relating to the delivery of care in an integrated way, we will also consider the potential for action to reduce inequalities, in line with our duty under the 2012 Act.¹¹

In assessing the extent to which action may benefit health care service users, we will be mindful of the likelihood of success, and the chances that the potential benefits of our actions will be realised. When we decide whether Monitor should take enforcement action we may assess, for example, whether we are likely to be able to fulfil the legal tests in the Procurement, Patient Choice and Competition Regulations to reach a decision whether a commissioner has breached the Regulations and whether we have the power to impose the remedy that we consider will address the potential breach.

¹¹ See section 62(4) and 62(5) of the 2012 Act.

Action by other regulators and NHS England

In determining the potential benefits of intervention by Monitor, we will also consider whether we can achieve the best outcome for health care service users or whether another organisation has regulatory or other tools that could tackle an issue more effectively, or is already taking steps that are likely to address the matter. For example, the Care Quality Commission (CQC), the Office of Fair Trading (and in the future, the Competition and Markets Authority) and NHS England are also able to take regulatory or other action within the health care sector.

Local resolution as a first step

As a general rule, we will expect a complainant to have attempted to resolve its concerns with the relevant commissioner directly before bringing a complaint to us (we would also generally expect a complainant to inform the local area team at NHS England about an unresolved dispute with a CCG). However, there may be circumstances where this is not practicable, unnecessary or not appropriate and we will consider each case on its facts. If complainants are unsure of whether to approach a commissioner before making a complaint to Monitor they can seek guidance from us on whether we would be likely to accept the case without such engagement taking place first.

Commissioning priorities

We recognise that commissioners have finite resources. Commissioners should allocate their resources in a way that is proportionate. This includes developing commissioning priorities that focus efforts on those areas where commissioners can achieve the greatest impact for patients (through, for example, improvements in service quality, improved patient outcomes and/or better value for money). Where a commissioner has developed a robust and transparent plan for reviewing different services based on such commissioning priorities, and Monitor receives a complaint regarding services that are due to be reviewed by the commissioner in the future under that plan, Monitor will take this into consideration in deciding whether to take action and what action to take.

2.1.2 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 consider the resources needed to take a particular course of action and compare them to the potential benefits. We will consider our staff and non-staff costs, and the likely duration of the work.

We also recognise that the actions we take may give rise to costs for other organisations in the health care sector. We will therefore consider the impact of our

possible actions on the commissioner that would be subject to the investigation as well as other parties such as providers and other commissioners. We will pay close attention to whether the burden our actions would impose is in proportion to the scale of the problem they aim to correct.

2.2 Deciding whether to take formal or informal action

When we receive a complaint or are considering how to respond to a potential breach of the prohibition on anti-competitive behaviour, Monitor may 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 formal powers under the Procurement, Patient Choice and Competition Regulations. For example, we may decide to carry out a more general review of the issues raised as they apply across the sector, review our own policies, or use our other formal powers.¹²

Even when a matter could be addressed by using our formal powers, it may still be appropriate to deal with it informally and to give the commissioner a chance 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 commissioner has taken steps that suggest that a breach is unlikely to occur, to continue, or to recur, for example, by:
 - notifying a breach or the risk of a breach to Monitor as soon as it was identified; and
 - voluntarily taking action to prevent a breach from occurring, to end a breach and/or limit the risk of similar future breaches;
- the context of the breach or potential breach, including whether conduct involves a repeat breach of the same requirement, a commissioner that has repeatedly breached different requirements in the Procurement, Patient Choice and Competition Regulations and/or the Responsibilities and Standing Rules Regulations, whether other regulators or relevant stakeholders have concerns about the commissioner's conduct, a commissioner's history of responding to

¹² These include the power to enforce the NHS provider licence and the Competition Act 1998.

breaches, the likelihood that the action being considered will result in compliance and the speed at which it will do so, and whether the type of breach is thought to be widespread in the health care sector; and

- whether any third parties (for example, other regulators or litigants) are taking relevant action in relation to the same conduct.

If Monitor decides to take informal action rather than formal action, or to take informal action 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 a commissioner to support them in achieving, maintaining or restoring compliance. This may include, for example, the use of agreed action plans containing specific milestones and deadlines;
- issuing an advisory letter to explain a commissioner's obligations and what action may be advisable to maintain compliance; and
- issuing a warning letter setting out our concerns, and notifying the commissioner that if it does not take action Monitor may commence a formal investigation.

In choosing the most effective response to a potential issue, we may consider the options set out above or any other proposals from the parties concerned in deciding what action is likely to create the greatest potential benefit to health care service users and is proportionate, in line with the principles outlined above.

We will consider on a case-by-case basis whether it is appropriate to publish details of informal action. Publishing details of informal action may help the sector to understand the types of behaviour that may give rise to concerns, how it can be addressed and ensure that informal action is taken seriously.

Where we choose to take informal action we will continue to have regard to our prioritisation criteria and, if we think that better outcomes would be achieved, we may escalate from informal action to formal action.

Section 3: The factors we will take into account when deciding whether to make a declaration of ineffectiveness and what, if any, directions to make or undertakings to accept

3.1 Introduction

The Procurement, Patient Choice and Competition Regulations give Monitor the power to take a range of enforcement action against commissioners. These include:

- the power to declare that an arrangement (or a term or a condition of an arrangement) for NHS health care services is ineffective;
- the power to direct commissioners to put in place measures to prevent breaches, to remedy breaches and/or to mitigate their effects; and
- the power to accept undertakings from commissioners.

This section outlines:

- the circumstances in which Monitor can make a declaration of ineffectiveness and the effect of a declaration;
- the types of directions that Monitor can make and the circumstances in which they can be made;
- the factors that Monitor may consider in determining whether to make a declaration of ineffectiveness and whether to issue a direction (and, if so, what direction); and
- when Monitor may accept undertakings.

3.2 Declaration of ineffectiveness

Monitor may declare that an arrangement for the provision of health care services for the NHS is ineffective where we are satisfied both that:

- a commissioner has breached a requirement in regulation 2, 3(1) to (4), 4(2) and (3), 5 to 8 or 10(1) of the Procurement, Patient Choice and Competition Regulations; and
- the breach is sufficiently serious.

The factors that we will take into account in deciding whether a breach is sufficiently serious are considered in Section 3.4.1 below.

Where Monitor makes a declaration of ineffectiveness, the contract will be void. This means that the contract will no longer be valid and neither the commissioner nor the provider will be able to enforce it. For example, if we declare that a contract awarded by a commissioner to a provider for certain community services is ineffective, the commissioner will not be able to require the provider to provide the services and the provider will not be able to require the commissioner to pay it to provide the services.

A declaration of ineffectiveness will not affect the validity of anything that has already been done pursuant to the contract, any right acquired or liability incurred under the contract, or any proceedings or remedy in respect of such a right or liability.

Monitor may also declare that a term or condition of a contract is ineffective where we are satisfied both that:

- the commissioner has breached regulation 10(2) (terms or conditions restricting competition) in relation to that term or condition; and
- the breach is sufficiently serious.

Where Monitor declares that a term or a condition of a contract is ineffective, that term or condition will be void. This means that the term or condition will no longer be valid and neither the commissioner nor the provider will be able to enforce it. However, a declaration that a term or condition of a contract is ineffective will not affect the validity of anything already done pursuant to that term or condition, any right or liability already incurred under the term or condition or any proceedings in respect of such a right or liability. A declaration that a term or condition is ineffective will also not affect the rest of the contract, which will remain enforceable in the normal way.

3.3 Directions

The types of directions that Monitor may make are specified in the Procurement, Patient Choice and Competition Regulations. They include the power to direct commissioners to:

- put in place measures for the purpose of preventing breaches of requirements in regulations 2 to 12 of the Procurement, Patient Choice and Competition Regulations or in regulations 39, 42 or 43 of the Responsibilities and Standing Rules Regulations. These could include, for example, measures to stop a breach that is about to occur from occurring or measures to stop a breach that has already occurred from recurring;
- put in place measures for the purpose of mitigating the effect of breaches of requirements in regulations 2 to 12 of the Procurement, Patient Choice and

Competition Regulations or in regulations 39, 42 or 43 of the Responsibilities and Standing Rules Regulations;

- vary or withdraw an invitation to tender for the provision of health care services for the purposes of the NHS to prevent or remedy a breach of a requirement in regulations 2 to 8 or 10 of the Procurement, Patient Choice and Competition Regulations;
- vary an arrangement for the provision of health care services for the purposes of the NHS made in consequence of putting the provision of services out to tender to remedy a breach of a requirement in regulations 2 to 8 of the Procurement, Patient Choice and Competition Regulations;
- vary an arrangement for the provision of health care services for the purposes of the NHS to remedy a breach of regulation 10 of the Procurement, Patient Choice and Competition Regulations. This could include a direction to amend an anti-competitive clause in an agreement between a commissioner and a provider that is in breach of the prohibition or to sever it from the agreement; and
- remedy a failure to comply with the requirements in regulations 2 to 12 of the Procurement, Patient Choice and Competition Regulations or in regulations 39, 42 or 43 of the Responsibilities and Standing Rules Regulations.

Regulation 15(2) of the Procurement, Patient Choice and Competition Regulations makes it clear that we may not direct a commissioner to hold a competitive tender for a contract for the provision of health care services for the purpose of the NHS.

3.4 Deciding whether or not to make a declaration of ineffectiveness or a direction

In considering whether to make a declaration of ineffectiveness or a direction, and if so, what direction to make, Monitor's main aim is to ensure that any action that we take helps to promote compliance and fulfil our 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, we intend to consider among other relevant considerations:

- the seriousness of the breach or potential breach;
- ensuring commissioner compliance;

- deterring similar breaches;
- mitigating the effect of a breach; and
- proportionality.

When deciding whether and what enforcement measures to impose, we will consider the effect that these measures may have on health care service users and other third parties. We will consider, for example, any impact that a declaration of ineffectiveness might have on the availability of services for health care users.

Monitor may decide not to make a declaration of ineffectiveness or a direction if, for example, we conclude that:

- the breach or potential breach caused (or was capable of causing) no material adverse effect for health care service users;
- a direction or declaration of ineffectiveness is not required to ensure commissioner compliance;
- a direction or declaration of ineffectiveness is not required to deter similar breaches or mitigate the effect of a breach;
- a direction or declaration of ineffectiveness would have an adverse impact on health care service users; and/or
- a direction or declaration of ineffectiveness would be disproportionate to the nature of the breach.

3.4.1 Seriousness

Monitor is only able to make a declaration of ineffectiveness where a breach is sufficiently serious. We will also consider the seriousness of a breach or potential breach when deciding what, if any, direction to make.

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

- the nature and the scale of the adverse effect that a breach or potential breach has caused or is capable of causing to health care service users. We will assess:
 - who has been or is likely to be affected;
 - 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; and

- the duration of any adverse effects or potential effects.
- whether the commissioner knew or should have known that its actions would risk non-compliance; and
- whether the commissioner has previously breached the Procurement, Patient Choice and Competition Regulations or one of the requirements in the Responsibilities and Standing Rules Regulations relating to patient choice.

3.4.2 Ensuring commissioner compliance

Monitor will consider what action may be needed to ensure that a breach does not occur, is remedied, does not continue and/or is not repeated. We will also consider what forms of intervention may be needed to deter similar breaches.

Ensuring a breach does not occur

Monitor is able to take enforcement action to prevent breaches of certain requirements in the Procurement, Patient Choice and Competition Regulations and the Responsibilities and Standing Rules Regulations. We can issue the following directions without a prior finding of a breach:

- a direction to put in place measures for the purpose of preventing breaches of requirements in regulations 2 to 12 of the Procurement, Patient Choice and Competition Regulations or in regulations 39, 42 or 43 of the Responsibilities and Standing Rules Regulations; and
- a direction to vary or withdraw an invitation to tender for the provision of health care services for the NHS to prevent a breach of requirements in regulations 2 to 8 or 10 of the Procurement, Patient Choice and Competition Regulations.

In considering whether it is necessary to make a direction in circumstances where there has been no breach, Monitor will consider the likelihood of a breach occurring. We will consider, among other factors:

- whether the commissioner has previously been in breach;
- what steps the commissioner has taken and/or proposes to take voluntarily in order to prevent the breach from occurring;
- whether, if the commissioner has proposed voluntary steps, it would anyway be beneficial to make a direction relating to those steps to ensure that the breach does not occur;

- whether there are other steps that Monitor considers should be taken in order to ensure the breach does not occur; and
- whether any third parties (for example, other regulators or litigants) are taking relevant action in relation to the same conduct.

Monitor is only likely to issue a direction to prevent a breach from occurring where it considers that there is a high degree of likelihood that a breach would occur without intervention by Monitor, or where the seriousness of the potential breach is such that a direction would be proportionate.

Ensuring a breach does not continue or is remedied

In considering whether it is necessary to impose enforcement measures to ensure that a breach does not continue or is remedied, Monitor will consider, among other factors:

- whether the breach has been brought to an end;
- what steps the commissioner has taken and/or proposes to take voluntarily in order to bring the breach to an end;
- whether, if the commissioner has proposed voluntary steps, it would anyway be beneficial to impose enforcement measures relating to those steps to ensure that the breach does not continue;
- whether there are other steps that Monitor considers should be taken in order to ensure that the breach does not continue or is remedied; and
- whether any third parties (for example, other regulators or litigants) are taking relevant action in relation to the same conduct.

Ensuring a breach is not repeated

In considering whether it is necessary to impose enforcement measures to deter further breaches by a commissioner, Monitor will consider, among other factors:

- whether the commissioner 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 commissioner has already taken steps to avoid non-compliance;
- how much the commissioner has gained, or is expected to gain, from the breach (including financial and reputational benefits);

- whether the commissioner has taken steps that suggest that the breach in question will not recur – this could include, for example:
 - 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 the future;
 - co-operating generally with Monitor’s investigation;
- whether the breach could represent part of a pattern of non-compliance, emerging or otherwise, such that Monitor considers that imposing enforcement measures is necessary to incentivise compliance in the future; and
- whether any third parties (for example, other regulators or litigants) are taking relevant action in relation to the same conduct.

3.4.3 Deterring similar breaches by other commissioners

In order to deter similar breaches by other commissioners, Monitor will consider how enforcement measures might affect the incentives on other commissioners to comply. For example, we may take into account the following in deciding what, if any, enforcement measures to adopt:

- the extent to which the type of breach under consideration appears to be widespread in the sector;
- the extent of the adverse effect which may be caused to health care services users by this type of breach; and
- whether previous enforcement measures have been effective or ineffective in deterring others from similar behaviour.

3.4.4 Mitigating the effect of a breach

Monitor will consider whether enforcement measures may mitigate the effect of a breach. Measures could include, for example, a direction to take practical steps that limit or avoid the adverse effects of a breach materialising.

There may be some practical limits to Monitor’s ability to mitigate the effects of a breach. For example, it may be difficult to establish which parties have been or are capable of being adversely affected by a breach, or the extent of any such adverse effect.

3.4.5 Proportionality

Monitor will ensure that the enforcement action that we take is proportionate and reasonable in the circumstances, and that we balance the need to ensure compliance, to deter breaches and to mitigate their effects with the need to ensure that health care service users continue to have access to the health care services that they need.

Before issuing a direction or making a declaration of ineffectiveness, Monitor will consider:

- the specific circumstances of the relevant commissioner;
- the likely effect on health care service users; and
- the likely effect on third parties that have acted in good faith, such as a provider that is party to a contract that has been awarded by a commissioner in breach of the Procurement, Patient Choice and Competition Regulations and the staff of that provider.

We expect providers to have an understanding of the framework in which they operate. In assessing whether a provider has acted in good faith we will consider whether the provider knew or should have known that there was a risk that the commissioner had breached the Procurement, Patient Choice and Competition Regulations in awarding the contract to the provider.

3.5 Undertakings

Monitor may accept an undertaking from a commissioner to take any action that could be the subject matter of a direction.

The decision whether to accept an undertaking rather than continue an investigation and potentially make a declaration of ineffectiveness or issue a direction is at Monitor's discretion and will depend on the relevant circumstances.

An agreed undertaking may be less burdensome on the commissioner than any enforcement measure that Monitor might otherwise have imposed. This is in recognition of:

- the co-operation demonstrated by the commissioner; and
- the fact that Monitor is able to devote resources to other matters on the basis that it can stop pursuing an investigation or parts of an investigation.

In deciding whether to accept an undertaking offered by a commissioner, Monitor will take into account the factors outlined in Section 3.4 above. As the resource saving to be

made from accepting an undertaking will be smaller the closer an investigation is to its conclusion, we are less likely to accept an undertaking at the later stages of an investigation.

Monitor will maintain a register of undertakings. We are likely to require commissioners that have given undertakings to report on compliance. Any reporting commitments will be agreed as part of the overall agreement on the content of the undertaking.

If a commissioner fails to comply with an undertaking, Monitor will consider whether to re-open its investigation, which may result in us making a direction or issuing a declaration of ineffectiveness.

Section 4: The processes that we follow when we decide to open a formal investigation

4.1 Introduction

This section outlines the general procedures that Monitor generally follows when conducting an investigation that may result in us taking formal enforcement action.

It may be appropriate to depart from this in certain circumstances. In particular, it may be necessary to adapt these procedures in order to allow an investigation to be completed in a shorter period of time, such as, for example, where an investigation relates to a procurement process that is underway.

Monitor, as a general rule, will seek to adopt a consistent approach when taking enforcement action under the different rules that we enforce unless there are reasons to take a different approach. In particular, we will seek to align procedures where the same conduct is being investigated under both the Procurement, Patient Choice and Competition Regulations and other rules such as the NHS provider licence.

4.2 Enforcement procedures

4.2.1 Case initiation

Monitor may open an investigation under the Procurement, Patient Choice and Competition Regulations in two circumstances:

- On its own initiative for investigations into breaches of the prohibition on anti-competitive conduct (regulation 10 of the Procurement, Patient Choice and Competition Regulations).¹³
- In response to a complaint that a commissioner has breached a requirement in regulations 2 to 12 of the Procurement, Patient Choice and Competition Regulations or regulation 39, 42 or 43 of the Responsibilities and Standing Rules Regulations where we consider that the complainant has a sufficient interest.¹⁴

We will consider on a case-by-case basis whether a complainant has a sufficient interest. The following complainants may have a sufficient interest (among others):

- providers;

¹³ Regulation 13(2) of the Procurement, Patient Choice and Competition Regulations.

¹⁴ Regulation 13(1) of the Procurement, Patient Choice and Competition Regulations.

- other commissioners;
- users of health care services (including individual patients); and
- patient groups.

Monitor cannot investigate a complaint where the complainant has brought proceedings against a commissioner under the Public Contracts Regulations 2006 (by issuing a claim form).

A person who considers that a commissioner may have breached or is going to breach the Procurement, Patient Choice and Competition Regulations or the relevant provisions of the Responsibilities and Standing Rules Regulations may contact Monitor to raise his or her concerns.

Further guidance on how to make a complaint to Monitor is available on our website.

When we become aware of a potential breach (whether as a result of a complaint or otherwise), we will consider how to proceed in accordance with our prioritisation principles (see Section 2).

When deciding whether to open a formal investigation, we may request information from the commissioner under investigation, any complainant and/or third parties on an informal basis. Information may be requested in writing or orally at a meeting.

Where we decide to begin an investigation, we will notify the commissioner under investigation and set out what Monitor is investigating, the key contacts at Monitor, and the expected timetable for the investigation.

Information about the investigation, including the expected timetable, will, where appropriate, be published on our 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 might help to deter inappropriate conduct, and help to 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 formal information gathering powers under regulation 13(4) to obtain information from the commissioner under investigation.

Monitor can require a commissioner to disclose any information in its possession and to provide explanations of the information provided.

Information includes information, documents or records kept by means of a computer. Where the information in question is kept by means of a computer, Monitor has the power to require the information in legible form.

We may also request information from third parties to assist us with our investigation. Who we approach will depend on the issues that we are investigating, but may include complainants, providers, other commissioners, patients, carers and professional bodies among others. Monitor may need to send a number of requests for information during the course of an investigation. Generally these requests will be subject to a deadline and depending on the circumstances of the case, in particular the urgency of resolving the matter, it may be necessary to provide information within a short period of time. Monitor will try to limit the burdens placed on commissioners and third parties as much as possible and ensure that our information gathering is focused and proportionate in line with our obligations under section 68 of the 2012 Act.

At any point during an investigation, Monitor may close a case without further action, if for example, we consider that continuing with a case would no longer be consistent with our prioritisation framework. 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 we must complete an investigation. How long an investigation lasts will vary depending on:

- the urgency with which the issue needs to be resolved (for example, an investigation is likely to proceed more quickly where it concerns a live procurement process);
- the complexity of the issue; and
- what information is available that is relevant to the issues, the speed with which information that we request is provided by the commissioner and third parties and the willingness of the parties to engage with us.

4.2.3 Case updates

In longer-running cases, we will give the relevant parties (typically the relevant commissioner and any complainants) regular updates about how the investigation is progressing and when key decisions are likely to be taken.

We will:

- 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 commissioners under investigation the opportunity to meet representatives of the case team at appropriate intervals, for example, every four to six months to ensure that they have the opportunity to raise points directly with us and to discuss the progress of an investigation.

4.3 Entering into enforcement undertakings

This section sets out our proposed procedure for entering into undertakings, which we are required to publish in accordance with schedule 9 to the 2012 Act.¹⁵

A commissioner may offer an undertaking at any point during the course of an investigation, up until a final decision is taken by Monitor that a breach has occurred or is likely to occur. It is up to a commissioner whether or not to offer an undertaking as a way of addressing a matter under investigation. Where Monitor considers it appropriate, we may discuss with a commissioner the possibility of accepting an undertaking.

4.3.1 Offering an undertaking

Where a commissioner is contemplating offering an 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. Monitor will inform the commissioner whether it considers it appropriate to enter into further discussions about undertakings or not.

In some circumstances, Monitor may wish to continue an investigation until we can be satisfied whether an undertaking is an appropriate way forward. In most circumstances, we will tell the commissioner when we expect to be in a position to respond to an offer of an undertaking.

When an undertaking has been offered and Monitor considers that it may be an appropriate way to resolve the matter, we are likely to discuss the form and content of

¹⁵ Monitor is required to consult such persons as it considers appropriate before publishing its proposed procedure for entering into undertakings (Paragraph 1(3) of Schedule 9 to the 2012 Act). Monitor has consulted on the proposed procedure set out in Section 4.3 of this guidance as part of its broader consultation on its substantive and enforcement guidance on the Procurement Patient Choice and Competition Regulations (see Section 1: Introduction).

the undertaking offered with the commissioner and will invite the commissioner to make any changes that we consider necessary.

In deciding whether to accept an undertaking, Monitor will assess the proposed undertaking by reference to the factors outlined in Section 3.4 above.

4.3.2 Accepting an undertaking

Where Monitor has received a proposed 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 undertaking, referring to the factors outlined in Section 3.4.

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 set out in Section 3.4.

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

4.3.3 After an undertaking has been accepted

Effect of an undertaking

Where Monitor has accepted an undertaking, we cannot continue the investigation into the relevant conduct and cannot make a declaration of ineffectiveness or issue a direction under the Procurement, Patient Choice and Competition Regulations.

Publication of undertakings

Monitor is under a legal obligation to publish any undertakings it accepts. That means that we cannot accept an 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 undertaking that contains information that we are satisfied is:

- commercial information, the disclosure of which would or might significantly harm the legitimate business interests of the person to whom it relates; or
- information about the private affairs of an individual, where disclosure would or might significantly harm that person's interests.

Variation of undertakings

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

Compliance certificates

Where Monitor is satisfied that a commissioner has complied with the terms of an undertaking, it must issue a compliance certificate to that effect. A commissioner that has given an undertaking can apply to Monitor for a compliance certificate at any time. The application must include evidence to demonstrate that the commissioner has complied with the action specified in the undertaking and other relevant information to be required and specified by Monitor at that point in time. Monitor must decide whether or not to issue a compliance certificate and notify the commissioner of its decision within 14 days after the day it receives the application.

A commissioner may appeal a decision by Monitor to refuse an application for a compliance certificate to the First-tier Tribunal. The First-tier Tribunal is a specialist judicial body established under the Tribunals, Courts and Enforcement Act 2007. The main function of the [First-tier Tribunal](#)¹⁶ is to hear and decide appeals in specified areas of law. The permissible grounds of appeal are that the decision was:

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

Failure to comply with an undertaking

If a commissioner fails to comply with an undertaking, or only partially complies with an undertaking, Monitor may re-open an investigation and issue a direction or make a declaration of ineffectiveness. Where the commissioner has failed to comply fully with an undertaking, but has complied with part of it, we will take the partial compliance into account in deciding whether to do so.

¹⁶ www.justice.gov.uk/tribunals

Undertakings based on inaccurate, misleading or incomplete information

If Monitor is satisfied that a commissioner that has given an undertaking has supplied inaccurate, misleading or incomplete information in relation to the undertaking, then we may treat the commissioner as having failed to comply with the undertaking. In such circumstances, we will revoke any compliance certificate given to that commissioner.

4.4 Making a direction or a declaration of ineffectiveness

4.4.1 Notice of intent

If Monitor intends to issue a direction or make a declaration of ineffectiveness, it will issue the commissioner with a “notice of intent” containing the following information:

- the proposal to make a direction or declaration of ineffectiveness;
- the effect of the direction or declaration of ineffectiveness;
- the grounds for making the proposal – the evidence and reasoning behind the proposal (including the evidence supporting a provisional finding that a breach has occurred or is likely to occur);
- an explanation of the effect of section 77 of the 2012 Act (undertakings) including whether Monitor has considered or may be considering accepting an undertaking; and
- the period for making representations.

Where we are considering issuing a direction or making a declaration of ineffectiveness, we may seek views on whether it is appropriate. When we choose to seek views, we will also give reasons why we consider the direction or declaration of ineffectiveness appropriate referring to the factors outlined in Section 3.4.

Seeking views may range from formal and extensive public engagement to informal, brief engagement with third parties. The decision 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 set out in Section 3.4.

4.4.2 Making representations to Monitor

On receiving a notice of intent, the commissioner will be invited to submit representations to Monitor in writing within a specified period (the notice period).

The notice period will depend on the circumstances of the case and will be proportionate to the nature of the enforcement action proposed.

Unless we consider that a shorter period of time is necessary, for example, to prevent further breaches or minimise the adverse effect caused by a breach, the commissioner will be given at least 28 days beginning with the day after that on which the notice of intent is received to make representations. Only in exceptional cases will the notice period be shorter than five days.

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

4.4.3 Final notice

At the end of the notice period, Monitor will decide whether to make a declaration of ineffectiveness and/or issue a direction with or without modification.

If, after issuing the notice of intent, we become aware of new information that the commissioner should be given an opportunity to comment on before we take a final decision, Monitor will make arrangements for the commissioner to be given that opportunity.

If the decision-makers (see Section 5) decide to make a declaration of ineffectiveness or issue a direction, Monitor will issue a further notice, known as a final notice. This will contain the following information:

- the enforcement measure that Monitor has decided to impose;
- the effect of the direction or declaration of ineffectiveness;
- the reasons for making the direction or the declaration of ineffectiveness – including the evidence and reasoning behind the decision (including the evidence supporting the finding that a breach has occurred or is likely to occur); and
- the rights of appeal.

Although we are not required by the 2012 Act to do so, Monitor will always publish final notices. Where appropriate, we will consider the need to confirm the factual accuracy of the final notice with the commissioner and any third parties whose views we have relied on prior to publication.

We will withhold any commercially sensitive information in the final notice from publication. For an explanation of what constitutes commercially sensitive information, please see Section 4.3.3.

Section 5: The decision-making procedures that we follow

5.1 Introduction

This section sets out Monitor’s proposed approach to taking three key decisions relevant to formal enforcement action:

- (i) the decision formally to investigate a potential breach;
- (ii) the decision to issue a “notice of intent”; and
- (iii) the decision to issue a “final notice”.

5.2 Who takes decisions

5.2.1 The decisions to launch a formal investigation and to issue a notice of intent

The following decisions will be taken by a senior member in the Monitor group responsible for enforcing the Procurement Patient Choice and Competition Regulations:

- the decision to launch a formal investigation; and
- the decision to issue a notice of intent (including the provisional finding that a breach has occurred or is likely to occur).

This person will oversee the investigation up to and including any decision to issue a notice of intent. This person will also take any decision about whether or not to accept any undertaking offered by a commissioner or to close an investigation before a notice of intent is issued.

5.2.2 Decision to issue a final notice

The decision to issue a final notice will be taken by a decision-making committee comprising a number of Monitor’s senior staff.

This will include the decision as to whether a breach has occurred or is likely to occur without intervention by Monitor and what enforcement measures, if any, should be taken.

The membership of the decision-making committee will be decided on a case-by-case basis and will reflect the complexity and risk involved. It may involve staff from any discipline throughout Monitor, including our board, executive team or other members of staff.

However the final decision-making committee is made up for the final decision, the majority of the decision makers on the committee will not have had any significant prior

involvement in the investigation, that is, they will provide a “fresh pair of eyes” to the matter.

The senior staff member responsible for the decision to open an investigation and to issue a notice of intent and other members of the investigating team may participate in discussions around making the final decision, but will not be a member of the decision-making committee for the purpose of making the decision. We have processes in place for the decision-makers to declare, where necessary, any conflicts of interest.

If a commissioner offers an undertaking after a notice of intent is issued, the decision-making committee will also decide whether that undertaking should be accepted.

To ensure that a commissioner has the opportunity to make representations directly to the decision-makers, members of the decision-making committee would hear any oral representations made in response to a notice of intent.



Making the health sector
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